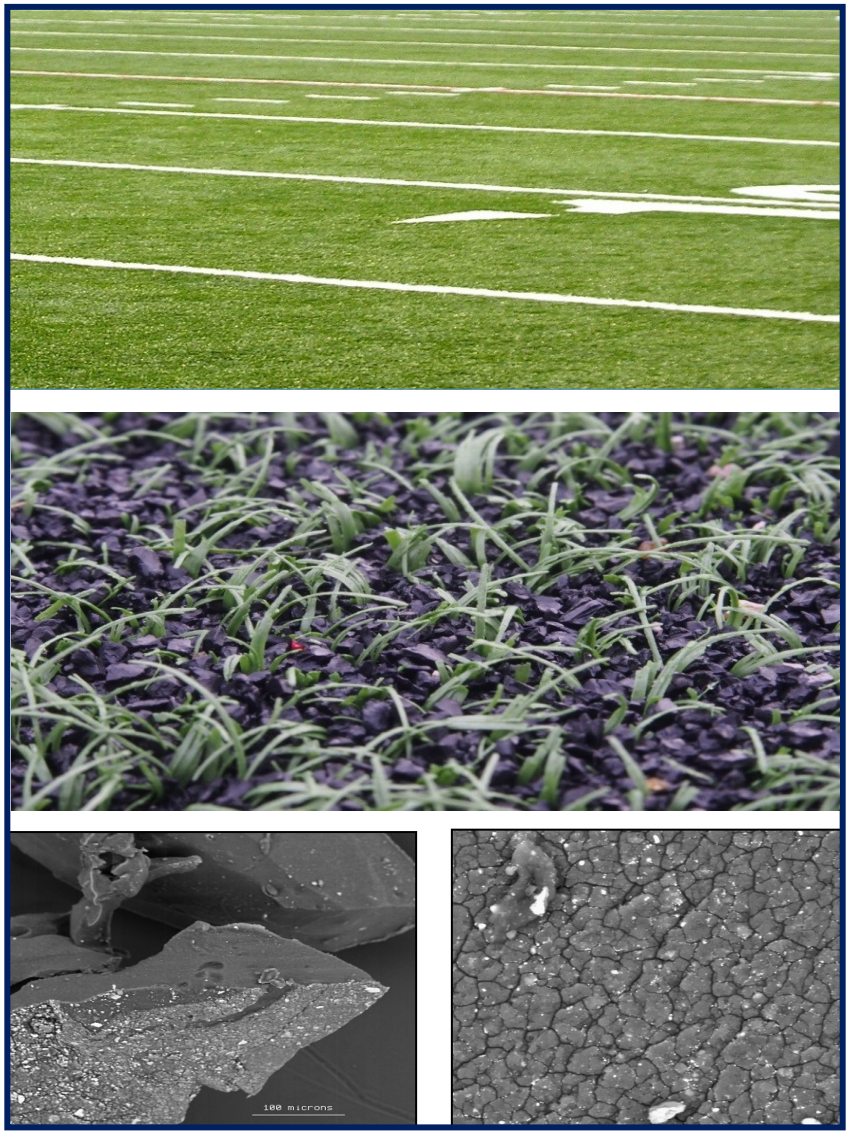
Research Protocol

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill



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This document has been reviewed by the U.S. Environmental Protection Agency, Office of Research and Development, and the Agency for Toxic Substances and Disease Registry and approved for release. In accordance with guidance in the US EPA's Peer Review Handbook, the document was sent out for an independent, external peer review to three subject matter experts with expertise in analytical chemistry, human exposure assessment, and human exposure modeling. The document was revised based on reviewer recommendations.

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Executive Summary

Concerns have been raised by the public about the safety of recycled tire crumb rubber used in synthetic turf fields and playgrounds in the United States. Several studies have been identified that examine exposure to tire crumb rubber infill in these settings. While, in general, these studies have not provided evidence for these health concerns, the existing studies do not comprehensively evaluate all aspects of exposure associated with these use scenarios. Additional research is needed to help fill important data gaps that will lead to improved exposure assessment and risk evaluation for children and adults using synthetic turf fields and playgrounds with tire crumb rubber. In response, the U.S. Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (ATSDR), and the U.S. Consumer Product Safety Commission (CPSC) launched a multi-agency federal action plan to study key environmental human health questions associated with tire crumb rubber on synthetic turf fields and playgrounds.

The "Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds" (referred to subsequently as the Federal Research Action Plan or FRAP) was finalized in February 2016. The U.S. EPA and CDC/ATSDR, in collaboration with CPSC, have prepared this research protocol to implement portions of the research activities outlined under the FRAP. Specifically, this research protocol is designed to implement three of the research elements described in the Federal Research Action Plan:

- Conduct a literature review and data gaps analysis;
- Perform tire crumb rubber characterization research;
- Perform human exposure characterization research.

The literature review and data gaps analysis is an important component of the Federal Research Action Plan and is needed to guide research in the near and longer terms. A number of previous research investigations have examined various aspects of the issues regarding tire crumb rubber, including the potential for human and ecological exposures and risks from recycled tire products used on synthetic fields and playgrounds. Literature identification and review is underway concurrently with development of this research protocol. Literature searches have been conducted through formal searches of multiple literature databases for published journal articles as well as internet searches and other approaches for identifying reports not available as published journal articles. Efforts are ongoing to finalize the information capture and consolidation, complete the data gaps analysis, and to prepare a white paper that will describe the review, summarize the literature, detail the gaps analysis, and provide conclusions.

The tire crumb rubber characterization study will involve the collection of crumb rubber material from tire recycling facilities and synthetic turf fields around the U.S., with laboratory analysis for a wide range of metals, volatile organic compounds (VOCs), and semi-volatile organic compounds (SVOCs) (summarized in Figure ES-1). Laboratory analyses will include dynamic emission chamber measurements for VOCs and SVOCs under different temperature conditions and bioaccessibility measurements for metals and SVOCs. The emissions and bioaccessibility experiments will provide important information about the types and amounts of chemical constituents in the tire crumb rubber material available for

human exposure through inhalation, dermal, and ingestion pathways. In addition to quantitative target chemical analyses, suspect screening and non-targeted analysis methods will be applied for VOCs and SVOCs in an attempt to identify whether there may be potential chemicals of interest that have not been identified or reported in previous research. The study will also collect tire crumb rubber infill from synthetic turf fields to assess microbial populations. A final piece of this research activity is to identify and collate extant toxicity reference data for selected chemical constituents and contaminants identified through the laboratory analyses.

The exposure characterization study is a pilot-scale effort to: (a) collect information on human activity parameters for synthetic turf field users that affect potential exposures to tire crumb rubber constituents; and (b) implement a human exposure measurement study to further develop and deploy appropriate sample collection methods and to generate data for improved exposure characterization (summarized in Figure ES-2). This data collection will use questionnaires administered to adults and youth (or the parents of children) who use synthetic turf fields with tire crumb rubber infill. Information will be collected to provide data about relevant parameters for characterizing and modeling exposures associated with the use of synthetic turf fields. A subset of participants will have video data collection performed during a physical activity on a synthetic turf field. In addition, publicly available videography of users engaged in activities on synthetic fields will, if feasible, be acquired to provide objective assessment of contact rates and types that are difficult to capture consistently using questionnaires. A subset of participants providing questionnaire responses will also be asked to participate in an exposure measurement study. A set of personal, biological, and field environment samples will be collected around a sport or training activity performed on a synthetic turf field. Personal and environmental samples will be analyzed for metal, VOC, and SVOC analytes, and a subset of SVOC samples will undergo suspect screening and non-targeted analysis. Biological samples will be held for future analysis once potential biomarker chemicals of interest are identified based on the tire crumb rubber and exposure characterization studies.

In summary, several of the key gaps and limitations identified in previous research will be addressed through the activities described in this research protocol. The results of the activities identified in the FRAP will be described in the key product, a report due in 2016. Hence, the research design is constrained by a number of factors most importantly including: the short timeline for initial research activity and reporting completion in 2016; and the resources available for implementing the research. By the end of 2016, the participating agencies anticipate releasing a draft status report that describes the preliminary findings of the research through that point in time. The draft status report will summarize the agencies' progress in: (1) Identifying key constituents of concern in recycled tire crumb used in artificial turf fields; (2) Assessing potential exposures to potentially harmful constituents; (3) Conducting an initial evaluation of potential cancer and non-cancer toxicity of key chemical constituents; and (4) Identifying follow-up activities that could be conducted to provide additional insights about potential risks. The report will also outline any additional research needs and next steps.

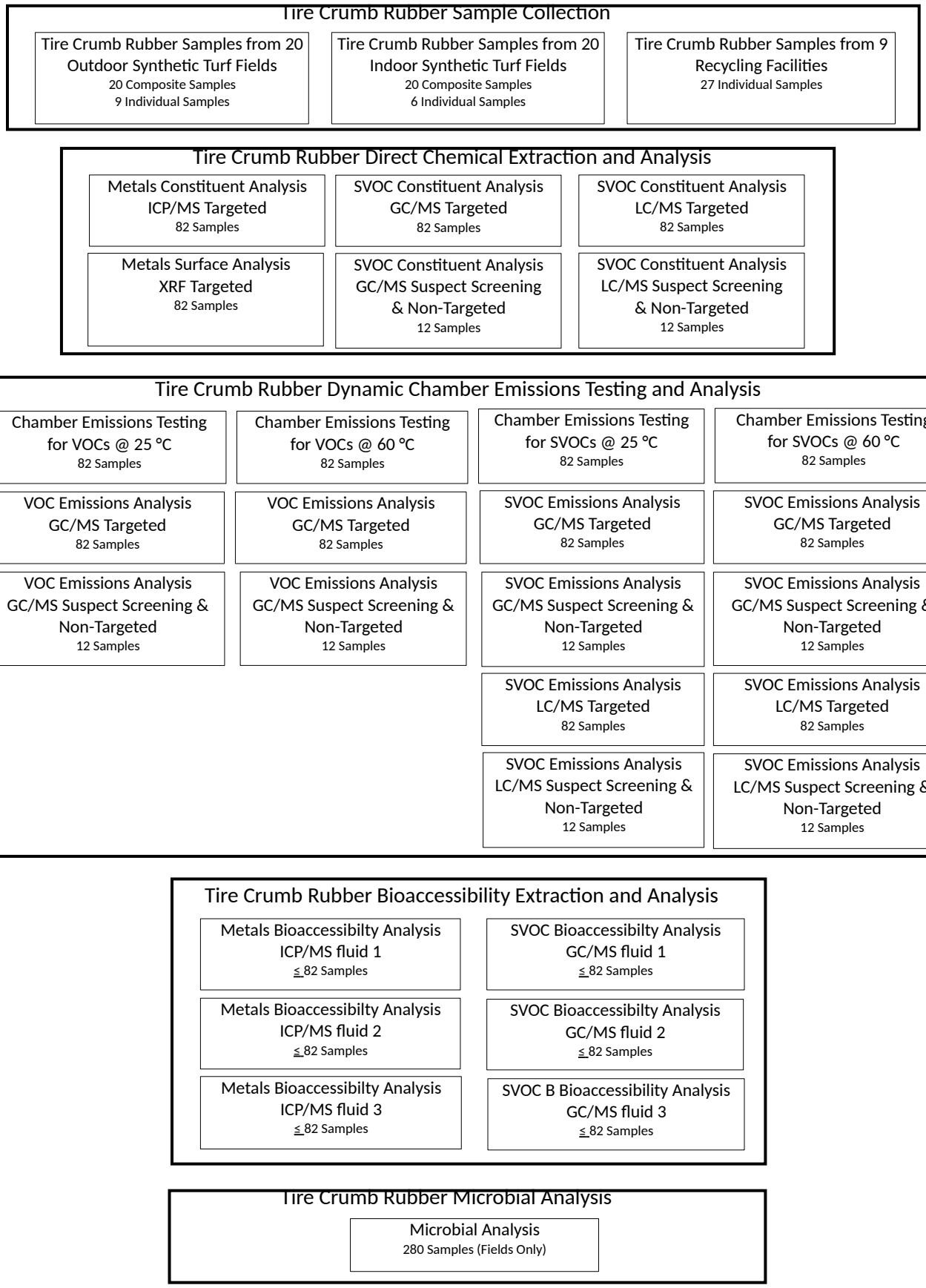

Figure ES-1. Tire crumb rubber characterization overview.

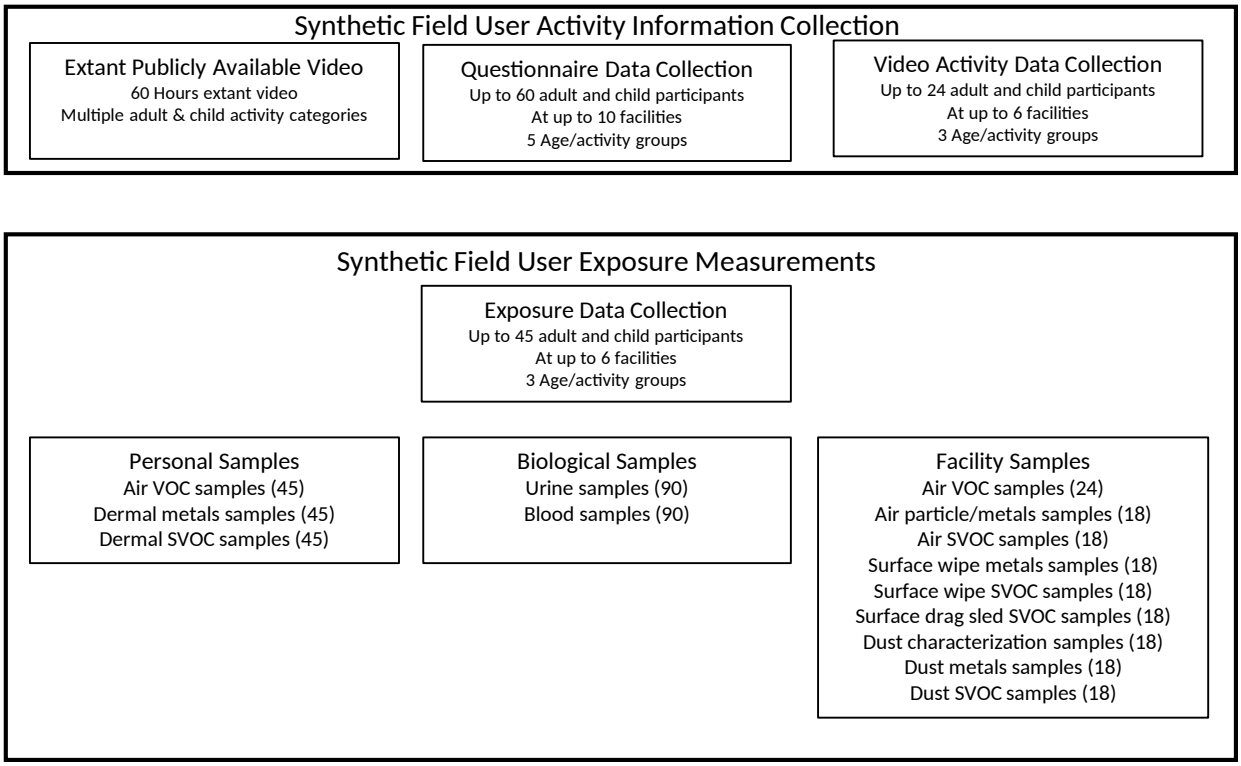

Figure ES-2. Exposure characterization overview.

List of Acronyms and Abbreviations

ACGIH	American Conference of Governmental Industrial Hygienists
ADQ	Audit of data quality
ASTM	American Society for Testing and Materials
ATSDR	Agency for Toxic Substances and Disease Registry
BEI	Biological exposure indices
CAI	Computer assisted interview
Cal-OEHHA	California Office of Environmental Health Hazard Assessment
CAS	Chemical Abstracts Service
CDC	Centers for Disease Control and Prevention
CICAD	Concise International Chemical Assessment Documents
CPSC	Consumer Products Safety Commission
DNPH	Dinitrophenyl hydrazine
EPDM	Ethylene propylene diene monomer
FRAP	Federal Research Action Plan
GC/MS	Gas chromatography/mass spectrometry
HEAST	Health effects assessment summary table
IARC	International Agency for Research on Cancer
ICP/MS	Inductively coupled plasma/mass spectrometry
IPCS	WHO International Programme on Chemical Safety
IRIS	Integrated risk information system
ISO	International Standards Organization
IUR	Inhalation unit risk
LC/MS	Liquid chromatography/mass spectrometry
MRL	Minimum risk level
MRM	Multiple reaction monitoring
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
OSF	Oral slope factor
OSHA	Occupational Safety and Health Administration
PAH	Polyaromatic hydrocarbon
PCDL	Personal compound database list
PCR	Polymerase chain reaction
PE	Physical education
PID	Participant identification number
PPRTV	Provisional peer-reviewed toxicity value
PTFE	Polytetrafluoroethylene
PUF	Polyurethane foam
QA	Quality assurance
QAM	Quality assurance manager
QAPP	Quality assurance project plan
QC	Quality control

QMP	Quality management plan
QSA	Quality systems audit
REL	Recommended exposure limit
RfC	Reference concentration
RfD	Reference dose
RH	Relative humidity
RMA	Rubber Manufacturers Association
RNA	Ribonucleic acid
SHEDS	Stochastic human exposure and dose simulation
SIM	Selected ion monitoring
SOP	Standard operating procedure
STC	Synthetic Turf Council
SUV	Sport utility vehicle
SVOC	Semi-volatile organic compound
TC	Tire crumb rubber
TLV	Threshold limit value
TOFMS	Time of flight mass spectrometer
TPE	Thermoplastic elastomers
TSA	Technical systems audit
U.S.	United States of America
U.S. EPA	United States Environmental Protection Agency
UV	Ultraviolet
VID	Video identification number
VOC	Volatile organic compound
WHO	World Health Organization
XRF	X-ray fluorescence

1. Introduction

1.1 Background

Concerns have been raised by the public about the safety of recycled tire crumb rubber used for surfaces in playing fields and playgrounds in the United States (U.S.). Several studies that have examined potential human health risks have not shown an elevated risk from playing on fields with tire crumb rubber infill, but the existing studies do not comprehensively evaluate the concerns about health risks from exposure to tire crumb rubber. Additional research is needed to help fill important data gaps that will lead to improved exposure assessment and risk evaluation for children and adults using synthetic turf fields and playgrounds with tire crumb rubber. The U.S. EPA and CDC/ATSDR, in collaboration with CPSC, have prepared a research protocol that will implement three elements of the research outlined under the "Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds" (Appendix A). These include the literature review and data gaps analysis and the tire crumb rubber characterization and exposure characterization research efforts related to synthetic turf fields. Background information and descriptions of some of the research performed to date on this topic is provided below; the research design and methods are described in later sections.

1.1.1 Waste Tire Generation and Recovery Estimates

A large volume of used automobile and truck tires enters the waste stream in the U.S. each year. The U.S. EPA estimated that 4.77 million tons of waste tires were generated in 2013, and 40.5% or 1.93 million tons were recovered through recycling and production of retreaded tires (U.S. EPA, 2015). Much of the waste tire material not recovered was used as fuel in cement kilns, utility boilers, pulp and paper mills, industrial boilers, and dedicated scrap tire-to-energy facilities. In 2013, approximately 172 thousand tons of scrap tires were converted to tire shreds for use in road and landfill construction, septic tank leach fields, and other construction applications (RMA, 2016a). Approximately 975 thousand tons of scrap tires (representing approximately 59.5 million tires) were used in the ground rubber applications market, which includes the manufacture of new rubber products, rubber-modified asphalt, and playground and sports surfacing (RMA, 2014 and 2016a). The Rubber Manufacturers Association estimated that in 2013 about 590 million kg (1.3 billion pounds) of ground rubber was produced with 33% used in molded extruded products, 31% for playground mulch, 17% for sports surfaces, 7% in asphalt, 6% in automotive products, and 6% was exported (RMA, 2016b). Recycled rubber from tires is used in several types of recreational venues, including use as infill material in synthetic turf fields, on playgrounds as tire crumb rubber or rubber mats, for running surfaces, and in horse equestrian arenas. Recycled tire material may also be used in other applications such as tire-derived rubber flooring materials (CalRecycle, 2010).

1.1.2 Tire Crumb Rubber Manufacturing Process

Two tire recycling processes, ambient and cryogenic, are used to create tire crumb rubber in the 10 – 20 mesh (0.84 – 2.0 mm) size for use as synthetic turf infill. The ambient process uses interlocking knives to chop tires into successively smaller pieces with screening to separate pieces into specific mesh sizes. The cryogenic process uses liquid nitrogen to freeze partially shredded tires, which are then fed into a

hammer mill to create tire crumb rubber. Fabric (including polyester, nylon, or other fibers) and steel belt materials are separated from the rubber using magnetic separators, air classifiers, or other separation equipment. Water may be used for cooling during the ambient process, otherwise no chemicals are added to the original rubber composition during either process. Seven rubber reprocessors produce approximately 95% or more of the recycled rubber used as infill in synthetic turf field applications (STC et al., 2016). Voluntary industry standards specify the use of only whole vulcanized auto, SUV, and light truck tires produced in North America that are less than seven years old from the date of production (STC et al., 2016). The extent of the use of large truck and bus tires as synthetic field infill is unclear, with at least one company describing an all-black crumb rubber infill product derived from truck tires that avoids fiber contamination that occurs from auto tires (Entech, 2016).

1.1.3 Synthetic Turf Fields

There are between 12,000 and 13,000 synthetic turf sports fields in the U.S., with approximately 1,200 – 1,500 new installations each year (STC et al., 2016). It is estimated that 95% of the fields utilize recycled rubber infill exclusively or in a mixture with sand or alternative infills (STC et al., 2016). Current generation synthetic turf fields are typically constructed using a gravel/stone base to allow drainage and a multi-layered polypropylene and urethane backing material with polyethylene fiber blades attached to the backing placed over the base. Sand or a sand/crumb rubber mix is often used as a lower layer infill material, with a top layer of infill material consisting of recycled tire crumb rubber, natural materials (such as ground coconut husk), ethylene propylene diene monomer (EPDM), or thermoplastic elastomers (TPE) granules (STC et al., 2016). Sand may also be used in a mixture with tire crumb rubber infill in top layers in some installations. Recycled tire crumb rubber synthetic turf infill serves as ballast, support for the synthetic grass blades, and as cushioning for field users. Infill material selection and installation may also be designed to aid water drainage. As many as 20,000 recycled tires are used to produce the rubber used in a field (STC et al., 2016). Routine synthetic turf field maintenance includes brushing for infill redistribution, raking or vacuuming for infill decompaction, and sweeping for debris removal (STC et al., 2016). New infill material is sometimes added to existing fields to refresh or replace existing tire crumb rubber.

Synthetic turf fields are installed at municipal and county parks; schools, colleges and universities; professional team stadiums and practice fields; and military installations. Both outdoor and indoor facilities have been widely constructed. Football, soccer, and baseball fields are among the most widespread types of fields. Synthetic turf fields are typically used for athletic, recreation, and physical education and physical training activities, although some fields may see multi-purpose uses, such as for concerts and ceremonies. No data were identified regarding the numbers of individuals using synthetic turf fields in the U.S.; however, given the large number of installed fields it can be reasonably anticipated that the number of users nationwide is in the millions. Users may include professional and college athletes, youth athletes in school and/or other athletic organizations, adult and youth recreational users, coaches, team and facility staff, referees, and fans and bystanders of all ages.

A Health Impact Assessment for the use of synthetic turf fields that examines evidence of benefits or harms has been prepared by Toronto Public Health (MacFarlane et al., 2015). Examples of benefits of synthetic turf fields with crumb rubber infill include reduced water use and increased number of

playable days per year. Examples of concerns related to synthetic field use include high heat stress under some conditions, the potential for increased risk of skin abrasions, and the potential for adverse chemical exposure impacts for aquatic ecosystems resulting from release of metals in the tire crumb rubber or synthetic blade material. Public concerns have been raised about human exposures to chemicals associated with tire crumb rubber and synthetic turf fields. Recent health concern reports have centered on a number of cancer cases among young adults and youth soccer athletes, and particularly for soccer goal keepers likely to have relatively high contact rates with synthetic turf field materials. The Washington State Department of Health is working with the University of Washington's School of Public Health to try to determine if there is an increased rate of a specific cancer or cancers among soccer players (WA DOH, 2016).

1.1.4 Chemicals of Interest or Concern in Tires

Many of the concerns that have been raised are about the potential exposure to chemicals in tire crumb rubber infill used in synthetic turf fields. Tires are manufactured with a range of materials including rubber/elastomers; reinforcement filler material; curatives including vulcanizing agents, activators, accelerators, antoxidants and antiozonants, inhibitors and retarders; extender oils and softeners; phenolic resins, plasticizers; metal wire; polyester or nylon fabrics; and bonding agents (Dick and Rader, 2014; Cheng et al., 2014; ChemRisk, 2008; NHTSA, 2006). Chemicals of interest or concern range from polyaromatic hydrocarbons (PAHs) in carbon black, to ZnO which is used as a vulcanizing agent and may contain trace amounts of lead and cadmium oxides. Chemicals in many other classes may be used in tires including sulphenamides, guanidines, thiazoles, thiuams, dithiocarbamates, sulfur donors, phenolics, phenylenediamines, and other chemicals (ChemRisk, 2008). There is limited information to assess whether some of these chemicals may carry impurities or byproducts, or whether they may undergo chemical transformation over time. In addition, the rubber material may serve as a sorbent for chemicals in the air and in dust that falls onto the field. One laboratory reported irreversible adsorption of VOC and SVOC analytes spiked onto tire crumb rubber (NYDEC, 2009).

1.1.5 Exposure to Microbes in Synthetic Turf Fields

In addition to the potential for chemical exposures at synthetic turf fields, concerns have been raised about the potential for exposure to microbial pathogens. For example, methicillin-resistant *Staphylococcus aureus* (MRSA) has caused outbreaks among athletic teams and artificial turf has been implicated as a fomite in transmission of MRSA among college athletes (Beigier et al., 2004). In this case a high-morbidity outbreak of methicillin-resistant *Staphylococcus aureus* among players on a college football team was observed, facilitated by cosmetic body shaving and turf burns. Another study examined a MRSA outbreak among members of a professional football team (Kazakova et al., 2005). Likewise, synthetic turf fields could serve as a route of transmission for additional pathogens derived from body fluids deposited onto fields by athletes, coaches and spectators. To date, human pathogens have not been detected in samples of tire crumb rubber infill from artificial turf fields. However, very few studies have been conducted and few potential pathogens have been investigated. Furthermore, all studies reported to date have used traditional culture methods to detect and quantify total bacteria and pathogen densities. These methods can underestimate densities because culture media cannot support the growth of all bacteria and pathogens. Furthermore, bacteria can enter a viable but nonculturable state in some environments (Oliver, 2005), which prohibits their detection by culture methods. The use of molecular methods, like polymerase chain reaction (PCR) and high throughput sequencing are not

hindered by these limitations and can provide a more thorough and robust analysis of bacteria and pathogens in tire crumb rubber infill.

1.1.6 Research Studies

Many studies have attempted to characterize chemical constituents of tire crumb rubber material through direct extraction or digestion (Marsili et al., 2014; Celeiro et al., 2014; Llompart et al., 2013; Simcox et al., 2011; Menichini et al., 2011; Highsmith et al., 2009; Mota et al., 2009), leaching experiments (Krüger et al, 2012; Rhodes et al., 2012; Li et al., 2010; NYDEC, 2009;) headspace or off-gassing analysis (Simcox et al., 2011; Nilsson et al., 2008; Incorvia et al., 2007), bioaccessibility testing (Pavilonis et al., 2014; Lioy and Weisel, 2011; Zhang et al., 2008; Cal-OEHHA, 2007; Highsmith et al., 2009), or through other techniques. Many of these studies have examined metal constituents, a modest number have measured VOCs, PAHs and benzothiazole, but relatively few studies have tried to measure or look for the presence or absence of many other organic chemicals potentially associated with tire materials.

Several studies have performed measurements at synthetic turf fields for selected metal or organic chemical analytes (Schiliro et al., 2013; Menchini et al., 2011; Shalat, 2011; Cal-OEHHA, 2010; Simcox et al., 2011; Van Rooij and Jongeneelen, 2010; Highsmith et al., 2009; NYDEC, 2009; Vetrano and Ritter, 2009; Castellano et al., 2008; Dye et al., 2006). Most of these measurements have been for particles, metals, or organics in air while only a few studies measured chemicals present on field surfaces using wipe samples (NYDEC, 2009; Highsmith et al., 2009; CPSC, 2008; Cal-OEHHA, 2007). Concentrations of chemicals in the air of indoor facilities have generally been found to be higher than those at outdoor facilities. Very few studies have reported biomonitoring data (Van Rooij and Jongeneelen, 2010; Castellano et al., 2008). In both cases, 1-hydroxypyrene was measured as a marker of exposure to pyrene, and no elevated levels were found following synthetic field sports use. Several studies collected personal air samples from people engaged in activities on synthetic turf fields (Menichini et al., 2011; Shalat, 2011; Simcox et al., 2011; Vetrano and Ritter, 2009; Moretto et al., 2007). No dermal sample collection reports have been identified. Only a few studies have examined microbiological populations at synthetic turf fields (Bass and Hintze, 2013; Keller, 2013; Cal-OEHHA, 2010; Vidair, 2010: McNitt et al., 2006).

Several studies have focused on assessing the toxicity of tire crumb rubber, or one or more of its constituents, either through testing or using available toxicity information (Dorsey et al., 2015; Schiliro et al., 2013; Ginsberg et al, 2011a; He et al., 2011; Gomes et al., 2010; Mota et al., 2009; Cal-OEHHA 2007; Birkholz et al., 2003). Several researchers and organizations have performed quantitative human health cancer and/or non-cancer risk evaluations or assessments using data from their measurement studies or data reported in the literature (Pavilonis et al., 2014; Ruffino et al., 2013; Cardno ChemRisk, 2013; Kim et al., 2012; Ginsberg et al., 2011b; NYDEC, 2009; Johns, 2008; Menichini et al., 2011; Denly et al., 2008; Cal-OEHHA, 2007). No significant human health risks from exposure to tire crumb rubber infill at synthetic turf fields have been identified in the studies listed above. Menichini et al. found that based on the 0.4 ng/m^3 of benzo(a)pyrene at an indoor facility, and using a conservative approach, there was the potential for an excess lifetime cancer risk of 1×10^{-6} for an athlete with an intense 30-year activity level. Marsili et al. (2014) found that the hazard indices and cumulative excess risk values for cancer were all below levels of concern for measured chemicals; however, based on laboratory tests of PAH

releases at 60° C, estimated air concentrations at fields under hot conditions, and assuming long-term frequent exposures at the high temperature, they concluded cumulative PAH exposures under high heat conditions may be of concern. Kim et al. (2012) identified a potential risk for children with pica behavior through ingestion of crumb rubber material at playgrounds.

A few studies have investigated the bacterial loads and occurrence of select pathogens in synthetic turf athletic fields. These investigations did not focus directly on tire crumb rubber infill material; rather the samples were collected from the fields. Miller et al. (2002) investigated the presence of *Burkholderia cepacia*, an opportunistic pathogen that most often causes pneumonia, in a variety of soil types, including turf fields. While *B. cepacia* was present in soil, it was not detected in turf samples. An investigation of athletic fields in Pennsylvania used by athletes of all levels, from elementary to professional, revealed an average of 9×10^3 colony forming units (CFU) of total culturable bacteria per gram on non-selective media. The presence of the pathogen *Staphylococcus aureus*, was investigated, but was not detected in turf samples (McNitt et al., 2006). Bass and Hintze (2013) investigated a new (1 year old) and old (6 year old) field and found higher levels of culturable bacteria on older fields than new fields (1×10^8 compared to 2.5×10^5 CFU/g). Colonies that grew on selective media were presumed to be staphylococci, but no testing was performed to determine presence of *S. aureus*. Finally, five artificial turf fields of high school or colleges/universities in the San Francisco Bay Area were sampled for total culturable bacterial on non-selective media and *Staphylococcus* species on selective media. Total culturable bacteria ranged from 0 – 10^4 CFU/g on the 5 artificial turf fields. While colonies of *Staphylococcus* were observed, none were identified as *S. aureus* (Vidair, 2010). In general, higher levels of culturable bacteria were found at natural grass fields than synthetic turf fields in the studies that performed comparative sampling.

While no significant human health risks have been identified in the research described above, no single systematic study has been performed with large numbers of fields or people. A limited number of potential tire crumb rubber related chemicals were measured in most studies, and there are gaps in exposure information and measurement data for dermal and ingestion pathways. Some of the gaps and limitations will be addressed through research described in this research protocol. The results of this research will be useful for designing and conducting larger scale exposure and biomonitoring studies, and for improving exposure and risk assessment.

There are other efforts in planning or ongoing to better understand this issue. A concerted effort will be made to understand what is being done in these studies to best leverage and contribute to reducing data gaps. Specifically, researchers at the California Office of Environmental Health Hazard Assessment (Cal-OEHHA) are designing a research study that is likely to have many parallels to the research described here. Consultation between the federal research team and Cal-OEHHA researchers will be used to identify and implement methods and approaches that will, where feasible, produce comparable data.

1.2 Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds

1.2.1 Federal Research

The Agency for Toxic Substances and Disease Registry (ATSDR), the United States Environmental Protection Agency (U.S. EPA), and the Consumer Product Safety Commission (CPSC) have drafted the "Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds" (Appendix A). Because of the need for additional information, these federal organizations are launching a multi-agency action plan to study key environmental health and human health questions. This coordinated federal action includes outreach to key stakeholders and seeks to fill important data and knowledge gaps, characterize constituents of recycled tire crumb rubber, and identify ways in which people may be exposed to tire crumb rubber based on their activities on the fields. While additional research questions may require evaluation beyond this year, the planned activities will help answer some of the key questions that have been raised.

1.2.2 Federal Research Action Plan Objectives

The specific objectives of research under the federal plan are to:

- Determine key knowledge gaps;
- Identify and characterize chemical compounds found in tire crumb rubber used in artificial turf fields and playgrounds;
- Characterize how people are exposed to these chemical compounds based on their activities on the fields;
- Identify follow-up activities that could be conducted to provide additional insights about potential risks.

The full Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds is provided in Appendix A.

1.3 Research Protocol Scope

This research protocol is designed to implement three of the research elements described in the Federal Research Action Plan:

- Conduct a literature review and data gaps analysis;
- Perform tire crumb rubber characterization research;
- Perform human exposure characterization research.

The focus of the work under this research protocol is on tire crumb rubber infill used in synthetic turf fields. The literature review and gaps analysis will examine information available for playgrounds in addition to synthetic fields. The tire crumb rubber characterization and exposure characterization research will not be performed for playgrounds as part of this research protocol. The CPSC is developing research plans for playgrounds.

Important research design constraints include the short timeline for initial research activity and reporting completion in 2016 under the Federal Research Action Plan, and the resources available for implementing the research. By the end of 2016, the participating agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time. The draft status report will summarize the agencies' progress in: (1) Identifying key constituents of concern in recycled tire crumb used in artificial turf fields; (2) Assessing potential exposures to potentially harmful constituents; (3) Conducting an initial evaluation of potential cancer and non-cancer toxicity of key chemical constituents; and (4) Identifying follow-up activities that could be conducted to provide additional insights about potential risks. The report will also outline any additional research needs and next steps.

2. Research Objectives

2.1 Objectives

The federal research described in this research protocol is intended to provide information needed to further characterize tire crumb rubber use in synthetic fields in the U.S. and to examine key factors that may affect human exposure to chemical and microbiological constituents. Specific research aims are described in the sections below.

2.2 Literature Review and Data Gap Analysis

Aim 1: Conduct a literature review and data gaps analysis of relevant literature addressing aspects of exposure to chemical and microbiological constituents for synthetic turf fields and playgrounds using recycled tire rubber products.

A substantial amount of research has been conducted to characterize tire crumb rubber constituents, and environmental concentrations of related chemicals. Less research has been performed to examine human exposures and potential risks to people using synthetic turf fields and playgrounds. It is important to examine the existing literature to collate and evaluate the currently available information and to identify key data gaps.

2.3 Tire Crumb Rubber Chemical and Microbiological Characterization

There are three primary aims for the tire crumb rubber characterization study.

Aim 1: Characterize a wide range of chemical, physical, and microbiological constituents and properties for tire crumb rubber infill material collected from tire recycling centers and synthetic turf fields around the U.S.

While a number of research studies have examined crumb rubber constituents, most studies have been relatively small, restricted to a few fields or material sources, and measured a limited number of constituents. Tire crumb rubber samples collected directly from tire recycling facilities will provide information on constituents in unused material while samples collected from outdoor and indoor synthetic turf fields will provide a better understanding of constituents potentially available for exposure under different conditions of weathering and facility type. Characterization will include direct measurement of metal and SVOC constituents of tire crumb rubber, studies of VOC and SVOC emissions and emission rates from tire crumb rubber, and bioaccessibility testing of metal and SVOC constituents. Multiple analytical methods will be used provide information on a wide range of metals and organic chemicals. A combination of targeted quantitative analysis, suspect screening, and non-targeted

approaches will be applied for VOCs and SVOCs. The research will help fill data gaps regarding the types and concentrations of the chemical constituents in crumb rubber material and their potential availability for human exposure. Physical characteristics such as particle size will be examined to better understand potential exposures. The research will also address gaps in our knowledge regarding microbial pathogens associated with tire crumb rubber on synthetic turf fields.

Aim 2: Collect information from facilities around the U.S. to better understand how synthetic turf fields with tire crumb rubber infill are operated, maintained, and used with regard to characteristics potentially impacting human exposure to tire crumb rubber constituents.

Questionnaires will be administered to facility owners/managers to obtain information about potential factors that may affect exposures, including source materials, material age, tire crumb rubber addition or replacement frequencies, maintenance procedures, facility operations, and how people use the facilities.

Aim 3: Identify and collate existing toxicity reference information for selected chemical constituents identified through the tire crumb rubber characterization measurements.

Toxicity reference information will be identified and collated from existing on-line databases and literature sources for selected chemical constituents identified as part of the tire crumb rubber chemical characterization research. Selection of chemicals for toxicity reference information gathering will be based on a combination of factors that may include presence/absence, frequency of detection, relative concentration magnitude, and other information.

2.4 Exposure Characterization

There are two primary aims of the pilot-scale human exposure characterization study.

Aim 1: Collect human activity data for synthetic turf field users that will reduce the reliance of default exposure factor assumptions in exposure and risk assessment.

There are important data gaps in human activity parameters for various synthetic turf field users that are needed for estimating exposures and evaluating risks from contact with tire crumb rubber constituents. While the potential for inhalation exposures has been characterized for some constituents there is far less information for characterizing dermal and ingestion exposure pathways. Improved exposure factor information is needed for estimating and modeling exposures from the inhalation, dermal, and ingestion pathways. This study is intended to collect information using questionnaires from adults and youth who use synthetic turf fields with crumb rubber infill for several types of active uses including athletics and possibly physical education or physical training. Video data collection for a subset of participants engaged in activity on synthetic fields will be used to obtain objective information about important dermal and ingestion contact rates. In addition, extant videography of users engaged in activities on synthetic fields will, if feasible, be acquired to provide additional data on contact rates for a

wider group of people and activities that are difficult to capture consistently using questionnaires. The human activity information will provide data for parameters used in characterizing and modeling exposures associated with the use of synthetic turf fields and is likely to substantially improve the information available for dermal and ingestion exposure pathways.

Aim 2: Conduct an exposure measurement sub-study for people using synthetic turf fields with tire crumb rubber infill, in what are likely to be among the higher exposure scenarios to improve understanding of potential exposures, particularly for the dermal and ingestion exposure pathways.

Human exposure measurement data for synthetic turf field users are limited. Important data gaps exist, particularly for potential dermal and ingestion exposures to synthetic turf field and tire crumb rubber chemical constituents. There are also important limitations in the types of methods that have been developed and used for human exposure measurements during activities on synthetic fields. Challenges include collecting relevant surface, dust, and personal air samples. Few studies have performed measurements of dermal exposures. In addition, few studies have collected urine or blood samples that might be used for measuring biomarkers of exposures to chemicals in crumb rubber infill. As a pilot scale effort, this study will implement a human exposure measurement study to further develop and deploy appropriate sample collection methods and to generate data for improved exposure characterization. The study will be aimed at generating data for field use scenarios anticipated to be among those with relatively high potential exposures with regard not only to frequency and duration of time spent on synthetic fields, but also based on the potential for contact with synthetic field materials.

3. Research Design

3.1 Research Design Overview

As part of the Federal Research Action Plan, three specific research study components are described in this research protocol. The first is a literature review and data gaps analysis. The second study component is a tire crumb rubber characterization effort aimed at obtaining information about synthetic turf field facilities and operations, collection of recycled tire crumb rubber infill samples from tire recycling facilities and synthetic turf fields, and chemical and microbiological constituent analyses. The third study component is a pilot-scale exposure characterization effort aimed at obtaining synthetic field facility user activity information and data, with a subset of respondents taking part in an exposure measurement study. The exposure characterization study is intended to provide information on human activity and exposures for synthetic turf field use scenarios that are likely to be associated with higher exposures.

Important research design constraints include the short timeline for initial research activity and reporting completion in 2016 under the Federal Research Action Plan, and the resources available for implementing the research. Therefore, a convenience sample will be used for both the tire crumb rubber characterization and exposure characterization studies. Because the studies will not involve probability-based sampling from the entire population of interest, the research will not provide data suitable for nationwide generalizations. However, the research is anticipated to provide more information than is currently available, fill key data gaps, and improve exposure characterization estimates needed for designing and implementing future studies which could include biomonitoring studies, epidemiologic investigations, and risk assessments. The study is being designed to include more fields and field users than any previous single study in the U.S. It will apply a wide range of analytical approaches for identifying and characterizing important chemical and microbiological constituents and the potential for human exposure. By the end of 2016, the participating agencies anticipate releasing a draft status report that describes the findings of the study to that date.

3.2 Literature Review and Gaps Analysis

The literature review and data gaps analysis is an important component of the Federal Research Action Plan and is needed to guide research in the near and longer terms. A number of previous research investigations have examined various aspects of the potential for human and ecological exposures and risks from recycled tire products used on synthetic fields and playgrounds. While the studies have typically been small in scope and often limited in the number and types of chemical or microbiological agents considered, they cumulatively offer insight on the current state of the science and data in our understanding about the potential risks.

Literature identification and review is underway concurrently with development of this research protocol. Literature searches have been conducted through formal searches of multiple literature databases for published journal articles as well as internet searches and other approaches for identifying reports not available as published journal articles. Using these approaches a preliminary list of 90 journal articles and reports have been identified that are most relevant for characterizing chemical constituents and microbiological populations and for understanding human and ecological exposures and risks from recycled tire products used on synthetic fields and playgrounds (Appendix B). Literature review efforts to date include preparing summaries of key articles or reports, performing a summary classification of information and key conclusions across all articles and reports, and extracting and summarizing chemical reporting information from studies where available. This draft information has informed development of this research protocol with regard to early identification of some data gaps (e.g., limited information on dermal and ingestion exposures and exposure pathways) and selection of proposed target chemical analytes. Further efforts are ongoing to finalize the information capture and consolidation, complete the data gaps analysis, and to prepare a white paper describing the review, summarizing the literature, performing the gaps analysis, and providing conclusions.

3.3 Tire Crumb Rubber Characterization

3.3.1 Overview

The tire crumb rubber characterization study will involve the collection of crumb rubber material from tire recycling facilities and synthetic turf fields around the U.S., with laboratory analysis for a wide range of metals, volatile organic compounds (VOCs), and semi-volatile organic compounds (SVOCs) (Figure 1). Laboratory analyses will include dynamic emission chamber measurements for VOCs and SVOCs under different temperature conditions and bioaccessibility measurements for metals and SVOCs. The emissions and bioaccessibility experiments will provide important information about the types and amounts of tire crumb rubber chemical constituents available for human exposure through inhalation, dermal, and inhalation pathways. In addition to quantitative target chemical analyses, suspect screening and non-targeted analysis methods will be applied for VOCs and SVOCs in an attempt to identify whether there may be potential chemicals of interest that have not been identified or widely reported in previous research. The study will also collect tire crumb rubber infill from synthetic turf fields to assess microbial populations; however, microbial assessments will not be conducted for tire crumb rubber collected at tire recycling facilities. A final piece of this research activity is to identify and collate extant toxicity reference data for selected chemical constituents identified through laboratory analysis.

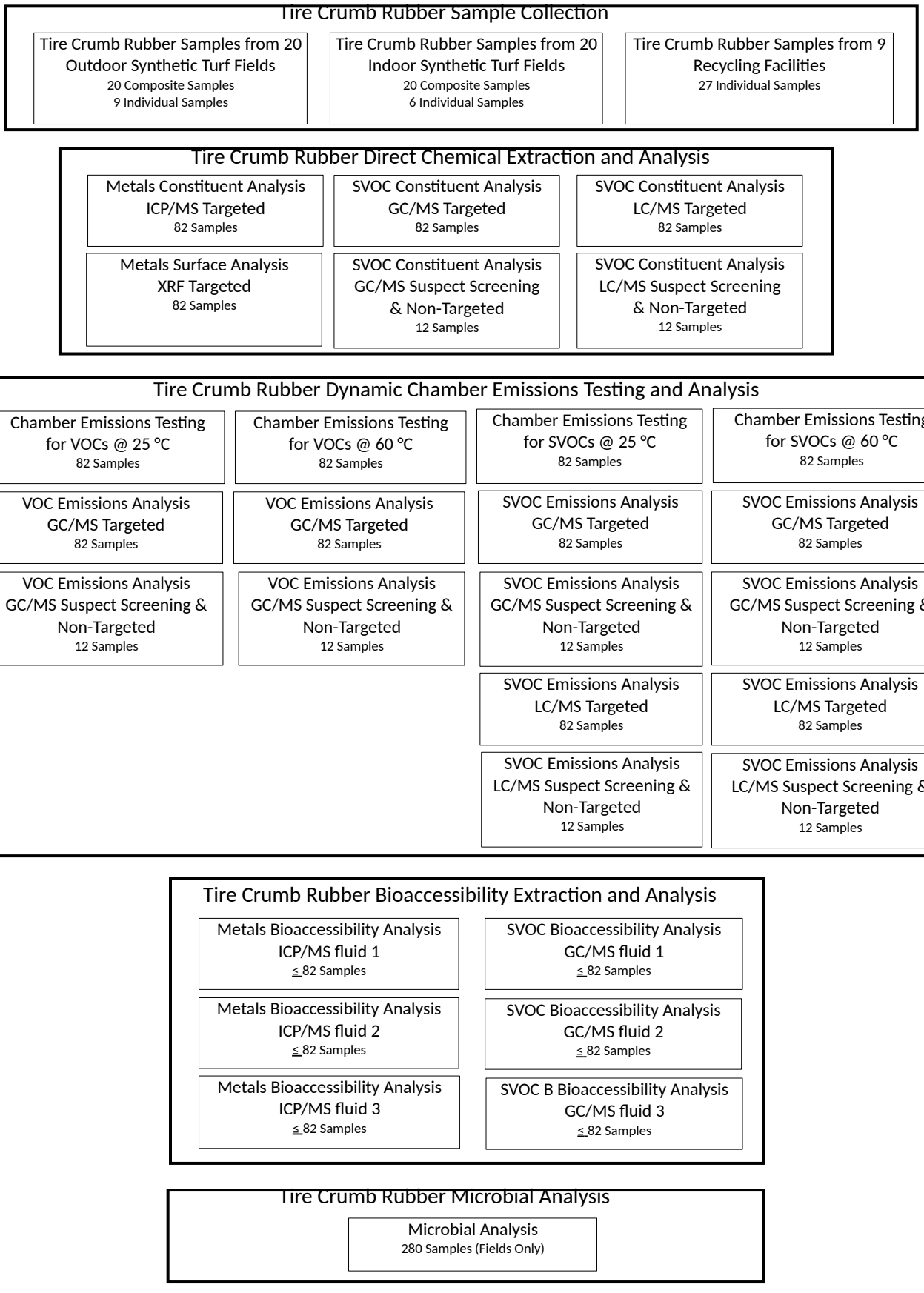

Figure 1. Tire crumb rubber characterization overview

3.3.2 Tire Recycling Facility and Synthetic Field Recruitment

Up to nine tire recycling facilities that produce tire crumb rubber for use on synthetic turf fields will be identified and asked to provide tire crumb rubber material samples. Outreach to the Recycled Rubber Council, the Synthetic Turf Council, and individual recycling companies will be used to gauge general interest in providing recycled tire crumb rubber samples. Following outreach discussions, specific companies will be contacted to determine interest in research participation and scheduling availability using a telephone script (Appendix C) with agreements finalized using a participation agreement form (Appendix D). Tire crumb rubber from recycling facilities will represent 'new' material that has not undergone weathering at synthetic fields for comparison with material from fields that has undergone weathering and active play. Three samples from different production batches and/or storage containers will be collected from each facility by research staff. If possible, about half of the samples from recycling facilities will be from the ambient production process and about half from the cryogenic production process. The actual numbers will depend on facility participation.

Forty facilities with synthetic turf fields with tire crumb rubber infill that has been present on the field for ≥ 2 years will be recruited across the four U.S. census regions. If feasible, additional fields may be recruited and sampled; however, the samples will not be analyzed for the current program but will be stored for future analysis. By studying unused material from recycling centers, and material that has been on the field for at least two years, we will get some insight as to whether organic chemical decreases as reported by Zhang et al. (2008) are common among outdoor and indoor fields. We anticipate that we will collect samples from field materials that have a range of ages, and to the extent feasible, we will assess whether there may be trends in chemical content and particle size distribution with age. The geographical diversity is likely to provide a range of material weathering conditions for outdoor fields and may include differences in tire crumb rubber source material. Stratification by facility type (indoor vs. outdoor) will be attempted at the facility identification and recruitment stage. Higher indoor air concentrations of organic chemicals potentially associated with tire crumb rubber have been measured in some studies as compared to levels measured at outdoor fields. Stratification of tire crumb rubber characterization by outdoor and indoor facilities will help determine whether the higher potential inhalation exposures are due to differential weathering effects on the amounts and types of chemicals available for exposure or a function of ventilation rates at indoor facilities. Chemical constituents from outdoor and indoor synthetic field samples will also be compared with unused samples from recycling facilities to better understand the impact of weathering and facility use on the types and amounts of constituents available for human exposure. The facilities sampling design goals are shown in Table 1.

Table 1. Goals for the number and types of tire recycling facilities and synthetic turf fields

U.S. Census Region	Outdoor Fields ≥ 2 Years Old	Indoor Fields ≥ 2 Years Old	Total Number of Fields or Recycling Facilities
Synthetic Turf Fields			
Northeast	5	5	10
South	5	5	10
Midwest	5	5	10
West	5	5	10
Total Number of Fields	20	20	40
Tire Recycling Facilities			
Ambient Recycling Process			5
Cryogenic Recycling Process			4
Total Number of Facilities			9[a]

[a]Samples from three different batches or containers per facility are planned for collection, so the total number of samples is expected to be 3 x 9 = 27 samples. The proportion of facilities using different processes is a goal; actual proportion will depend on availability and participation.

Multiple outreach mechanisms will be used to identify and recruit synthetic turf field facilities. The Department of Defense or specific military branches may be interested in participation of facilities at military installations. Specifically, the U.S. Army Medical Command may be able to facilitate access to fields at military installations and has expressed interest in a possible research collaboration. Federal contacts and outreach with state government organizations, including state and local departments of health, may identify state and local facilities, or serve as an intermediary for introduction to other state and local government organizations. Consideration will be given to including fields offered by local municipalities that are interested in participating. Professional and college athletic organizations may be contacted. Additionally, individual institutions or municipalities may be contacted directly in our recruitment efforts.

Contacts will be made with facility owners/managers to determine their level of interest, potential eligibility (facilities with fields in Table 1 categories), and availability during the research implementation time frame for answering a questionnaire and providing or allowing collection of tire crumb rubber material samples. Up to 70 facilities may be contacted for eligibility determination using a structured eligibility assessment screening form (Appendix E) with agreements finalized using a participation agreement form (Appendix D).

3.3.3 Statistical Design Considerations

The research is not being conducted under a representative sampling design due to time and resource constraints. A convenience sample of tire recycling facilities and synthetic turf field facilities will be used. Statistical power was considered in the stratified facility design (Table 1). The statistical power for assessing differences in tire crumb rubber chemical constituents, emissions, and bioaccessibility is of interest to determine if there are likely to be meaningful differences in exposures based on tire crumb rubber age and weathering (unused recycling facility tire crumb rubber vs. synthetic field tire crumb rubber) and based on the synthetic field facility type (indoor vs. outdoor location). Although the potential difference in chemical concentrations between and among fields in different U.S. regions is of interest, this study is likely to be underpowered for assessing those differences.

Measurement data for two chemicals of possible interest, lead and benzo(a)pyrene (BaP), were obtained from the literature. Using reported means and standard deviations, a range of powers for detecting significant differences in group means was calculated for sample sizes of 20 in each group (Table 2).

These estimates suggest that for measurements of chemicals in tire crumb rubber materials with relatively low variability (low coefficients of variation or CV) differences in means below 20% for 20 in each group may be detected with reasonable statistical power (power ≥ 0.8). For chemicals with higher variability among fields, statistically significant differences may only be detected for differences in means above 100% when group sizes are 20. While larger samples sizes would be preferred, the proposed sample size offers the opportunity to assess whether there are likely to be important differences that may affect human exposure.

Beyond statistical tests of differences of data between groups, the proposed data collection across a diverse range of facilities in the U.S. will provide important information for characterizing exposures to tire crumb rubber constituents:

a) facility installation and operation information and data,
b) the spectrum of user groups, activity types, use durations and frequencies,
c) the concentrations and bioaccessibility of selected tire crumb rubber chemical constituents,
d) emission rates of selected tire crumb rubber constituents under different conditions,
e) potential identification of tire crumb rubber constituents not previously measured or identified,
f) frequencies of tire crumb rubber constituents found across all analyses, and,
g) toxicological information for identified tire crumb rubber constituents of interest.

The information and data will be made available for human exposure screening assessments and more detailed exposure modeling.

Table 2. Power of the t-test to detect differences between two groups (α=0.05)

	N = 20/facility group	
	Lead	BaP
	CV1 = 0.18	CV1 = 1.13
Difference	CV2 = 0.18	CV2 = 1.13
20%	0.925	0.085
50%	>0.99	0.278
100%	>0.99	0.782
200%	>0.99	>0.99

[a] Lead measured in tire crumb rubber from 5 fields, mean 26.6 ± 4.1 µg/g; Highsmith R., Thomas K.W., Williams R.W. (2009). A Scoping-Level Field Monitoring Study of Synthetic Turf and Playgrounds; EPA/600/R-09/135. National Exposure Research Laboratory, U.S. Environmental Protection Agency.

[b] Benzo(a)pyrene measured in uncoated tire crumb rubber from four fields, mean 4.1 ± 4.5 µg/g ; Menichini et al. (2011). Artificial-turf Playing Fields: Contents of Metals, PAHs, PCBs, PCDDs and PCDFs, Inhalation Exposure to PAHs and Related Preliminary Risk Assessment. Sci Total Environ. 409(23):4950-7.

3.3.4 Tire Crumb Rubber Characterization Data Collection

The numbers and types of questionnaires and samples scheduled for collection at recycling and synthetic turf facilities are shown in Table 3. Synthetic turf field facility owners/managers agreeing to participate will be asked to complete a questionnaire (Appendix F) administered by trained research staff in-person or over the phone using a Computer Assisted Interview. Samples will be collected following methods described in Section 4. Trained research study staff will collect most of the samples following specific protocols. Some organizations may have staff members with skills and knowledge (e.g. industrial hygiene or environmental assessment) required to implement standard protocols. In order to reduce research costs, in some cases consideration will be given to training facility organization staff to collect samples following standard protocols and using research study supplied materials.

Table 3. Number and types of facilities, questionnaires, and tire crumb rubber samples

	Number of Facilities or Questionnaires	Number of Individual Crumb Rubber Samples[a]	Number of Composite Crumb Rubber Samples[b]
Facilities			
Tire recycling	9		
Synthetic turf field	40		
Questionnaires			
Synthetic Field facility owner/manager	40		
Recycling Facility Sample Collection			
For metals analysis (3 per facility)		27	
For organics analysis (3 per facility)		27	
Synthetic Field Sample Collection			
For metals analysis		15	40
For organics analysis		15	40
For microbial analysis		280	

[a]For tire recycling facilities individual samples will be collected from separate batches or storage containers, if available. For synthetic fields a subset of three individual samples collected at five fields will be analyzed to assess within-field variability for metal and organic chemical analytes. Seven individual samples from each field will be collected for microbial analysis.

[b]Composite samples prepared from seven individual samples collected at each field will be used for metal and organic chemical analysis.

3.3.5 Tire Crumb Rubber Chemical and Microbiological Analysis

The numbers and types of sample analyses scheduled for tire crumb rubber characterization are described in Table 4. Tire crumb rubber material will be analyzed by laboratories for a wide range of volatile and semi-volatile organic (VOC and SVOC) and metals constituents. SVOC analyses will be performed using both GC/MS and LC/MS methods to capture a wide potential range of chemicals with differing chemical and physical properties. Quantitative analyses will be performed for some target analyte chemicals (Tables 5 - 7). Suspect screening and non-targeted analysis methods will be applied to a subset of SVOC constituent analyses. Suspect screening analyses for SVOCs may result in semi-quantitative estimates of concentrations. Sample analysis methods are described in more detail in Section 4.

Table 4. Number and types of samples and analyses for tire crumb rubber characterization

Sample Type	Number of Samples/ Analyses[a]	Additional Information
Direct Constituent Analysis		
Samples for metals constituent ICP/MS analyses	82[b]	
Samples for metals constituent XRF analyses	82	
Samples for targeted SVOC constituent LC/MS analyses	82	
Samples for non-targeted SVOC constituent LC/MS analyses	12	subset of samples
Samples for targeted SVOC constituent GC/MS analyses	82	
Samples for non-targeted SVOC constituent GC/MS analyses	12	subset of samples
Bioaccessibility Analysis		
Samples for metals bioaccessibility analyses	246	Maximum of 82 samples with 3 simulated fluids/sample
Samples for SVOC bioaccessibility analyses	246	Maximum of 82 samples with 3 simulated fluids/sample
Dynamic Chamber Emissions Experiments		
Chamber experiments for VOCs in TC[c]	82	at 25 °C
Chamber experiments for VOCs in TC	82	at 60 °C
Chamber experiments for SVOCs in TC	82	at 25 °C
Chamber experiments for SVOCs in TC	82	at 60 °C
Emissions Sample Analyses		
Samples for targeted VOC emissions analyses	164	
Samples for non-targeted VOC emissions analyses	12	subset of 60 °C samples
Samples for targeted SVOC emissions LC/MS analyses	164	
Samples for non-targeted SVOC emissions LC/MS analyses	12	subset of 60 °C samples
Samples for targeted SVOC emissions GC/MS analyses	164	
Samples for non-targeted SVOC emissions GC/MS analyses	12	subset of 60 °C samples
Microbial Sample Analysis		
Samples for TC microbial analyses	280	

[a]Does not include quality control/quality assurance samples or analyses.

[b]The total of 82 samples is based on 40 synthetic field composite samples, 15 synthetic field individual samples, and 27 individual facility samples.

[c]TC = tire crumb rubber samples.

Both bioaccessibility testing and dynamic chamber emission experiments will be used to generate measurement data useful for gaining a better understanding of the potential for human exposure through inhalation, dermal, and ingestion pathways. Samples will be analyzed for assessing bioaccessibility of selected metals and SVOCs using three different simulated biological fluids. For the in vitro analysis, metals and SVOCs will be selected based on existing data and on data from the current activities, if available. Bioaccessibility testing results will only be reported for the analytes with concentrations above the limit of quantitation.

Tire crumb rubber samples will be placed in dynamic emission chambers under controlled conditions of ventilation, temperature, and humidity. Laboratory chamber emission experiments will be made using two temperature conditions, including a temperature that may represent a warm indoor facility (25 °C) and an upper temperature that approaches what has been reported for synthetic field surfaces under hot ambient conditions (60 °C). Emission rates will be measured for selected VOCs and SVOCs for which quantitative analyses are performed. Suspect screening and non-targeted chemical analysis techniques will also be applied to a subset of VOC and SVOC emission samples.
There is interest in how silicone wristbands might be used in future exposure measurement studies for synthetic field users. As a first step towards determining feasibility, it is important to understand how to measure the relevant chemicals in wristbands and to assess the sorption of chemicals when exposed to tire crumb rubber materials. Exploratory tests are intended to provide the initial assessment and demonstration, which can then inform decisions about using the wristbands in future exposure studies. If time and resources permit, a small number (≤ 5) of exploratory chamber experiments will be performed to evaluate the uptake of selected chemical constituents by silicone wristbands, one buried in tire crumb rubber material and one suspended in the chamber air. The results are intended to inform evaluation of the potential utility in future facility and personal monitoring research studies.

Tire crumb rubber samples will also be analyzed to assess the presence and densities of *Staphylococcus* species, and specifically, *S. aureus* using droplet digital PCR (ddPCR). In addition, the Panton-Valentine leucocidin cytotoxin virulence gene of *S. aureus* and antibiotic resistance genes will be quantified in samples. To investigate the presence of potential pathogens and relative contribution of human-associated microbes to the artificial turf field microbiome, non-targeted analysis of the bacteria in samples will be conducted using high throughput genomic sequencing.

3.3.6 Proposed Target Analytes

An important goal of this research study is to apply a range of sensitive and specific analytical methods that are likely to provide quantitative measurement or presence/absence data for a wide range of chemicals potentially associated with tire crumb rubber. Proposed metal, VOC, and SVOC target analytes are shown in Tables 5 - 7. Target analyte selection was based on a combination of information from previous tire crumb rubber research studies, information on potential tire manufacturing chemical ingredients, and analytical laboratory and method capabilities. The table includes reference ID numbers linking to the preliminary literature review citations in Appendix B. Many of the citations include measurement results for the listed chemical in tire crumb rubber or playground surface rubber, rubber leachate, headspace analysis, or an environmental measurement. In some cases the study reported only presence without quantitative results. Some chemicals are included because they were reported

through the literature or other sources to be potential tire manufacturing component or process chemicals.

Many of the chemicals are proposed as target chemicals for quantitative analysis as noted in Tables 5 - 7. Other chemicals are proposed for suspect screening where standards and mass spectra may be available to identify the presence of the chemical with some degree of confidence. In some cases where standards can be obtained and analyzed, it may be possible to provide semi-quantitative or relative amount estimates. A subset of VOC and SVOC samples will also be analyzed using non-targeted approaches, which will generate characteristic mass spectra that can be explored to tentatively identify or propose chemical presence for further investigation. Non-targeted measurement data analysis is very time consuming and initial efforts will likely focus on chromatographic peaks and spectra for unidentified chemicals appearing in relatively large amounts.

The proposed target analyte list may change during the study as experience is gained through implementation of the methods and the analytical processes. We may find that some chemicals included for suspect screening can be part of the quantitative analysis. For other chemicals we may find that the proposed methods do not provide adequate sensitivity or there are degradation or chromatography problems under the established conditions that will prevent acceptable analysis under defined QA/QC specifications.

3.3.7 Extant Toxicological Reference Information

Extant toxicological reference information will be compiled for selected tire crumb rubber chemical constituents of interest identified in the tire crumb rubber characterization and exposure characterization studies. Selection criteria may include frequency and magnitude of detection, detection in multiple media, and other factors including measurement reports from other studies as identified in the literature review. Multiple sources of toxicity reference information will be used to identify and compile values for chemicals where available, and to demonstrate gaps where not available. Identification and compilation of other extant toxicity data from primary sources may also be considered for some chemicals.

Table 5. Proposed metals for analysis in tire crumb rubber samples

Metal Name	CAS Number	Literature Review Reference ID (see Appendix B)
Aluminum	7429-90-5	6, 7, 36, 49, 63, 66, 71
Antimony	7440-36-0	6, 7, 49
Arsenic	7440-38-2	6, 7, 17, 36, 45, 49, 51, 60, 63, 66, 71, 79
Barium	7440-39-3	6, 7, 17, 36, 49, 51, 57, 63, 71, 78
Beryllium	7440-41-7	6, 45, 49, 60
Cadmium	7440-43-9	6, 7, 17, 28, 34, 45, 47, 49, 51, 60, 63, 66, 71, 79, 89
Chromium	7440-47-3	6, 7, 17, 28, 32, 36, 45, 47, 49, 51, 57, 60, 63, 66, 71, 76, 78, 79, 89
Cobalt	7440-48-4	6, 7, 49, 63
Copper	7440-50-8	6, 7, 17, 36, 45, 47, 49, 51, 57, 60, 63, 66, 71
Iron	7439-89-6	6, 7, 36, 47, 49, 57, 63, 66, 71
Lead	7439-92-1	6, 7, 16, 17, 20, 28, 32, 34, 36, 45, 47, 49, 51, 57, 60, 63, 66, 71, 78, 79, 89
Magnesium	7439-95-4	6, 7, 36, 45, 49, 60, 66
Manganese	7439-96-5	6, 17, 36, 49, 57, 63, 66, 71
Mercury	7439-97-6	6, 7, 28, 49, 51, 78, 89, 71
Molybdenum[a]	7439-98-7	6, 7, 49, 66
Nickel	7440-02-0	6, 7, 17, 47, 49, 51, 57, 63, 66, 71
Rubidium[a]	7440-17-7	6, 36, 49
Selenium	7782-49-2	6, 7, 34, 45, 49, 51, 60, 66, 71
Strontium	7440-24-6	6, 36, 49
Tin[a]	7440-31-5	6, 28, 49, 63, 71, 89
Vanadium	7440-62-2	6, 7, 45, 49, 60, 71
Zinc	7440-66-6	6, 7, 17, 28, 32, 34, 36, 47, 49, 51, 54, 57, 61, 63, 66, 71, 72, 79, 89

[a]These metals are not listed in EPA methods 3051A and/or 6020B for digestion and ICP-MS analysis.

Table 6. Proposed VOCs for targeted and suspect screening analysis in tire crumb rubber samples

VOC Name	CAS Number	Target Analyte[a]	Suspect Screening[b]	Literature Review Reference ID (see Appendix B)
Acetone	67-64-1	Yes		15, 16, 55, 57, 76
Aniline	62-53-3	Yes		7, 54, 57
Benzene	71-43-2	Yes		2, 10, 11, 12, 15, 16, 32, 55, 57, 63, 65, 71
Benzothiazole	95-16-9	Yes		7, 15, 16, 17, 34, 3646, 51, 54, 55, 57, 82
t-Butylamine	75-64-9	Yes		
Carbon disulfide	75-15-0	Yes		12, 15, 16, 71, 78
Carbon tetrachloride	56-23-5	Yes		16, 32, 57
Chlorobenzene	108-90-7	Yes		16
Chloroform	67-66-3	Yes		76
Chloromethane	74-87-3	Yes		15, 16, 32, 76
Ethyl benzene	100-41-4	Yes		10, 11, 15, 16, 57, 61
Formaldehyde	50-00-0	Yes		94
Hexane	110-54-3	Yes		2, 11, 12, 15, 16, 32, 57, 76
Methyl ethyl ketone	78-93-3	Yes		12, 15, 16, 32, 76, 78,
Methylene chloride	75-09-2	Yes		2, 15, 16, 32, 57, 76
Methyl isobutyl ketone	108-10-1	Yes		15, 16, 32, 54, 55, 57, 71
Naphthalene	91-20-3	Yes		7, 10, 12, 15, 17, 23, 28, 45, 46, 47, 57, 61, 72, 79, 82,
Styrene	100-42-5	Yes		11, 12, 15, 16, 55
Toluene	108-88-3	Yes		8, 10, 11, 12, 15, 16, 32, 55, 57, 61, 63, 65, 71, 76, 78
Tetrachloroethylene	127-18-4	Yes		16, 57
Trichloroethylene	79-01-6	Yes		16
m-Xylene	108-38-3	Yes		8, 10, 11, 12, 15, 16, 32, 55, 57, 61, 63, 65
p-Xylene	106-42-3	Yes		8, 10, 11, 12, 15, 16, 32, 55, 57, 61, 63, 65
o-Xylene	95-47-6	Yes		16, 55, 57, 61
1,1,1-Trichloroethane	71-55-6	Yes		12
1,3-Butadiene	106-99-0	Yes		
2-Butene (cis and/or trans)	590-18-1; 624-64-6	Yes		
cis-1,2-Dichloroethene	156-59-2	Yes		61
1,1,2-Trichloro-1,2,2-trifluoroethane	76-13-1	Yes		16, 32
1,2,4-Trimethyl benzene	95-63-6	Yes		8, 11, 16, 57, 61
1,3,5-Trimethyl Benzene	108-67-8	Yes		16, 61
4-Ethyltoluene	622-96-8	Yes		
Acetonitrile	75-05-8		Yes	2, 16
Acrolein	107-02-8		Yes	16
Biphenyl	92-52-4		Yes	23
Butylbenzene	104-51-8		Yes	55, 61
Chloromethane	74-87-3		Yes	15, 16, 32, 76
Decane	124-18-5		Yes	11
Ethanol	64-17-5		Yes	16, 76
Heptane	142-82-5		Yes	11, 12, 15, 16
Isopropylbenzene	98-82-8		Yes	8, 61
Isopropyltoluene	527-84-4		Yes	61
Methyl Alcohol	67-56-1		Yes	16
Nonane	111-84-2		Yes	11
Octane	111-65-9		Yes	11
Pentane	109-66-0		Yes	16
Phenol	108-95-2		Yes	7, 12, 71, 57, 78
Propylbenzene	103-65-1		Yes	11, 61
1,2,3-Trimethyl benzene	526-73-8		Yes	71
2-Methylbutane	78-78-4		Yes	16
3-Methylpentane	96-14-0		Yes	16

[a]These VOCs are proposed for quantitative analysis through the use of calibration standards. Some analytes have not yet been tested for quantitative analysis using the proposed methods and the list is subject to change.

[b]These VOCs are proposed for suspect screening or non-targeted analysis for presence/absence.

Table 7. Proposed SVOCs for targeted and suspect screening analysis in tire crumb rubber samples

SVOC Name	CAS Number	Target Analyte[a]	Suspect Screening[b]	Literature Review Reference ID (see Appendix B)
PAHs				
Acenaphthene	83-32-9	Yes		15, 23, 28, 45, 46, 47, 61, 79, 82, 89
Acenaphthylene	208-96-8	Yes		15, 23, 28, 45, 46, 61, 82, 89
Anthracene	120-12-7	Yes		23, 45, 46, 47, 61, 79, 82, 82, 89
Benz[a]anthracene	56-55-3	Yes		15, 23, 28, 45, 46, 47, 49, 63, 65, 79, 82, 89
Benzo(b)fluoranthene	205-99-2	Yes		7, 15, 28, 45, 46, 47, 49, 63, 65, 79, 82, 89
Benzo(k)fluoranthene	207-08-9	Yes		15, 28, 45, 46, 47, 63, 79, 82, 89
Benzo[a]pyrene	50-32-8	Yes		15, 23, 28, 45, 46, 47, 49, 63, 65, 79, 82, 89
Benzo[b]fluoranthene	205-99-2	Yes		7, 15, 28, 45, 46, 47, 49, 63, 65, 79, 82, 89
Benzo[ghi]perylene	191-24-2	Yes		15, 23, 28, 46, 47, 49, 63, 6579, 89
Chrysene	218-01-9	Yes		7, 15, 23, 28, 45, 46, 47, 49, 63, 65, 79, 82, 89
Dibenz[a,h]anthracene	53-70-3	Yes		28, 45, 47, 63, 65, 79, 89
Fluoranthene	206-44-0	Yes		7, 10, 15, 17, 23, 28, 45, 46, 47, 61, 65, 79, 82, 89
Fluorene	86-73-7	Yes		7, 15, 23, 28, 45, 46, 47, 61, 65, 79, 82, 89
Indeno[1,2,3-cd]pyrene	193-39-5	Yes		23, 28, 46, 49, 65, 79, 89
Naphthalene	91-20-3	Yes		7, 10, 15, 17, 23, 28, 45, 46, 47, 57, 61, 65, 79, 82, 89
Phenanthrene	85-01-8	Yes		7, 10, 15, 17, 23, 28, 45, 46, 47, 61, 65, 79, 82, 89
Pyrene	129-00-0	Yes		7, 10, 15, 17, 23, 28, 45, 46, 47, 49, 61, 63, 65, 79, 82, 89
1-Hydroxypyrene	5315-79-7		Yes	10, 82
1-Methyl naphthalene	90-12-0		Yes	15, 17, 23
1-Methyl phenanthrene	832-69-9		Yes	15, 17, 23
2-Bromomethylnaphthalene	939-26-4		Yes	36
2-Methyl naphthalene	91-57-6		Yes	15
2-Methyl phenanthrene	2531-84-2		Yes	23
3-Methyl phenanthrene	832-71-3		Yes	23
9-Methylphenanthrene	883-20-5		Yes	23
Benzo(e)pyrene	192-97-2		Yes	15, 23
Coronene	191-07-1		Yes	23
Phthalates				
Benzylbutyl phthalate	85-68-7	Yes		10, 82
Di(2-ethylhexyl)adipate	103-23-1	Yes		15, 17, 23
Di(2-ethylhexyl)phthalate	117-81-7	Yes		15, 17, 23
Dibutyl phthalate	84-74-2	Yes		36
Diethyl phthalate	84-66-2	Yes		15
Diisobutyl phthalate	84-69-5	Yes		23
Diisononyl phthalate	28553-12-0	Yes		23
Dimethyl phthalate	131-11-3	Yes		23
Di-n-octyl phthalate	117-84-0	Yes		15, 23
Diisodecyl phthalate	26761-40-0		Yes	23

[a]These SVOCs are proposed for quantitative analysis through the use of calibration standards. Some analytes have not yet been tested for quantitative analysis using the proposed methods and the list is subject to change.
[b]These SVOCs are proposed for suspect screening or non-targeted analysis for presence/absence.

Table 7. Proposed SVOCs for targeted and suspect screening analysis in tire crumb rubber samples (continued)

SVOC Name	CAS Number	Target Analyte[a]	Suspect Screening[b]	Literature Review Reference ID (see Appendix B)
Potential Turf Field Biocides[c]				
Alkylbenzyldimethyl ammonium chloride	68424-85-1	Yes		
Alcohol Ethoxylate 6	68439-45-2	Yes		
Dioctyldimethyl-ammonium chloride	5538-94-3	Yes		
Didecyl dimethyl ammonium chloride	7173-51-5	Yes		
Alkyl dimethyl benzyl ammonium chloride	68391-01-5	Yes		
Alkyl dimethyl ethyl benzyl ammonium chloride	68956-79-6	Yes		
Potential Rubber Curatives, Antioxidants/Antizonants, and Other Chemicals Reported in Literature				
2-Mercaptobenzothiazole (MBT)	149-30-4	Yes		46, 57
4-tert-(octyl)-phenol	140-66-9	Yes		16, 17, 34, 51
Aniline	62-53-3	Yes		7, 54, 57
Benzothiazole	95-16-9	Yes		7, 15, 16, 17, 34, 3646, 51, 54, 55, 57, 82
Benzothiazolone	934-34-9	Yes		54, 57
Bis-(2,2,6,6-tetramethyl-4-piperidinyl)sebacate	52829-07-9	Yes		54
Butylated hydroxytoluene	128-37-0	Yes		15, 16, 17, 34, 46, 54, 82
Butylbenzene	104-51-8	Yes		55, 61
Cyclohexamine, N-cyclohexyl-	101-83-7	Yes		7, 54
Cyclohexanamine	108-91-8	Yes		54
Cyclohexanamine, N-cyclohexyl-N-methyl-	7560-83-0	Yes		54, 57
Cyclohexane, isothiocyanato-	1122-82-3	Yes		54, 57
Dibenzothiophene	132-65-0	Yes		23, 46
Hexadecane	544-76-3	Yes		17, 34
Phthalimide	85-41-6	Yes		7, 57
Resorcinol	108-46-3	Yes		94
1,3-Dicyclohexylurea	2387-23-7		Yes	54
1,4-Benzenediamine, N,N0-diphenyl-	74-31-7		Yes	36, 94
1-Phenanthrenecarboxylic acid, 1,2,3,4,4	1740-19-8		Yes	36
2-(1-phenylethyl)-phenol	26857-99-8		Yes	54
2-(Methylthio)benzothiazole	615-22-5		Yes	54
2-(4-morpholinothio)benzothiazole (MBS)	102-77-2		Yes	94
2,2,4-Trimethyl-1,2-dihydroquinoline (TMQ)	147-47-7		Yes	94
2,2'-Methylene-bis-(4-methyl-6-tert-butylphenol)	119-47-1		Yes	94
2,4-Dimethylphenol	105-67-9		Yes	57
2,6-Di-tert-butyl-4-methylphenol (BHT)	128-37-0		Yes	94
2,2'Dithiobis(benzothiazole) (MBTS) (MBTS)	120-78-5		Yes	
2-Ethylanthracene-9,10-dione	84-51-5		Yes	36
o-cresol	95-48-7		Yes	57
2-Morpholinodithiobenzothiazole (MBSS)	95-32-9		Yes	
2-Phenylbenzimidazole	716-79-0		Yes	36
2-Phenylbenzothiazole	883-93-2		Yes	36

[a]These SVOCs are proposed for quantitative analysis through the use of calibration standards. Some analytes have not yet been tested for quantitative analysis using the proposed methods and the list is subject to change.
[b]These SVOCs are proposed for suspect screening or non-targeted analysis for presence/absence.
[c]Reported by the California Office of Environmental Health Hazard Assessment as potential turf biocides. These compounds are not amenable to gas chromatographic analysis. It is not clear yet whether they can be successfully analyzed using the proposed liquid chromatography procedures.

Table 7. Proposed SVOCs for targeted and suspect screening analysis in tire crumb rubber samples (continued)

SVOC Name	CAS Number	Suspect Screening[a]	Literature Review ID (see Appendix B)
Potential Rubber Curatives, Antioxidants/Antiozonants, and Other Chemicals Reported in Literature			
3,5-Di-tert-Butyl-4-hydroxybenzaldehyde	1620-98-0	Yes	54
p-cresol	106-44-5	Yes	57
4-Nonylphenol	104-40-5	Yes	54, 61
4-tert-butylphenol	98-54-4	Yes	46
5-Methyl-2-hexanone	110-12-3	Yes	54
Acetophenone	98-86-2	Yes	54, 57
Benzene, isocyanato-	103-71-9	Yes	54
Benzoic acid	65-85-0	Yes	55, 57
Benzyl alcohol	100-51-6	Yes	57
Biphenyl	92-52-4	Yes	55
Butylated hydroxyanisole (isomeric mixture)	25013-16-5	Yes	15, 17, 82
Caprolactam disulfide (CLD)	23847-08-7	Yes	94
Carbazole	86-74-8	Yes	45, 57
Cyclohexane, isocyanato	3173-53-3	Yes	54
Cyclohexanone	108-94-1	Yes	7, 54
Cyclohexylthiophthalimide (CTP)	17796-82-6	Yes	
Di-(2-ethyl)hexylphosphorylpolysulfide (SDT)	Not Found	Yes	94
Dibenzofurane	132-64-9	Yes	23
Dicyclohexylamine	101-83-7	Yes	
Dimethyldiphenylthiuram disulfide (MPTD)	53880-86-7	Yes	94
Di-ortho-tolylguanidine (DOTG)	97-39-2	Yes	94
Dipentamethylenethiuram tetrasulfide (DPTT)	120-54-7	Yes	94
Diphenylamine	122-39-4	Yes	2, 36
Dithiodimorpholine (DTDM)	103-34-4	Yes	94
Docosanoic acid	112-85-6	Yes	36
Dodecanoic acid	143-07-7	Yes	54
Dotriacontane	544-85-4	Yes	36
Drometrizol	2440-22-4	Yes	54
Eicosane	112-95-8	Yes	36
Erucylamide	112-84-5	Yes	54
Ethanol, 1-(2-butoxyethoxy)	54446-78-5	Yes	54
Ethanol, 2-butoxy-	111-76-2	Yes	54
Ethanone, 1,1'-(1,3-phenylene)bis-	6781-42-6	Yes	54
Ethanone, 1,1'-(1,4-phenylene)bis-	1009-61-6	Yes	54
Ethanone, 1-[4-(1-methylethenyl)phenyl]-	5359-04-6	Yes	54
Ethylenethiourea (ETU)	96-45-7	Yes	94
Formamide, N-cyclohexyl	766-93-8	Yes	54
Heptadecane	629-78-7	Yes	36
Hexa(methoxymethyl)melamine	3089-11-0	Yes	54
Hexacosane	630-01-3	Yes	36
Hexanoic acid, 2-ethyl-	149-57-5	Yes	54
iso-Nonylphenol	11066-49-2	Yes	61
Isophorone	78-59-1	Yes	57
N,N'-Bis(1,4-dimethylpentyl)phenylendiamine (77PD)	3081-14-9	Yes	94
N,N-Dicyclohexyl-2-benzothiazolesulfenamide (DCBS)	4979-32-2	Yes	94

[a]These SVOCs are proposed for suspect screening or non-targeted analysis for presence/absence.

Table 7. Proposed SVOCs for targeted and suspect screening analysis in tire crumb rubber samples (continued)

SVOC Name	CAS Number	Suspect Screening[a]	Literature Review ID (see Appendix B)
Potential Rubber Curatives, Antioxidants/Antiozonants, and Other Chemicals Reported in Literature			
N,N'-Diethylthiourea (DETU)	105-55-5	Yes	94
N,N'-Diphenylguanidine (DPG)	102-06-7	Yes	94
N,N'-Diphenyl-p-phenylenediamine (DPPD)	74-31-7	Yes	94
N,N'-Ditolyl-p-phenylenediamine (DTPD)	27417-40-9	Yes	94
N-1,3-(dimethyl-butyl)-N'-phenyl-p-phenylenediamine (6PPD)	793-24-8	Yes	94
N-Cyclohexyl-2-benzothiazolesulfenamide (CBS)	95-33-0	Yes	94
n-Isopropyl-n'-phenylparaphenylenediamine (IPPD)	101-72-4	Yes	
N-Methyl-2-pyrrolidone	872-50-4	Yes	54
n-Nitrosodiphenylamine	86-30-6	Yes	57
Nonadecane	629-92-5	Yes	36
N-Oxydiethylenedithiocarbamyl-N`-oxydiethylenesulfenamide (OTOS)	13752-51-7	Yes	94
N-tert-Butyl-2-benzothiazolesulfenamide (TBBS)	95-31-8	Yes	94
Octadecane	593-45-3	Yes	36
Octadecanoic acid, methyl ester	112-61-8	Yes	36
o-Cyanobenzotic acid	3839-22-3	Yes	7, 36
Pentacosane	629-99-2	Yes	36
Phenol, 2,4-bis(1,1-dimethylethyl)-	96-76-4	Yes	54
Phenol, 2,4-bis(1-methyl-1-phenylethyl)-	2772-45-4	Yes	36, 54
Phenol, m-tert-butyl-	585-34-2	Yes	54
p-phenylenediamine (PPD)	106-50-3	Yes	
Pyrazole	288-13-1	Yes	36
Pyrimidine, 2-(4-pentylphenyl)-5-propyl-	94320-32-8	Yes	36
Tetrabenzylthiuram disulfide (TBZTD)	10591-85-2	Yes	94
Tetrabutylthiuram disulfide (TBTD)	1634-02-2	Yes	94
Tetracosane	646-31-1	Yes	36
Tetramethylthiuram disulfide (TMTD)	137-26-8	Yes	94
Tetramethylthiuram monosulfide (TMTM)	97-74-5	Yes	94
Tricosane	638-67-5	Yes	36
Zn-Dibenzyldithiocarbamate (ZBEC)[b]	14726-36-4	Yes	94
Zn-dibutyldithiocarbamate (ZDBC)	136-23-2	Yes	94
Zn-diethyldithiocarbamate (ZDEC)	136-94-7	Yes	94
Zn-dimethyldithiocarbamate (ZDMC)	137-30-4	Yes	94

[a]These SVOCs are proposed for suspect screening or non-targeted analysis for presence/absence.

[b]Some of the dithiocarbamates of these Zn salts may be volatile chemicals in samples.

3.4 Exposure Characterization

3.4.1 Overview

The exposure characterization study is a pilot-scale effort to: (a) collect information on human activity parameters for synthetic turf field users that affect potential exposures to tire crumb rubber constituents; and (b) implement a human exposure measurement study to further develop and deploy appropriate sample collection methods and to generate data for improved exposure characterization (Figure 2).

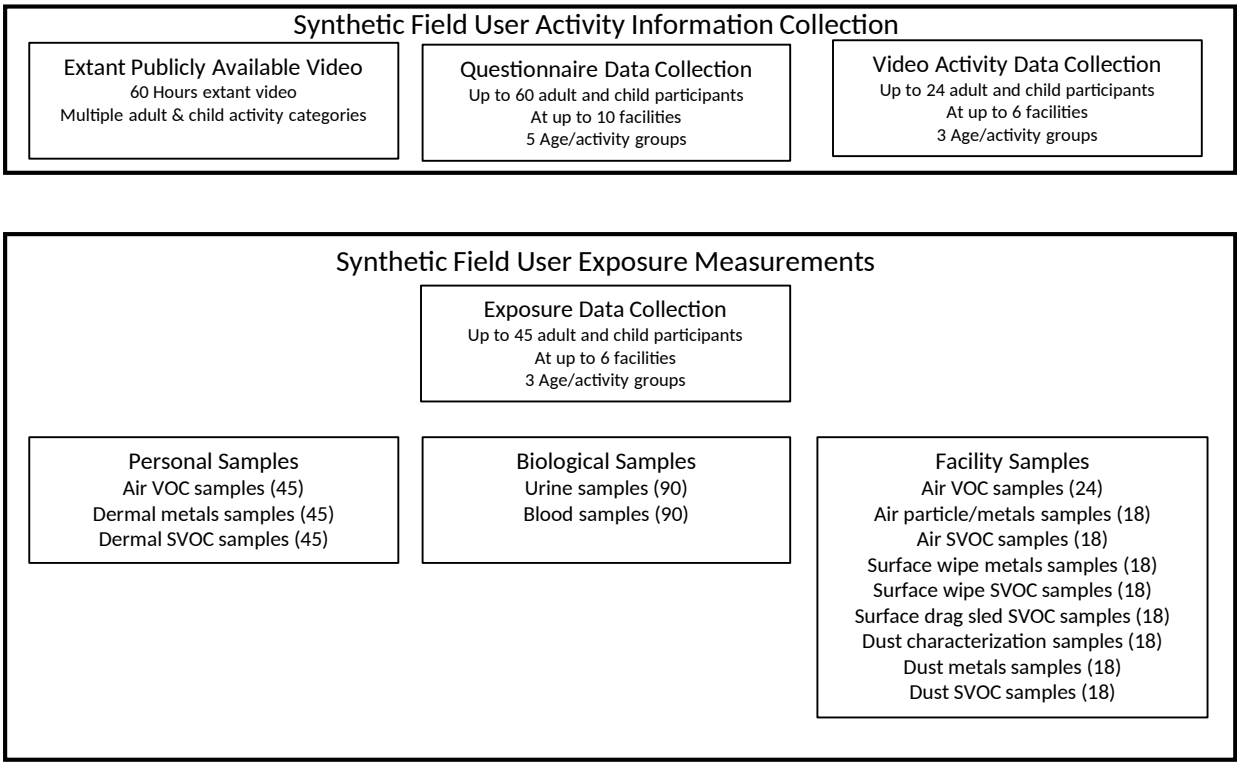

Figure 2. Exposure characterization overview

Several different age groups are included in the research described below; for this research the age group definitions include ≥ 18 years old (adults), 7 to 9 years old (child), 10 to 12 years old (youth), and 13 to 17 years old (adolescent).

The human activity data collection will use questionnaires administered to adults and adolescents; and to the parents of youth and child participants who use synthetic turf fields with tire crumb rubber infill for several types of activities, including athletics and possibly physical education or physical training. Information will be collected to provide data about relevant parameters for characterizing and modeling exposures associated with the use of synthetic turf fields. A subset of participants in the exposure

measurement study will have video data collection performed during a physical activity on a synthetic turf field. In addition, publicly available videography of users engaged in activities on synthetic fields will, if feasible, be acquired to provide objective assessment of contact rates and types that are difficult to capture consistently using questionnaires.

A subset of participants providing questionnaire responses will be asked to participate in an exposure measurement study. A set of personal, biological, and field environment samples will be collected around a sport or training activity performed on a synthetic turf field with tire crumb rubber infill. The personal and field environment samples will be analyzed for a range of target metal, VOC, and SVOC analytes, and a subset of SVOC samples will undergo suspect screening and non-targeted analysis (see Tables 5 – 7). It is possible that the exposure measurement study samples will not be collected in time for analyses that will allow inclusion of results in the 2016 status report.

The biological samples will be held for future analysis. The decision to delay analysis of biological samples is intentional. The tire crumb rubber characterization and exposure characterization measurements and analyses need to be completed prior to analyzing biological samples. It will be important to apply biological specimen analysis for chemicals that have a high likelihood of demonstrating exposure to tire crumb rubber constituents and not simply reflect exposures to chemicals from other sources in people's lives. At this time, we do not know what the most relevant chemicals might be for the synthetic turf field exposure scenarios. The research may identify a need to develop or assess analysis methods not currently used as part of the routine CDC biomonitoring analysis program prior to analyzing the biological samples.

The human activity and exposure measurements study is intended to provide information and fill key data gaps on routes of exposure to synthetic field and tire crumb rubber chemical constituents, particularly for the dermal and ingestion pathways where key data gaps exist. While the study is aimed at collecting data that will improve exposure assessment and risk assessment across all exposure pathways, another purpose is the development and application of information collection and measurement approaches that can be applied in future studies. For example, dust associated with the fields may be an important source of inhalation, dermal absorption, and ingestion exposure, yet dust collection methods have been tested in only a small number of studies to date (NYDEC, 2009; Shalat, 2011). Dust sample collection and analysis method development will be attempted as part of this effort. In another example, future biomonitoring studies may be designed to assess differential exposures between synthetic turf field users and those not using synthetic turf fields. Before that can be done effectively, it is important to determine which chemicals are most relevant. Data and samples that will allow further development and application of biomonitoring approaches for this exposure scenario will be collected.

3.4.2 Activity and Exposure Measurement Participant Recruitment

Up to 75 people who engage in physical activities at facilities with synthetic turf fields with tire crumb rubber infill will be contacted for recruitment across several use-type categories. We anticipate up to 60 people will agree to participate in providing questionnaire responses. The categories will include activity

types anticipated to be among those resulting in higher exposure scenarios either because of the intensity and frequency of field use or because of potentially inherent differences in activity factors (e.g., soccer goalkeepers expected to have repeated contact with turf materials or children age 12 or younger that are likely to have higher hand-to-mouth contact rates). Examples of user types and categories and number of respondents of interest for data collection are shown in Table 8.

Table 8. Number and types of facility users to be recruited for questionnaire and videography data collection

Example Activity Types[a]	Total Number Of Users Recruited	Total Number Of Users Participating[b]	Questionnaires: Indoor Facility	Questionnaires: Outdoor Facility	Total Number Of Facilities
Professional athletics (Group A)	15	12	6	6	2
College athletics (Group B)	15	12	6	6	2
High school P.E. or athletics (Group C)	15	12	6	6	2
Youth ages 10 – 12 athletics (Group D)	15	12	6	6	2
Children ages 7 – 9 athletics (Group E)	15	12	6	6	2
Total Number of Users	75	60	30	30	10

[a]These are examples of activity types of potential interest; the final categories will depend on recruitment success. Different activity types of interest for higher exposure scenarios may be identified through the facility information gathering process.
[b]It is anticipated that up to 60 of the 75 people recruited will participate.

Participants will be recruited from users of a subset of non-military facilities recruited for participation in the tire crumb rubber characterization study described in Section 3.3. As part of the contact with facility owners and managers (identified and contacted as part of the tire crumb rubber characterization study), the respondents will be asked whether they can assist in identifying and providing contact information for facility users. We anticipate recruiting facility users in a specific activity type category from only two different facilities (ideally, one indoor and one outdoor facility, Table 8) to minimize time and cost. Facility users will be contacted to determine eligibility using an eligibility screening form (Appendix G)

and to request participation in the questionnaire and exposure measurement research activities (for a subset of questionnaire respondents). Based on a priori decisions regarding activities that may be among higher exposure scenarios, the recruitment may focus on specific types of users among a larger group. For example, more soccer goalies than field players may be recruited from a soccer team or league based on their likely higher contact rates with field materials.

Up to 45 people who engage in physical activities at facilities with synthetic turf fields with tire crumb rubber infill will be recruited across one to three use categories for participation in the exposure measurement portion of the research study (Table 9). These participants will be a subset of those who respond to the questionnaire administration. The category or categories will include activity types expected to be among those resulting in higher exposures either because of the intensity and frequency of field use or because of differences in activity factors and likely contact rates. Examples of user types and categories and number of respondents of interest for data collection are shown in Table 9. We will recruit facility users in a given activity type category from only two different facilities (ideally, one indoor and one outdoor facility, Table 9) to minimize time and cost. Specifically, we will first attempt to recruit participants from Groups A, B, and E (consent and permission forms H2, H12, and H13 in Appendix H). If the participant sample size is not reached within those three groups, we will recruit in Groups C and D until the sample size requirement is met. It is important to recognize that the activity type categories shown in Table 9 may change based on interest and availability of potential participants.

3.3.4 Questionnaire and Video Data Collection

Facility users who agree to participate will be administered a questionnaire (Appendix I) by trained research staff in person or over the phone using a Computer Assisted Interview program. All consented participants will be asked to complete the questionnaire component of the study. For youth and child participants (Groups D and E), a parent or guardian will be asked to complete the questionnaire. For all other groups, the participant will complete the questionnaire. The questionnaire will collect Information about characteristics and activity parameters that may affect the magnitude of exposure to tire crumb rubber infill constituents, including:

a) demographic characteristics,
b) frequency of field use across a range of activity types,
c) duration of field use across a range of activity types,
d) levels of physical exertion that affect breathing rates,
e) contact rates for different types of activities,
f) clothing types and uses, and,
g) hygiene practices.

Table 9. Number and types of facility users to be recruited for exposure measurements

Example Activity Types[a]	Exposure measurement Indoor Facility[b]	Exposure measurement Outdoor Facility[b]	Total Number of Users	Videography Indoor Facility[c]	Videography Outdoor Facility[c]	Total Number of Facilities
Professional athletics (Group A)	8	7	15	4	4	2
College athletics (Group B)	8	7	15	4	4	2
Children 7 – 9 athletics (Group E)	8	7	15	4	4	2
Total Number of Users			45	12	12	6

[a]These are examples of activity types of potential interest; the final categories will depend on recruitment success. Different activity types of interest for higher exposure scenarios may be identified through the facility information gathering process.
[b]It is assumed that all of the people recruited for questionnaire administration in selected activity categories will participate in the exposure measurement portion of the study. Up to two facilities for each type of activity; the facilities are likely to be different for each activity type.
[c]Videography will be done for a subset of participants who complete the questionnaire and participate in the exposure measurements (see recruitment description below).

Two types of videography data collection are proposed for this study. Publicly available videography of physical activities for adult and youth sports participating on synthetic turf fields will be identified. A range of activities, including those in team practices and in games, may be considered for video information collection and analysis. Information about types and frequencies of various contact rates, along with clothing and protective equipment usage, will be collected. A subset of participants in the exposure measurement study will also have videography performed for a specific sports or training activity on a synthetic turf field with tire crumb rubber. We anticipate enrolling 24 participants in the videography component of the study. Enrollment in the videography component will be co-initiated with the exposure measurement sub-study until the minimum sample size has been reached (consent and permission form addenda H3, H10, H11, H14, H15 in Appendix H). Once the videography target sample size has been reached, the videography consent addendum will be removed from the consent form package. Video data collection will include simple counts of specific activity types, including but not limited to hand-to-mouth, diving on turf, falling on turf, laying on turf, sitting on turf, and hand contact with turf. Questionnaire and video data collection methods are described in Section 5.

Questionnaire and video data will be organized into a database suitable for exposure characterization purposes, including exposure screening calculations and exposure modeling. Although time and cost constraints limit participant numbers across different use categories, differences among user groups will be explored to assess whether differences in activity types, durations, and frequencies occur that may affect exposure to tire crumb rubber constituents.

3.3.5 Exposure Measurement Data Collection

Several types of personal, biological and facility samples will be collected (Table 10). Specific sample collection and analysis methods are described in Section 5. Some methods, including collection of dust from synthetic turf fields, will require method development in advance of conducting the exposure measurement study. For collection of SVOCs in facility air, a low-volume collection method is proposed to facilitate sampling at fields. However, if adequate detection limits cannot be achieved, a high-volume sample collection method will be considered. For both metals and SVOC facility air samples, two on-field samples are proposed, with a third sample collected upwind off of the field to serve as a background sample. No background samples will be collected for field wipe and dust samples due to the difficulty in interpreting results collected from other types of surfaces.

Personal air and dermal samples will be collected during or immediately following one sports or training activity on the synthetic turf field. Although it would be ideal to collect personal air samples for metals and SVOC analysis, the size of the pumps and filters able to achieve desired detection limits for short activity time periods make them unsuitable for participants engaged in vigorous physical activity, and could pose a safety hazard. Personal air sampling for VOCs will be attempted using a passive sorbent device that will be attached to participant clothing for the duration of the participant's time on the field before, during, and following a sports or training activity. The personal passive VOC sample is collected using a 6.5 x 1.6 cm Radiello^{R} tube mounted on a triangular back-plate with 8.5 cm edge lengths. The entire assembly weighs just 23 g, and is unlikely to impede activities and has a low likelihood of causing injury even during falls or collisions. Both metal and dermal SVOC samples will be collected from participants following their sports or training activity. Separate wipe samples will be collected for metals analysis from the hand, forearm, and leg on the participant's left side, while separate wipe samples for SVOC analysis will be collected from the hand, forearm, and leg on the participant's right side.

Urine samples will be collected by participants at three time points around the monitored sports or training activity. One sample will be collected prior to the activity, a second sample will be collected following the activity, and a third sample will be collected 24 hours later (Sample Collection SOPs, Appendix J). Participants will be asked to provide blood samples at two time points around the monitored sports or training activity. For participants agreeing to provide blood samples, one sample (15mL) will be collected prior to the activity and a second sample (15mL) will be collected 24 hours later (Sample Collection SOPs, Appendix J). Blood samples will be collected by qualified phlebotomists or nurses. For participants weighing less than 110 pounds, study staff will ensure no more than 3mL per kg are collected. Participants declining to provide urine or blood samples can still participate in other study activities.

Table 10. Number and types of samples for exposure characterization measurements[a]

Sample Type	Number of Users	Number of Facilities[c]	Number of Locations or Samples	Analytes[d]	Total Samples or Analyses
Personal Samples					
Air	45		1	VOCs	45
Dermal	45		3	SVOCs	135
Dermal	45		3	Metals	135
Urine	45		2	PAH metabolites	90
Urine	45		2	Metals	90
Urine	45		2	Creatinine	90
Urine	45		2	VOC metabolites	90
Blood	45		3	Metals	90
Serum	45		2	Metals	90
Facility Samples[b]					
Air		6	3[e]	VOCs	18
Air		6	3	SVOCs	18
Air		6	3	Particulates/Metals	18
Surface wipe (drag sled)		6	3	SVOCs	18
Surface wipe (by hand)		6	3	SVOCs	18
Surface wipe (by hand)		6	3	Metals	18
Dust[f]		6	3	SVOCs	18
Dust[f]		6	3	Metals	18
Dust[f]		6	3	Characterization	18

[a]These are anticipated types and numbers of samples. Final decisions will be based on method availability, resources, participant burden, and participant safety considerations
[b]Samples of tire crumb rubber infill analyzed for constituents as part of Study 1.
[c]Includes one indoor and one outdoor facility for each activity type
[d]Each analyte type will require a separate sample
[e]Includes one-off field background location for each field.
[f]Dust sample collection method development is required.

Exposure measurement data will be organized into a database suitable for exposure characterization purposes, including exposure screening calculations and exposure modeling. Although a statistical design is not being implemented, differences among user groups will be explored to assess whether differences in activity and/or facility types result in differences in exposure to tire crumb rubber constituents. Estimation of population distributions of exposures will not be possible using these data; however, if the scenarios do represent those leading to higher exposures then the data will the assessment of exposures that are likely to be in the upper end of the distribution.

3.5 Limitations

There are important limitations in the research described in this research protocol. Several key limitations are described below.

3.5.1 Research on Playgrounds

This research protocol is directed primarily at characterizing tire crumb rubber material and exposure characterization for synthetic turf field users. It will not directly study playgrounds or playground users. However, some of the information collected as part of the literature review and gaps assessment will be based on research for playground settings and materials. In addition, the tire crumb rubber chemical characterization may be informative with regard to recycled tire products used on playgrounds.

3.5.2 Assessing the Safety of Synthetic Fields with Tire Crumb Rubber Infill

There is continuing public concern about the safety of synthetic turf fields with tire crumb rubber infill. Public expectations for the federal research effort center on the question of whether these facilities are safe for use by children and adults, posing no short-term or long-term health risks. It is important to communicate to the public and other stakeholders that the study activities that can be completed in 2016 are not designed to, and will not be sufficient by themselves to directly answer the public's question about safety, but will implement research necessary to achieve that goal in the longer term. From a science perspective, we consider the question of safety from a risk assessment framework, which requires information on both exposure and hazard (toxicity). This research will provide more information on the types of chemical and microbiological agents of potential interest or concern, will improve our understanding of the potential for exposure to these agents (particularly for the dermal and ingestion exposure pathways), and will organize available information from this and other research studies in a way suitable for incorporation in exposure modeling and risk assessment. This work will also provide information for assessing risks and designing meaningful studies, including biomonitoring studies and epidemiology studies.

3.5.3 Design Constraints

The requirement to complete work under the Federal Research Action Plan in 2016 and research funding limitations place important constraints on the research that are reflected in design choices. For example, the tire crumb rubber characterization study is limited to 40 fields and 9 recycling facilities, with modest power for detecting difference between strata. A representative sampling design was

considered, but the time and costs required to develop and implement a study based on a national sampling frame of synthetic turf fields are well beyond the scope of time and funds available. Likewise, the exposure characterization study is not based on a representative sampling design, and is likely underpowered for assessing differences among potential exposure factors. However, the exposure characterization study is intended as a pilot-scale effort to further develop measures and approaches suitable for providing relevant exposure information in larger studies. Another design constraint was a decision to focus characterization research on the tire crumb rubber infill and not to include other synthetic turf field materials (synthetic grass blades and backing material) because there is not currently sufficient time and resources for a high-quality characterization of all three types of materials. However, to the extent that permission is provided by synthetic field facilities, we will attempt to separate and store for potential future analysis the synthetic field blades that are inadvertently collected as a by-product of tire crumb rubber sample collection.

3.5.4 No Characterization of Other Types of Fields

The research described in this research protocol is exclusively aimed at synthetic turf fields with tire crumb rubber and does not have sufficient time and resources to investigate other types of fields (e.g. natural grass, synthetic fields with natural product infill, synthetic fields with EPDM or TPE infill). However, people use different types of fields, and communities are faced with having to make choices among several field types with incomplete information regarding chemical exposure and risk. While there is concern about chemical exposures resulting from the use of recycled tire and other materials in synthetic fields, it is important to recognize that chemicals are present in other types of fields, including natural grass fields. Metals (including lead) and PAHs (including benzo(a)pyrene) of concern at synthetic fields with tire crumb rubber infill are also often found in surface soil in the U.S. and are likely to be present at natural grass playing fields. In addition, insecticides and herbicides may be used on some natural grass fields, leading to exposures that may not be experienced by synthetic turf field users. Because many recreational and sports field users spend time on both natural grass and synthetic fields (either concurrently or during different life stages) an understanding of relative exposures across different field types is important for risk assessment and epidemiological investigations. An ideal research investigation would perhaps characterize chemical and microbiological agents at all relevant types of fields to enable improved risk and safety assessments and to allow communities to make more informed choices when selecting fields for their schools and communities.

3.5.5 Multi-source and Pathway Exposure Characterization

People are exposed to many of the chemicals of interest at synthetic turf fields (e.g., metals, PAHs, phthalates, VOCs) from other sources and environmental media, including ambient and indoor air, soil, house dust, food, and water. Other types of chemicals (e.g., rubber vulcanization agents or accelerators, antioxidants) may have relatively unique exposure relationships with the use of synthetic turf fields with tire crumb rubber infill, although people are likely exposed to tire wear particles in the environment as well and many rubber products are used in buildings and transportation systems. Field users and athletes may also experience chemical exposures from uniforms and equipment (e.g., goalie gloves, uniforms, mouth guards) that will not be directly assessed as part of this research.

In any risk assessment or epidemiological investigation, it would be important to try to understand the relative exposures from all sources and pathways, including synthetic turf fields. This study will provide some information that could be used in multi-source and multi-pathway modeling assessments for some chemicals with sufficient data, but doing those assessments is beyond the current time and resources available for this research. Design limitations will not allow for control of exposures that occur for off-field activities and/or exposures when urine, blood, and dermal wipe sampling take place. Therefore, relating these measures to measures of exposure from tire crumb field samples will involve significant uncertainty.

3.5.6 Other Limitations

Data will not be collected to directly address the potential for ecological exposure and risks beyond performing chemical characterization of tire crumb rubber material. The study will not address potential heat exposure concerns and injury. The focus of this research will be on the potential for human exposures to chemicals and microbes at synthetic turf fields. In the dermal measurements as part of the exposure characterization study, it would be ideal to collect pre- and post-activity samples; however, given the time and complexity for collecting two types of samples from six body areas, we have judged that the participant burden and time to complete make this not feasible in the current assessment and there are insufficient resources to analyze the large numbers of additional samples that would be generated.

4. Tire Crumb Rubber Characterization Methods

4.1 Tire Crumb Rubber Sample Collection at Synthetic Turf Fields

4.1.1 Sample Collection for Semi-Volatile Organic Compound and Metal Analysis

Tire crumb rubber samples will be collected from tire crumb processing facilities and synthetic turf fields to support characterization of chemical constituents. Characterization includes analysis of SVOC and metal analytes in the tire crumb rubber, bioaccessibility analysis of SVOCs and metals from tire crumb rubber, and emissions testing of VOCs and SVOCs from tire crumb rubber. Substantial variability in tire crumb rubber chemical concentrations have been reported. Therefore, a composite sample collection approach will be used at synthetic turf fields. Individual samples will be collected from seven locations at each field (Figure 3) for SVOC analysis, and another seven samples will be collected at the same locations for metals analysis. Additional samples will be collected from each field to support particle characterization analysis. Different sampling locations may be identified if different types of fields (e.g., baseball fields) are recruited into the study. In this case, a chart will be prepared for each field showing the seven selected sampling locations.

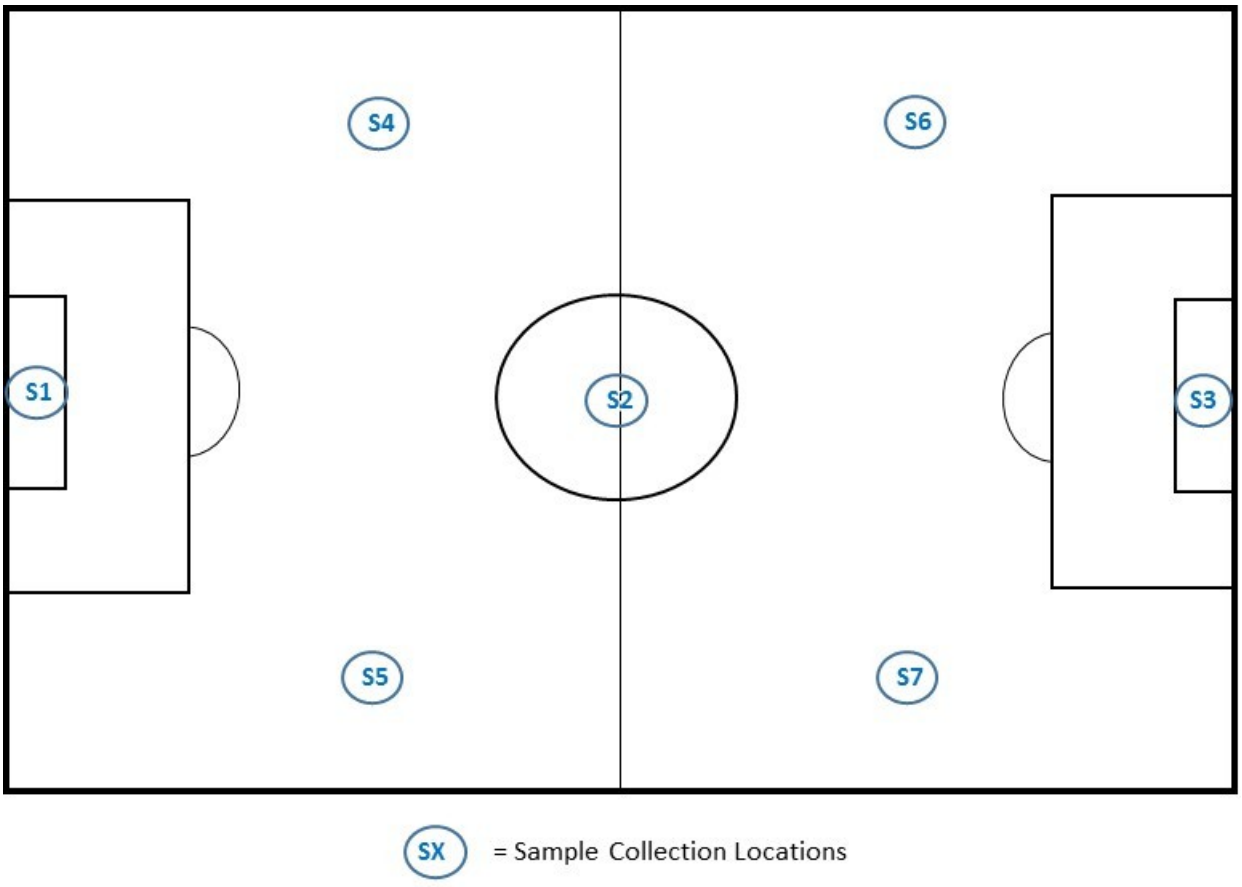

Figure 3. Locations for collecting tire crumb rubber samples at synthetic turf fields.

For SVOC samples, a small handheld metal rake will be used to pull tire crumb rubber from the field at each location. Ideally, the collection depth in the field will be no more than about 3 cm from the surface. Collected tire crumb rubber will be placed into certified pre-cleaned 250-mL amber glass wide-mouth containers with Teflon-lined lids. The containers will be completely filled with tire crumb rubber material. For metals samples, a small handheld plastic rake will be used to pull tire crumb rubber from the field at each location. Ideally, the collection depth in the field will be no more than about 3 cm from the surface. Collected tire crumb rubber will be placed into certified pre-cleaned 250-mL polyethylene wide-mouth containers. The containers will be completely filled with tire crumb rubber material. Additional tire crumb material will be collected across the seven field locations to fill two 1-L certified pre-cleaned polyethylene wide-mouth containers to support particles size characterization analysis. Samples will be shipped overnight to a central processing laboratory.

A single composite sample will be prepared from the seven SVOC samples at the central processing laboratory. Approximately 35 g of the tire crumb rubber material from each of the seven individual location samples will be added to a single certified pre-cleaned 500-mL amber wide mouth glass container with Teflon-lined lid. The same weight or volume of each individual sample will be added to the larger container to obtain a representative composite sample. The composite sample will be thoroughly mixed in the sealed 500-mL container through rotation and shaking. The remainder of the individual samples will be retained in their sealed containers, and all samples will be placed in a freezer at -20 °C. The same procedure will be used to prepare composite samples for metals analysis using certified pre-cleaned HPDE containers. The remaining sample from each individual field location (approx. 90g each) will be used to support analyses from individual field locations for a subset of three field locations (location numbers 1, 2, and 3 in Figure 3) at five fields.

4.1.2 Sample Collection for Microbiome Analysis

Tire crumb rubber samples will also be collected from synthetic turf fields to support microbiome analysis. Samples collected from tire recycling facilities will not be analyzed for microbes. Individual samples will be collected from each field at all seven as shown in Figure 3. Aseptic techniques must be employed while collecting and handling samples or sampling equipment. Nitrile (or appropriate alternative) gloves must be worn at all times when handling the sample or sampling equipment. A clean disposable lab coat will be worn during sample collection. A sterile polypropylene spatula will be used to collect each sample. To collect samples, the sterile spatula will be inserted into the athletic field surface at an approximate 30 degree angle to maximum depth of 3 cm from the surface and moved forward to collect tire crumb material. The tire crumb rubber will be added to a sterile 50 mL polypropylene container with volumetric lines. The container will be filled with tire crumb rubber material to the 25 ml line. Once samples are collected, samples will immediately be placed in a cooler with ice packs. Samples will be shipped the same day as they are collected, in a container with ice packs, to the appropriate laboratory.

4.2 Synthetic Turf Field Facility Owner/Manager Questionnaire

A questionnaire will be used to collect information from managers or owners of athletics facilities that have synthetic turf fields with tire crumb rubber infill (Appendix F). The purpose of the questionnaire is to collect information on general facility operations, turf history and maintenance, and public use at the facilities. The questionnaire will record specific types of data including type of fields (e.g., indoor or outdoor), age of fields, sports/activities played on fields, frequency and hours of field use, and turf maintenance, cleaning, and replacement practices. The questionnaire will be administered by trained study staff members in person or over the phone using a computer assisted interview (CAI), and responses will be entered directly into the computer interview form. Skip patterns and several response range limits are built into the CAI software instrument. All questionnaires and responses will be reviewed by the field study leader prior to incorporation in the study database. In addition to the questionnaire, the location of the field facility will be geo-located using either exact address or, if necessary, through GPS coordinate identification.

4.3 Tire Crumb Rubber Sample Collection from Recycling Facilities

Recycled tire crumb rubber samples of the size category used in synthetic turf fields (typically 10 – 20 mesh) will be collected from tire recycling facilities by research staff members. Six samples will be collected from each facility for metals analysis, six samples will be collected for organics analysis, and three samples will be collected for particle characterization. Ideally, the samples will come from three different manufacturing batches, storage containers, and/or the production line in. For each manufacturing batch, storage container, or production line sample, one 1-L HPDE jars will be filled for metals analysis, two 1-L amber glass jars will be filled for organic chemical analysis, and two 1-L HPDE jar will be filled for particle characterization.

Pre-cleaned stainless steel scoops will be used to gather tire crumb rubber into pre-cleaned and certified 1-L amber glass wide mouth jars with Teflon-lined lids for organics analysis. The jars will be completely filled. The same scoop may be used to gather samples into all sample containers. Pre-cleaned plastic scoops will be used to gather tire crumb rubber into pre-cleaned and certified 1-L polyethylene wide mouth jars for metals analysis. The jars will be completely filled. The same scoop may be used to gather samples into all three sample containers. Each sealed sample container will be placed into a zip-lock plastic bag, sealed, bubble wrapped, and shipped to the laboratory. Upon arrival at the laboratory, the samples will be stored in a freezer (at -20 °C).

4.4 Analysis of Metal Constituents in Tire Crumb Rubber

Tire crumb rubber samples will be extracted using EPA Method 3051A “Microwave Assisted Acid Digestion of Sediments, Sludges, Soils, and Oils” (U.S. EPA, 2007a). It is anticipated that 1-g samples of tire crumb rubber will be used in the digestion method, but this amount may change based on experience with initial samples. This method is a rapid multi-element microwave assisted digestion

method that does not intend to accomplish total decomposition of the sample. The method is applicable to the microwave-assisted acid extraction of 26 metals (aluminum, antimony, arsenic, barium, beryllium, boron, cadmium, calcium, chromium, cobalt, copper, iron, lead, magnesium, manganese, mercury, molybdemum, nickel, potassium, selenium, silver, sodium, strontium, thallium, vanadium, zinc). The sample is placed in a fluorocarbon polymer or quartz vessel with concentrated nitric acid or a combination of concentrated nitric acid and concentrated hydrochloric acid. The vessel is sealed and heated in the microwave unit for a specified period of time. Once the extraction time is completed, the vessel is allowed to cool down and its contents are filtered, centrifuged, or allowed to settle. The extract is then diluted to volume and analyzed. The extracted samples will be analyzed by EPA Method 6020B "Inductively Couple Plasma-Mass Spectrometry" (U.S. EPA, 2014a). The method is applicable to the determination of sub-µg/L concentrations of a large number of elements in water samples and in waste extracts or digests. The performance acceptability for the ICP-MS method has been determined for the following analytes: aluminum, antimony, arsenic, barium, beryllium, cadmium, calcium, chromium, cobalt, copper, iron, lead, magnesium, manganese, mercury, nickel, potassium, selenium, silver sodium, thallium, vanadium and zinc. The analyst will monitor potential sources of interferences and evaluate the performance of the method for the tire crumb rubber matrix.

4.5 Analysis of Semi-Volatile Organic Compounds (SVOC) Compounds in Tire Crumb Rubber

4.5.1 Gas Chromatography/Mass Spectrometry Targeted Analysis

The semi-volatile organics in tire crumb rubber consist primarily of the constituents present from tire manufacturing, but may also include chemicals that the tire material has been exposed to in significant quantities since production. As semi-volatile compounds, these components may exist both in the gas phase and as residues in the condensed state with vapor pressures typically between 10^{-14} and 10^{-4} atm. The SVOC residues will be extracted using dispersive solvent extraction or through sonication using 1:1 acetone:hexane using available test methods (U.S. EPA 3500C, 2007b; U.S. EPA 3550C, 2007c; with modification as needed for the tire crumb rubber matrix). It is anticipated that 1-g samples of tire crumb rubber will be used in the extraction method, but this amount may change based on experience with initial samples. Reference materials consisting of isotopically labelled analogs of representative chemicals will be used as internal standards and will be added during sample preparation to enable quantitative analysis. Interferences that may be present in sample extracts will be monitored and addressed through sample clean-up if necessary through filtration or use of procedures listed in U.S. EPA 3500C (2007b). Extracts may also be split or solvent exchanged in order to analyze using other analytical conditions or instruments.

After extraction, samples will be analyzed by gas chromatography with mass spectrometry (GC/MS) using either an Agilent model 5973 single quadrupole instrument in SIM (selected ion monitoring) mode or an Agilent model 7010 triple quadrupole instrument in MRM (multiple reaction monitoring) mode. Instruments will be standardized using autotune parameters built into the instrument software. Component-specific calibration will be performed using a least squares regression model generated from the area and nominal concentration ratios from a series of calibration standards and their associated internal standards. Component data for each sample will be calculated using the

corresponding regression equation. Measured concentrations that exceed the highest calibration level by more than 30% will require the sample to be diluted to a concentration within calibration limits.

4.5.2 Gas Chromatography/Mass Spectrometry Suspect Screening and Non-Targeted Analysis
Non-targeted screening by GC/MS will be performed using the extracts from the targeted analysis if possible, otherwise a similar approach will be taken for extraction with minimal processing. Data will be acquired using an Agilent 5973 mass spectrometer with electron impact (EI) fragmentation in scan mode (50-550 m/z). Chromatographic separation will be performed using an Agilent 6890 gas chromatograph with a 60m capillary column running a thermal gradient from 40°C to 340°C at 5°C per minute. Those data will be deconvoluted and compared to a screening database and the NIST.11 spectral database for tentative identification using AMDIS or Agilent Unknowns Analysis software packages.

The screening database will be populated with chemicals where standards have been prepared and analyzed using the same instrument and conditions in order to have confirmed presence/absence. Components not identified within the screening database will be ranked by abundance and match score for further analysis. It is likely that the time-consuming data reduction and analysis of non-targeted GC/MS spectra will not be completed in time for inclusion in a 2016 report.

4.5.3 Liquid Chromatography/Mass Spectrometry Targeted Analysis
The aforementioned extracts described in section 4.5.1 will be solvent exchanged from acetone:hexane in to a solvent amenable for LC/MS analysis (methanol and/or acetonitrile). Back-calculation of the portion of the total SVOC extract will be recorded for LC/MS analysis to estimate concentrations. A personal compound database list (PCDL) of all suspect analytes will be used to screen for presence of target analytes in SVOC extracts using an Agilent 6200 series Time of Flight Mass Spectrometer (TOFMS). The PCDL will consist of neutral monoisotopic mass, CAS# and molecular formula for suspect screening. Select compounds where standards are available and are amenable for LC/MS analysis will be quantitated. Compounds where standards are not available will be estimated in concentration based on relative response to the most similar analyte a standard is available for.

4.5.4 Liquid Chromatography/Mass Spectrometry Suspect Screening and Non-Targeted Analysis
Suspect screening and nontargeted screening of tire crumb rubber will be performed by sonic extraction of the media of interest in an organic solvent amenable to HPLC-MS analysis. This will be with in acetonitrile and/or methanol depending on the performance on test samples. After extraction samples with be filtered for particle removal and reduced in volume for preparation for analysis. Samples with be injected onto an Agilent 6200 series Time of Flight Mass Spectrometer (TOFMS) for suspect screening and non-targeted screening analysis.

Samples with be processed according to the procedures of Rager et al. (2015). In brief after running of samples in both positive and negative mode samples with be subjected to a molecular feature extraction (MFE) algorithm to identify peaks for further exploration. Features identified for suspect screening purposes will be compared to the US EPA's DSS-TOX database (~33,000 chemicals). Chemicals matching within 5ppm of the suspect chemical according to accurate mass and scoring >90% will be deemed as a provisional match. Features not matching will be subjected to a nontargeted screening workflow where by features will be prioritized based on occurrence and abundance into discrete data packets. Further

work on these peaks may include compound discovery, verification with authentic standards and comparison to outside databases (Chemspider, Scifinder) for provisional matching. Suspect and non-targeted screening features will be summarized with descriptive statistics. It is likely that the time-consuming data reduction and analysis of non-targeted LC/MS spectra will not be completed in time for inclusion in the 2016 report.

4.6 Characterization of Dust Associated with Tire Crumb Rubber

Dust often consists of atmospherically-deposited particles that are derived from various sources such as soil, pollen, and pollution. In the indoor environment, dust may also contain small amounts of dander, hair, textile fibers, paper fibers, minerals from outdoor soil, and human skin cells. In cases where tire crumb rubber is used on sports fields not only is there dust as previously described but there is also likely to be dust-sized particles that are created due to the breakdown/weathering of the tire crumb rubber. All these dust sources can be trapped in the mass of tire crumb rubber particles and within the plastic “blades of grass” that make up the sports field. Due to the smaller particle sizes associated with dust particles, exposures to dust occurs through inhalation, ingestion, and through dermal contact as the dust can cling to skin and clothes.

To investigate the potential for exposure to chemicals attached to or released from dust particles, we propose analyses that include particle size characterization (% sand, silt, and clay), nano-particle size analysis, and metals analyses via X-ray fluorescence. Determination of the particle-size distribution will be performed following a method derived from Miller and Miller (1987), which employs a micro-pipetting method. This method allows for the use of very small sample sizes that we anticipate receiving for this study versus the 50 to 100 gram samples used in standard soil-based particle-size determinations. Associated with the determination of the clay fraction (particles with mean diameters < 0.002 mm) will be the determination of the nano-sized fraction (particles between about 0.3 and 10 nm mean diameter). The nano fraction analyses will be performed using the Malvern Nanosizer which employs dynamic light scattering as the detection method. X-ray fluorescence will be used to determine metal contents following the premises in SW-846 Method 6200. A field-portable X-ray fluorescence device was selected for laboratory analyses due to the advantages that a single run detects multiple elements simultaneously and the analyses are non-destructive such that dust mass can be conserved and used for other analyses.

4.7 Bacterial Community Composition and Antibiotic Resistance Genes in Tire Crumb Rubber

A preliminary literature review revealed very limited data on the microbiology of tire crumb rubber infill used on artificial turf athletic fields. Therefore, to assess the possibility of microbial risks to individuals exposed to tire crumb rubber infill, a study to examine the composition of the microbial communities and occurrence of pathogens and select antibiotic resistance genes is proposed. Microbial communities will be sampled at each of the seven sample collection locations on every field. Once at the laboratory, five grams of each sample will be processed to dissociate microbes from tire crumb rubber using surfactants and physical disruption. Microbial genomes will be extracted from dislodged communities

using commercial kits. The purified genomes will be interrogated by deep sequencing techniques targeting the 16S small subunit ribosomal RNA gene to taxonomically classify the community members and identify potential pathogens. In addition, the concentration of *Staphylococcus* species, *S. aureus* and antibiotic resistance genes within the community will be determined by droplet digital PCR.

4.8 Chamber Testing for Tire Crumb Rubber Constituent Emissions

Constituents such as volatile organic compounds (VOCs) and semi-volatile organic compounds (SVOCs) can be released to the environment from tire crumb rubber under different environmental conditions. Laboratory chamber tests will be performed to characterize the emissions of VOCs and SVOCs under two different chamber conditions (e.g. 25 ℃ and 50% relative humidity (RH); 60 ℃ and approx. 9% RH) and defined air change rates. Emissions of VOCs from tire crumb rubber samples will be investigated using 53-L electro-polished stainless steel small chambers and emissions of SVOCs will be investigated using micro chambers. Test conditions are described below and may be adjusted as experience is gained during sampling and analysis. For example, the 24-hour equilibration period may be reduced if timed experiments demonstrate that a quasi-steady state for analyte concentrations in chamber air is reached in a shorter time period.

53-L small chambers are housed in temperature-controlled incubators. Nominal dimensions of the chambers are 51 cm (width) by 25 cm (height) by 41 cm (depth). In a dynamic chamber test, clean, VOC-free air will be supplied to the chamber through a dedicated system consisting of an air compressor, dryer, pure air generator, and gross particle filters. The chambers are equipped with inlet and outlet manifolds for the air supply, as well as with temperature and RH sensors. The RH of the air supply to the chamber will be controlled by blending dry air with humidified air. All air transfer and sampling lines are composed of glass, stainless steel, or Teflon. An OPTO 22 data acquisition system (DAS) continuously records mass flow controllers' outputs, temperature, and RH in the chamber and inlet air. A 1 ½" computer cooling fan will be placed in the chamber to provide mixing for tests. During tests, clean air flow will be supplied to the test chamber where a test sample is placed with a ventilation rate equivalent to one air change per hour. A total of 15 g of tire crumb rubber sample material will be placed in the center of the chamber. Air samples for analysis of most VOCs will be collected on pre-cleaned Carpopack X tubes at a flow rate of 100 mL/min for 60 min following a 24-hr equilibration period. Samples for formaldehyde analysis will be collected using dinitrophenyl hydrazine (DNPH) sampling cartridges. The small chamber tests will be consistent with the methods described in the ASTM Standard Guide D5116-10 (ASTM, 2010).

Two micro chamber systems, µ-CTE and M-CTE250, will be used for the project. The systems consist of four (M-CTE250) or six (µ-CTE) micro chambers that allow surface or bulk emissions to be tested simultaneously from up to six samples at the same temperature and flow rate. Each µ-CTE micro chamber consists of an open-ended cup constructed of silicone-coated stainless steel measuring 30-mm deep with a diameter of 45 mm and a volume of 44 mL. Each M-CTE250 micro chamber consists of an open-ended cup constructed of Silicosteel® measuring 36-mm deep with a diameter of 64 mm and a volume of 114 mL. Both systems have temperature and humidity control that allows the tests to be conducted at 50% RH and at ambient temperature or at elevated temperatures up to 120 ℃ (µ-CTE) or

250 ˚C (M-CTE250). The chamber's flow distribution system maintains a constant flow of air through each sample chamber, independent of sorbent-tube impedance and whether or not a sorbent tube is attached. The flow rate is controlled by the source air pressure and the flow distribution device in the unit. During tests, clean air flow will be supplied to the chambers. A total of 10 g of tire crumb rubber sample material will be placed in the chamber. Air samples will be collected on pre-cleaned polyurethane foam (PUF) tubes at a flow rate of 60 mL/min for 3 hours following a 24-hr equilibration period. The micro chamber tests will conform to ASTM D7706-11 (2010) and ISO- 16000-25 (2011).

4.9 Analysis of Volatile Organic Compound (VOC) Emissions from Tire Crumb Rubber

4.9.1 GC/MS Analysis of Target Analyte VOCs in Tire Crumb Rubber Emissions Samples
VOC chamber emission samples will be collected on reusable industry standard PerkinElmer-style ceramic coated stainless steel tubes containing Carbopack X sorbent and analyzed by thermal desorption/GC/MS. Carbopack X is a graphitized carbon sorbent suitable for the collection and quantitative analysis of hydrocarbons and chlorinated compounds containing 3 to 9 carbons. The PerkinElmer-style tube configuration allows the collection of samples by either a diffusion (passive) process or an active process whereby a measured volume of air is pumped through the tube. The tire crumb rubber chamber emission samples will be sampled using the active process as described above in Section 4.8. The sampling tubes are reusable and will be prepared for sample collection prior to each use by thermally conditioning for a minimum 1 hour at 350 ℃ while purging with research grade helium. This conditioning removes most contaminants from the sorbent tube remaining after analysis. It should be noted that some small residuals of benzene remain on the tubes that cannot be completely eliminated due to the nature of the sorbent; however, backgrounds can be reduced to minimal levels that can be corrected using background subtraction techniques.

The system used to analyze collected tube samples will be a PerkinElmer TurboMatrix ATD interface attached to an Agilent 6890 gas chromatograph and Agilent 5975 mass spectrometer. The analytical process is described as follows. Sample tubes for analysis are loaded into an automated carousel and the system is programmed to individually retrieve and thermally desorb each tube. Compounds desorbed during this process are then trapped and concentrated on a Peltier cooled sorbent trap containing sorbents of different retention strengths. The trap is then rapidly heated and backflushed with helium to transfer the compounds to the chromatographic column for separation and the mass spectrometer for detection and response. Quantitation is based on comparison of sample responses to a multipoint calibration curve. The thermal desorption, gas chromatography, and mass spectrometry conditions will be optimized for the target compounds of interest. Samples are proposed to be analyzed in SIM/Scan mode. The advantage of SIM/Scan mode is that in addition to the lower sensitivity possible with SIM monitoring, full scan data is also available for non-targeted compound identification. Appropriate QA/QC will be implemented to assure quality data.

4.9.2 Non-Targeted GC/MS Screening of VOCs in Tire Crumb Rubber Emissions Samples
As described above in Section 4.9.1, PerkinElmer-style tubes containing Carbopack X sorbent are proposed for sample collection. Selected samples will be analyzed on a Markes TOF (time-of-flight) GC/MS to provide detailed compound identifications and approximate quantitation of non-targeted

compounds observed in the tire crumb rubber emission samples. Analytical instrumentation used for this analysis will include a Markes Ultra 2 thermal desorption auto sample/Unity 2 thermal desorber coupled to an Agilent 7890B GC and Markes BenchTOF-Select time-of-flight mass spectrometer.

The principle of sample introduction to this system is described as follows. Sample tubes for analysis are loaded into the Ultra 2 thermal desorption autosampler and the system is programmed to individually retrieve and thermally desorb each tube. Compounds desorbed during this process are trapped and concentrated on an internal sorbent trap containing sorbents of different retention strengths. The trap is then rapidly heated and backflushed with helium to transfer the compounds to the chromatographic column for separation and the TOF mass spectrometer for detection and response.

Standards for targeted compounds will be prepared and analyzed from Carbopack X tubes. A multipoint calibration curve will be developed. Standards will not be available for the non-targeted compounds so estimates of compound concentrations will be determined based on relative concentrations to known compounds. Compound identifications will be determined based on comparisons to the NIST spectral database. Appropriate QA/QC will be implemented to assure quality data.

4.9.3 Formaldehyde Analysis

Small chamber air samples collected on DNPH cartridges will be analyzed for formaldehyde by high performance liquid chromatography using an ultraviolet detector (HPLC-UV) following EPA Method TO-11A. A subset of samples will be analyzed by LC/MS for analyte identity confirmation.

4.10 Analysis of Semi-Volatile Organic Compound (SVOC) Emissions from Tire Crumb Rubber

4.10.1 GC/MS Analysis of Target Analyte SVOCs in Tire Crumb Rubber Emissions Samples

SVOC emissions from tire crumb rubber will be measured from components in air captured on polyurethane foam (PUF). The collection media will be solvent extracted by either Soxhlet or sonication using 1:1 acetone:hexane (EPA 3540C, 2007d; EPA 3550C, 2007c) and the extract volume will be reduced as necessary. Internal standards consisting of isotopically labelled analogs of representative chemicals will be added during sample preparation to enable quantification. Interferences will be monitored and samples will be cleaned-up as necessary using an appropriate procedure as prescribed in EPA 3500C (U.S. EPA 2007b). Extracts may also be split or solvent exchanged in order to analyze using other analytical conditions or instruments.

After extraction, samples will be analyzed by gas chromatography with mass spectrometry (GC/MS) using either an Agilent model 5973 single quadrupole instrument in SIM (selected ion monitoring) mode or an Agilent model 7010 triple quadrupole instrument in MRM (multiple reaction monitoring) mode. Instruments will be standardized using autotune parameters built into the instrument software. Component-specific calibration will be performed using a least squares regression model generated from the area and nominal concentration ratios from a series of calibration standards and their associated internal standards. Component data for each sample will be calculated using the corresponding regression equation. Measured concentrations that exceed the highest calibration level by more than 30% will require the sample to be diluted to a concentration within calibration limits.

4.10.2 Non-Targeted GC/MS Screening of SVOCs in Tire Crumb Rubber Emission Samples
Non-targeted screening by GC/MS will be performed using the extracts from the targeted analysis if possible, otherwise a similar approach will be taken for extraction with minimal processing. Data will be acquired using an Agilent 5973 mass spectrometer with electron impact (EI) fragmentation in scan mode (50-550 m/z). Chromatographic separation will be performed using an Agilent 6890 gas chromatograph with a 60m capillary column running a thermal gradient from 40°C to 340°C at 5°C per minute. Those data will be deconvoluted and compared to a screening database and the NIST.11 spectral database for tentative identification using AMDIS or Agilent Unknowns Analysis software packages.

The screening database will be populated with chemicals where standards have been prepared and analyzed using the same instrument and conditions in order to have confirmed presence/absence. Components not identified within the screening database will be ranked by abundance and match score for further analysis.

4.10.3 LC/MS Analysis of Target Analyte SVOCs in Tire Crumb Rubber Emission Samples
The extracts described in section 4.10.1 will be solvent exchanged from acetone:hexane into a solvent amenable for LC/MS analysis (methanol, acetonitrile). Back-calculation of the portion of the total SVOC extract will be recorded for LC/MS analysis to estimate concentrations. A personal compound database list (PCDL) of all suspect analytes will be used to screen for presence of target analytes in SVOC extracts using an Agilent 6200 series Time of Flight Mass Spectrometer (TOFMS). The PCDL will consist of neutral monoisotopic mass, CAS# and molecular formula for suspect screening. Select compounds where standards are available and are amenable for LC/MS analysis will be quantitated. Compounds where standards are not available will be estimated in concentration based on relative response to the most similar analyte a standard is available for.

4.10.4 Non-Targeted LC/MS Screening of SVOCs in Tire Crumb Rubber Emission Samples
Suspect screening and nontargeted screening of tire crumb rubber will be performed by sonic extraction of the media of interest in an organic solvent amenable to HPLC-MS analysis. This will be with in acetonitrile or methanol depending on the performance on test samples. After extraction samples with be filtered for particle removal and reduced in volume for preparation for analysis. Samples with be injected onto an Agilent 6200 series Time of Flight Mass Spectrometer (TOFMS) for suspect screening and non-targeted screening analysis.

Samples with be processed according to the procedures of Rager et al. (2015). In brief after running of samples in both positive and negative mode samples with be subjected to a molecular feature extraction (MFE) algorithm to identify peaks for further exploration. Features identified for suspect screening purposes will be compared to the US EPAs DSS-TOX database (~33,000 chemicals). Chemicals matching within 5ppm of the suspect chemical according to accurate mass and scoring >90% will be deemed as a provisional match. Features not matching will be subjected to a nontargeted screening workflow where by features will be prioritized based on occurrence and abundance into discrete data packets. Further work on these peaks may include compound discovery, verification with authentic standards and comparison to outside databases (Chemspider, Scifinder) for provisional matching. Suspect and non-targeted screening features will be summarized with descriptive statistics.

4.11 Bioaccessibility Analysis of Metals and SVOCs in Tire Crumb Rubber

Reliable assessment of potential hazard to human from exposure to chemicals in tire crumb rubber materials depends on accurate information on a number of key parameters, including (1) chemicals and their concentrations in tire crumb rubber; (2) toxicity of the chemicals; (3) exposure pathways, including dermal contact, ingestion, and inhalation of vapors and particulates; (4) pathway-specific exposure dose of the tire crumb rubber materials or the chemical constituents in the materials; and (5) the extent of chemical absorption from the tire crumb rubber ("bioavailability") from each pathway. The amount of chemicals that actually enters the blood and body tissues from an exposure depends on the physical-chemical properties of the chemicals, as well as the composition of the body fluids. Therefore, knowledge of bioavailability is important in assessing potential health effect of exposure to chemicals in tire crumb rubber. In the case of tire crumb rubber, exposure potential will likely be influenced by additional factors, such as the age and wear of the materials, manufacture-related factors (e.g., manufactures and manufacturing processes), and environmental conditions (e.g., indoor or outdoor, ambient temperature and humidity). Therefore, this project will investigate tire crumb rubber samples taken from various manufacturers and up to 40 fields that are currently in-use.

For the purposes of this study design document, the term *bioavailability* refers to the fraction of dose that can cross biological barriers and become available for distribution to internal target tissues and organs. The term *bioaccessibility* refers to an *in vitro* measure of the physiological solubility of chemicals that may be available for absorption into the body. Bioaccessibility data can be used to estimate bioavailability using different established models. Since solubilization is usually required for absorption across membranes, poorly soluble forms of constituents with low bioaccessibility (such as metals) may also have low bioavailability. In certain circumstances (such as lead in soil), if solubility is the major determinant of absorption at the portal of entry, bioaccessibility may be a main predictor of bioavailability.

Metals and SVOCs selected for bioaccessibility testing will be based on existing data on chemical concentrations and on data from current and future laboratory analyses. For metals, it is likely that lead and zinc are required, although other metals may be identified and measured in the tests. For SVOCs, target analytes likely include polycyclic aromatic hydrocarbons (PAHs), phthalates, benzothiazole, etc. Bioaccessibility testing results will only be reported for the analytes that are present in the specific tire crumb rubber materials with concentrations above the limit of quantitation. We propose a tiered approach for project implementation and laboratory analyses:

- Phase 1: Optimization of the Methods. This phase will be devoted to method optimization and validation using a research tire crumb rubber material. Both constituent analysis methods and *in vitro* bioaccessibility methods will be finalized. At the end of Phase 1, the contractor will prepare and submit a Standard Operation Procedure of the final methods.
    - Phase 1a. Optimization of the Methods for constituent analysis and bioaccessibility testing of metals in tire crumb rubber
    - Phase 1b. Optimization of the Methods for constituent analysis and bioaccessibility testing of SVOCs in tire crumb rubber

- Phase 2: Determination of the *in vitro* Bioaccessibility. In this phase, the methods optimized in Phase 1 will be applied on up to 67 "unknown" tire crumb rubber samples (up to 27 manufacturer-provided samples and up to 40 composite field samples). At the end of Phase 2, the contractor will report the results (constituent analyses and *in vitro* bioaccessibility testing) on all "unknown" tire crumb rubber samples.
    - Phase 2a: Determination of the *in vitro* bioaccessibility of metals in tire crumb rubber samples
    - Phase 2b: Determination of the *in vitro* bioaccessibility of SVOCs in tire crumb rubber samples

- Phase 3: Assessment of the Bioavailability. In this phase, the bioaccessibility data obtained in Phase 2 will be used to estimate bioavailability using established models. At the end of Phase 3, the contractor will report the bioavailability assessment of chemicals in all "unknown" tire crumb rubber samples.
    - Phase 3a: Assessment of the bioavailability of metals in tire crumb rubber samples
    - Phase 3b: Assessment of the bioavailability of SVOCs in tire crumb rubber samples

The purpose of this work is to provide *in vitro* bioaccessibility testing of metals and SVOCs in tire crumb rubber materials to simulate ingestion and dermal absorption exposures. Artificial bio-fluids (e.g. gastric, saliva, and sweat) will be prepared using established recipes from reputable sources, such as ATSM, ISO, EPA, CDC/NIOSH, and CSPC. For the method to prepare artificial sweat, it is desirable to include an appropriate component, e.g., artificial sebum, to simulate the skin oil that can be present in humans sweat and affect the dermal absorption of target analytes. Methodologies for formulation of artificial saliva, artificial gastric fluid, and artificial sweat and sebum are provided in Appendix K; however, the specific composition can change after optimization of laboratory procedures.

The method for extraction of metals and SVOCs in tire crumb rubber by artificial biofluids can be adopted from established bioaccessibility method for lead in soil, e.g., EPA Method 1340, *In Vitro* Bioaccessibility Assay for Lead in Soil (U.S. EPA, 2013), and/or, EPA Method 9200.2-86, Standard Operating Procedure for an *In Vitro* Bioaccessibility Assay for Lead in Soil (U.S. EPA, 2007e). An example procedure is described as follows. All test tire crumb rubber samples should be dried (<40°C) and thoroughly mixed prior to use to ensure homogenization. After drying, 1 g of tire crumb rubber sample is rotated (30±2 rpm) with 100 mL of buffered extraction fluid (artificial gastric fluid, saliva, and sweat) at 37 °C for one hour. The supernatant is separated from the sample by filtration.

For metal analysis, the supernatant analyzed by an appropriate analytical method to measure multiple metals, e.g., EPA Method 6020B (EPA, 2014a) "Inductively coupled plasma—mass spectrometry" (This analytical method can measure 26 metals including zinc and lead).

To determine the concentration of SVOCs, the supernatant will first need to undergo sample preparation steps (e.g., solvent extraction, clean-up, and evaporation), before the analytical measurement. The sample preparation method can be referenced from EPA methods measuring SVOCs in soil using ultrasonic extraction (Method 3550C; U.S. EPA, 2007c), microwave extraction (Method

3546; U.S. EPA, 2007f), or pressurized fluid extraction (Method 3545A; U.S. EPA, 1998). The analytical method to quantify SVOCs in the extracts can be referenced from an appropriate analytical method, e.g., EPA Method 8270D, "Semivolatile Organic Compounds by Gas Chromatography/Mass Spectrometry (GC/MS)" (U.S. EPA, 2014b).

4.12 Identifying and Collating Extant Toxicity Reference Data for Chemical Constituents

Selection of chemicals for toxicity reference information identification and compilation will be based primarily on measurement results produced in both the tire crumb rubber characterization and the exposure characterization studies. Selection criteria may include a combination of measurement detection frequency, magnitude of concentrations or estimated levels, and presence in multiple media. Consideration may also be given to chemicals that have been measured in other studies of tire crumb rubber and synthetic turf fields. We will develop a list of chemicals (including Chemical Abstract Services registry numbers) and compile extant toxicity reference data using the following sources of information shown below, and others, as deemed appropriate. Identification and compilation of other toxicity data from primary sources may also be considered for some chemicals. A summary of high-throughput toxicity screening data that are available on EPA's ToxCast database for the identified list of chemicals will be provided.

- EPA Integrated Risk Information System (IRIS)
- EPA Provisional Peer-reviewed Toxicity Value (PPRTV)
- EPA Health Effects Assessment Summary Table (HEAST)
- Agency for Toxic Substances and Disease Registry (ATSDR) Minimal Risk Levels (MRLs)
- World Health Organization (WHO) International Programme on Chemical Safety (IPCS) Concise International Chemical Assessment Documents (CICAD)
- International Agency for Research on Cancer (IARC) Monographs
- California Environmental Protection Agency (CalEPA) Toxicity Criteria Database
- Occupational Safety and Health Administration (OSHA) Permissible Exposure Limits (PELs)
- California Division of Occupational Safety and Health (Cal/OSHA) Permissible Exposure Limits (PELs).
- National Institute for Occupational Safety and Health (NIOSH) Recommended Exposure Limits (RELs).
- American Conference of Governmental Industrial Hygienists (ACGIH) Threshold Limit Values (TLVs) and Biological Exposure Indices (BEIs).

EPA IRIS provides toxicity values for health effects resulting from chronic exposure to chemicals, including cancer and noncancer hazard characterization and oral reference doses (RfDs), inhalation reference concentrations (RfCs), oral slope factors (OSFs) and inhalation unit risk (IURs). An RfD is an estimate (with uncertainty spanning perhaps an order of magnitude) of a daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime, while RfCs similarly represent an inhalation exposure. An OSF is an upper-bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime oral exposure to an agent. This estimate, usually expressed in terms of the proportion (of a population) affected per mg/kg-day, is generally reserved for use in the low-dose region of the dose-response relationship; that is, for exposures corresponding to risks less than 1 in 100, while IURs are similarly an estimate of the increased cancer risk from inhalation exposure. OSFs and IURs can be multiplied by

estimated lifetime exposures to estimate the lifetime cancer risk. EPA PPRTVs have been developed for EPA's Superfund program and can also include provisional RfDs and RfCs for non-cancer effects, and provisional OSFs and IURs for cancer. HEAST also provides oral and inhalation toxicity values developed for EPA's Superfund program.

Like RfDs, ATSDR oral and inhalation MRLs represent estimates of the daily human exposure to a hazardous substance that is likely to be without appreciable adverse non-cancer health effects over a specified duration of exposure. WHO CICAD provides summaries of potential health effects of chemicals on human health and the environment, and IARC Monographs provide summary information on chemicals that can increase the risk of human cancer. CalEPA provides no Significant Risk Levels (NSRLs) for carcinogens and Maximum Allowable Dose Levels (MADLs) for chemicals causing reproductive toxicity, and Reference Exposure Levels (RELs) which represent air concentrations at or below which no adverse health effects are anticipated to occur in human populations, including sensitive subgroups. While not directly applicable to all populations that may be exposed to tire crumb rubber, occupational limits developed by OSHA, CalOSHA, NIOSH, and ACGIH will also be reviewed for tire crumb rubber constituents. Typically, these values represent recommended levels of chemicals in workplace air that should not be exceeded over an 8- or 10-hour workday.

A database will be developed that cross-references chemicals in the tire crumb rubber constituent list with toxicity reference data from the sources described above. The database will be useful for informing future screening level health risk assessments, and for identifying toxicity information data gaps.

5. Exposure Characterization Methods

5.1 Exposure Characterization Overview

As described in the Federal Research Action Plan, this portion of the research is a pilot-scale effort aimed at providing information and data for characterizing exposures to chemical constituents for users of synthetic turf fields with tire crumb rubber infill. Participants will be recruited from among those thought to be in one or more higher-exposure scenarios based on the frequency and duration of synthetic turf field use, as well as specific activities that may be involved in higher levels of contact with synthetic turf field materials including tire crumb rubber. We anticipate that the facilities used by the participants will be a subset of the facilities participating in the tire crumb rubber characterization portion of the study (Section 4). There are two components to the exposure characterization research, a) activity information collection and b) exposure measurement. Methods for activity information collection and exposure measurements, including both facility and personal sample collection and analysis, are described in this section.

5.2 Activity Data Collection for Synthetic Field Users

5.2.1 Collection and Use of Extant Publicly-Available Video

Using publicly available videos (e.g., YouTube), videography will be used to collect activity pattern data on adults, adolescents, youth, and/or children playing and/or practicing on artificial turf fields that contain tire crumb rubber infill at athletic facilities. The purpose of the extant videography is to provide an objective assessment of user activity patterns potentially impacting exposure to chemicals found in tire crumb rubber infill that are difficult to capture consistently using questionnaires. The videography will record specific types of data about the participants and their activities, including: type of activity or sport; type of field (e.g., indoor or outdoor); participant's age group; durations of rest or low, moderate, and high activity; and mouthing and contact rates on turf for different types of activities. In total, up to 60 hours of videotaped footage will be collected on adults, adolescents, youth, and/or children actively engaged in sporting activities on artificial turf fields.

Selection criteria for the types of specific activities for video assessment will be informed by initial review of the types of extant videos available from the internet to determine which players (soccer goalies, football linemen etc.) and which activities (games, practices, training) are likely be in higher contact-rate scenarios based on activity patterns. These criteria have not been pre-defined as some flexibility is needed in gaining a better understanding of the types of public video information available.

Acceptance criteria for downloading video data for activity characterization include activity on a synthetic turf field, resolution (i.e., must be high enough to discern an athlete's contact with field), continuity (whether one athlete can be tracked for 30 continuous minutes of activity), and applicability

for research goals (user and activity must correspond with the groups and activities targeted for high-end exposure characterization).

EPA staff and/or contractors will download public video recordings that meet the study's acceptance criteria from YouTube and similar publically available video-hosting Web sites onto a non-networked, password-protected computer at an EPA facility. The EPA research leader or designee will maintain custody of this computer and require staff and/or contractors to sign out the computer for the purpose of downloading or viewing extant video. Video downloading will only occur on-site at an EPA facility with information technology firewall protections in place.

The staff and/or contractors will assign each downloaded video with a video identification number (VID) and save each video onto a computer folder labeled "Tire Crumb Extant Video," exclusively using VIDs in lieu of filenames and descriptions. The EPA research leader will also copy the downloaded extant video files onto a portable USB drive or external hard drive to be kept in a locked cabinet. In order to minimize bias, staff and/or contractors who shall review, extract, and analyze the downloaded extant videos must not have participated in selecting or downloading any of those videos. Activity pattern data (e.g., hand-to-mouth and object-to-mouth, skin-to-surface contact rates, etc.) will be recorded using a paper template by the reviewer/analyst. Upon completing data tabulation from the videos, the EPA staff and/or contractors will enter the handwritten data into a spreadsheet or database in Microsoft Excel to be input into exposure modeling software such as SHEDS-Multimedia. The exact format of database entry is to be specified by the EPA-internal model developers. A subset of videos will be subjected to data extraction and entry by a second trained staff member or contractor to assess comparability and inter-reviewer consistency.

The videography will collect images that may be considered to be personally identifiable participant data. Also, it is likely that the video footage will include other players and bystanders that are not the focus of activity data collection, as well as inclusion of field or geographic features that may make the video location discernible. No data extraction will be performed for non-participants. No organization name, team name, or location information will be collected in the information extraction. The electronic video files will be treated as personally identifiable data and will be managed and secured to allow access and use only by trained study staff for the intended purpose of field-related activity data collection. No video or still images will be publicly released as part of the research effort and research reporting. The video recordings will be destroyed no later than five years following downloading.

5.2.2 Synthetic Turf Field Facility User Questionnaire

A questionnaire will be used to collect data from participants who routinely play on artificial turf fields that contain tire crumb rubber infill at athletic facilities (Appendix I). The purpose of the questionnaire is to collect information on the participants' activity patterns that may impact the magnitude, frequency, and duration of their exposures to chemicals found in tire crumb rubber infill. The questionnaire is intended to produce information that will improve exposure screening and modeling of inhalation, dermal, and ingestion pathways of exposures to constituents of synthetic turf fields with tire crumb rubber infill. The questionnaire will record specific types of data about the participants, including demographics (i.e., age, gender, and race), education levels, activity levels, types and frequency of sports played on fields, frequency and duration of field use, hygiene practices (e.g., hand washing and

eating events), types of clothing worn, and contact rates on turf for different types of activities. The questionnaire will be administered by trained study staff members in person or over the phone using a computer assisted interview (CAI) and responses will be entered directly into the computer interview form. Two versions of the facility user questionnaires will be used, one for adults and adolescents and another for youth and child. For youth and child (Groups D and E), the parents/guardians will be asked to complete the questionnaire for his/her child. Skip patterns and several response range limits are built into the CAI software instrument. All questionnaires and responses will be reviewed by the field study leader prior to incorporation in the study database. No names or other personally identifiable data will be collected in the questionnaire. Only a study ID number will be used in the questionnaire for linking participants to other study data sets. The questionnaire data will be managed and secured to allow access and use only by trained study staff for the intended study purposes.

5.2.3 Videography of Exposure Measurement Study Participants

Videography will be used to collect activity pattern data on participants who routinely play on artificial turf fields that contain tire crumb rubber infill at athletic facilities. The purpose of the video data collection is to supplement the information obtained from the facility user questionnaire on the participants' activity patterns that may impact the magnitude and frequency of their exposures to chemicals found in tire crumb rubber infill. About 24 participants will have their activities videotaped for up to 1 hour while playing or practicing sports at the facilities.

Trained EPA staff or contractors will assign each participant with a participant identification number (PID). The EPA staff or contractor shall record the activities of the participants on artificial turf fields for 1 hour using a video camera that contains a video data card. The staff or contractor shall make two copies of all the participants' video data cards. The staff or contractor shall send the EPA research leader via certified mail the original and one copy of the video data cards of all study participants (with PIDs, only). Also, the staff or contractor shall keep the second copy of the video data cards in a secured location (e.g., locked cabinet in an office). After receiving the video data cards, the EPA research leader or designee will also keep the video data cards in a locked cabinet in his/her office. Trained EPA staff and/or contractors shall sign out the video data cards from the EPA research leader and view them using a non-networked computer that is password protected. Activity pattern data (e.g., hand-to-mouth and object-to-mouth, skin-to-field contact rates) will be recorded using a paper template. Upon completing data tabulation from the videos, the EPA staff and/or contractors will enter the handwritten data into a spreadsheet or database in Microsoft Excel to be input into exposure modeling software such as SHEDS-Multimedia. A subset of videos will be subjected to data extraction and entry by a second trained staff member or contractor to assess comparability and inter-reviewer consistency.

The videography will collect images that are considered to be personally identifiable participant data. Also, it is likely that the video footage will include other players and bystanders that are not videography participants, as well as inclusion of field or geographic features that may make the video location discernible. The videographer will attempt to minimize videotaping other players or bystanders as much as possible. No names or personal information will be collected from non-participants. No data extraction will be performed for non-participants. The electronic video files will be treated as personally identifiable data and will be managed and secured to allow access and use only by trained study staff for

the intended purpose of field-related activity data collection. No video or still images will be publically released. Video recordings will be destroyed no later than five years after collection.

5.3 Collection of Exposure Measurement Facility Samples

5.3.1 Air Samples for Particulate and Metals

PM_{10} is defined as airborne particulate matter with an aerodynamic size less than 10 µm. A total of three samples will be collected simultaneously at each synthetic turf field. Air samples will be collected from two points at each synthetic field as close as possible to where activities occur without posing an obstruction or safety hazard. A third sample will be collected upwind and at a sufficient distance from the field to represent background. In the case of indoor fields, the background sample will be collected outside of the facility building and in an upwind direction. Selection of locations for background samples will consider and attempt to avoid other potential exposure sources such as parking lots and roads. Air sample inlets will be located 1 meter above the field or ground surface.

Samples will be collected at a nominal flow rate of 20 L/min using metered, direct-current-supplied active samplers (SKC-HV-30 air pumps or equivalent) and size-selective impactor inlets (Harvard Impactor Inlets, Air Diagnostic and Engineering or equivalent), enabling PM_{10} mass loading on 47-mm Teflo filter media (Williams et al., 2008). Air sampling will be initiated for all monitors in quick order on their setup and calibration and continued without interruption through the monitoring event. It is anticipated that sample collection durations will be approximately three hours to represent an exposure period that includes time spent at the field prior to an athletic activity, the athletic activity period ranging up to two hours, and a short time spent at the field following the athletic activity. Sampler flow rates will be measured and recorded, along with the start and stop times at the beginning and completion of the sampling period. At the conclusion of the sampling event, filter samples will be recovered, stored in sealed transportation containers, and returned to the laboratory under ambient temperatures.

5.3.2 Air Samples for VOCs

Two types of VOC samples will be collected at the synthetic turf fields. Air samples will be collected from two points at each synthetic fields as close as possible to where activities occur without posing an obstruction or safety hazard. A third sample will be collected upwind and at a sufficient distance from the field to represent background. The primary sampling approach will employ passive samplers (Radiello™ passive diffusive bodies containing Carbopack X sorbent, SigmaAldrich) deployed at the same three locations at each field described in section 5.3.1. The Radiello™ samplers were selected due to their relatively high effective sampling rates which is anticipated to provide improved limits of detection for short duration sampling events. The on field use of the Radiello™ passive samplers will be used to provide comparability to the proposed personal sample collection approach (Section 5.4.1) and to reduce the amount of equipment and set-up time for sample collection. In addition, another sample for VOC analysis will be collected using an active pumping system and Carbopack X sampling tubes. One active sampling system will be deployed at each field and will be located at one of the two on-field locations. This active VOC sampler will be used to help calibrate effective sampling rates of analytes on the Radiello™ passive samplers.

It is anticipated that sample collection durations will be approximately three hours to represent an exposure period that includes time spent at the field prior to an athletic activity, the athletic activity period ranging up to two hours, and a short time spent at the field following the athletic activity. Active sampler flow rates will be measured and recorded at the start and completion of the sampling period. Passive samplers will be removed from their storage containers to start sampling, and will be returned to the storage containers immediately at the end of the sampling period. All sampling start and stop times will be recorded. Air sample inlets will be located 1 meter above the field or ground surface. At the conclusion of the sampling event, filter samples will be recovered, stored in sealed transportation containers, and returned to the laboratory with ice packs at 4 °C or lower. Following receipt at the laboratory, samples will be stored at -20 °C until analysis.

5.3.3 Air Samples for SVOCs

SVOCs comprise many potential chemical analytes with large ranges of vapor pressures and physical/chemical properties. Some SVOCs with higher vapor pressures will be found primarily in the vapor phase in air, while SVOCs with low vapor pressures will be found primarily on airborne particles. In this study, air samples will be collected without a size-selective particle inlet and will simultaneously collect both vapor- and particle-phase SVOCs.

Air samples will be collected from two points at each synthetic fields as close as possible to where activities occur without posing an obstruction or safety hazard. A third sample will be collected upwind and at a sufficient distance from the field to represent background. Samples will be collected on pre-cleaned open-cell polyurethane foam (PUF) filters in 30-mm × 70-mm tubes. Pre-cleaned total suspended particle quartz filters will be used as part of the sample filter assembly; however, the filter and the PUF will be extracted and analyzed together as a single sample. Separate particle- and gas-phase air concentrations will not be measured. A total of three samples will be collected simultaneously at each synthetic turf field and will be collocated with the particulate sample locations described in 5.3.1. Air sample inlets will be located 1 meter above the field or ground surface.

Samples will be collected at a nominal flow rate of 10 L/min using metered, direct-current-supplied active samplers (SKC-HV-30 air pumps or equivalent). Air sampling will be initiated for all monitors in quick order on their setup and calibration and continued without interruption through the monitoring event (day). It is anticipated that sample collection durations will be approximately three hours to represent an exposure period that includes time spent at the field prior to an athletic activity, the athletic activity period ranging up to two hours, and a short time spent at the field following the athletic activity. Sampler flow rates will be measured and recorded, along with the start and stop times at the beginning and completion of the sampling period. At the conclusion of the sampling event, filter samples will be recovered, stored in sealed transportation containers, and returned to the laboratory with ice packs at 4 °C or lower. Following receipt at the laboratory, samples will be stored at -20 °C until extraction.

[If preliminary laboratory preparation suggests that adequate detection limits will not be achieved using the low-volume sample collection method proposed for this study, a hi-volume method such as EPA

Method TO-13A (U.S. EPA, 1999) will be considered for collecting adequate amounts of target analytes for analysis.]

5.3.4 Field Surface Wipe Samples for Metals

Surface wipe samples for metals analysis will be collected at synthetic turf field sites using a wet (water) wipe (Environmental Express, Ghost Wipe No. 4210) conforming to American Society for Testing and Materials (ASTM) E1792 (ASTM-03, 2016a) requirements. Samples will be collected at times when it was safe to do so with regard to any activities occurring on the field. Sample collection time is not critical for these samples, but the samples should be collected at a convenient time during the overall exposure measurement activities at each field. Samples will be collected at positions #1, #2, and#3 as shown in Figure 3, for a total of three separate samples. No background sampling location wipe sample will be collected.

Samples will be collected following the ASTM E1728 method (ASTM 1728-16, 2016b), a standard wet-wipe method for collecting dust from indoor floor surfaces that used water as the wetting agent. Specifically, a 929 cm^2 (1-ft^2) template is placed on the surface of the field. Using clean, powderless plastic gloves, the field sampling technician remove the wet wipe from the foil packet. Using one side of the wipe, the turf surface is wiped in a U-shaped pattern within the template area. After folding the wipe in half to get a fresh wipe surface, the area is wiped again in a U-shaped pattern perpendicular to the first wipe pattern. The wipe is then folded in half again and the edges near the interior portion of the template were wiped. Prior to placing the wipe in a storage tube, plastic forceps are used to remove full size tire crumb rubber infill granules, synthetic grass blades, and other large debris or litter. Finally, the wipe is folded and placed in a pre-cleaned 50-mL polyethylene tube (Environmental Express, Disposable Digestion Cup No. SC475 or equivalent) for storage. The tube is tightly capped and transported at ambient temperature or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

5.3.5 Field Surface Wipe Samples for SVOCs

Two types of field surface wipe samples will be collected for SVOCs analysis. One method uses a dry wipe material attached to a heavy sledge. The second uses an isopropanol-wetted wipe.

Surface wipe aledge samples for SVOC analysis will be collected at synthetic turf field sites using a dry wipe material (Texwipe TX312 Cleanroom Twill, 30.5 cm × 30.5 cm, cotton) that is cleaned by pre-extraction using a series of solvents including acetone and hexane prior to use. Samples will be collected at times when it was safe to do so with regard to any activities occurring on the field. Sample collection time is not critical for these samples, but the samples should be collected at a convenient time during the overall exposure measurement activities at each field. Samples will be collected at positions #1, #2, and#3 as shown in Figure 3, for a total of three separate samples. Samples will be collected from different areas than the areas used for metals wipe sample collection. No background sampling location wipe sample will be collected. Using clean, powderless nitrile gloves, the field sampling technician remove the wipe material from its storage container and clamps it to a wipe sampling push sledge device. The device has a 10 kg aluminum block of the dimensions 25.4 x 25.4 x 5.1 cm with clamps on one side for securing the wipe material and an attached handle for pushing the device. The wipe material is secured so that the bottom face of the block with an area of 645 cm^2 is completely covered by the wipe material. Using a tape measure and marking tape, a 4 m x 1 m area (4 m^2) will be marked on

the synthetic turf field. With the wipe sampler starting in one corner of the marked area, six wipe sampling passes will be made in one direction to cover the entire area one time. The sampler will then be moved to another corner, and six more wipe sampling passes will be made in one direction to cover the entire area. The second group of wipe sampling passes will be made in a direction perpendicular to the direction of the first. Prior to placing the wipe back into the storage container, synthetic grass blades, and other large debris or litter on the sides of the filter that did not contact the field will be removed to the extent possible. Finally, the wipe is folded and placed in the clean 500 mL amber glass wide mouth storage bottle with Teflon cap liner. The bottle is tightly capped and transported at 4 °C or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

Wetted surface wipe samples for SVOC analysis will be collected at synthetic turf field sites using a wipe material (Texwipe TX312 Cleanroom Twill, 10 cm × 10 cm, cotton) that is cleaned by pre-extraction using a series of solvents including acetone and hexane prior to use. Samples will be collected at times when it was safe to do so with regard to any activities occurring on the field. Sample collection time is not critical for these samples, but the samples should be collected at a convenient time during the overall exposure measurement activities at each field. Samples will be collected at positions #1, #2, and#3 as shown in Figure 3, for a total of three separate samples. Samples will be collected from different areas than the areas used for metals wipe sample collection. No background sampling location wipe sample will be collected. Using clean, powderless nitrile gloves, the field sampling technician remove the wipe material from its storage container and adds 3 mL of 1:1 deionized water:isopropanol to the wipe, wetting the material evenly. Specifically, a 929 cm^2 (1-ft^2) template is placed on the surface of the field. Using one side of the wipe, the turf surface is wiped in a U-shaped pattern within the template area. After folding the wipe in half to get a fresh wipe surface, the area is wiped again in a U-shaped pattern perpendicular to the first wipe pattern. The wipe is then folded in half again and the edges near the interior portion of the template were wiped. Prior to placing the wipe in a storage tube, forceps are used to remove full size tire crumb rubber infill granules, synthetic grass blades, and other large debris or litter. Finally, the wipe is folded and placed in a pre-cleaned 60-mL amber wide-mouth glass jar. The bottle is tightly capped and transported at 4 °C or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

5.3.6 Field Dust Samples for Metals and SVOCs

Dermal, inhalation, and ingestion of dust at synthetic turf fields may represent important pathways of exposure to chemicals associated with tire crumb rubber, other synthetic field materials, and environmental dust deposited on the field. At the time of research protocol preparation, no method has been selected for collection of dust samples at synthetic turf fields for metal and SVOC analysis. Method development will be performed for the dust collection method(s), conditional to gaining access to one or more synthetic turf fields for methods testing and evaluation.

5.3.7 Meteorological Information

Air temperature, field surface temperature, relative humidity, and wind speed and direction will be measured during the field measurement period. Information will also be obtained from each field's nearest NWS reporting site for sampling day temperature and wind conditions; precipitation information will be obtained for the sampling day and 6 preceding days.

5.4 Collection of Exposure Measurement Personal Samples

5.4.1 Personal Air Samples for VOCs

Personal sampling for VOCs will use a passive sampler (Radiello™ passive diffusive body containing Carbopack X sorbent, SigmaAldrich) attached to participants engaged in a sports activity on a synthetic turf field with tire crumb rubber infill. It is anticipated that sample collection durations will be approximately three hours to represent an exposure period that includes time spent at the field prior to an athletic activity, the athletic activity period ranging up to two hours, and a short time spent at the field following the athletic activity. Passive samplers will be removed from their storage containers to start sampling, and will be returned to the storage containers immediately at the end of the sampling period. The sampler will be clipped or pinned to the participant's shirt or jersey, ideally near the back neckline, to minimize interference or impacts during the sports activity. However, the field staff will discuss the placement with the participant and may chose an alternate location. All sampling start and stop times will be recorded. At the conclusion of the sampling event, filter samples will be recovered, stored in sealed transportation containers, and returned to the laboratory with ice packs at 4 °C or lower. Following receipt at the laboratory, samples will be stored at -20 °C until analysis.

5.4.2 Dermal Samples for Metals

Three dermal wipe samples will be collected for metal analysis from each participant following an on-field sports activity in the exposure characterization study. One sample will be a hand wipe sample, the second sample will be from defined areas of the forearm, and the third sample will be collected from the leg (either calf or thigh depending on which area had more exposed skin area during the sports activity). Wipe samples for metals will be collected from one hand, one arm, and one leg on the left side of the participant's body.

Hand wipe samples for metal analysis will be collected using a wet (water) wipe (Environmental Express, Ghost Wipe No. 4210) conforming to American Society for Testing and Materials (ASTM) E1792 requirements (ASTM-03, 2016a). Using clean, powderless nitrile gloves, the field sampling technician removes the wet wipe from the foil packet and unfolds the wipe to its full dimensions. With moderately firm pressure, the left hand is wiped, including the back, front, and sides of the hand, fingers, and thumb. The wipe is folded with the exposed (contacted) surface on the inside and placed into a pre-cleaned 50-mL polyethylene tube (Environmental Express, Disposable Digestion Cup No. SC475 or equivalent) for storage. The tube is tightly capped and transported at ambient temperature or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

Forearm wipe samples for metals analysis will be collected using a wet (water) wipe (Environmental Express, Ghost Wipe No. 4210). Using a fresh pair of clean, powderless nitrile gloves, the field sampling technician removes the wet wipe from the foil packet and unfolds the wipe to its full dimensions. With moderately firm pressure, the top side of the left forearm is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded inside out along the 15 cm length, with the exposed (contacted) surface now on the inside. The wipe is now a 7.5 cm × 15 cm rectangle.
With the 7.5 cm × 15 cm rectangle, the bottom side of the left forearm is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded with the exposed (contacted) surface on the inside and placed into a pre-cleaned 50-mL polyethylene tube (Environmental Express, Disposable Digestion Cup

No. SC475 or equivalent) for storage. The tube is tightly capped and transported at ambient temperature or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

Leg wipe samples for metals analysis will be collected using a wet (water) wipe (Environmental Express, Ghost Wipe No. 4210). Using a fresh pair of clean, powderless nitrile gloves, the field sampling technician removes the wet wipe from the foil packet and unfolds the wipe to its full dimensions. With moderately firm pressure, the outer facing side of the left calf or thigh is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded inside out along the 15 cm length, with the exposed (contacted) surface now on the inside. The wipe is now a 7.5 cm × 15 cm rectangle.
With the 7.5 cm × 15 cm rectangle, the inner facing side of the left calf or thigh is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded with the exposed (contacted) surface on the inside and placed into a pre-cleaned 50-mL polyethylene tube (Environmental Express, Disposable Digestion Cup No. SC475 or equivalent) for storage. The tube is tightly capped and transported at ambient temperature or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

5.4.3 Dermal Samples for SVOCs
Three dermal wipe samples will be collected for SVOC analysis from each participant following an on-field sports activity in the exposure characterization study. One sample will be a hand wipe sample, the second sample will be from defined areas of the forearm, and the third sample will be collected from the leg (either calf or thigh depending on which are had more exposed skin area during the sports activity). Wipe samples for SVOCs will be collected from one hand, one arm, and one leg on the right side of the participant's body.

Hand wipe samples for SVOC analysis will be collected using a wetted (1:1 water:isopropanol) cotton wipe material (M.G. Chemicals, Cleanroom Twill, 10.2 x 10.2 cm, cotton). Using clean, powderless nitrile gloves, the field sampling technician removes the wipe from its glass storage jar to its full dimensions. The wipe is evenly wetted with 3 mL of 1:1 deionized water:isopropanol using a transfer pipette. With moderately firm pressure, the left hand is wiped, including the back, front, and sides of the hand, fingers, and thumb. The wipe is folded with the exposed (contacted) surface on the inside and placed back into the glass storage jar. The jar is tightly capped and transported at 4 °C or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

Forearm wipe samples for SVOC analysis will be collected using a wetted (1:1 water:isopropanol) cotton wipe material (M.G. Chemicals, Cleanroom Twill, 10.2 x 10.2 cm, cotton). Using clean, powderless nitrile gloves, the field sampling technician removes the wipe from its glass storage jar to its full dimensions. With moderately firm pressure, the top side of the right forearm is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded inside out along the 15 cm length, with the exposed (contacted) surface now on the inside. The wipe is now a 7.5 cm × 15 cm rectangle. With the 7.5 cm × 15 cm rectangle, the bottom side of the right forearm is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded with the exposed (contacted) surface on the inside and placed back into the glass storage jar. The jar is tightly capped and transported at 4 °C or lower to the laboratory, where the samples are placed in a freezer at -20 °C.

Leg wipe samples for SVOC analysis will be collected using a wetted (1:1 water:isopropanol) cotton wipe material (M.G. Chemicals, Cleanroom Twill, 10.2 x 10.2 cm, cotton). Using clean, powderless nitrile gloves, the field sampling technician removes the wipe from its glass storage jar to its full dimensions. With moderately firm pressure, the top side of the outer facing side of the right calf or thigh is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded inside out along the 15 cm length, with the exposed (contacted) surface now on the inside. The wipe is now a 7.5 cm × 15 cm rectangle. With the 7.5 cm × 15 cm rectangle, the inner facing side of the right calf or thigh is wiped over a 48 cm^2 area using a rectangular template. The wipe is folded with the exposed (contacted) surface on the inside and placed back into the glass storage jar. The jar is tightly capped and transported at 4 ℃ or lower to the laboratory, where the samples are placed in a freezer at -20 ℃.

5.5 Collection of Exposure Measurement Biomonitoring Samples

Urine and blood biological specimens will be collected from participants in the exposure characterization sub-study. In order to control for baseline body burden levels and allow for metabolic processes, blood and urine will be collected prior to the exposure measurement activities and post exposure measurement activities. Samples will be aliquoted at the time of collection and stored at appropriate temperatures for shipment and storage. Samples will be stored for the indefinite future. The purpose of indefinite storage is to determine what chemicals to look for and potentially to develop new analytical methods for analysis of these chemicals. Urine and blood sample collection, processing, shipment, and storage protocols are described in more detail in Appendix J.

5.6 Exposure Measurement Sample Analysis

5.6.1 Metals Analysis of Air, Dust, and Wipe Samples

The air, wipe, and dust samples will be extracted using EPA Method 3051A “Microwave Assisted Acid Digestion of Sediments, Sludges, Soils, and Oils” (U.S. EPA, 2007a) adapted as necessary for the range of different sample media. It is anticipated that 1-g samples of dust will be used in the digestion method, but this amount may change based on experience with initial samples. For field wipe and dermal wipe samples the entire wipe will be used after removing any turf blades or pieces of the infill material that was not removed in the field. For air samples the entire filter will be used. This method is a rapid multi-element microwave assisted digestion method that does not intend to accomplish total decomposition of the sample. The method is applicable to the microwave-assisted acid extraction of 26 metals (aluminum, antimony, arsenic, barium, beryllium, boron, cadmium, calcium, chromium, cobalt, copper, iron, lead, magnesium, manganese, mercury, molybdemum, nickel, potassium, selenium, silver, sodium, strontium, thallium, vanadium, zinc). The sample is placed in a fluorocarbon polymer or quartz vessel with concentrated nitric acid or a combination of concentrated nitric acid and concentrated hydrochloric acid. The vessel is sealed and heated in the microwave unit for a specified period of time. Once the extraction time is completed, the vessel is allowed to cool down and its contents are filtered, centrifuged, or allowed to settle. The extract is then diluted to volume and analyzed. The extracted samples will be analyzed by EPA Method 6020B “Inductively Couple Plasma-Mass Spectrometry” (U.S. EPA, 2014a). The method is applicable to the determination of sub-µg/L concentrations of a large

number of elements in water samples and in waste extracts or digests. The performance acceptability for the ICP-MS method has been determined for the following analytes: aluminum, antimony, arsenic, barium, beryllium, cadmium, calcium, chromium, cobalt, copper, iron, lead, magnesium, manganese, mercury, nickel, potassium, selenium, silver sodium, thallium, vanadium and zinc. The analyst will monitor potential sources of interferences and evaluate the performance of the method for the tire crumb rubber matrix.

5.6.2 GC/MS Analysis of Target Analyte SVOCs in Air, Dust, and Wipe Samples
SVOCs in air filter, field dust, field wipe, and dermal wipe sample media will be solvent extracted by either Soxhlet or sonication using 1:1 acetone:hexane (U.S. EPA 3540C, 2007d; U.S. EPA 3550C, 2007c) and the extract volume will be reduced as necessary. Internal standards consisting of isotopically labelled analogs of representative chemicals will be added during sample preparation to enable quantification. Interferences will be monitored and samples will be cleaned-up as necessary using an appropriate procedure as prescribed in U.S. EPA 3500C (2007b). Extracts may also be split or solvent exchanged in order to analyze using other analytical conditions or instruments.

After extraction, samples will be analyzed by gas chromatography with mass spectrometry (GC/MS) using either an Agilent model 5973 single quadrupole instrument in SIM (selected ion monitoring) mode or an Agilent model 7010 triple quadrupole instrument in MRM (multiple reaction monitoring) mode. Instruments will be standardized using autotune parameters built into the instrument software. Component-specific calibration will be performed using a least squares regression model generated from the area and nominal concentration ratios from a series of calibration standards and their associated internal standards. Component data for each sample will be calculated using the corresponding regression equation. Measured concentrations that exceed the highest calibration level by more than 30% will require the sample to be diluted to a concentration within calibration limits.

5.6.3 Non-Targeted GC/MS Screening of SVOCs in Air, Dust, and Wipe Samples
Non-targeted screening by GC/MS will be performed using the extracts from the targeted analysis if possible, otherwise a similar approach will be taken for extraction with minimal processing. Data will be acquired using an Agilent 5973 mass spectrometer with electron impact (EI) fragmentation in scan mode (50-550 m/z). Chromatographic separation will be performed using an Agilent 6890 gas chromatograph with a 60m capillary column running a thermal gradient from 40°C to 340°C at 5°C per minute. Those data will be deconvoluted and compared to a screening database and the NIST.11 spectral database for tentative identification using AMDIS or Agilent Unknowns Analysis software packages.

The screening database will be populated with chemicals where standards have been prepared and analyzed using the same instrument and conditions in order to have confirmed presence/absence. Components not identified within the screening database will be ranked by abundance and match score for further analysis.

5.6.4 LC/MS Analysis of Target Analyte SVOCs in Air, Dust, and Wipe Samples
The extracts described in section 5.6.2 will be solvent exchanged from acetone:hexane into a solvent amenable for LC/MS analysis (methanol, acetonitrile). Back-calculation of the portion of the total SVOC extract will be recorded for LC/MS analysis to estimate concentrations. A personal compound database

list (PCDL) of all suspect analytes will be used to screen for presence of target analytes in SVOC extracts using an Agilent 6200 series Time of Flight Mass Spectrometer (TOFMS). The PCDL will consist of neutral monoisotopic mass, CAS# and molecular formula for suspect screening. Select compounds where standards are available and are amenable for LC/MS analysis will be quantitated. Compounds where standards are not available will be estimated in concentration based on relative response to the most similar analyte a standard is available for.

5.6.5 Non-Targeted LC/MS Screening of SVOCs in Air, Dust, and Wipe Samples

Suspect screening and nontargeted screening of tire crumb rubber will be performed by sonic extraction of the media of interest in an organic solvent amenable to HPLC-MS analysis. This will be with in acetonitrile or methanol depending on the performance on test samples. After extraction samples with be filtered for particle removal and reduced in volume for preparation for analysis. Samples with be injected onto an Agilent 6200 series Time of Flight Mass Spectrometer (TOFMS) for suspect screening and non-targeted screening analysis.

Samples with be processed according to the procedures of Rager et al., 2015. In brief, after running of samples in both positive and negative mode samples with be subjected to a molecular feature extraction (MFE) algorithm to identify peaks for further exploration. Features identified for suspect screening purposes will be compared to the US EPAs DSS-TOX database (~33,000 chemicals). Chemicals matching within 5ppm of the suspect chemical according to accurate mass and scoring >90% will be deemed as a provisional match. Features not matching will be subjected to a nontargeted screening workflow where by features will be prioritized based on occurrence and abundance into discrete data packets. Further work on these peaks may include compound discovery, verification with authentic standards and comparison to outside databases (Chemspider, Scifinder) for provisional matching. Suspect and non-targeted screening features will be summarized with descriptive statistics.

5.6.5 Biomonitoring Samples

The biological specimens, blood and urine, will be archived with the intent to analyze at a later date as more information on tire crumb rubber chemical composition and bioavailability of chemicals in the tire crumb rubber become available. However, potential analyses include urine metals, urine PAHs, urine VOCs, urine creatinine, blood metals, and serum metals. Blood samples will be collected by a trained phlebotomist from participants; the sample collection protocols indicate a blood draw of 6mL for serum metals and 5mL for blood metals (total of 11mL). The maximum blood draw per participants will not exceed 25mL.

6. Data Analysis

Measurement, questionnaire, videography data sets will be compiled into one or more analytical data sets for analysis. Data analyses will be performed to address the research objectives described in Section 2. Table 11 summarizes the data analysis plan.

Summary statistics will be prepared for each target analyte, questionnaire response, and videography metric. Categorical variables will be summarized by frequencies and response ranges, while continuous variables will be summarized by mean, standard deviation, median, and range. Tire crumb rubber characterization and exposure characterization study measured analyte concentrations will be characterized by mean and standard deviation (or geometric mean and geometric standard deviation), median, range, appropriate distribution percentile values, and percent of measurements above the detection limit.

Data quality (e.g., percent completion or detect, accuracy, precision) will be assessed to help make decisions on the statistical analyses that can be conducted with the available data. Several different types of data analyses will be applied to the different tire crumb rubber characterization and exposure characterization study data sets. These include between-group statistical tests of differences of measurement and questionnaire data where sample sizes are sufficient. For selected analytes with high detection rates, logistic modeling will be explored to assess the potential predictive power of selected facility or user characteristic variables for explaining differences in measured values. Because not all chemical analytes will be quantitatively measured, between-group statistical testing based on presence or absence will be performed for selected chemicals.

For detection limit censored data distributions, appropriate approaches for reducing bias in distributional parameter estimates will be considered (substitution, maximum-likelihood estimation, or beta-substitution, depending on the degree of censoring and sample sizes). Measurement distributions will be assessed for linearity using the Shapiro-Wilks or other appropriate normality test. Depending on the distribution, measurement values may be log-transformed to compute geometric means and geometric standard deviations. Other types of transformations and/or non-parametric analysis methods will be considered, if necessary.

Much of the data being collected under this research protocol is intended to be used in exposure screening and exposure modeling efforts. However, there will not be sufficient time to complete these analyses in time for inclusion in a 2016 report. Data and information extracted from the literature review, as well as questionnaire, videography, and measurement data will be organized for exposure modeling using Version 4.1 of the Stochastic Exposure and Dose Simulation (SHEDS) multi-media model (SHEDS, 2016). An example of an application of the SHEDS modeling approach is an assessment of children's exposure to chemicals in CCA-treated playsets and decks (Zartarian et al., 2006).

Table 11. Summary of the data analysis plan

Objective	Measurements Required	Proposed Analysis Approach
Literature Review and Gap Analysis Aim 1: Conduct a literature review and data gaps analysis of relevant literature addressing aspects of exposure to chemical and microbiological constituents for synthetic turf fields and playgrounds using recycled tire rubber products	No measurements are required; extracted information from the literature review will be applied in gaps assessment and for future exposure modeling efforts	Prepare frequency tables of numbers of articles based on topic areas, analytes measured, findings, and other parameters for coverage and gaps assessment; extract measurement data and exposure factor data for exposure modeling; perform qualitative gaps analysis assessment informed by frequency measures
Tire Crumb Rubber Characterization Aim 1: Characterize a wide range of chemical and microbiological constituents in tire crumb rubber infill material collected from tire recycling centers and synthetic turf fields around the U.S.	Tire crumb rubber chemical constituent analysis results from recycling facilities and synthetic turf fields; tire crumb rubber microbiological analysis results from synthetic turf fields; dynamic chamber experiment emission rate measurements; bioaccessibility measurements; facility questionnaire data	Descriptive and summary univariate statistics for analytical measurement data; conduct t-tests of differences in analyte concentrations between facility types for constituent, emission, and bioaccessibility data; logistic regression analysis for selected analytes with high detection rates and questionnaire data across facility types; prepare presence/absence matrices and perform frequency analyses and tests of presence/absence of analytes within and between facility types and within and between constituent, emission, and bioaccessibility analyses using Chi-square tests (regression models using questionnaire data will be explored); examine within-field and between-field variability in analyte concentrations

Objective	Measurements Required	Proposed Analysis Approach
Tire Crumb Rubber Characterization Aim 2: Collect information from facilities around the U.S. to better understand how synthetic turf fields with tire crumb rubber infill are operated, maintained, and used with regard to characteristics potentially impacting human exposure to tire crumb rubber constituents	Synthetic turf field owner/manager questionnaire data; tire crumb rubber chemical emission rate data	Frequencies for categorical responses; descriptive statistics for ordinal responses; assessment of between group (indoor vs. outdoor) differences using Chi-square tests; translation of relevant responses into parameters for exposure modeling; estimation of potential air concentrations of chemicals for indoor facilities where building ventilation data are available
Tire Crumb Rubber Characterization Aim 3: Identify and collate existing toxicity reference information for selected chemical constituents identified through the tire crumb rubber characterization measurements.	Extant toxicity reference information gathered from multiple data sources; tire crumb rubber and exposure characterization measurement data	Selection of chemicals for toxicity reference information collation will be based on a combination of measurement detection frequency, magnitude of concentrations or estimated levels, and other information; extant toxicity reference information will be compiled and organized to facilitate future analysis but no direct analysis will be performed in the 2016 time frame
Exposure Characterization Aim 1: Collect human activity data for synthetic turf field users that will reduce the reliance of default exposure factor assumptions in exposure and risk assessment	Facility user questionnaire data; participant videography data; extant videography data; exposure factor data extracted from literature	Frequencies for categorical responses; descriptive statistics for ordinal responses; assessment of between group (activity type, indoor/outdoor, adult/youth) differences using Chi-square or Fisher's exact tests; translation of relevant responses into parameters for exposure modeling

Objective	Measurements Required	Proposed Analysis Approach
Exposure Characterization Aim 2: Conduct a pilot-scale exposure measurement study for people using synthetic turf fields with tire crumb rubber infill in what are likely to be among higher exposure scenarios to improve understanding of potential exposures, particularly for the dermal and ingestion exposure pathways.	Chemical analysis results from personal and facility measurements at synthetic turf fields; facility user questionnaire data; exposure factor and chemical measurement data extracted from literature review	Descriptive and summary univariate statistics for analytical measurement data; where there are sufficient data with high percent detection rates conduct t-tests of differences in analyte concentrations between activity groups, age groups, or facility types for measurement data; logistic regression analysis for selected analytes with high detection rates and questionnaire data across facility and activity types; prepare presence/absence matrices and perform frequency analyses and tests of presence/absence of analytes within and between facility types and within and between activity groups using Chi-square or Fisher's exact tests; prepare measurement data, questionnaire data, and data extracted from literature review for human exposure modeling using the Stochastic Human Exposure and Dose Simulation multi-media model (SHEDS v. 4.4) configured for the synthetic turf field exposure scenario https://www.epa.gov/chemical-research/stochastic-human-exposure-and-dose-simulation-sheds-estimate-human-exposure

7. Quality Assurance/Quality Control

The research described in this research protocol requires a rigorous quality assurance (QA) approach following U.S. EPA policies and procedures. To ensure that results are scientifically defensible, the research will comply with the EPA Quality Policy CIO 2106, the EPA Procedure for Quality Policy CIO 2106-P-01.0, and other quality requirements. Under the graded approach as defined ORD Policies and Procedures Manual, Chapter 13, Quality Assurance, the research described in this protocol is designated QA Category B.

Quality assurance for the research described in this protocol will be implemented under a study-specific Quality Management Plan (QMP) developed in coordination with existing organizational QMPs. Several project-specific Quality Assurance Project Plans (QAPPs) will be developed and implemented under the EPA Requirements for Quality Assurance Project Plans, QA/R-5, EPA/240/B 01/003, March 2006. QAPPs will be developed to specify and describe appropriate quality control and quality assurance measures and activities to ensure that data of known and high quality will be produced. Written sample collection and analysis standard operating procedures (SOPs) or research protocols will be included as part of the QAPPs where applicable.

The following elements will be critical for producing high quality research results:

- Research projects that comply with Agency requirements and guidance for QAPPs, including the use of systematic planning;
- Technical Systems Audits (TSAs), Audits of Data Quality (ADQs), and Quality System Audits (QSAs) conducted as described in this Quality Management Plan (QMP) and project-specific QAPPs;
- Performance evaluations of analytical systems conducted, if available;
- QA review of all products that include environmental data (including existing data and models), and;
- Reports that have a readily identifiable QA section.

The research is supported by a Program QA Manager (PQAM), who is independent of the technical work and will assist the QA staff in the implementation of the tire crumb rubber research quality program and the requirements of this QMP. All technical and QA personnel will implement their organization's QMP in all cases where the programmatic research study QMP is either silent or points to the organizational QMPs. Requirements, where specified, in the research study QMP will ensure consistency in the QA approach for all participating organizations.

Quality control and quality assurance activities and analyses performed over the course of the study will include, but are not limited to:

- All sample collection media will be pre-cleaned or purchased as certifiably clean;

- Whenever possible, media will be evaluated prior to field deployment to ensure minimal background or interferences and blank media will be analyzed to assess potential background contamination;
- Field quality control samples will consist of blank, spike, and duplicate samples where applicable; location-specific field blanks will be taken to and handled in the field in the same manner as samples including opening and closing containers where appropriate;
- Chain of custody procedures will be implemented for all samples;
- Laboratory quality control samples will consist of procedure blanks and spikes, matrix blanks and spikes where feasible, and replicate sample analysis;
- Appropriate methods will be used to determine analytical and method limits of detection. If needed, blank and recovery correction will be used;
- Reference standards will be obtained from reputable and traceable sources;
- Solvents used in the field for device cleaning or media preparation will be HPLC grade or better in purity;
- Laboratory notebooks will be maintained, and;
- Quality assurance review will be performed for all datasets.

No appropriate reference standard material for tire crumb rubber has been identified to date. In the absence of a reference standard the researchers propose to identify, sequester and thoroughly mix at least 1 kg of tire crumb rubber from a single source. At least seven aliquots will be analyzed for SVOCs and metals. Depending on the analysis variability across multiple aliquots a decision will be made to determine the suitability for use as a performance evaluation material such that an aliquot would be included for analysis with each batch of samples processed in the laboratories.

Contract support for laboratory, field work, and other activities are anticipated during the course of this research. In general, the originating contracting officer representative, in consultation with the Quality Assurance Manager (QAM), has the responsibility for QA for the procurement activity. The contracting officer representative must then ensure that the requirements are included in the contract language. Contracted laboratories, other facilities, and field personnel have QA responsibilities that are specified in their respective statement of work.

QA responsibilities and requirements for contractors include, but are not limited to the following:

- Accredited laboratories must be used for critical target analytes. If accreditation is not feasible, then laboratory competency must be demonstrated (documented quality system and methods, instrumentation, and experience; performance evaluations; and independent audits);
- Maintain communication with EPA;
- Develop or implement QAPPs as specified in the statement of work;
- Perform the required QA/QC procedures during technical or analytical activities;
- Report technical or analytical results with the associated QA/QC summary and datum-specific information;
- Perform corrective actions or other necessary steps when QA issues are identified and report this information to the associated EPA Laboratory/Center Organization;
- EPA will audit contractor activities that perform analysis of critical target analytes.

The contracted laboratory, field, or facility personnel should have a QAM, QA officer, or similar defined position with the responsibility of ensuring these QA requirements are met. The QAM/officer of the contractor must be independent of the data being collected.

8. Human Subjects

8.1 Overview

Elements of this research protocol will involve human subjects, requiring human subject reviews and protections. The elements involving human subjects include:

- Participation by adults, adolescents, youth, and children in the exposure characterization study involving collection of questionnaire data, videography, and personal, biological, and field facility environmental sample collection.

- Use of publically available extant video media showing adults, adolescents, youth, and children engaged in sports or training activities on synthetic turf fields with tire crumb rubber, which may also be determined to be human subjects research

The study will be performed in accordance with all required human subjects reviews and protections specified in the Code of Federal Regulations (45 CFR 46 for HHS; 40 CFR 26 for the U.S. EPA) and in other applicable policies on human subjects at the U.S. EPA and CDC/ATSDR.

8.2 Human Subject Research and Reviews

8.2.1 CDC IRB/EPA HSRRO Approvals

The study protocol; consent, permission, and assent forms (Appendix H); eligibility screening forms (Appendix G); and the questionnaires (Appendix I) will be submitted for review and approval by the CDC Institutional Review Board (CDC IRB) responsible for human subject protections. Following CDC IRB approval, the protocol and IRB materials will be submitted to the U.S. EPA Human Subjects Research Review Official (HSRRO) for review and approval. No study recruitment or data collection involving human subjects shall proceed until the CDC IRB and EPA HSRRO approvals are obtained.

8.2.2 Informed Consent and Assent

Informed consent is a critical element for protection of human research subjects. All adult participants recruited into the exposure characterization study will provide informed written consent for their participation. For participants younger than 18 years old (or otherwise appropriate age of majority) and who will respond for themselves, parent/guardian informed written permission and child informed written assent are required (Appendix H). Parents who respond to questionnaires for their children (children and youth ages 7-12) will require both parent informed written consent and permission for their children to participate in other parts of the research.

Only a parent or legal guardian can provide consent for child participants under 18 years of age. A separate assent procedure will be used for children, youth, and adolescents. The research team will

describe the study and information collection procedures to the children and adolescents, and they will be asked to sign an assent form that explains the research procedures in simplified terms (Appendix H). Children, youth, and adolescents may refuse to assent to participate. The eligible age ranges for non-adult participants are 7 to 9 years (child), 10 to 12 years (youth), and 13 to 17 years (adolescent). Children, youth, and adolescents may refuse to assent to participate.

The research team will discuss with potential participants, and the consent form will describe, the purpose of the research, what participants will be asked to do, and potential risks and benefits. Participants will be informed that their participation is voluntary, they can refuse to answer any question or decline any study activity, and they may withdraw at any time. Participants will be informed that a decision to participate, not to participate, or withdrawing from participation will not affect their rights or benefits they are otherwise entitled to receive, nor will it have any adverse impact on employment or organizational status or relationships. Participants will sign a secondary part of the consent/permission/assent form indicating whether they do or do not want to provide urine and blood samples in the different phases to be stored for future laboratory analysis. They will be informed that they will not receive their test results.

Information about intended uses and protections for their data or sample specimens will be provided and discussed. Contact information for an IRB representative and research team representative will be provided in case they have any questions or concerns. This study will not provide any direct benefit to the participants.

Informed consent will not be obtained from people depicted in extant publicly available videos used for activity data collection. Privacy protections related to data abstraction from these extant videos will include not recording people's names or organization names, not recording metadata for the recording or any internet IP address, uploading identification data, or file names. If the video recording is saved for by the research team, it will be stored on a password protected computer behind a federal agency firewall, with access limited to research and QA staff. Extant video recordings used in the research will not be provided to the public, to the extent allowed by law.

Participant video recording is included as a research element for a subset of participants in the exposure characterization study. The study activities of interest will be mostly or exclusively done as part of team sports, team practice, or group training activities. Therefore, it is likely that people not participating in the research, including other players, coaches, referees, and bystanders will be recorded. Informed consent will not be obtained from people other than the study participants. In the case of team or group activities, the team or group and the team/group leader or coach will be generally informed that video recording will be performed. Privacy protections for non-participants will include not capturing people's names during data collection and storage of recordings on a password protected computer behind a federal agency firewall, with access limited to research and QA staff. Video recordings used in the research will not be provided to the public, to the extent allowable by law.

8.2.3 Special Populations

No exposure characterization research will be performed on U.S. military installations with active duty military service members and/or their family members. The study will not recruit or enroll prisoners.

8.2.4 Reimbursement to Participants

Based on past experience, tokens of appreciation in the form of gift cards will increase the ability of this program to recruit participants and to collect more reliable information. Participants may receive up to a total of $100 in gift cards for completing the questionnaire and all elements of the exposure measurement study. Distribution will be as follows:

- Phase 1: $25 as a token of appreciation for completing the questionnaire;
  - 60 participants will receive $25

- Phase 2: $25 as a token of appreciation for giving or attempting to give blood and/or urine specimens pre-and post-exposure assessment activities (pre-activity – blood and urine, post-activity – urine and blood);
  - 45 participants will receive $50 for the biological specimen collection (a total of $75)

- Phase 3: $25 as a token of appreciation for completing the videography activity
  - 24 participants will receive $25

Item non-response for blood sample collection will be allowed. The Phase 2 gift cards will be given to participant if they give or attempt to give urine samples but not blood samples.

8.2.5 Scripted Activities

The research will be conducted only as observational research for participants taking part in their normal and routine activities on synthetic turf fields. No scripted activities will be required or performed.

8.2.6 Confidentiality

Participant confidentiality will be maintained at all times and at all stages of research, reporting, and results dissemination. All samples and information shall be coded with unique identification numbers, with one ID code translation record that include personal identifiers to be maintained securely by the recruiting organization. Identifying information will not be made publicly available in any report, presentation, or data set. Synthetic turf facility addresses or geospatial information will be collected and may be used in analyses.

8.2.7 Data Security

The research staff will maintain all study records in a secure manner. Paper records will be stored in locked offices or locked file cabinets. Electronic records will only be stored on password-protected IT systems that are protected by the agency's firewall and security systems. Access to project data files will be restricted to project research and QA staff. All electronic records will be backed-up on secure servers.

8.2.8 Data Reporting and Sample Archival

The research staff will use coded participant data and information in reports, presentations, and/or publications, and is required to make research data and information available to the public based on executive order. No identifying information will be included with or associated with any such public use

of the data or information. The CDC/ATSDR principal investigator or their designee will be responsible for maintaining the master code links with participant identifying information and will maintain the link information in a locked area.

The biological samples (urine and blood) will not be immediately analyzed, and will be banked for future analyses informed by other data and information produced in this research study. Other remaining samples and sample extracts will be stored under appropriate conditions for possible future analyses of unspecified chemical or microbiological agents.

8.2.9 U.S. EPA SEAOES

EPA researchers use the information and guidance in the Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES) document and the Guidance for Human Subjects Research in the National Exposure Research Laboratory (EPA 600/R-10/175, U.S. EPA, National Exposure Research Laboratory, Research Triangle Park, NC, 2009) in the design of observational human exposure research studies. Human subject research elements outlined in SEAOES are addressed in Appendix L.

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Appendix A: Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds

science in ACTION
INNOVATIVE RESEARCH FOR A SUSTAINABLE FUTURE

Federal Research Action Plan on Recycled Tire Crumb Used on Playing Fields and Playgrounds

Background

Concerns have been raised by the public about the safety of recycled tire crumb used in playing fields and playgrounds in the United States. Limited studies have not shown an elevated health risk from playing on fields with tire crumb, but the existing studies do not comprehensively evaluate the concerns about health risks from exposure to tire crumb.

Federal Research

Because of the need for additional information, the U.S. Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (ATSDR), and the U.S. Consumer Product Safety Commission (CPSC) are launching a multi-agency action plan to study key environmental human health questions. This coordinated federal action includes outreach to key stakeholders, such as athletes and parents, and seeks to fill important data and knowledge gaps, characterize constituents of recycled tire crumb, and identify ways in which people may be exposed to tire crumb based on their activities on the fields. The Federal Research Action Plan includes numerous activities, including research studies. While additional research questions may require evaluation beyond this year, the information will help answer some of the key questions that have been raised.

Objectives

The specific objectives of this research effort are to:

- Determine key knowledge gaps.
- Identify and characterize chemical compounds found in tire crumb used in artificial turf fields and playgrounds.
- Characterize exposures, or how people are exposed to these chemical compounds based on their activities on the fields.
- Identify follow-up activities that could be conducted to provide additional insights about potential risks.

Research Summary

Conduct Data and Knowledge Gap Analysis: The Agencies will evaluate the existing scientific information related to recycled tire crumb used in artificial turf fields and other types of playing fields to build on current understanding of the state-of-the-science and inform the research activities.

Outreach to Key Stakeholders, Including Parents and State Agencies: EPA, ATSDR, and CPSC will convene discussions with members of the public and organizations with an interest in studying tire crumb. These parties have ongoing tire crumb studies or can provide expertise to inform the federal study. The agencies will meet with:

- ***Athletes, parents, and coaches*** to get first-hand perspectives on potential exposures.
- ***Government agencies*** to discuss the federal research, share relevant information from state-level studies, request support, and identify current best practices for minimizing exposures. One important state partner is California. California's Office of Environmental Health Hazard Assessment has an in-depth tire crumb study underway. This study includes a series of scientific studies to determine if chemicals in tire crumb can potentially be released under various environmental conditions and what, if any, exposures or health risks these potential releases may pose to players who frequently play on artificial fields constructed with tire crumb. The evaluation includes expert solicitation and stakeholder participation to help guide the design and EPA and other federal agencies are actively engaged in that process.
- ***Industry representatives*** to better understand the manufacturing process and use parameters for recycled tire crumb used in artificial turf and for recycled tire-derived playground surface materials.

Testing of Tire Crumb to Characterize Chemicals, Potential Emissions, and Toxicity: The agencies will test different types of tire crumb. These tests – along with existing scientific information from the literature – will help us better understand the tire crumb materials. For example, this will help the scientists working on this effort to understand chemicals that are found in tire crumb and might be emitted from the material. It will also help us understand if chemicals can be released from tire crumb when a person comes into contact with them – for example, when tire crumb comes in contact with sweat on the skin or are accidentally ingested by athletes playing on turf fields. Once we better understand what chemicals are in tire crumb, we will also be able to search existing databases of information to understand the potential health effects of those chemicals. Some examples of research activities are listed below.

- Based on information obtained through the efforts described above, evaluate various manufacturing process (for example, the tire crumb manufacturing process and the tire-derived playground surface materials manufacturing process), including an analysis of the diversity of these processes, material blends, components of the material (metals, volatile and semi-volatiles, particulate matter).
- Conduct laboratory analyses to characterize components of the chemicals in newer and older (aged) tire crumb materials at different temperatures.
- Determine the rate at which tire crumb components are absorbed by the body using simulations of biological processes in the lab, for example simulations of activities in the stomach as well as salivating and sweating.
- Evaluate potential cancer and non-cancer toxicity of key tire crumb constituents based on existing databases of information.

Launch Pilot-Scale Study to Characterize Exposure Under Use Conditions: The agencies will conduct several activities to better understand potential exposures that may occur when individuals

frequently use artificial turf fields. Scientists will identify various exposure scenarios (ways in which people may be exposed based on their activities on the fields) and then design and conduct a pilot-scale exposure study to characterize people's exposures on these fields. This work will consider possible ways that one may be exposed – including by breathing, accidentally ingesting, or physical contact with tire crumb. Some examples of research activities are listed below.

- Develop exposure scenarios, paying particular attention to high-end exposure scenarios.
- Identify activity patterns for athletes and other relevant populations.
    - Estimate nature, duration, and frequency of exposures.
    - Evaluate other relevant factors, such as the standard operation and maintenance of the fields (e.g., replacement of materials, use of biocides) and how the materials change over time.
- Design and conduct pilot-scale exposure study to characterize exposures on select playing fields, considering all relevant routes of exposure (inhalation, dermal, oral).
- Develop methods, as necessary, for measuring exposure to both targeted and non-targeted analytes.

Public Comment Opportunities: Some studies that are part of this research plan are posted for public comment through a Federal Register Notice (available at Regulation.Gov, search by docket number Docket No. ATSDR–2016–0002). For example, one study that is part of the Federal Register Notice will gather data from facilities with fields that contain tire crumb materials, and another study will gather activity data from persons who routinely perform activities on artificial turf fields with tire crumb. The number of fields that will be sampled as well as the number of field users who will be surveyed are described in the Federal Register Notice. We encourage you to review the Federal Register Notice and provide your comments.

Additional Research Activities: EPA, CDC/ATSDR, and CPSC have set an ambitious schedule for this effort in 2016. A number of additional activities may also be initiated during this time, depending upon further consideration of their value to the overall effort, their feasibility, the availability of resources, and other factors. Additional research could include identifying potential biomarkers of exposure, collecting preliminary biomonitoring data, analyzing samples of recycled tire crumb used on playground surfaces, and evaluating the feasibility of conducting an epidemiologic study. CPSC is exploring conducting a survey of parents to get first-hand perspectives on potential exposures from playground surface materials. As part of this coordinated effort, CPSC plans to conduct additional work on the safety of playgrounds.

Timeline and Deliverables

By the end of 2016, the agencies anticipate releasing a draft status report that describes the preliminary findings and conclusions of the research through that point in time. The draft status report will summarize the agencies' progress in: (1) Identifying key constituents of concern in recycled tire crumb used in artificial turf fields; (2) Assessing potential exposures to potentially harmful constituents; (3) Conducting an initial evaluation of potential cancer and non-cancer toxicity of key chemical constituents; and (4) Identifying follow-up activities that could be conducted to provide additional insights about potential risks. The results of the preliminary work on recycled tire-derived playground surface materials will also be described. The report will also outline any additional research needs and next steps.

More Information

Information and updates about this research will be posted to EPA's website – http://www.epa.gov/TireCrumb

Appendix B: Preliminary Literature Review Citations

Preliminary Reference List – Tire Crumb Rubber and Artificial Turf (Note: Some ID numbers were skipped after being found to be duplicative or not relevant)	
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Appendix C: Telephone Script for Recycling Facilities

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Telephone Script for Recycling Facilities

Caller: May I speak to [NAME OF Facility Owner/Operator]? I am _____ from the United States Environmental Protection Agency, and I am calling you to tell you about a federally funded study on synthetic turf fields. In response to concerns raised by the public about the safety of synthetic turf fields, the United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry are working together to study synthetic turf fields with crumb rubber infill. Are you interested in hearing more about this study?

Recycling Facility is not interested in the project:
Recycling Facility: No, I am not interested.
Caller: Ok, thank you for your time and have a good day.
END CALL.

Recycling Facility is interested in the project:
Recycling Facility: Yes, please tell me more.
Caller:

The EPA and ATSDR are initiating a series of activities to look at tire crumb rubber used in synthetic turf fields. One study is a tire crumb rubber characterization study that will collect samples from tire recycling facilities and analyze the material found for different chemicals. EPA and ATSDR would like to identify up to nine recycling facilities that produce tire crumb rubber for use on synthetic fields to participate in the tire crumb rubber characterization study. Would you like to participate in this study by allowing us to collect samples from your facility?

Recycling Facility is not interested in participating:
Recycling Facility: No, I am not interested at this time.
Caller: Ok, thank you for your time and have a good day.
END CALL.

CDC estimates the average public reporting burden for this collection of information as xx minutes/hours per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-xxxx).

Recycling Facility is interested in participating:
Recycling Facility: Yes, I am interested in participating.
Caller:
Thank you for your willingness to participate. To participate, we are asking you allow us to collect tire crumb rubber samples. We need samples from three different production batches and/or storage containers from your facility. We will collect about four pounds of crumb rubber from each batch or container. These samples will be tested by EPA and ATSDR for a wide range of chemicals including metals, volatile organic compounds, and semi-volatile organic compounds. They will also be tested for emissions and bioaccessibility, and particle size assessments will be performed.

Would you like to schedule an appointment for us to come and collect the samples?

Recycling Facility is not interested in scheduling an appointment immediately:
Recycling Facility: No, I do not have time at the moment.
Caller: OK, I will call at a better time to schedule an appointment. Thank you for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Recycling Facility is interested in scheduling an appointment immediately:
Recycling Facility: Yes, I am interested in scheduling an appointment now.
Caller: OK, we are able to come and collect on XX at XX:XX or XX at XX:XX. Do either of these times work for you?

Recycling Facility: Yes, you can collect the samples on XX at XX:XX.
Caller: I have you scheduled for ----------. Thank you for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Recycling Facility: No, I am not available during those times.
Caller: OK, I will call you at a later date to schedule the appointment. Thank for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Appendix D: Recycling Facility and Synthetic Turf Field Facility Participation Agreement Forms

D1. Recycling Facility Participation Agreement Form
D2. Synthetic Turf Field Facility Participation Agreement Form

Appendix D1. Tire Recycling/Crumb Rubber Manufacturing Facility Collection Agreement
(Flesch-Kincaid Reading Level: Grade 9.5)

COLLECTION AGREEMENT

United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you to be in a project to measure the amount of chemicals in crumb rubber infill used in synthetic turf fields.

You are being asked to participate in this project. Your participation is voluntary. After you read about the project and before you decide to participate, please ask questions if there is anything that you do not understand.

What is the purpose of this project?

The purpose is to see what chemicals are present in newly manufactured tire crumb rubber infill used in synthetic turf fields.

We will use the results of this project to guide actions that will protect people from exposure to contaminants in the environment.

Why are you being asked to be in this project?

You were chosen to participate in this research project because your facility was identified as manufacturing tire crumb rubber used as infill in synthetic turf fields and you completed a survey that indicated you willing to participate. ATSDR and EPA hope to get 9 facilities to participate.

What are we asking you to do?

- We will ask you to provide permission for us to collect samples of the crumb rubber manufactured at your facility. We need samples from three different production batches and/or storage containers from your facility. We will collect about four pounds of crumb rubber from each batch or container.

How long will this take?

It will take about 90 minutes for us to collect the samples.

What will the field samples be tested for?

We will look for chemicals in the crumb rubber, including

- Metals
- Volatile Organic Compounds
- Semi-Volatile Organic Compounds

We will also characterize particle sizes in the collected material.

We would like your permission to store the leftover samples to possibly test for other chemicals in the future.

Are there any risks or discomforts to you if you decide to be in this project?

There are no risks from the sample collection. The facility owners will not incur any costs for the laboratory tests performed by the federal government.

Are there any benefits to you from being in this project?

There are no direct benefits from being a part of the project.

Who will see the information you give the researchers?

All information about your facility will be secure. We keep track of your information using a code number rather than the facility name. We will keep paper records in locked files and electronic records are stored on password protected computers at the USEPA. Only staff working on the project will be allowed to look at the paper and electronic records. Federal policy requires making the data we collect available to the public, but we will not include your name or other identifying information in public release. However, identifying information may be released in the event of a Freedom of Information Act request.

What is the cost to you and what compensation will you get?

The only cost to you for being in our project is your time to take part.

What are your choices about participating?

Your participation in this project is voluntary. You are free to be a part of it or not.

Who should you contact if you have questions later on?

If you have any question about the project or wish to drop out, please contact:

Elizabeth Irvin-Barnwell, CDC/ATSDR Project Officer
Jcx0@cdc.gov
770-488-3684

What should you do after reading this information?

If you do not understand what we are asking you to do, please ask questions. After all your questions have been answered to your satisfaction and if you want to be in this project, please sign the consent form on the next page.

United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Sample Collection Agreement

I have read the above information about the project "*Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*." I have been allowed to ask questions and I had all my questions answered.

By signing below, I agree to allow USEPA and ATSD to collect crumb rubber samples from my manufacturing facility.

_____
Participant's name (Print)

_____
Participant's signature / Date

_____

Organization/Facility Name Participant Position/Title

By signing below, I give USEPA and ATSDR permission to store my leftover field samples to test for other contaminants at a later date.

_____
Participant's name (Print)

_____
Participant's signature / Date

By signing below, I am indicating I would like to receive a copy of the laboratory results from the crumb rubber samples collected from my facility.

_____

Participant’s name (Print)

_____

Participant's signature / Date

_____

Mailing Address for results

Site ID Number	Collection Date	Field Staff Id

Appendix D2. Synthetic Turf Field Facility Participation Agreement
(Flesch-Kincaid Reading Level: Grade 9.5)

PARTICIPATION AGREEMENT

United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you to be in a project to measure the amount of chemicals in crumb rubber infill used in synthetic turf fields and to look at field conditions that might affect the chemicals in the crumb rubber infill.

You are being asked to participate in this project. Your participation is voluntary. After you read about the project and before you decide to participate, please ask questions if there is anything that you do not understand.

What is the purpose of this project?

The purpose is to see what chemicals and microbes are present in crumb rubber infill used in synthetic turf fields. To help us understand the results, we also want to know about standard operating procedures for the synthetic turf fields, such as rubber redistribution.

We will use the results of this project to guide actions that will protect people from exposure to contaminants in the environment.

Why are you being asked to be in this project?

You were chosen to participate in this research project because your facility was identified as having synthetic turf fields with crumb rubber infill, and you completed a survey that indicated you were eligible and willing to participate. ATSDR and EPA hope to get 10 facilities in each of the 4 US regions for a total of 40 facilities.

What are we asking you to do?

- We will ask you a few questions about yourself then we will interview you and ask questions about the facility. The interview will take 30 minutes. During the interview we will ask questions about the facility use, the types of synthetic turf fields, and the standard operating procedures for the synthetic turf fields.

- You will be asked to provide permission for us to collect samples of the crumb rubber infill in synthetic turf fields.
- USEPA and ATSDR are also conducting a sub-study looking at exposure measurements in people who play on synthetic turf fields. We will also ask you if you are willing to allow us to recruit people who play on the synthetic turf fields at your facility. People would be asked to complete a questionnaire about their activities on synthetic turf fields. Some people would also be asked to participate in an exposure measurement study. If people agree, we would return and make additional measurements while they are using the facility, including air samples, surface wipe samples, and dust samples from the field they use.

How long will this take?

It will take about 30 minutes to complete the interview.

It will take about 3 hours to collect crumb rubber samples from the field.

What will the field samples be tested for?

We will collect tire crumb rubber samples from seven different locations on one field. The total amount collected will be about six pounds. We will look for chemicals and evidence of microbes in the crumb rubber infill, including

- Metals
- Volatile Organic Compounds
- Semi-Volatile Organic Compounds
- Microbial activity

We will also characterize particle sizes for the collected material.

We would like your permission to store the leftover samples to possibly test for other chemicals in the future.

Are there any risks or discomforts to you if you decide to be in this project?

There are no risks from the field collection or the questionnaire. The facility owners will not incur any costs for the laboratory tests performed by the federal government.

Are there any benefits to you from being in this project?

There are no direct benefits from being a part of the project.

Who will see the information you give the researchers?

All information about you (including your name and address, this form, and your interview answers) will be secure. We keep track of your information using a code number rather than your name. We will keep paper records in locked files and electronic records are stored on password protected computers at the USEPA. Only staff working on the project will be allowed to look at the paper and electronic records. Federal policy requires making the data we collect available to the public, but we will not

include your name or other identifying information in public release. However, identifying information may be released in the event of a Freedom of Information Act request.

What is the cost to you and what compensation will you get?

The only cost to you for being in our project is your time and effort to take part.

What are your choices about participating?

Your participation in this project is voluntary. You are free to be a part of it or not. You can refuse to answer any interview questions. You can choose to leave at any time, even after you have signed the participation agreement form.

Who should you contact if you have questions later on?

If you have any question about the project or wish to drop out, please contact:

Elizabeth Irvin-Barnwell, CDC/ATSDR Project Officer
Jcx0@cdc.gov
770-488-3684

What should you do after reading this information?

If you do not understand what we are asking you to do, please ask questions. After all your questions have been answered to your satisfaction and if you want to be in this project, please sign the consent form on the next page.

United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Access Agreement and Consent to Participate

I have read the above information about the project "*Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*." I have been allowed to ask questions and I had all my questions answered.

By signing below, I agree to take part in the interview and to allow USEPA and ATSD to collect crumb rubber samples from my synthetic turf fields.

_____
Participant's name (Print)

_____
Participant's signature / Date

_____

Organization/Facility Name Participant Position/Title

By signing below, I give USEPA and ATSDR permission to store my leftover field samples to test for other contaminants at a later date.

_____
Participant's name (Print)

_____
Participant's signature / Date

By signing below, I am indicating I would like to receive a copy of the laboratory results from the crumb rubber samples collected from my facility.

_____

Participant's name (Print)

_____

Participant's signature / Date

_____

Mailing Address for results

By signing below, I will volunteer information to USEPA and ATSDR on individuals who use the synthetic turf field facilities. This information can include individual names of field users and/or dates and times of group activities (i.e. intramural sports activities). I also agree to hand out information sheets to individuals who use the synthetic turf field facilities.

_____

Participant's name (Print)

_____

Participant's signature / Date

By signing below, I give USEPA and ATSDR permission to recruit players at my facility, and if they participate, to allow USEPA and ATSDR to collect air, wipe, and dust samples.

_____

Participant's name (Print)

_____

Participant's signature / Date

Site ID Number	Interview Date	Interviewer Id

Appendix E: Synthetic Field Facility Eligibility Screening Form

Appendix E. Telephone Script for Facility Owner/Operator
(Flesch-Kincaid Reading Level: Grade 9.5)

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Telephone Script for Facility Owner/Operator

Caller: May I speak to [NAME OF Facility Owner/Operator]? I am _____ from the Agency for Toxic Substances and Disease Registry (ATSDR), and I am calling you to tell you about a federally funded study on synthetic turf fields. In response to concerns raised by the public about the safety of synthetic turf fields, the United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry are working together to study human health questions associated with using synthetic turf fields and playgrounds. Are you interested in hearing more about this study?

Facility Owner/Operator is not interested in the project:
Facility Owner/Operator: No, I am not interested.
Caller: Ok, thank you for your time and have a good day.
END CALL.

Facility Owner/Operator is interested in the project:
Facility Owner/Operator: Yes, please tell me more.
Caller: The EPA and ATSDR are initiating a series of activities to look at tire crumb rubber used in synthetic turf fields. One activity aims at collecting samples from synthetic turf fields and analyzing the material for different chemicals and bacteria. For the this activity, EPA and ATSDR would like to recruit forty facilities with synthetic turf fields containing tire crumb infill that has been present on the field for at least 2 years. As a synthetic turf facility, are you interested in participating in a short 5 minute survey to find out if you are eligible to participate in the project?

Facility Owner/Operator is not interested in participating:
Facility Owner/Operator: No, I am not interested at this time.
Caller: Ok, thank you for your time and have a good day.
END CALL.

Facility owner/operator is interested in the project:
Facility owner/operator: Yes, I would like to learn more.
Caller: To find out if you are eligible I will read the questions to you over the phone. If you are ready I'm going to read you a few questions.

ATSDR estimates the average public reporting burden for this collection of information as xx minutes/hours per response, including the time for reviewing instructions, searching existing data/information sources, gathering and maintaining the data/information needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Information Collection Review Office, 1600 Clifton Road NE, MS D-74, Atlanta, Georgia 30333; ATTN: PRA (0923-xxxx).

1. Do you currently own a facility with synthetic turf fields? .....

2. Do you currently operate a facility with synthetic turf fields? .....
   If both #1 and #2 are no respondent is ineligible.
   Caller: You did not answer "Yes" to either question so you are not eligible to participate in this project. I am sorry. Thank you for your time.
   END CALL.

   If #1 and/or #2 are yes:
3. Would you be willing to be enrolled in this new study about facilities like yours that use and maintain of synthetic turf fields with crumb rubber infill? .....
   If no, respondent is a refusal.
   Caller: Ok, thank you for your time and have a good day.
   END CALL.

   If #3 is yes:
   In order to help us determine if your facility is eligible, we have some additional questions specific to your facility:

4. Are there outdoor synthetic turf fields with crumb rubber infill at your facility?.....
   If no, skip to question #8.

   If yes:
5. How many outdoor synthetic turf fields are present at your facilities?....._____

6. What was the installation date(s)?
   ....._____

7. What was the date of the most recent tire crumb replenishment?....._____

8. Are there indoor synthetic turf fields with crumb rubber infill at your facility?.....
   If no, skip to eligibility decision following question #11.

   If yes:
9. How many indoor synthetic turf fields are present at your facilities?....._____

10. What was the installation date(s)?……
    _____

11. What was the date of the most recent tire crumb replenishment?……-
    _____

If all outdoor and indoor fields are less than two years old, the facility is not eligible.
Caller: Thank you for your interest; however, the fields must be at least two years old. Thank you for your time and have a good day.

12. In addition to a short survey, would you be willing to allow EPA to collect samples of crumb rubber infill from a synthetic turf field at your facility?……

Facility Owner/Operator is willing to participate:
Facility Owner/Operator: Yes, I will allow samples to be collected.
Caller: Thank you for your willingness to participate. To participate, we will ask you to sign an agreement form allowing us to collect samples from your facility. We will need to collect tire crumb samples from multiple locations on the field to collect about six pounds. Then, these samples will be tested by EPA and ATSDR for a wide range of chemicals including metals, volatile organic compounds, and semi-volatile organic compounds. They will also be tested for emissions and bioaccessibility, particle size, as well as assessed for microbes like bacteria. We will also ask synthetic field owners or managers to complete a questionnaire to provide us information about these fields like how they are installed, maintained, and used.

13. Are you the correct person to sign the agreement?
If yes, skip to question #15.

If no:
14. Please provide the name and contact information for the correct contact person:
Name _____ phone: _____
Thank you for your willingness to participate. We will contact _____ to complete the necessary forms and schedule a collection appointment. *End Call.*

15. Would you like to schedule an appointment for us to come and collect the samples?

Facility owner/operator is not interested in scheduling an appointment immediately:
Facility Owner/Operator: No, I do not have time at the moment.
Caller: OK, I will call at a better time to schedule an appointment. Thank you for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Facility owner/operator is interested in scheduling an appointment immediately:
Facility owner/operator: Yes, I am interested in scheduling an appointment now.
Caller: OK, we are able to come and collect on XX at XX:XX or XX at XX:XX. Do either of these times work for you?

Facility owner/operator: Yes, you can collect the samples on XX at XX:XX.
Caller: I have you scheduled for ----------. Thank you for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Facility owner/operator: No, I am not available during those times.
Caller: OK, I will call you at a later date to schedule the appointment. Thank for your time today and please feel free to contact me at XXX-XXX-XXXX with any questions you have about the project.
END CALL.

Appendix F: Synthetic Turf Field Facility Owner/Manager Questionnaire

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Owner/Manager Synthetic Turf Fields Questionnaire

Site ID number	Interview Date	Interviewer ID

Interviewer: In this interview, I would like to ask you some general questions about your role and responsibilities at this facility and about the operation, maintenance, and use of the synthetic turf fields with crumb rubber infill at your facility.

A1. Who owns the facility?

A1.a What type of organization owns the facility?

- Private
- School
- City
- County
- State
- Military/Federal
- (enter other if necessary)

A2. What is your profession and relationship to this facility?

(owner or manager)

A3. How long have you operated this facility?

yrs months

A4. May I have your phone number and E-mail address for future contact? ☐

Phone

E-Mail

ATSDR estimates the average public reporting burden for this collection of information as 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-XXXX).

Facility User Information

A5. Are the synthetic fields at this facility open to the public?

- Yes
- No
- Don't Know
- Refused

A6. Is there an open or free-play schedule at this facility?

- Yes
- No
- Don't Know
- Refused

A7. Is field use at this facility limited to organization membership or school use only?

- Yes
- No
- Don't Know
- Refused

If yes, what organization(s) use the synthetic fields?

A8. How many days per week are the synthetic fields open at this facility during each season?

Days per Week Spring

Days per Week Summer

Days per Week Fall

Days per Week Winter

A9. What is average number of hours per day that people use the synthetic fields at this facility during the four seasons?

Hours per Day Spring

Hours per Day Summer

Hours per Day Fall

Hours per Day Winter

A10a. On average, how many people per day use the synthetic fields at this facility during Spring? ☐

A10b. On average, how many people per day use the synthetic fields at this facility during Summer? ☐

A10c. On average, how many people per day use the synthetic fields at this facility during Fall? ☐

A10d. On average, how many people per day use the synthetic fields at this facility during Winter? ☐

A11. For each of the different age groups, what sports or other activities are played on the synthetic turf fields at this facility during which seasons (check all that apply)?

			Spring	Summer	Fall	Winter
☐	< 6	☐ Soccer	☐	☐	☐	☐
		☐ Football	☐	☐	☐	☐
		☐ Field Hockey	☐	☐	☐	☐
		☐ Baseball	☐	☐	☐	☐
		☐ Softball	☐	☐	☐	☐
		☐ Rugby	☐	☐	☐	☐
		☐ Ultimate Frisbee	☐	☐	☐	☐
		☐ Physical Training (PT)	☐	☐	☐	☐
		☐ Physical Education (PE)	☐	☐	☐	☐
		☐ Other: ☐	☐	☐	☐	☐
		☐ Other: ☐	☐	☐	☐	☐
☐	6 - 11	☐ Soccer	☐	☐	☐	☐
		☐ Football	☐	☐	☐	☐
		☐ Field Hockey	☐	☐	☐	☐
		☐ Baseball	☐	☐	☐	☐
		☐ Softball	☐	☐	☐	☐
		☐ Rugby	☐	☐	☐	☐
		☐ Ultimate Frisbee	☐	☐	☐	☐
		☐ Physical Training (PT)	☐	☐	☐	☐
		☐ Physical Education (PE)	☐	☐	☐	☐
		☐ Other: ☐	☐	☐	☐	☐
		☐ Other: ☐	☐	☐	☐	☐

A11. For each of the different age groups, what sports or other activities are played on the synthetic turf fields at this facility during which seasons (check all that apply)? (continued)

☐ 12 - 18

	Spring	Summer	Fall	Winter
☐ Soccer	☐	☐	☐	☐
☐ Football	☐	☐	☐	☐
☐ Field Hockey	☐	☐	☐	☐
☐ Baseball	☐	☐	☐	☐
☐ Softball	☐	☐	☐	☐
☐ Rugby	☐	☐	☐	☐
☐ Ultimate Frisbee	☐	☐	☐	☐
☐ Physical Training (PT)	☐	☐	☐	☐
☐ Physical Education (PE)	☐	☐	☐	☐
☐ Other:	☐	☐	☐	☐
☐ Other:	☐	☐	☐	☐

☐ 18 +

	Spring	Summer	Fall	Winter
☐ Soccer	☐	☐	☐	☐
☐ Football	☐	☐	☐	☐
☐ Field Hockey	☐	☐	☐	☐
☐ Baseball	☐	☐	☐	☐
☐ Softball	☐	☐	☐	☐
☐ Rugby	☐	☐	☐	☐
☐ Ultimate Frisbee	☐	☐	☐	☐
☐ Physical Training (PT)	☐	☐	☐	☐
☐ Physical Education (PE)	☐	☐	☐	☐
☐ Other:	☐	☐	☐	☐
☐ Other:	☐	☐	☐	☐

Facility Information

A12. Do you have any standard practices in place to reduce tire crumb exposure to people using the synthetic fields? ☐

If so (describe):

Outdoor Fields Only

A13. Are there outdoor fields at this facility? ☐

A14. When was each outdoor synthetic field installed at this facility?

Field	Month	Year

A15. Which company or companies installed these fields?

A16. Do you ever replace all of the tire crumb infill on the outdoor synthetic turf field(s) at your facility?

- ○ Yes
- ○ No
- ○ Don’t Know
- ○ Refused

If yes, how often do you replace all of the tire crumb infill on the synthetic turf fields?

- ○ Never/rarely
- ○ Every 6 months
- ○ Yearly
- ○ Every 2-3 years
- ○ Every 3-5 years
- ○ Every 5-7 years
- ○ More than 7 years
- ○ Don't Know
- ○ Refused

A17. Do you ever refresh or add tire crumb infill to your outdoor synthetic turf field(s) at your facility?

- ○ Yes
- ○ No
- ○ Don't Know
- ○ Refused

If yes, how often do you refresh or add tire crumb infill to your synthetic turf fields?

- ○ Rarely/Never
- ○ Every 6 months
- ○ Yearly
- ○ Every 2-3 years
- ○ Every 3-5 years
- ○ Every 5-7 years
- ○ More than 7 years
- ○ Don't Know
- ○ Refused

A18. What was the date of the most recent replacement/refreshment? _____

A19. Which company or companies provides crumb rubber infill material for replacement/refreshment?

_____

A20. Are the following routine field maintenance activities performed on the outdoor synthetic field(s) at this facility?

	Activity	Times	per
☐	Sweeping		Day/week/month/year
☐	Brushing		Day/week/month/year
☐	Redistribution/leveling		Day/week/month/year
☐	Aerating		Day/week/month/year
☐	Magnet sweep		Day/week/month/year
☐	Rejuvenation		Day/week/month/year
☐	Deep Cleaning		Day/week/month/year

A21. Has the outdoor synthetic field(s) ever been treated with biocides, herbicides, insecticides, fungicides, or other agents?

- ○ Yes
- ○ No
- ○ Don't know
- ○ Refused

A22. Have any of the following chemicals been used on the field? (check all that apply) and how often?

	Chemical	Times	per
☐	Algae Died B		Day/week/month/year
☐	Qualgex		Day/week/month/year
☐	Steri-maX		Day/week/month/year
☐	Other (specify)		Day/week/month/year
☐	Unknown Biocide		Daily/weekly/ monthly/annually

Indoor Fields Only

A23. Are there indoor fields at this facility? ☐

A24. When was each indoor synthetic field installed at this facility?

Field	Month	Year

A25. Which company or companies installed these fields?

A26. Do you ever replace all of the tire crumb infill on the indoor synthetic turf field(s) at your facility?

- ○ Yes
- ○ No
- ○ Don't Know
- ○ Refused

If yes, how often do you replace all of the tire crumb infill on the synthetic turf fields?

- ○ Rarely/Never
- ○ Every 6 months
- ○ Yearly
- ○ Every 2-3 years
- ○ Every 3-5 years
- ○ Every 5-7 years
- ○ More than 7 years
- ○ Don't Know
- ○ Refused

A27. Do you ever refresh or add tire crumb infill to your indoor synthetic turf field(s) at your facility?

- ○ Yes
- ○ No
- ○ Don't Know
- ○ Refused

If yes, how often do you refresh or add tire crumb infill to your synthetic turf fields?

- ○ Rarely/Never
- ○ Every 6 months
- ○ Yearly
- ○ Every 2-3 years
- ○ Every 3-5 years
- ○ Every 5-7 years
- ○ More than 7 years
- ○ Don't Know
- ○ Refused

A28. What was the date of the most recent replacement/refreshment? ☐

A29. What company or companies provides crumb rubber infill material for replacement/refreshment?

☐

A30. Are the following routine field maintenance activities performed on the indoor synthetic field(s) at this facility?

	Activity	Times	per
☐	Sweeping		Day/week/month/year
☐	Brushing		Day/week/month/year
☐	Redistribution/leveling		Day/week/month/year
☐	Aerating		Day/week/month/year
☐	Magnet sweep		Day/week/month/year
☐	Rejuvenation		Day/week/month/year
☐	Deep Cleaning		Day/week/month/year

A31. Has the outdoor synthetic field(s) ever been treated with biocides, herbicides, insecticides, fungicides, or other agents?

- ○ Yes
- ○ No
- ○ Don't Know
- ○ Refused

A32. Have any of the following chemicals been used on the field? (check all that apply) and how often?

☐	Algae Died B		Daily/weekly/ monthly/annually
☐	Qualgex		Daily/weekly/ monthly/annually
☐	Steri-maX		Daily/weekly/ monthly/annually
☐	Other (specify)		Daily/weekly/ monthly/annually
☐	Unknown Biocide		Daily/weekly/ monthly/annually

A33. Do you know the outdoor air fraction ventilation rates for this facility during each season? ☐

If yes (please specify):

Spring		(cfm)
Summer		(cfm)
Fall		(cfm)
Winter		(cfm)

If you do not know, can you identify a person, including their phone number, who can provide us with your facility ventilation rates?

(full name) (phone number)

Thank you so much for your time. I know that your time is valuable. If you have any questions or concerns, please, refer to the contact sheet for information on who to contact.

Appendix G: Synthetic Field User Eligibility Screening Form

Appendix G. Telephone Script for Facility User
(Flesch-Kincaid Reading Level: Grade 9.5)

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Facility User Eligibility Screening Form

Caller: May I speak to [NAME OF Facility User or NAME OF Parent of Facility User]? I am _____ from the Agency for Toxic Substances and Disease Registry (ATSDR), and I am calling you to tell you about a federally funded study being conducted by the United States Environmental Protection Agency and the Agency for Toxic Substances and Disease Registry to study synthetic turf fields with crumb rubber infill and to determine your willingness to participate in the study. We received your name from FACILITY XX as someone who has used or the parent of someone who has used their synthetic turf fields.
Are you at least 18 years of age and interested in participating in a short 5 minute survey to find out if you (your child) can participate in this project?

Facility user is not 18 years of age:
Facility User: No, I am not 18 years of age.
Caller: May I please speak to your parent or guardian?

Facility user is not interested in the project:
Facility User: No, I am not interested at this time.
Caller: Ok, thank you for your time and have a good day.
END CALL.

Facility user is interested in the project:
Facility user: Yes, I would like to learn more.
Caller: The purpose of the exposure characterization study is to determine how people might be exposed to chemicals in the tire crumbs on synthetic turf fields. We need synthetic turf field users to:

1. Respond to a questionnaire to provide information about the types of activities performed on these fields and

2. Participate in an exposure measurement study during an athletic or training activity on a synthetic field with tire crumb rubber infill.

EPA and ATSDR need up to 60 people who engage in physical activities on synthetic turf fields with tire crumbs to fill out a questionnaire about how they use the fields. The questionnaire will ask field users about the types of activities (sports, physical education and training), how much time they spend on fields and how they come in contact with the tire crumbs on the fields. EPA and ATSDR hope to perform measurements for a subset of the people (up to 45) who fill out the questionnaire. Additionally, we will be doing a video recording on a subset of those who participate in the exposure measurements (up to 24).

ATSDR estimates the average public reporting burden for this collection of information as 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-XXXX).

To find out if you are eligible, I will read the questions to you over the phone. If you are ready I'm going to read you a few questions.

If respondent is an adult, ask question #1. If respondent is the parent/guardian of a child, skip question #1 and go straight to question #2:

1. What is your age?....._____

If greater than 18 years of age, go to question #4.

If respondent is the parent/guardian of a child:

2. What is your child's age?....._____
   If the child is less than 7 years old, the respondent is not eligible to participate.
   Caller: As your child is not at least seven years old, your child is not eligible to participate in this project. I am sorry. Thank you for your time.
   END CALL.

   If child is 7 years or older:
3. What is your child's grade in school? ..... _____

   For respondents greater than 18 years of age and respondents that are parents/guardians of children at least seven years of age:

4. Did you (did your child) participate in activities on a synthetic turf field with crumb rubber infill during the previous year? .....

   If no, respondent is not eligible to participate.

   Caller: You are not eligible to participate in this project. I am sorry. Thank you for your time.
   END CALL.

   If yes, the following questions will be used to determine eligibility:
5. During the previous year, how many months did you (*did your child*) participate in activities on synthetic turf with crumb rubber infill? ....._____

6. On average, how many days per week did you (did your child) practice or play football as part of an organized team on outdoor synthetic turf fields with crumb rubber infill? ..._____
   On indoor synthetic turf fields with crumb rubber infill?....._____

7. On average, how many days per week did you (did your child) practice or play soccer as part of an organized team on outdoor synthetic turf fields with crumb rubber infill? ....._____

On indoor synthetic turf fields with crumb rubber infill?....._____

8. On average, how many days per week did you (did your child) participate in physical training, physical education classes, or general recreation use on outdoor synthetic turf fields with crumb rubber infill? ....._____
   On indoor synthetic turf fields with crumb rubber infill?....._____

9. Would you (would your child) be willing to complete a short survey to collect information about your time and activities that might affect exposures to chemical and microbiological agents associated with synthetic turf fields?..... ☐

10. Would you (would your child) be willing to be recorded on video during a sports practice or play activity on a synthetic turf field with crumb rubber infill? The video would be used to collection information about how people contact the fields and field materials that might affect exposures to chemical and microbiological agents. Yes..... ☐
    No.....☐
    Will Not Have Eligible Activity in Study Time Frame .....☐

11. In addition to the survey, would you (would your child) be willing to participate in a study that measures potential chemical exposures while participating in an activity on a synthetic turf field with crumb rubber infill? This may include collecting a personal air sample (a small tube pinned to your/your child's shirt), dermal wipe and cotton garment samples, and urine samples around a normal period of your (*his or her*) activity on a synthetic turf field. Air, wipe, and dust samples would be collected around the field during the activity area as well. Yes..... ☐
    No.....☐
    Will Not Have Eligible Activity in Study Time Frame .....☐

12. Do you know anyone else who uses this facility and would you be willing to share their contact information?
    Yes..... ☐

    Contact Information:_____

    No.....☐

The answers from the above questions will be used to determine eligibility at a later time.

Caller: Thank you for answering my questions today. We will use the information you have provided to determine whether or not you (your child) meet the requirements to participate in the study. If you (your child) is determined to be eligible, may I contact you in the future for participation in our study?
Facility user is not interested in participating:
Caller: Thank you for your time.
END CALL.

If facility user is willing to participate:
Caller: Thank you for your willingness to participate. I will call you at a later date to notify you of your eligibility and to schedule an appointment time. If you have any questions in the meantime, please feel free to contact me at xxx-xxx-xxxx.
END CALL.

Appendix H. Exposure Characterization Pilot Study and Exposure Measurement Sub-Study Consent, Assent, Permission Forms

H1. Adult Consent – Adult Activity Questionnaire
H2. Adult Consent – Exposure Measurement
H3. Adult Consent – Activity Video

H4. Parental Permission (Adolescent) – Human Activity Questionnaire
H5. Adolescent Assent - Human Activity Questionnaire
H6. Parental Permission (Youth) - Human Activity Questionnaire
H7. Youth Assent - Human Activity Questionnaire
H8. Parental Permission (Adolescent/Youth) - Exposure Measurement
H9. Adolescent/Youth Assent - Exposure Measurement
H10. Parental Permission (Adolescent/Youth) - Activity Video
H11. Adolescent/Youth Assent - Activity Video

H12. Parental Consent and Permission – Child Activity Questionnaire and Exposure Measurement
H13. Child Assent – Child Activity Questionnaire and Exposure Measurement
H14. Parental Permission Consent – Activity Video
H15. Child Assent – Activity Video

Appendix H1. Adult Consent – Adult Activity Questionnaire
Flesch-Kincaid Reading Level 8.9

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you, as an adult aged 18 or older (or the legal age in your state), to be in a research study. Your participation is voluntary. We invite you to read or hear about the study. Before you decide to take part, please ask questions if there is anything that you do not understand.

What is the purpose of this study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We want to ask some questions about your activities on synthetic turf fields. This information will help us see if people might be exposed to chemicals from playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why are you being asked to be in this study?

You were chosen to take part in this study because you work out on synthetic turf fields. We want to talk to people like you take part in recreation, training, or organized sports on these fields.

ATSDR and EPA hope to enroll 60 people to answer some questions.

- We also want you to know about other parts of the research for some of the people who are interviewed.
    - We will conduct a sub-study of exposure measures in 45 of these people.
    - We will videotape 24 of these people during their on-field activities.

What are we asking you to do?

We will ask you a few questions about yourself in an interview. We will ask questions about your activities on synthetic turf fields. We want to know about the types of your activities, how often you play on the fields, and how long you have been playing on the fields.

We also want you to tell us if you are interested in hearing more about the exposure sub-study and the activity videotape.

How long will this take?

It will take about 30 minutes to complete the interview. We want you to know if you are selected to take part in the exposure sub-study, it will take about two more hours. If you are selected to take part in the activity videotaping, it will take about an hour.

Are there any risks or discomforts to you if you decide to be in this study?

We don't think these questions are sensitive. But the interview may be stressful if you have to recall events that are upsetting. You are free to skip any question for any reason.

Are there any benefits to you from being in this study?

There will be no direct benefits to you from being in this study.

Who will see the information you give the researchers?

All information about you (including name and address, this form, and interview answers) will be secure. We will track your information using a code number rather than name. We will keep paper records in locked files. Electronic records will be stored on password protected computers at USEPA and at ATSDR. Only trained study staff will be allowed to look at your records. Federal policy requires making the data we collect available to the public, but we will never include your name or other identifying information in a public release.

What is the cost to you and what compensation will you get?

The only cost for being in our study is your time and effort to take part. We will give you a $25 gift card as a "thank you" when you complete the interview. You can use the gift card at most stores or for online shopping.

People who go on and take part in the exposure measures or the video component of the study will get additional gift cards.

What are your choices about participating?

Your taking part in the interview is voluntary. You are free to be a part of it or not. You can refuse to answer any questions. You can choose to leave the research study at any time, even after you have signed the consent form.

Who should you contact if you have questions later on?

If you have any questions about the study or wish to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel you have been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you do not understand what we are asking you to do, please ask questions. After all your questions have been answered to your satisfaction and if you want to be in this study, please sign the consent form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

CONSENT TO PARTICIPATE IN A RESEARCH STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions and I had all my questions answered.

By signing below, I agree to take part in the research and the interview.

_____
Participant's name (Print)

_____
Participant's signature / Date

By signing below, I agree to be contacted about the exposure measures sub-study.

_____
Participant's name (Print)

_____
Participant's signature / Date

CONSENT TO PARTICIPATE IN A RESEARCH SUB-STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you, as an adult aged 18 or older (or legal age in your state), to be in a research sub-study about personal exposure measures from synthetic turf fields. Your participation is voluntary. We invite you to read or hear about the sub-study. Before you decide to take part, please ask questions if there is anything that you do not understand.

What is the purpose of this exposure measures sub-study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We will collect some personal samples from you. This information will help us see if people might be exposed to chemicals from playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why are you being asked to be in this exposure measures sub-study?

You were chosen to take part in this sub-study because you work out on synthetic turf fields, and you agreed to be in the main part of the study. We want to talk to people who take part in recreation, training, or organized sports on these fields.

ATSDR and EPA hope to enroll 45 people to take part in this sub-study.

What are we asking you to do?

- We will take some personal measures during one of your normal activities on synthetic turf fields. These measures will include personal air monitoring with a small sampling tube attached to your clothes during the activity. Your personal air sample will analyzed by laboratories at the EPA.
- Following the activity we will collect wipe samples of your hands and areas of your arms and legs. The wipe sampling will be done with pads wetted with water, and pads wetted with a water and alcohol mixture. Your skin wipe samples will be analyzed by laboratories at the EPA.
- We will collect urine and blood samples two times: before your activity and directly after your activity. We will ask you a few questions to be sure that you can safely give blood. Each time:
    - A person trained to draw blood will collect about 15 ml (about 1 tablespoon) of blood from a vein in your arm.
    - You will be asked to provide 50-100 ml (about ½ cup) of urine in a cup. You will do this in private in a restroom.

- Your blood and urine samples will be stored for the indefinite future. This is in case we get more information in the future about what chemicals to look for and new analytical methods are developed to test for these chemicals.
- You will not receive a copy of your test results.
- In the future, your results may be linked to the rest of your study data for research purposes.

How long will this take?

It will take about two hours to finish the sub-study. This includes setting up and collecting the personal air sampler, collecting the skin wipe, urine, and blood samples.

Are there any risks or discomforts to you if you decide to be in this exposure measures sub-study?

You may feel a slight sting or "pinch" in your arm when the blood is drawn. You may also get a small bruise. Some people may faint, but this is rare. There are no risks from giving urine.

The skin wipe sampling will involve personal contact by a research staff member with your hands, arms, and legs.

Are there any benefits to you from being in this exposure measures sub-study?

There will be no direct benefits to you from being in this sub-study.

Who will see the information you give the researchers?

All information about you (including name and address, this form, and interview answers) will be secure. We keep track of your information using a code number rather than a name. We will keep paper records in locked files and electronic records are stored on password protected computers at USEPA and ATSDR. Only staff working on the study will be allowed to look at the paper and electronic records. Federal policy requires making the data we collect available to the public, but we will never include your name or other identifying information in public release.

Who will get my samples?

Your personal air sample and skin wipe samples will be shipped to and analyzed by the laboratory at the EPA. Your blood and urine samples will be shipped to and stored at the Centers for Disease Control and Prevention (CDC) laboratory in Atlanta, GA. These samples will be analyzed at a later time. The chemical tests have not been chosen yet. Your samples will be labeled with a code number only.

What is the cost to you and what compensation will you get?

The only cost for being in our study is your time and effort to take part. We will give you a $25 gift card each time you give us blood and urine samples (or up to $50). You can use the gift cards at most stores or for online shopping.

What are your choices about participating?

Your participation in this study is voluntary. You are free to be a part of it or not. You can refuse to have your blood drawn, give a urine sample, and take part in air and skin wipe sampling. You can choose to leave at any time, or withdraw your blood and urine samples from storage, even after you have signed the consent form.

Who should you contact if you have questions later on?

If you have any questions about the study or wish to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel you have been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you do not understand what we are asking you to do, please ask questions. After all your questions have been answered to your satisfaction and if you want to be in this study, please sign the consent form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

CONSENT TO PARTICIPATE IN A RESEARCH SUB-STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions, and I had all my questions answered.

By signing below, I agree to provide personal air monitoring and skin wipe samples. The personal air and skin wipe samples will not be immediately tested for chemicals. I give ATSDR and USEPA permission to store my personal air and skin wipe samples to do the tests later. I understand that USEPA and ATSDR will not send my test results to me.

_____

Participant's name (Print)

_____

Participant's signature / Date

By signing below, I agree to provide blood and urine samples. The blood and urine samples will not be immediately tested for chemicals. I give ATSDR and USEPA permission to store my blood and urine to do the tests later. I understand that USEPA and ATSDR will not send my test results to me.

_____

Participant's name (Print)

_____

Participant's signature / Date

Appendix H3. Adult Consent – Activity Video
Flesch-Kincaid Reading Level 9.4

CONSENT TO PARTICIPATE IN A RESEARCH SUB-STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you, as an adult aged 18 or older (or legal age in your state), to be in a research sub-study to videotape people's activities at synthetic turf fields. Your participation is voluntary. We invite you to read or hear about the sub-study. Before you decide to take part, please ask questions if there is anything that you do not understand.

What is the purpose of this video sub-study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We will ask to videotape people's on-field activities. Videos will help us see how much people come in contact with crumb rubber while playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why are you being asked to be in this video sub-study?

You were chosen to take part in this sub-study because you work out on synthetic turf fields and you agreed to be in the main part of the study. We want to talk to people who take part in recreation, training, or organized sports on these fields.

ATSDR and EPA hope to enroll 24 people to take part in this sub-study.

What are we asking you to do?

- We will videotape you during a physical activity on a synthetic turf field.

How long will this take?

It will take about one hour.

Are there any risks or discomforts to you if you decide to be in this video sub-study?

You may feel uncomfortable being videotaped. You are free to stop recording at any time.

Are there any benefits to you from being in this video sub-study?

There will be no direct benefits to you from being in this sub-study.

Who will see the information you give the researchers?

All information about you (including name and address, this form, and interview answers) will be secure. We keep track of your information using a code number rather than a name. We will keep paper records in locked files and electronic records are stored on password protected computers at USEPA. Only staff working on the study will be allowed to look at the paper and electronic records. Federal policy requires making the data we collect available to the public, but we will never include your name or other identifying information in public release.

The videos will be shipped to USEPA labeled only with a code number. The files will be secured to allow access only by trained study staff. No video or still images will be made public.

What is the cost to you and what compensation will you get?

The only cost for being in our study is your time and effort to take part. We will give you a $25 gift card for being videotaped. You can use the gift cards at most stores or for online shopping. Video recordings will be destroyed no later than 5 years from now.

What are your choices about participating?

Your taking part in this study is voluntary. You are free to be a part of it or not. You can choose to leave at any time, or withdraw your videotape from storage, even after you have signed the consent form.

Who should you contact if you have questions later on?

If you have any questions about the study or wish to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel you have been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you do not understand what we are asking you to do, please ask questions. After all your questions have been answered to your satisfaction and if you want to be in this study, please sign the consent form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

CONSENT TO PARTICIPATE IN A RESEARCH SUB-STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions, and I had all my questions answered.

By signing below, I agree to being videotaped while I am playing or training on synthetic turf fields.

_____

Participant's name (Print)

_____

Participant's signature / Date

PARENTAL/GUARDIAN PERMISSION FOR YOUTH PARTICIPATION IN A RESEARCH STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you to give permission for your adolescent, aged 13 to 17 years (or up to the legal age in your state), to be in a research study. Your adolescent's participation is voluntary. We invite you both to read or hear about the study. Before you decide to permit him/her to take part, please ask questions if there is anything that you both do not understand.

What is the purpose of this study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We want to ask some questions about your adolescent's activities on synthetic turf fields. This information will help us see if people might be exposed to chemicals from playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why is your adolescent being asked to be in this study?

Your adolescent was chosen to take part in this study because he/she works out on synthetic turf fields. People like him/her take part in recreation, training, or organized sports on these fields.

- ATSDR and EPA hope to enroll 60 people to answer some questions.
- We also want you both to know about other parts of the research for some of the people who are interviewed.
    - We will conduct a sub-study of exposure measures in 45 of these people.
    - We will videotape 24 of these people during their on-field activities.

What are we asking you to do?

We will ask him/her a few questions in an interview. We will ask questions about his/her activities on synthetic turf fields. We want to know about the types of his/her activities, how often he/she plays on the fields, and how long he/she has been playing on the fields.

We also want you both to tell us if you are interested in hearing more about the exposure sub-study and the activity videotape. Indicating interest in the sub-study does not mean that you will be asked to participate in the sub-study or the video activity.

How long will this take?

It will take about 30 minutes to complete the interview. We want you and your adolescent to know if he/she is selected to take part in the exposure sub-study, it will take about two more hours. If he/she is selected to take part in the activity videotaping, it will take about an hour.

Are there any risks or discomforts to your youth if he/she decides to be in this study?

We don't think these questions are sensitive. But the interview may be stressful if he/she has to recall events that are upsetting. Your adolescent is free to skip any question for any reason.

Are there any benefits to your adolescent from being in this study?

There will be no direct benefits from being in this study.

Who will see the information your adolescent gives the researchers?

All information about your adolescent (including name and address, this form, and interview answers) will be secure. We will track his/her information using a code number rather than name. We will keep paper records in locked files. Electronic records will be stored on password protected computers at USEPA and at ATSDR. Only trained study staff will be allowed to look at your adolescent's records. Federal policy requires making the data we collect available to the public, but we will never include your adolescent's name or other identifying information in a public release.

What is the cost to your youth and what compensation will he/she get?

The only cost for being in our study is your adolescent's time and effort to take part. We will give him/her a $25 gift card as a "thank you" when the interview is completed. He/she can use the gift card at most stores or for online shopping.

People who go on and take part in the exposure measures or the video sub-study will get additional gift cards**.**

What are your adolescent's choices about participating?

Your adolescent's taking part in the interview is voluntary. He/she is free to be a part of it or not. He/she can refuse to answer any questions. Your adolescent can choose to leave the research study at any time, even after you both have signed the permission form and the assent form.

Who should you contact if you have questions later on?

If you or your adolescent have any questions about the study or he/she wishes to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your adolescent's rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel your adolescent has been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you or your adolescent do not understand what we are asking him/her to do, please ask questions. After all your questions have been answered to your satisfaction and if you permit your adolescent to be in this study, please sign the permission form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

PARENTAL/GUARDIAN PERMISSION FOR ADOLESCENT PARTICIPATION IN A RESEARCH STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions and I had all my questions answered.

By signing below, I permit my adolescent to take part in the research and the interview.

_____

Adolescent name (Print) / Relationship to Parent/Legal Guardian

_____

Parent/Legal Guardian's name (Print)

_____

Parent/Legal Guardian's signature / Date

By signing below, I agree to be contacted about the exposure measures sub-study for my adolescent.

_____

Parent/Legal Guardian's name (Print)

_____

Parent/Legal Guardian's signature / Date

Appendix H5. Adolescent Assent – Human Activity Questionnaire
Flesch-Kincaid Reading Level 5.7

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

ADOLESCENT ASSENT TO BE IN A RESEARCH STUDY

We are doing a study to learn about how people use playing fields with crumb rubber and to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black stuff that makes the fields soft to play on. It is usually made from recycled tires. We also want to learn if people are exposed to chemicals from the crumb rubber. We are asking you to help because we do not know very much about how young people play or practice on these fields.

If you agree to be in our study, we are going to ask you some questions about how you play or practice on the fields. For example, we want to know how often you fall or slide on the ground.

You can ask questions about this study at any time. It should take about 30 minutes to finish the interview. If you decide at any time not to finish, you can ask us to stop.

The questions we will ask are about how you play or practice on the fields. There are not right or wrong answers because this is not a test.

Your mom/dad has said it is ok for you to be in the study. But it is up to you if you want to take part. If you sign this paper, it means that you have read this, or had this read to you, and that you want to be in the study. If you don't want to be in this study, don't sign this paper. Being in the study is up to you, and no one will be upset if you don't sign this paper or if you change your mind later.

<u>If You Have Questions</u>

If you have any questions now, please ask us. If you have questions later, your parents/guardians have information about who to call.

_____

Adolescent's name (Print)

_____

Adolescent's signature / Date

_____

Person obtaining assent's name (Print)

_____

Person obtaining assent's signature / Date

Appendix H6. Parental Consent and Permission –Youth Activity Questionnaire
Flesch-Kincaid Reading Level 8.9

PARENTAL/GUARDIAN CONSENT AND PERMISSION FOR YOUTH PARTICIPATION IN A RESEARCH STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you and your youth, aged 10-12 years, to be in a research study. Your and your youth's participation is voluntary. We invite you both to read or hear about the study. Before you both decide to take part, please ask questions if there is anything that you do not understand.

What is the purpose of this study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We want to ask you some questions about your youth's activities on synthetic turf fields. This information will help us see if people might be exposed to chemicals from playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why are you and your youth being asked to be in this study?

We are asking you to answer some questions about your youth's activities on synthetic turf fields. Your youth was chosen to take part in this study because he/she works out on synthetic turf fields. People like him/her take part in recreation, training, or organized sports on these fields.

- ATSDR and EPA hope to enroll 60 people to answer some questions.
- We also want you both to know about other parts of the research for some of the people who are interviewed.
    - We will conduct a sub-study of exposure measures in 45 of these people.
    - We will videotape 24 of these people during their on-field activities.

What are we asking you and your youth **to do?**

We will ask you a few questions about your child in an interview. We will ask questions about his/her activities on synthetic turf fields. We want to know about the types of his/her activities, how often he/she plays on the fields, and how long he/she has been playing on the fields.

We also want you both to tell us if you are interested in hearing more about the exposure sub-study and the activity videotape.

How long will this take?

It will take about 30 minutes to complete the interview. We want you and your youth to know if he/she is selected to take part in the exposure sub-study, it will take about two more hours. If he/she is selected to take part in the activity videotaping, it will take about an hour.

Are there any risks or discomforts to you and your youth if you both decide to be in this study?

We don't think these questions are sensitive. But the interview may be stressful if you have to recall events that are upsetting about your youth. You are free to skip any question for any reason.

Are there any benefits to you and your youth from being in this study?

There will be no direct benefits from being in this study.

Who will see the information you or your youth gives the researchers?

All information about you and your youth (including name and address, this form, and interview answers) will be secure. We will track you information using a code number rather than name. We will keep paper records in locked files. Electronic records will be stored on password protected computers at USEPA and at ATSDR. Only trained study staff will be allowed to look at both your records. Federal policy requires making the data we collect available to the public, but we will never include your or your youth's name or other identifying information in a public release.

What is the cost to you and your youth and what compensation will you get?

The only cost for being in our study is your time and effort to take part. We will give you a $25 gift card as a "thank you" when the interview is completed. You can use the gift card at most stores or for online shopping.

People who go on and take part in the exposure measures or the video sub-study will get additional gift cards.

What are your and your youth's choices about participating?

Your taking part in the interview is voluntary. You are free to be a part of it or not. You can refuse to answer any questions. You and your youth can choose to leave the research study at any time, even after you both have signed the permission form and the assent form.

Who should you contact if you have questions later on?

If you or your youth have any questions about the study or he/she wishes to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your youth's rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel your youth has been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you or your youth do not understand what we are asking him/her to do, please ask questions. After all your questions have been answered to your satisfaction and if you permit your youth to be in this study, please sign the permission form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

PARENTAL/GUARDIAN CONSENT AND PERMISSION FOR YOUTH PARTICIPATION IN A RESEARCH STUDY

I have read the above information, or it has been read to me, about the study *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions and I had all my questions answered.

By signing below, I permit my youth to take part in the research, and I agree to take part in the interview about my youth.

_____
Youth name (Print) / Relationship to Parent/Legal Guardian

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

By signing below, I agree to be contacted about the exposure measures sub-study for my youth.

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

By signing below, I agree to be contacted about the activity videotaping for my youth.

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

Appendix H7. Youth Assent – Youth Activity Questionnaire
Flesch-Kincaid Reading Level 5.6

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

YOUTH ASSENT TO BE IN A RESEARCH STUDY

We are doing a study to learn about how people use playing fields with crumb rubber and to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black stuff that makes the fields soft to play on. It is usually made from recycled tires. We also want to learn if people are exposed to chemicals from the crumb rubber. We are asking you to help because we do not know very much about how kids your age play or practice on these fields.

If you agree to be in our study, we are going to ask your Mom/Dad/guardian some questions about how you play or practice on the fields. You can help with the answers. For example, we want to know how often you fall or slide on the ground.

You and your Mom/Dad/guardian can ask questions about this study at any time. It should take about 30 minutes to finish the interview. If you both decide at any time not to finish, you can ask us to stop.

We will ask are about how you play or practice on the fields. There are not right or wrong answers because this is not a test.

Your mom/dad has said it is ok for you to be in the study but it is up to you if you want to take part. If you sign this paper, it means that you have read this, or had this read to you, and that you want to be in the study. If you don't want to be in this study, don't sign this paper. Being in the study is up to you. No one will be upset if you don't sign this paper or if you change your mind later.

<u>If You Have Questions</u>

If you have any questions now, please ask us. If you have questions later, your parents/guardians have information about who to call.

_____

Youth's name (Print)

_____

Youth's signature / Date

_____

Person obtaining assent's name (Print)

_____

Person obtaining assent's signature / Date

Appendix H8. Parental Permission (Adolescent/Youth) –
Exposure Measurement
Flesch-Kincaid Reading Level 9.6

PARENTAL/GUARDIAN PERMISSION FOR ADOLESCENT/YOUTH PARTICIPATION IN A RESEARCH SUB-STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you to give permission for your adolescent/youth, aged 10 to 17 years (or up to the legal age in your state), to be in a research sub-study about personal exposure measures from synthetic turf fields. Your youth's participation is voluntary. We invite you both to read or hear about the sub-study. Before you decide to permit him/her to take part, please ask questions if there is anything that you both do not understand.

What is the purpose of this exposure measures sub-study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We will collect some personal samples from your adolescent/youth. This information will help us see if people might be exposed to chemicals from playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why are you being asked to be in this exposure measures sub-study?

Your adolescent/youth was chosen to take part in this sub-study because he/she works out on synthetic turf fields, and you agreed to allow him/her to participate in the main part of the study. We want to talk to people who take part in recreation, training, or organized sports on these fields.

- ATSDR and EPA hope to enroll 45 people to take part in this sub-study.

What are we asking your adolescent/youth to do?

- We will take some personal measures during one of your adolescent/youth's normal activities on synthetic turf fields. These measures will include personal air monitoring with a small sampling tube attached to his/her clothes during the activity. The personal air monitoring samples will be analyzed by the laboratory at EPA.
- Following the activity we will collect wipe samples of your adolescent/youth's hands and areas of his/her arms and legs. The skin wipe sampling will be done with pads wetted with water, and pads wetted with a water and alcohol mixture. The skin wipe samples will be analyzed by the laboratory at EPA.
- We will collect urine and blood samples two times: before the activity and directly after activity. We will ask him/her a few questions to be sure that he/she can safely give blood. Each time:

- A person trained to draw blood will collect about 15 ml (about 1 tablespoon) of blood from a vein in his/her arm.
- Your adolescent/youth will be asked to provide 50-100 ml (about ½ cup) of urine in a cup. Your adolescent/youth will do this in private in a restroom.

- Your adolescent/youth's blood and urine samples will be stored for the indefinite future. This is in case we get more information in the future about what chemicals to look for and new analytical methods are developed to test for these chemicals. You and your adolescent/youth will not receive a copy of his/her test results.
- In the future, your adolescent/youth's results may be linked to the rest of his/her study data for research purposes.

How long will this take?

It will take about two hours to finish the sub-study. This includes setting up and collecting the personal air sampler, collecting the skin wipe, urine, and blood samples.

Are there any risks or discomforts to your adolescent/youth if he/she decides to be in this exposure measures sub-study?

Your adolescent/youth may feel a slight sting or "pinch" in his/her arm when the blood is drawn. He/she may also get a small bruise. Some people may faint, but this is rare. There are no risks from giving urine.

The skin wipe sampling will involve personal contact by a research staff member with your adolescent/youth's hands, arms, and legs.

Are there any benefits to your adolescent/youth from being in this exposure measures sub-study?

There will be no direct benefits from being in this sub-study.

Who will see the information your youth gives the researchers?

All information about your adolescent/youth (including name and address, this form, and interview answers) will be secure. We will track his/her information using a code number rather than name. We will keep paper records in locked files. Electronic records will be stored on password protected computers at USEPA and at ATSDR. Only trained study staff will be allowed to look at your adolescent/youth's records. Federal policy requires making the data we collect available to the public, but we will never include your adolescent/youth's name or other identifying information in a public release.

Who will get my youth's samples?

Your adolescent/youth's personal air sample and skin wipe samples will be shipped to and analyzed by the laboratory at EPA. His/her blood and urine samples will be shipped to and stored by the Centers for Disease Control and Prevention (CDC) laboratory in Atlanta, GA. His/her samples will be labeled with a code number only.

What is the cost to your adolescent/youth and what compensation will he/she get?

The only cost for being in our study is your adolescent/youth's time and effort to take part. We will give him/her a $25 gift card each time he/she gives us blood and urine samples (or up to $50). Your adolescent/youth can use the gift cards at most stores or for online shopping.

What are your adolescent/youth's choices about participating?

Your adolescent/youth's participation in this study is voluntary. He/she is free to be a part of it or not. He/she can refuse to have his/her blood drawn, give a urine sample, and take part in air and skin wipe sampling. Your adolescent/youth can choose to leave at any time, or withdraw his/her blood and urine samples from storage, even after you both have signed the permission and the assent form.

Who should you contact if you have questions later on?

If you or your adolescent/youth have any questions about the study or he/she wishes to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your adolescent/youth's rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel your adolescent/youth has been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you or your youth do not understand what we are asking him/her to do, please ask questions. After all your questions have been answered to your satisfaction and if you permit your adolescent/youth to be in this study, please sign the permission form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

PARENTAL/GUARDIAN PERMISSION FOR ADOLESCENT/YOUTH PARTICIPATION IN A RESEARCH SUB-STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions, and I had all my questions answered.

By signing below, I permit my adolescent/youth to provide personal air monitoring and skin wipe samples. The personal air and skin wipe samples will not be immediately tested for chemicals. I give ATSDR and USEPA permission to store my youth's personal air and skin wipe samples to do the tests later. I understand that USEPA and ATSDR will not send my adolescent/youth's test results to me.

_____
Youth name (Print) / Relationship to Parent/Legal Guardian

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

By signing below, I permit my adolescent/youth to provide blood and urine samples. The blood and urine samples will not be immediately tested for chemicals. I give ATSDR and USEPA permission to store my adolescent/youth's blood and urine to do the tests later. I understand that USEPA and ATSDR will not send my adolescent/youth's test results to me.

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

Appendix H9. Adolescent/Youth Assent – Exposure Measurement
Flesch-Kincaid Reading Level 5.7

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

ADOLESCENT AND YOUTH ASSENT TO BE IN A RESEARCH SUB-STUDY

We are doing a study to learn about how people use playing fields with crumb rubber. Crumb rubber is the black stuff that makes the fields soft to play on. It is usually made from recycled tires. We also want to learn if people are exposed to chemicals from the crumb rubber. We are asking adolescents and youths, 10 to 17 years of age, to participate in this study. You were selected to take part in this study because you play on synthetic turf with crumb rubber and because you said you would be in the main part of the study.

If you decide to take part, we will take some measurements while you are playing on the field. We will ask you to wear a small tube that collects some of the chemicals in the air you are breathing; the small tube will be pinned to your clothing. This will take about 15 minutes to set up. After the activity, we will wipe your hands and parts of your arms and legs with a wet cloth to see what you came into contact with on the field. This will take about 45 minutes.

We will also ask you to collect two urine and blood samples, one before you begin your activity on the field and one after you finish your activity on the field. We will ask you to collect your urine in a cup we will give you. It should take you less than 5 minutes to do this. We will also collect some of your blood (about 3 teaspoons) at each of these points. This should take about 15 minutes.

The total time to collect all samples is about two hours.

<u>Other Information</u>

You may feel a slight sting or "pinch" in your arm when the blood is drawn. You may also get a small bruise. Some people may faint, but this is rare. There are no risks from giving urine.

You might be uncomfortable at having a person wiping your hands, arms, and legs.

Your mom/dad has said it is ok for you to be in the study but it is up to you if you want to take part. You can decide whether or not to take part in this study. You can ask questions about this study at any time. If you decide at any time not to finish, you can ask us to stop.

<u>If You Have Questions</u>

If you have any questions now, please ask us. If you have questions later, your parents/guardians have information about who to call.

Adolescent/Youth’s name (Print)

Adolescent/Youth’s signature / Date

Person obtaining assent’s name (Print)

Person obtaining assent’s signature / Date

Appendix H10. Parental Permission – Activity Video
Flesch-Kincaid Reading Level 9.6

PARENTAL/GUARDIAN PERMISSION FOR YOUTH/ADOLESCENT PARTICIPATION IN A RESEARCH SUB-STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you to give permission for your adolescent or youth, 10 to 17 years of age (or up to the legal age in your state), to be in a component of the research sub-study to videotape people's activities at synthetic turf fields. Your adolescent/ youth's participation is voluntary. We invite you both to read or hear about the activity. Before you decide to permit him/her to take part, please ask questions if there is anything that you both do not understand.

What is the purpose of this video component?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We will ask to videotape your adolescent/youth's on-field activities. Videos will help us see how much people come in contact with crumb rubber while playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why is your adolescent/youth being asked to be in this video activity?

Your adolescent/ youth was chosen to take part in this activity because he/she works out on synthetic turf fields, and you agreed for him/her to participate in the main part of the study. We want to talk to people who take part in recreation, training, or organized sports on these fields.

- ATSDR and EPA hope to enroll 24 people to take part in this activity.

What are we asking your youth to do?

- We will videotape your adolescent/youth during a physical activity on a synthetic turf field.

How long will this take?

It will take about one hour.

Are there any risks or discomforts to your adolescent/youth if he/she decides to be in this video activity?

Your adolescent/youth may feel uncomfortable being videotaped. He/she is free to stop recording at any time.

Are there any benefits to your adolescent/youth from being in this video sub-study?

There will be no direct benefits from being in this sub-study.

Who will see the information your adolescent/youth gives the researchers?

All information about your adolescent/youth (including name and address, this form, and interview answers) will be secure. We keep track of his/her information using a code number rather than a name. We will keep paper records in locked files and electronic records are stored on password protected computers at USEPA. Only staff working on the study will be allowed to look at the paper and electronic records. Federal policy requires making the data we collect available to the public, but we will never include your adolescent/ youth's name or other identifying information in public release.

The videos will be shipped to USEPA labeled only with a code number. The files will be secured to allow access only by trained study staff. No video or still images will be made public. Video recordings will be destroyed no later than 5 years from now.

What is the cost to your adolescent/youth and what compensation will he/she get?

The only cost for being in our study is your adolescent/youth's time and effort to take part. We will give him/her a $25 gift card for being videotaped. He/she can use the gift cards at most stores or for online shopping.

What are your adolescent/youth's choices about participating?

Your adolescent/youth taking part in this study is voluntary. He/she is free to be a part of it or not. He/she can choose to leave at any time, or withdraw his/her videotape from storage, even after you both have signed the permission form and assent form.

Who should you contact if you have questions later on?

If you or your adolescent/youth have any questions about the study or he/she wishes to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your adolescent/youth's rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel your adolescent/youth has been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you or your adolescent/youth do not understand what we are asking him/her to do, please ask questions. After all your questions have been answered to your satisfaction and if you permit your adolescent/youth to be in this study, please sign the permission form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

PARENTAL/GUARDIAN PERMISSION FOR YOUTH PARTICIPATION IN A RESEARCH SUB-STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions, and I had all my questions answered.

By signing below, I permit my adolescent/youth to be videotaped while he/she is playing or training on synthetic turf fields.

_____

Parent/Legal Guardian's name (Print)

_____

Parent/Legal Guardian's signature / Date

Appendix H11. Adolescent/Youth Assent –
Activity Video
Flesch-Kincaid Reading Level 6.4

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

ADOLESCENT/YOUTH ASSENT TO BE IN A RESEARCH SUB-STUDY

We are doing a study to learn about how people use playing fields with crumb rubber. Crumb rubber is the black stuff that makes the fields soft to play on. It is usually made from recycled tires. We also want to learn if people are exposed to chemicals from the crumb rubber. We will videotape their activity while playing on the field. This will help us find out how much contact people have with field materials.

We are asking adolescents and youth, 10 to 17 years of age, to participate in this sub-study. You were selected to take part in this study because you play on synthetic turf with crumb rubber and because you said you would be in the main part of the study.

If you decide to take part, we will videotape you while you are playing on the field. This will take about one hour.

Other Information

You might be uncomfortable about people recording your play on the field.

Your mom/dad has said it is ok for you to be in the study, but it is up to you if you want to take part. You can decide whether or not to take part in this study. You can ask questions about this study at any time. If you decide at any time not to finish, you can ask us to stop.

If You Have Questions

If you have any questions now, please ask us. If you have questions later, your parents/guardians have information about who to call.

_____

Adolescent/Youth's name (Print)

_____

Adolescent/Youth's signature / Date

_____

Person obtaining assent's name (Print)

_____

Person obtaining assent's signature / Date

Appendix H12. Parental Permission – Activity
Questionnaire and Exposure Measurement Sub-Study
Flesch-Kincaid Reading Level 8.3

PARENTAL/GUARDIAN CONSENT AND PERMISSION FOR CHILD PARTICIPATION IN A RESEARCH STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you and your child, aged 7-9 years, to be in a research study. Your and your child's participation is voluntary. We invite you both to read or hear about the study. Before you both decide to take part, please ask questions if there is anything that you do not understand.

What is the purpose of this study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We want to ask you some questions about your child's activities on synthetic turf fields. This information will help us see if people might be exposed to chemicals from playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why are you and your child being asked to be in this study?

We are asking you to answer some questions about your child's activities on synthetic turf fields. Your child was chosen to take part in this study because he/she works out on synthetic turf fields. People like him/her take part in recreation, training, or organized sports on these fields.

- ATSDR and EPA hope to enroll 60 people to answer some questions.
- We will also be taking exposure measurements in 45 of these people and we will videotape about half of the 45 people (a total of 24 will be videotaped).

What are we asking you and your child to do?

We will ask you a few questions about your child in an interview. We will ask questions about his/her activities on synthetic turf fields. We want to know about the types of his/her activities, how often he/she plays on the fields, and how long he/she has been playing on the fields. We will also be asking for the following items/activities from your child:

- We will take some personal measures during one of your child's normal activities on synthetic turf fields. These measures will include personal air monitoring with a small sampling tube attached to his/her clothes during the activity. The personal air monitoring samples will be analyzed by the laboratory at EPA.

- Following the activity we will collect wipe samples of your child's hands and areas of his/her arms and legs. The skin wipe sampling will be done with pads wetted with water, and pads wetted with a water and alcohol mixture. The skin wipe samples will be analyzed by the laboratory at EPA.
- We will collect blood and urine samples two times: before activity and directly after activity. We will ask him/her a few questions to be sure that he/she can safely give blood. Each time:
    - A person trained to draw blood will collect about 15 ml (about 1 tablespoons) of blood from a vein in his/her arm.
    - Your child will be asked to provide 50-100 ml (about ½ cup) of urine in a cup. Your child will do this in private in a restroom.
- Your child's blood and urine samples will be stored for the indefinite future. This is in case we get more information in the future about what chemicals to look for and new analytical methods are developed to test for these chemicals. You and your child will not receive a copy of his/her test results.
- In the future, your child's results may be linked to the rest of his/her study data for research purposes.

How long will this take?

It will take about 30 minutes to complete the interview. It will take about two more hours to finish the sub-study. This includes setting up and collecting the personal air sampler, collecting the skin wipe, urine, and blood samples.

Are there any risks or discomforts to you and your child if you both decide to be in this study?

We don't think these questions are sensitive. But the interview may be stressful if you have to recall events that are upsetting about your child. You are free to skip any question for any reason.

Your child may feel a slight sting or "pinch" in his/her arm when the blood is drawn. He/she may also get a small bruise. Some people may faint, but this is rare. There are no risks from giving urine.

The skin wipe sampling will involve personal contact by a research staff member with your child's hands, arms, and legs.

Are there any benefits to you and your child from being in this study?

There will be no direct benefits from being in this study.

Who will see the information you or your child gives the researchers?

All information about you and your child (including name and address, this form, and interview answers) will be secure. We will track your information using a code number rather than name. We will keep paper records in locked files. Electronic records will be stored on password protected computers at USEPA and at ATSDR. Only trained study staff will be allowed to look at both your records. Federal policy requires making the data we collect available to the public, but we will never include your or your child's name or other identifying information in a public release.

Who will get my child's samples?

Your child's personal air sample and skin wipe samples will be shipped to and analyzed by the laboratory at US EPA. His/her blood and urine samples will be shipped to and stored by the Centers for Disease Control and Prevention (CDC) laboratory in Atlanta, GA. His/her samples will be labeled with a code number only.

What is the cost to you and your child and what compensation will you get?

The only cost for being in our study is your and your child's time and effort to take part. We will give you a $25 gift card as a "thank you" when the interview is completed. We will give your child a $25 gift card each time he/she gives us blood and urine samples (or up to $50). We will give your child a $25 gift card when he/she completes the activity videotaping. The gift cards can be used at most stores or for online shopping.

What are your and your child's choices about participating?

Your taking part in the interview is voluntary. You are free to be a part of it or not. You can refuse to answer any questions. Your child's participation in this study is voluntary. He/she is free to be a part of it or not. He/she can refuse to have his/her blood drawn, give a urine sample, and take part in air and skin wipe sampling. Your child can choose to leave at any time, or withdraw his/her blood and urine samples from storage, even after you both have signed the permission and the assent form.

You and your child can choose to leave the research study at any time, even after you both have signed the permission form and the assent form.

Who should you contact if you have questions later on?

If you or your child have any questions about the study or he/she wishes to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your child's rights as a research subject, please contact:

Centers for Disease Control and Prevention CDC/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel your child has been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you or your child do not understand what we are asking him/her to do, please ask questions. After all your questions have been answered to your satisfaction and if you permit your child to be in this study, please sign the permission form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

PARENTAL/GUARDIAN CONSENT AND PERMISSION FOR CHILD PARTICIPATION IN A RESEARCH STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions and I had all my questions answered.

By signing below, I permit my child to take part in the research, and I agree to take part in the interview about my child.

_____
Child name (Print) / Relationship to Parent/Legal Guardian

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

By signing below, I permit my child to provide personal air monitoring and skin wipe samples. The personal air and skin wipe samples will not be immediately tested for chemicals. I give ATSDR and USEPA permission to store my child's personal air and skin wipe samples to do the tests later. I understand that USEPA and ATSDR will not send my child's test results to me.

_____
Child name (Print) / Relationship to Parent/Legal Guardian

_____
Parent/Legal Guardian's name (Print)

_____
Parent/Legal Guardian's signature / Date

By signing below, I permit my child to provide blood and urine samples. The blood and urine samples will not be immediately tested for chemicals. I give ATSDR and USEPA permission to store my child's blood and urine to do the tests later. I understand that USEPA and ATSDR will not send my child's test results to me.

_____

Parent/Legal Guardian's name (Print)

_____

Parent/Legal Guardian's signature / Date

Appendix H113. Child Assent – Exposure Measurements
Flesch-Kincaid Reading Level 5.0

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Child Assent Form

We are doing a study to learn about how people use playing fields with crumb rubber. Crumb rubber is the black stuff that makes the fields soft to play on. It is usually made from recycled tires. We also want to learn if people are exposed to chemicals from the crumb rubber. We are asking kids ages 7-9 to participate in this study. You were picked because you play on fields with crumb rubber.

If you decide to be in the study, we are going to ask your Mom or Dad some questions about how you play on the fields. You can help with the answers. For example, we want to know how often you fall or slide on the ground.

We will ask you to pee in a cup two times, once before you play and once after you play. It should take you less than 5 minutes to do this. We will also take some of your blood (about three teaspoons) before and after you play on the field. This should take about 15 minutes.

We will pin a small tube on your clothes to wear while you are playing on the field. The tube helps us measure chemicals in the air. After you finish playing, we will wipe your hands and parts of your arms and legs with a wet cloth. This will let us measure chemicals on your skin. This will take about 45 minutes.

<u>Other Information</u>

You might feel a small sting or "pinch" in your arm when we take your blood. You might also get a small bruise. Some people may faint, but this doesn't happen very often. Peeing in a cup might be a bit weird but it can't hurt you. You will do this in private in the restroom. You might be uncomfortable at having a person wiping your hands, arms, and legs.

Your mom/dad has said it is ok for you to be in the study, but it is up to you if you want to take part. You can ask us to stop at any time if you don't want to finish.

If You Have Questions

If you have any questions now, please ask us. If you have questions later, your Mom or Dad will know who to call.

Your signature: _____ Date: _____ 2016

Your printed name: _____ Date: _____ 2016

Signature of person obtaining consent: _____ Date: _____ 2016

Printed name of person obtaining consent: _____ Date: _____ 2016

Appendix H14. Parental Permission – Activity Video
Flesch-Kincaid Reading Level 9.4

PARENTAL/GUARDIAN PERMISSION FOR CHILD PARTICIPATION IN A RESEARCH SUB-STUDY

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

Overview

The Agency for Toxic Substances and Disease Registry (ATSDR) and the United States Environmental Protection Agency (USEPA) invite you to give permission for your child, 7 to 9 years of age, to be in a research sub-study to videotape people's activities at synthetic turf fields. Your child's participation is voluntary. We invite you both to read or hear about the sub-study. Before you decide to permit him/her to take part, please ask questions if there is anything that you both do not understand.

What is the purpose of this video sub-study?

The purpose is to see how people might be exposed to chemicals in crumb rubber infill in synthetic turf. Crumb rubber is the black material used as cushioning in synthetic turf fields. The crumb rubber is most often made from recycled tires. We will ask to videotape your child's on-field activities. Videos will help us see how much people come in contact with crumb rubber while playing on synthetic turf fields. We will use the results of this study to guide public health actions.

Why is your child being asked to be in this video sub-study?

Your child was chosen to take part in this sub-study because he/she works out on synthetic turf fields, and you agreed for him/her to participate in the main part of the study. We want to talk to people who take part in recreation, training, or organized sports on these fields.

- ATSDR and EPA hope to enroll 24 people to take part in this sub-study.

What are we asking your child to do?

- We will videotape your child during a physical activity on a synthetic turf field.

How long will this take?

It will take about one hour.

Are there any risks or discomforts to your child if he/she decides to be in this video sub-study?

Your child may feel uncomfortable being videotaped. He/she is free to stop recording at any time.

Are there any benefits to your child from being in this video sub-study?

There will be no direct benefits from being in this sub-study.

Who will see the information your child gives the researchers?

All information about your child (including name and address, this form, and interview answers) will be secure. We keep track of his/her information using a code number rather than a name. We will keep paper records in locked files and electronic records are stored on password protected computers at USEPA. Only staff working on the study will be allowed to look at the paper and electronic records. Federal policy requires making the data we collect available to the public, but we will never include your child's name or other identifying information in public release.

The videos will be shipped to USEPA labeled only with a code number. The files will be secured to allow access only by trained study staff. No video or still images will be made public. Video recordings will be destroyed no later than 5 years from now.

What is the cost to your child and what compensation will he/she get?

The only cost for being in our study is your child's time and effort to take part. We will give him/her a $25 gift card for being videotaped. He/she can use the gift cards at most stores or for online shopping.

What are your child's choices about participating?

Your child taking part in this study is voluntary. He/she is free to be a part of it or not. He/she can choose to leave at any time, or withdraw his/her videotape from storage, even after you both have signed the permission form and assent form.

Who should you contact if you have questions later on?

If you or your child have any questions about the study or he/she wishes to drop out, please contact:

Dr. Elizabeth Irvin-Barnwell
Jcx0@cdc.gov
770-488-3684

For questions about your child's rights as a research subject, please contact:

Centers for Disease Control and Prevention (CDC)/ATSDR Human Research Protection Helpline
800-584-8814
Please leave a message and say you are calling about protocol 6881.

If you feel your child has been harmed by this study please contact:

Dr. Angela Ragin
atr0@cdc.gov
770-488-3807

What should you do after reading this information?

If you or your child do not understand what we are asking him/her to do, please ask questions. After all your questions have been answered to your satisfaction and if you permit your child to be in this study, please sign the permission form on the next page. You will be given a copy of this form for your records.

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

PARENTAL/GUARDIAN PERMISSION FOR CHILD PARTICIPATION IN A RESEARCH SUB-STUDY

I have read the above information, or it has been read to me, about the study titled *Collections Related to Synthetic Turf Fields with Crumb Rubber Infill*. I have been allowed to ask questions, and I had all my questions answered.

By signing below, I permit my child to be videotaped while he/she is playing or training on synthetic turf fields.

_____

Parent/Legal Guardian's name (Print)

_____

Parent/Legal Guardian's signature / Date

Appendix H15. Child Assent – Activity Video
Flesch-Kincaid Reading Level 5.1

United States Environmental Protection Agency and Agency for Toxic Substances and Disease Registry

Collections Related to Synthetic Turf Fields with Crumb Rubber Infill

CHILD ASSENT TO BE IN A RESEARCH SUB-STUDY

We are doing a study to learn about how people use playing fields with crumb rubber. Crumb rubber is the black stuff that makes the fields soft to play on. It is usually made from recycled tires. We also want to learn if people are exposed to chemicals from the crumb rubber. We will videotape their activity while playing on the field. This will help us find out how much contact people have with field materials.

We are asking kids, 7 to 9 years of age, to take part in this sub-study. You were picked to take part because you play on synthetic turf with crumb rubber and because you said you would be in the main part of the study.

If you decide to take part, we will videotape you while you are playing on the field. This will take about one hour.

Other Information

You might be uncomfortable about people recording your play on the field.

Your mom/dad has said it is ok for you to be in the study but it is up to you if you want to take part. You can decide whether or not to take part in this study. You can ask questions about this study at any time. If you decide at any time not to finish, you can ask us to stop.

It should take an hour to finish.

If You Have Questions

If you have any questions now, please ask us. If you have questions later, your Mom or Dad will know who to call.

_____
Child's name (Print)

_____
Child's signature / Date

_____
Person obtaining assent's name (Print)

_____
Person obtaining assent's signature / Date

Appendix I: Synthetic Field Facility User Questionnaires – Adult/Adolescent and Youth/Child Versions

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Adult/Adolescent Facility User Questionnaire

PID		Site ID Number	
Facility Name		Facility Location	
Interview Date		Interviewer ID	

Interviewer: I would like to ask you some questions about activities that may affect your exposures to, and contact with synthetic turf fields that contain crumb rubber materials.

Field Contact Frequency and Duration Questions

Interviewer: I have several questions about the time you spend on synthetic turf fields at this facility.

B1. How long have you been coming to this facility?

	(years)
	(months)

B2. Over the past year, what sports, physical education classes, or other activities have you actively participated in by season (specify) on the synthetic fields at this facility?

Season	Sport	Specify Other

ATSDR estimates the average public reporting burden for this collection of information as 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-XXXX).

B3. Over the past year, how many days per week by season have you typically spent on synthetic fields at this facility?

Spring		(days per week)
Summer		(days per week)
Fall		(days per week)
Winter		(days per week)

B4. Over the past year, how many hours per day by season have you typically spent on synthetic fields at this facility?

Spring		(hours per day)
Summer		(hours per day)
Fall		(hours per day)
Winter		(hours per day)

B5. Over the past year, what was the longest period of time that you spent on the synthetic fields at this facility during a single day?

	(number of hours)

Contact Types and Scenarios per Each Type of Field Use

Interviewer: I have several questions about the kinds of activities that you take part in on synthetic turf fields installed at this facility.

For the following question, please use one of the three responses (often, sometimes, and rarely/never). "Often" means > 50% of the time and "sometimes" means < 50%.

B6. How frequently do you do the following activities while on synthetic fields at this facility each season?

	Dive on ground	Fall on ground	Sit on turf	Eat snacks	Drink
Spring					
Summer					
Fall					
Winter					

Inhalation Exposure-Related Questions

B7. When using synthetic fields at this facility:

What % of your time are you highly active, for example, running?

What % of your time are you moderately active, for example, jogging?

What % of the time do you have low activity, for example, walking?

What % of the time are you resting, for example, sitting or standing?

Dermal and Non-dietary Ingestion Exposure-related Questions

For the following questions, please use one of the four responses (every time, often, sometimes, or rarely/never):

B8. When using synthetic turf fields at this facility:

	Every Time	Often	Some times	Rarely /Never
How often do you chew gum?	3	2	1	0
How often do you use a mouth guard?	3	2	1	0
How often do you eat?	3	2	1	0
How often do you drink?	3	2	1	0
How often do you play in the rain?	3	2	1	0
How often do you wipe your hands with a hand wipe before eating?	3	2	1	0
How often do you sweat?	3	2	1	0
How often do you touch the turf with your hand?	3	2	1	0
How often do you touch the turf with your other body parts excluding hands?	3	2	1	0
How often do you sit on the turf with bare skin wearing shorts?	3	2	1	0
How often are you barefooted on the turf?	3	2	1	0
How often do you play with the turf materials or rubber granules?	3	2	1	0
How often do you touch your mouth with your hands or fingers?	3	2	1	0
How often do you place non-food objects in your mouth like toothpicks, or pens or use your mouth to hold an object?	3	2	1	0

If rarely/never, skip next.

What type of object do you most often place in your mouth while at this facility?	

How often to you get cuts or abrasions from contact with the turf?	3	2	1	0

If rarely/never, skip next.

What is the body part that usually has the most cuts or abrasions: knee, elbow, hand, thigh, shin, or other?	

B9. What clothing do you typically wear in this facility during each season (check all that apply)?

	Spring	Summer	Fall	Winter
Shorts	☐	☐	☐	☐
Short-sleeve shirt	☐	☐	☐	☐
Long pants	☐	☐	☐	☐
Long-sleeve shirt	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Socks	☐	☐	☐	☐
Helmet	☐	☐	☐	☐
Hat	☐	☐	☐	☐
Pads	☐	☐	☐	☐

Tire Crumb Take-Home Questions

For the following questions, please use one of the four responses (every time, often, sometimes, or rarely/never):

B10. After using this facility:

How often do you notice tire crumbs, dirt, or debris

	Every Time	Often	Sometimes	Rarely/Never
on your body?	3	2	1	0
in your car?	3	2	1	0
in your home?	3	2	1	0
In your laundry room/mudroom?	3	2	1	0
In your living room?	3	2	1	0
In your bedroom?	3	2	1	0
In your bathroom(s)?	3	2	1	0

Post-Use Hygiene Practices Questions

For the following questions, please use one of the four responses (every time, often, sometimes, or rarely/never):

B11. After using this facility:

	Every Time	Often	Sometimes	Rarely/Never
How often do you take actions to prevent tire crumbs from getting on your body?	3	2	1	0
How often do you take actions to prevent tire crumbs from getting into your car?	3	2	1	0
How often are your shoes/equipment wiped or removed before entering your home?	3	2	1	0

For the following questions, please use one of the six responses (never, once a month, 2 to 3 times a month, once a week, 2-3 times a week, or four or more times a week).

B12. At other locations:

	Never	*Once a month*	2 to 3 times a month	Once a week	2 to 3 times a week	4 or more times a week
How often have you played on any synthetic turf fields during the past year?	0	1	2	3	4	5
How often have you played on any synthetic turf fields in the last five years?	0	1	2	3	4	5
How often have you played on any natural grass fields during the past year?	0	1	2	3	4	5
How often have you played on any natural grass turf fields in the last five years?	0	1	2	3	4	5
How often have you played on playgrounds with rubber mulch, mats or synthetic turf during the past year?	0	1	2	3	4	5
How often have you played on playgrounds with rubber mulch, mats or synthetic turf during in the last five years?	0	1	2	3	4	5

General Hygiene Questions

B13. How many times in general do you wash hands per day? ☐

B14. How many times in general do you bathe or shower per week? ☐

General Demographic Questions

D1. How old are you? ☐

D2. Are you male or female? ◉ Male ◉ Female ◉ Refused

D3. Which of the following categories best describes your race? (select one)

◉ Non-Hispanic White ◉ Hispanic ◉ Native American ◉ Refused
◉ Non-Hispanic Black ◉ Asian ◉ Other

Specify other race ☐

D4. How tall are you? ☐ (ft) ☐ (in)

D5. How much do you weigh? ☐ (lbs)

D6. Are you still in school? ☐ yes ☐ no

If so, what is your current grade in school?

◉ 7th ◉ 8th ◉ 9th
◉ 10th ◉ 11th ◉ 12th
◉ Technical School ◉ College ◉ Graduate School
◉ Other ◉ Refused

Specify Other Grade ☐

D7. If No, what is your highest education level?

- ◉ 11th or less
- ◉ High School Graduate/ GED
- ◉ Post High School Training
- ◉ Some College
- ◉ College Graduate School
- ◉ Post-graduate
- ◉ Other
- ◉ Refused

D8. What is your occupation?

This concludes the survey. Thank you for your time. I know that your time is valuable.

If you have any questions or concerns, please, refer to the contact sheet for information on who to contact.

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Youth/Child Facility User Questionnaire

PID		Site ID Number	
Facility Name		Facility Location	
Interview Date		Interviewer ID	

Interviewer: I would like to ask you some questions about activities that may affect your child's exposures to, and contact with synthetic turf fields that contain crumb rubber materials.

Field Contact Frequency and Duration Questions

Interviewer: I have several questions about the time your child spends on synthetic turf fields at this facility

B1. How long has your child been coming to this facility?

	(years)
	(months)

B2. Over the past year, what sports, physical education classes, or other activities has your child actively participated in by season (specify) on the synthetic fields at this facility?

Season	Sport	Specify Other

ATSDR estimates the average public reporting burden for this collection of information as 30 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-XXXX).

B3. Over the past year, how many days per week by season has your child typically spent on synthetic fields at this facility?

Spring		(days per week)
Summer		(days per week)
Fall		(days per week)
Winter		(days per week)

B4. Over the past year, how many hours per day by season has your child typically spent on synthetic fields at this facility?

Spring		(hours per day)
Summer		(hours per day)
Fall		(hours per day)
Winter		(hours per day)

B5. Over the past year, what was the longest period of time that your child has spent on the synthetic fields at this facility during a single day?

	(number of hours)

Contact Types and Scenarios per Each Type of Field Use

Interviewer: I have several questions about the kinds of activities that your child takes part in on synthetic turf fields installed at this facility.

For the following question, please use one of the three responses (often, sometimes, and rarely/never). "Often" means > 50% of the time and "sometimes" means < 50%.

B6. How frequently does your child do the following activities on synthetic fields at this facility each season?

	Dive on ground	Fall on ground	Sit on turf	Eat snacks	Drink
Spring					
Summer					
Fall					
Winter					

Inhalation Exposure-Related Questions

B7. When using synthetic fields at this facility:

What % of the time is your child highly active, for example, running?

What % of the time is your child moderately active, for example, jogging?

What % of the time does your child have low activity, for example, walking?

What % of the time is your child resting, for example, sitting or standing?

Dermal and Non-Dietary Ingestion Exposure-Related Questions

For the following questions, please use one of the four responses (every time, often, sometimes, or rarely/never):

B8. When using synthetic turf fields at this facility:

	Every Time	Often	Some times	Rarely / Never
How often does your child chew gum?	3	2	1	0
How often does your child use a mouth guard?	3	2	1	0
How often does your child eat?	3	2	1	0
How often does your child drink?	3	2	1	0
How often does your child play in the rain?	3	2	1	0
How often does your child wipe their hands with a hand wipe before eating?	3	2	1	0
How often does your child sweat?	3	2	1	0
How often does your child touch the turf (with their hand)?	3	2	1	0
How often does your child touch the turf with their body excluding hands?	3	2	1	0
How often does your child sit on turf with bare skin wearing shorts?	3	2	1	0
How often is your child barefooted on the turf?	3	2	1	0
How often does your child play with the turf materials or rubber granules?	3	2	1	0
How often does your child touch their mouth with their hands or fingers?	3	2	1	0
How often does your child place non-food objects in their mouth every time like toothpicks, or pens or use their mouth to hold an object? If rarely/never, skip next.	3	2	1	0
What type of object does your child most often places in their mouth while at this facility?				
How often does your child get cuts or abrasions from contact with the turf?	3	2	1	0
If rarely/never, skip next.				
What is the body part that usually has the most cuts or abrasions: knee, elbow, hand, thigh, shin, or other?				

B9. What clothing does your child typically wear in this facility during each season (check all that apply)?

	Spring	Summer	Fall	Winter
Shorts	☐	☐	☐	☐
Short-sleeve shirt	☐	☐	☐	☐
Long pants	☐	☐	☐	☐
Long-sleeve shirt	☐	☐	☐	☐
Gloves	☐	☐	☐	☐
Socks	☐	☐	☐	☐
Helmet	☐	☐	☐	☐
Hat	☐	☐	☐	☐
Pads	☐	☐	☐	☐

Tire Crumb Take-Home Questions

For the following questions, please use one of the four responses (every time, often, sometimes, or rarely/never):

B10. After using this facility:

How often do you notice tire crumbs, dirt, or debris

	Every Time	Often	Sometimes	Rarely/Never
on your child‘s body?	3	2	1	0
in your car?	3	2	1	0
in your home?	3	2	1	0
In your laundry room/mudroom?	3	2	1	0
in living room?	3	2	1	0
in your child’s bedroom?	3	2	1	0
in your bathroom(s) your child uses?	3	2	1	0

Post-Use Hygiene Practices Questions

For the following questions, please use one of the four responses (every time, often, sometimes, or rarely/never):

B11. After using this facility:

	Every Time	Often	Sometimes	Rarely/Never
How often do you or your child take actions to prevent tire crumbs from getting on your child's body?	3	2	1	0
How often do you or your child take actions to prevent tire crumbs from getting into your car?	3	2	1	0
How often are your child's shoes/equipment wiped or removed before entering your home?	3	2	1	0

For the following questions, please use one of the six responses (never, once a month, 2 to 3 times a month, once a week, 2-3 times a week, or four or more times a week).

B12. At other locations:

	Never	Once a month	2 to 3 times a month	Once a week	2 to 3 times a week	4 or more times a week
How often has your child played on any synthetic turf fields during the past year?	0	1	2	3	4	5
How often has your child played on any synthetic turf fields in the last five years?	0	1	2	3	4	5
How often has your child played on any natural grass fields during the past year?	0	1	2	3	4	5
How often has your child played on any natural grass turf fields in the last five years?	0	1	2	3	4	5
How often has your child played on playgrounds with rubber mulch, mats or synthetic turf during the past year?	0	1	2	3	4	5
How often has your child played on playgrounds with rubber mulch, mats or synthetic turf during in the last five years?	0	1	2	3	4	5

General Hygiene Questions

B13. How many times in general does your child wash their hands per day? ☐

B14. How many times in general does your child bathe or shower per week? ☐

General Demographic Questions

D1. How old is your child? ☐

D2. Is your child male or female? ◉ Male ◉ Female ◉ Refused

D3. Which of the following categories best describes your child's race? (select one)

◉ Non-Hispanic White ◉ Hispanic ◉ Native American ◉ Refused
◉ Non-Hispanic Black ◉ Asian ◉ Other

Specify other race ☐

D4. How tall is your child? ☐ (ft) ☐ in)

D5. How much does your child weigh? ☐ (lbs)

D6. What is your child's current grade in school?

◉ 2nd ◉ 6th ◉ Other
◉ 3rd ◉ 7th ◉ Refused
◉ 4th ◉ 8th
◉ 5th ◉ 9th

Specify other grade ☐

That concludes the survey. Thank you for your time. I know that your time is valuable.

If you have any questions or concerns, please, refer to the contact sheet for information on who to contact.

Appendix J: Biological Specimen Collection, Preparation, and Storage Standard Operating Procedures

Appendix J1. Protocol – Basic Urine Collection

Appendix J2. Protocol – Urine Collection for Mercury and Other Metals

Appendix J3. Protocol – Urine Collection Urine Polyromantic Hydrocarbons

Appendix J4. Protocol – Urine Collection Volatile Organic Compound Metabolites

Appendix J5. Phlebotomist Safety Exclusion Questions

Appendix J6. Protocol – Whole Blood Metals

Appendix J7. Protocol – Serum Metals

Appendix J1

BASIC URINE COLLECTION PROTOCOL

Urine Cup Collection (for toilet-trained children/adults)

A. COLLECTION PROCEDURE

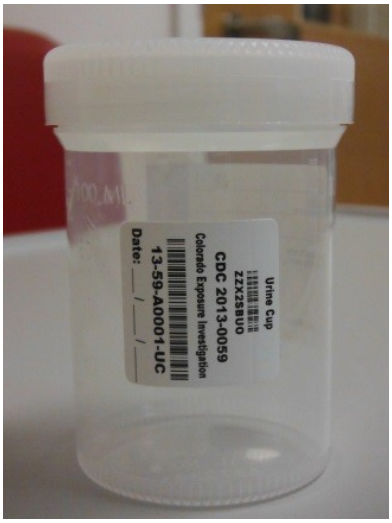
Urine collection cups are sterile and have a tamper seal on the lid. First morning void is preferred but random collection during the day is acceptable. The following items are provided:

1. Materials needed per participant (provided by CDC).

    - Pre-screened urine collection cups
    - Bar-coded labels

2. The following instructions should be provided to the participant at the time of collection.

    - 1Hands should be washed with soap and water and air dry. (It is important to rinse all the soap off)
    - Do not remove the cap from the cup until ready to void.
    - Collect at least 60 mL urine in the cup.
    - Do not touch the inside of the cup or cap at any time.
    - Replace the screw cap and tighten to avoid leakage
    - Place **URINE CUP** label on the side of the cup (**not the cap**) with participant ID. The barcode should resemble a ladder as the picture below depicts.
    - Individual zip bags are provided for each urine cup



B. URINE PROCESSING PROCEDURE

1. Materials and Equipment Needed per Participant (Some items provided by CDC)

    - Disposable gloves
    - Disposable transfer pipet
    - Sample vial depending on analyte
    - Preprinted bar-coded labels
    - Sample boxes
    - Freezer (-20^{o}C) or dry ice (not provided)

2. Processing

Urine Splits:

If you do not want to prepare the aliquots in the field, you can send the urine cup back to the CDC and we can prepare the specific aliquots. If you want the aliquots prepared in the field, please request additional processing information, which varies depending on the analyte.

Pediatric Urine Bag Collection (for infants/children not toilet-trained)

A. COLLECTION PROCEDURE

Pediatric urine collection bags are sterile and have been pre-screened for all metals by the CDC lot-screening laboratory. This bag is designed to fit over the infant's genital area in order to effectively collect the urine. The following items are provided:

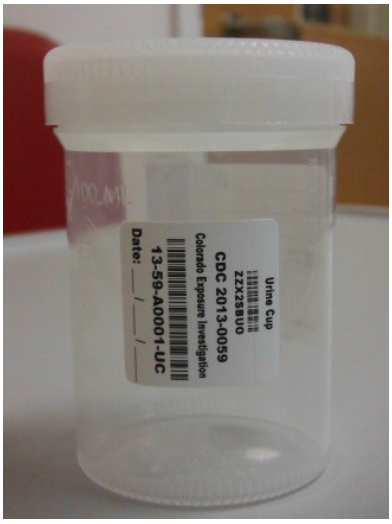
1. Materials needed per participant (provided by CDC).

    - 2 Pre-screened pediatric urine collection bags
    - Pre-screened urine collection cups
    - Bar-coded labels

2. The following instructions should be provided to the participant at the time of collection.

    - 1Thoroughly wash the area around the urethra (the hole where the urine flows out). Allow the area to air dry. Make sure this area is clean and dry before attaching the bag. Do not apply powders, oils or lotion to skin.
    - Open the bag and place it on the infant

- For males, place the entire genital area (penis and scrotum) in the bag and attach the adhesive to the skin.
- For females, place the bag over the two folds of skin on either side of the vagina (labia) and attach the adhesive to the skin.
- It may be easier to remove the adhesive backing after proper placement of the bag; make sure the adhesive patch is firmly against the skin to prevent leakage
- Put a diaper on the infant (over the bag)
- Leave bag in place for approximately 2 hours (need at least 10-15mLs of urine)
- Once adequate urine is collected, gently remove the collection bag
- Transfer the urine to a labeled pre-screened urine cup.
- Do not touch the inside of the cup or cap at any time.
- Replace the screw cap and tighten to avoid leakage
- Place **URINE CUP** label on the side of the cup (**not the cap**) with participant ID. The barcode should resemble a ladder as the picture below depicts.
- Individual zip bags are provided for each urine cup



B. URINE PROCESSING PROCEDURE

3. Materials and Equipment Needed per Participant (Some items provided by CDC)

    - Disposable gloves
    - Disposable transfer pipet
    - Sample vial depending on analyte
    - Preprinted bar-coded labels

- Sample boxes
- Freezer (-20^{o}C) or dry ice (not provided)

4. Processing

Urine Splits:

If you do not want to prepare the aliquots in the field, you can send the urine cup back to the CDC and we can prepare the specific aliquots. If you want the aliquots prepared in the field, please request additional processing information, which varies depending on the analyte.

If you have any questions or would like more information please contact Makeda Kay at xll0@cdc.gov or 770-488-7227. An illustration on attaching the pediatric urine bag can be provided if requested.

Appendix J2

URINE COLLECTION FOR MERCURY AND OTHER METALS

Urine collection cups are sterile and have a tamper seal on the lid. First morning void is preferred but random collection during the day is acceptable. The following items are provided:

- Pre-screened urine collection cups
- Pre-screened 5 ml cryovial with 30ul of preservative for Urine Mercury
- Pre-screened 2 ml ml cryovial (no preservative) for Urine Metals other than Mercury
- Pre-screened 2 ml cryovial with no preservative for Urine Creatinine
- Pre-screened disposable pipets
- Bar-coded labels

The following instructions should be provided to the participant at the time of collection.

- 1Hands should be washed with soap and water.
- Do not remove the cap from cup until ready to void.
- Collect at least 10 mL urine in the cup.
- Do not touch the inside of the cup or cap at anytime.
- Replace the screw cap and tighten to avoid leakage
- Place **URINE CUP** label on the side of the cup (**not the cap**) with participant ID.
- Individual zip bags are provided if the sample will be transported before making splits.

Urine Splits:

Aliquots/splits should be prepared as soon as possible after the urine is collected. Split as follows using a disposable pipet:

Volume	Container	Analyte	Comments	Storage
3.0 ml	5 ml cryovial with 30ul preservative (green dot or mark)	Urine Mercury Mix well	Add 3 mls of urine	Store all vials at -20°C or lower until shipment
3-5	5 ml cryovial with no preservative	Urine Metals	Add 3-5 mls of urine; don't overfill	
1.0 ml	2 ml cryovial with no preservative	Urine Creatinine	0.5 ml min	

Label each container with the appropriate bar-coded label. The labels should be affixed to each container so that the barcode is flat and not wrapped around the container. The barcode cannot be scanned if the label is placed around the container.

Log:

Make a record of the urine collection using the attached log sheet. A copy of this log should be sent with the shipment.

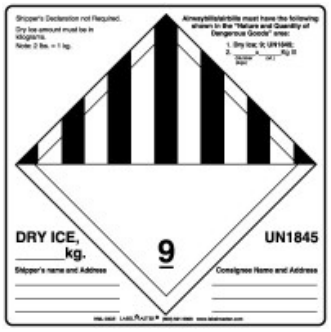
Place a label marked for the log in the space provided on the Specimen Collection and Shipping Log and check the appropriate boxes. If there were any problems in the collection and processing of the specimens, please indicate this in the comments space provided on the log.

Shipping Instructions:

Supplies needed:

- Styrofoam lined shipping container with outer cardboard container
- Saf-T-Pak 95kPa leak-proof shipping bags with absorbent material or Biohazard Bags
- Filled specimen storage boxes
- 10-15 lbs dry ice per shipping container
- Packing material or newspaper to fill extra space
- Completed FedEx air-bill
- Dry Ice label
- Tape for sealing shipping boxes
- Completed collection log

1. Storage boxes are provided for each vial/tube type. Place each of these boxes inside one of the plastic Saf-T-Pak or biohazard bags along with an absorbent pad, snap the bag shut.
2. Place the bagged specimen boxes inside the styrofoam shipping container. Add 10-15 lbs of dry ice to the shipper and place extra packing material around the specimens (newspaper, paper towels, etc.)
3. Prepare the proper documents needed for shipping and mark the appropriate boxes including the one for **dry ice** shipment and priority delivery.
4. Place the following labels on the outside of the shipping container.



Shipping address:

CDC Warehouse,

3719 N Peachtree Road

Chamblee, GA 30341

ATTN: Sample Logistics- Makeda Kay

Chamblee Building 109, Room 1312B

TEL: 770-488-4289/7227

FAX: 770-488-4301

EMAIL: NCEHSampleLogistics@cdc.gov

Please phone, fax or email to the above numbers to inform the day the package is shipped. Ship only on Monday - Thursday to insure that the package will arrive during a regular work day and not over a weekend day or on a Federal Holiday.

URINE COLLECTION SHIPPING LOG

CDC STUDY NO.

SHIPMENT DATE:_____	RECEIPT DATE:_____
SHIPPED BY:_____	RECEIVED BY:_____

U1=URINE MERCURY (Hg) U2=URINE METALS U3=URINE CREATININE

□=SPECIMEN COLLECTED □=SPECIMEN NOT COLLECTED

LABEL	**U1**		**Comments:**	**LABEL**	**U1**		**Comments:**
	U2				**U2**		
	U3				**U3**		
LABEL	**U1**		**Comments:**	**LABEL**	**U1**		**Comments:**
	U2				**U2**		
	U3				**U3**		
LABEL	**U1**		**Comments:**	**LABEL**	**U1**		**Comments:**
	U2				**U2**		
	U3				**U3**		
LABEL	**U1**		**Comments:**	**LABEL**	**U1**		**Comments:**
	U2				**U2**		
	U3				**U3**		
LABEL	**U1**		**Comments:**	**LABEL**	**U1**		**Comments:**
	U2				**U2**		
	U3				**U3**		

LABEL	U1		Comments:	LABEL	U1		Comments:
	U2				U2		
	U3				U3		
LABEL	U1		Comments:	LABEL	U1		Comments:
	U2				U2		
	U3				U3		

Appendix J3

URINE COLLECTION FOR PAHs

***URINE COLLECTION* (FIRST MORNING VOID SPECIMEN IF POSSIBLE)**

Supplies needed:

- Urine collection cup
- Biohazard bag for transporting urine from collection point to processing point
- Bar-coded labels

Sterile individually wrapped urine collection cups are provided for each participant. Instruct each person to do the following for urine collection:

- Hands should be washed with water and air-dried.
- Do not remove the cap from cup until ready to void.
- Collect at least 25 mLs urine in the cup.
- Do not touch the inside of the cup or cap at anytime.
- Recap the specimen after participant has voided.
- Place a participant label on cup (not the cap).
- Place in biohazard bag for transport to processing site

SAMPLE PREPARATION

Supplies needed:

- 15 ml (1/2 oz) square glass bottle with green screw cap for Urine PAHs
- Individually wrapped sterile disposable plastic pipet
- Storage/shipping boxes
- Disposable gloves
- Bar-coded labels
- Blue absorbent pads

Ideally, processing should be done in a clean lab area with access to a biological safety hood. If this is not available, prepare the samples in a dust free area with access to a bench top using the blue pads as a table cover to absorb any spills that might occur. After preparing the aliquots, the urine cups should be emptied into a sink (follow with a 10% bleach solution) or toilet and placed in a biohazard bag and disposed of using established procedure for the processing facility. Split the sample as follows:

(U1) URINE PAHs

Pour or pipet **10 mLs** urine (**Do Not Over-fill**) into one of the ½ oz (15 ml) square glass bottles with the green cap. There is an example bottle included in this shipment that is marked and filled with 10 mls of colored water. Do not add more than 10 mls. Adding more volume to the bottle will increase the chance the bottle will crack after freezing. Place the (U1) label on the container and freeze (**barcode labels are oriented like a ladder up the vial**).

COLLECTION LOG AND SHIPPING LIST

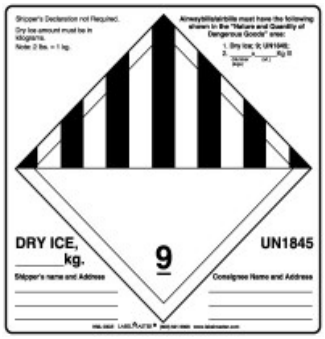
A collection log is provided to record samples that are collected. Please mark the appropriate spaces indicating which aliquots were collected, date collected and any problems that were encountered in collection, storage, or shipping.

SHIPPING PROCEDURE

Supplies needed:

- Styrofoam lined shipping container with outer cardboard container
- Saf-T-Pak 95kPa leak-proof shipping bags with absorbent material or Biohazard Bags
- Filled specimen storage boxes
- 10-15 lbs dry ice per shipping container
- Packing material or newspaper to fill extra space
- Completed FedEx air-bill
- Dry Ice label
- Tape for sealing shipping boxes
- Completed collection log

1. Storage boxes are provided for each vial/tube type. Place each of these boxes inside one of the plastic Saf-T-Pak or biohazard bags along with an absorbent pad, snap the bag shut.
2. Place the bagged specimen boxes inside the styrofoam shipping container. Add 10-15 lbs of dry ice to the shipper and place extra packing material around the specimens (newspaper, paper towels, etc.)
3. Prepare the proper documents needed for shipping and mark the appropriate boxes including the one for **dry ice** shipment and priority delivery.
4. Place the following labels on the outside of the shipping container.



Shipping address:

CDC Warehouse,

3719 N Peachtree Road

Chamblee, GA 30341

ATTN: Sample Logistics- Makeda Kay

Chamblee Building 109, Room 1312B

TEL: 770-488-4289/7227

FAX: 770-488-4301

EMAIL: NCEHSampleLogistics@cdc.gov

Please phone, fax or email to the above numbers to inform the day the package is shipped. Ship only on Monday - Thursday to insure that the package will arrive during a regular work day and not over a weekend day or on a Federal Holiday.

Appendix J4

URINE COLLECTION FOR VOC METABOLITES

Urine collection cups will be provided in 6-9 count boxes. Instruct each person to do the following for urine collection:

- Hands should be washed with soap and water.
- Do not remove the cap from cup until ready to void.
- Collect at least 30 mL urine in the cup.
- Do not touch the inside of the cup or cap at anytime.
- Recap the specimen after participant has voided.
- Place a participant label on cup (not the cap).
- Place in biohazard zip bag with absorbent gel sheet (already in bag)

Place the bagged urine cups in provided box and freeze upright until shipment to CDC.

COLLECTION LOG AND SHIPPING LIST

A collection log is provided for Participant IDs. Place the appropriate label for each participant on the respective log sheet.

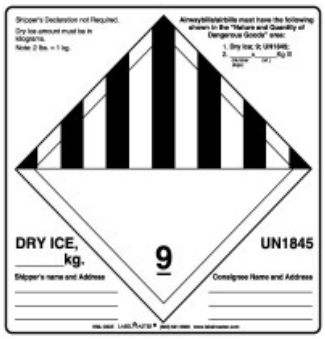
SHIPPING PROCEDURE

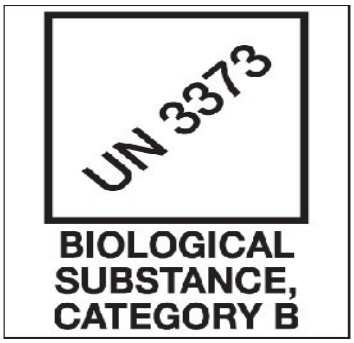
Supplies needed:

- Styrofoam lined shipping container with outer cardboard container
- Saf-T-Pak 95kPa leak-proof shipping bags with absorbent material or Biohazard Bags
- Filled specimen storage boxes
- 10-15 lbs dry ice per shipping container
- Packing material or newspaper to fill extra space
- Completed FedEx air-bill
- Dry Ice label
- Tape for sealing shipping boxes
- Completed collection log

1. Storage boxes are provided for each vial/tube type. Place each of these boxes inside one of the plastic Saf-T-Pak or biohazard bags along with an absorbent pad, snap the bag shut.

2. Place the bagged specimen boxes inside the styrofoam shipping container. Add 10-15 lbs of dry ice to the shipper and place extra packing material around the specimens (newspaper, paper towels, etc.)
3. Prepare the proper documents needed for shipping and mark the appropriate boxes including the one for **dry ice** shipment and priority delivery.
4. Place the following labels on the outside of the shipping container.





Shipping address:

CDC Warehouse,

3719 N Peachtree Road

Chamblee, GA 30341

ATTN: Sample Logistics- Makeda Kay

Chamblee Building 109, Room 1312B

TEL: 770-488-4289/7227

FAX: 770-488-4301

EMAIL: NCEHSampleLogistics@cdc.gov

Please phone, fax or email to the above numbers to inform the day the package is shipped. Ship only on Monday - Thursday to insure that the package will arrive during a regular work day and not over a weekend day or on a Federal Holiday.

Form Approved
OMB No. 0923-xxxx
Exp. Date xx/xx/201x

Appendix J5

Phlebotomist Safety Exclusion Questions

Safety Exclusion Questions (All Participants)

Q1. "Do you have hemophilia?"

If yes, the participant is ineligible for a blood draw. Inform the participant and thank them for their willingness to participate in this component.

If no, the participant is eligible for a blood draw. Proceed with sample collection.

Q2. Have you received cancer chemotherapy in the past four weeks?

If yes, the participant is ineligible for a blood draw. Inform the participant and thank them for their willingness to participate in this component.

If no, the participant is eligible for a blood draw. Proceed with sample collection.

Additional Safety Exclusion Questions (for participants < 18 years of age)

Q3. Do you weigh less than 25 pounds?

If yes:

How much do you weigh? _____

*Maximum blood draw is = (weight/2.2)*3*

If no, the participant is eligible for the maximum blood draw required by the study (15mL x 2 collections).

ATSDR estimates the average public reporting burden for this collection of information as 2 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road, MS D-74, Atlanta, GA 30333, ATTN: PRA (0923-XXXX).

Appendix J6

WHOLE BLOOD COLLECTION FOR LEAD, CADMIUM, AND MERCURY

Whole Blood Collection:

Note: All blood collection supplies have been pre-screened at CDC for use in the collection of samples tested for Blood Metals

Blood should be collected using an appropriate gauge needle (i.e.,21g or 23g butterfly needle for multiple tube collections) attached to a vacutainer needle holder (yellow plastic barrel). One 3 ml EDTA tube should be collected for Blood Metals. Assemble all supplies before attempting venipuncture. The following items should be used:

- Tourniquet
- Vacutainer needle holder
- 21g butterfly needle (23g butterfly is also included but should not be used unless the participant cannot be collected with the larger 21g needle)
- Alcohol pad
- Sterile gauze
- Bandage
- 3 ml EDTA purple top tube (**tube is engineered to collect only 3 mls in a 5 ml volume tube**; fill line is marked on the paper label)
- Sharps container
- Bar coded labels

Blood Collection Procedure:

- Apply the tourniquet to the upper arm. Select a vein for venipuncture. Placing the tourniquet as high up on the upper arm will help the vein become more evident.

- After a vein has been selected, remove the tourniquet and cleanse the antecubital space (inside bend of the elbow) of the forearm with an alcohol pad. Allow to air dry or pat dry with a sterile gauze pad. Place the tourniquet on the arm as before and locate the selected vein. Insert the butterfly needle and secure it in place with an adhesive bandage. **Collect one EDTA purple top tube first** and any other tubes needed should be collected second. Allow all tubes to fill to the stated volume on the tube. The EDTA purple top tube will fill to the black line on the paper label and **should be mixed well** after collection or placed in a tube rocker. Label each tube with a participant ID.

- After all tubes have filled to their stated capacity and the last tube has been removed from the needle holder, remove the needle in a swift motion and apply pressure with a gauze pad to the venipuncture site. Have the participant apply pressure over the gauze for about 5 minutes. Label each tube with the appropriate bar-coded label.

- After mixing well, label and place the EDTA tube in one of the storage boxes provided and store in a refrigerator until shipment can be made to CDC.

Log:

Make a record of the whole blood, and urine collections using the attached log sheet. A copy of this log should be sent with the shipment.

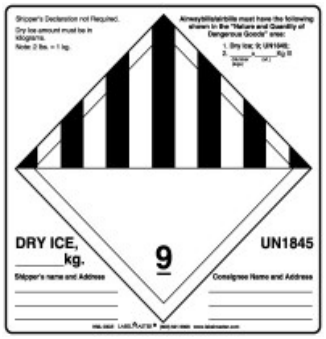
Place a label marked for the log in the space provided on the Specimen Collection and Shipping Log and check the appropriate boxes. If there were any problems in the collection and processing of the specimens, please indicate this in the comments space provided on the log.

Shipping Instructions:

There are storage boxes provided for each container type. These should be used for storage of samples in the freezer or refrigerator and when samples are shipped to CDC.

SHIPPING PROCEDURE

1. Storage boxes are provided for each vial/tube type. Place each of these boxes inside one of the plastic Saf-T-Pak or biohazard bags along with an absorbent pad, snap the bag shut.
2. Place the bagged specimen boxes inside the styrofoam shipping container. Add 10-15 lbs of dry ice to the shipper and place extra packing material around the specimens (newspaper, paper towels, etc.)
3. Prepare the proper documents needed for shipping and mark the appropriate boxes including the one for **dry ice** shipment and priority delivery.
4. Place the following labels on the outside of the shipping container.



Shipping address:

CDC Warehouse

3719 N Peachtree Road

Chamblee, GA 30341

ATTN: Sample Logistics-Cynthia Weekfall

Chamblee Building 109, Room 1312B

TEL: 770-488-4289/7227

FAX: 770-488-4301

EMAIL: NCEHSampleLogistics@cdc.gov

Please phone, fax or email to the above numbers to inform the day the package is shipped. Ship only on Monday - Thursday to insure that the package will arrive during a regular work day and not over a weekend day or on a Federal Holiday

EDTA WHOLE BLOOD FOR METALS (Lead, Cadmium, and Mercury)	
SHIPMENT DATE:_____	RECEIPT DATE:_____
SHIPPED BY:_____	RECEIVED BY:_____

B1=BLOOD METALS

□=SPECIMEN COLLECTED **□=SPECIMEN NOT COLLECTED**

LABEL	**B1**		**Comments:**	**LABEL**	**B1**		**Comments:**
LABEL	**B1**		**Comments:**	**LABEL**	**B1**		**Comments:**
LABEL	**B1**		**Comments:**	**LABEL**	**B1**		**Comments:**
LABEL	**B1**		**Comments:**	**LABEL**	**B1**		**Comments:**
LABEL	**B1**		**Comments:**	**LABEL**	**B1**		**Comments:**

LABEL	B1		Comments:	LABEL	B1		Comments:
LABEL	B1		Comments:	LABEL	B1		Comments:

Appendix J7

1SPECIMEN COLLECTION AND PROCESSING FOR SERUM METALS

BLOOD COLLECTION PROCEDURE

1. It is recommended as good laboratory practice that all blood specimens, used needles and other items associated with the specimen collection should be treated as though they were infectious for HIV and hepatitis B virus. All used needles should be placed in puncture-resistant containers; then along with used gauze, Vacutainer tubes, pipettes, vials, etc., they should be autoclaved prior to disposal. Use of disposable gloves when collecting and processing blood is also required. (See Centers for Disease Control & Prevention, recommendations for prevention of HIV transmission in health-care settings MMWR 1987;26 (suppl 2S) and Centers for Disease Control and Prevention. Updated U.S. Public Health Service Guidelines for the Management of Occupational Exposures to HBV, HCV, and HIV and Recommendations for Post-exposure Prophylaxis MMWR 2001:50 (RR11):1-42.

2. Have the following items on hand and available for use. Some of the blood collection and processing supplies need to be pre-screened and will be provided by CDC if needed.

   - Powder-free disposable gloves (nitrile if available)
   - Vacutainer needle holder
   - Tourniquet
   - Alcohol disinfectant swabs
   - Gauze bandages
   - Bandaid
   - Permanent markers
   - Sharps disposal container for used needles
   - Pre-printed bar-coded labels
   - 21g or 23g BD Butterfly Vacutainer needle
   - 6 or 7 ml royal blue top tubes for specific for metals (1 per participant plus extras for serum cleanup if needed)
   - Plastic tube rack

3. Tie the tourniquet onto the upper arm so that it can be quickly released with one hand.
4. Swab the venipuncture area with alcohol swabs.
5. Wipe off excess alcohol with the gauze bandages.
6. Allow to air dry for 5 - 10 seconds.

7. Puncture the vein.
8. Push the royal blue top tube into the needle holder. If other tubes are to be collected, they should follow the collection of the tube for metals.
9. After blood flow is established, loosen the tourniquet.
10. Allow the vacutainer tubes to completely fill.
11. After the last tube has filled, remove it from the needle holder.
12. Withdraw the needle and dispose of in the sharps disposal container.
13. Apply pressure on the venipuncture site and apply a bandage.
14. Affix the bar-coded labels to the sides of the vacutainer tubes.
15. Place the royal blue top tubes upright in a tube rack and allow them to clot upright at room temperature for no longer than one hour. If necessary, the blood specimens may be allowed to clot for 2 hours to allow more time between the collection and processing phases.

SERUM PROCESSING PROCEDURE

1. Materials and Equipment Needed per Participant
   Centrifuge capable of 1500 X G

   - Freezer (not frost-free) capable of -20°C or lower with a high temperature alarm
   - Powder-free disposable gloves (nitrile if available)
   - Pre-printed bar-coded labels
   - Permanent markers
   - Biohazard disposal
   - 2 ml polypropylene Nalgene cryovials pre-screened for serum metals
   - Tube racks for blood tubes
   - Cryovial racks for 2 ml cryovials
   - Individually wrapped disposable plastic pipets
   - 10x10 grid boxes

2. Processing
   - After the blood has been allowed to clot at room temperature for a minimum of 30 minutes and up to 1 hour (2 hours if refrigerated), centrifuge the royal blue top tubes for 15 minutes at 2400-3000 rpm. Do not remove the tops of the tubes before centrifugation. Do not “rim” the tubes prior to centrifugation; this may introduce contamination. After the tubes have been sufficiently centrifuged, do the following:

     - Remove 1 ml of serum from the royal blue top tube and transfer it to one of the 2 ml Nalgene cryovials pre-screened for serum metals. Label the cryovial with the appropriate bar-coded label and place in one of the 10x10 grid storage boxes. If the remaining serum is to be used for other serum based tests, any clear serum that can be recovered without

mixing with red cells can be removed and transferred to other storage vials.

- Cap the 2 ml cryovial and tighten. Store in the 10x10 grid boxes in a freezer until ready to ship to CDC.

SHIPPING INSTRUCTIONS FOR SPECIMENS TO CDC

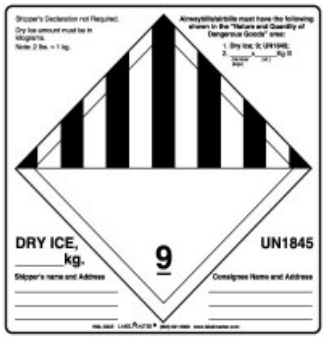
Specimen shippers will be supplied by CDC. Use either cubed or palletized dry ice (10-12 lbs per shipper). A completed shipping manifest should be included with each shipment. Information should include participant identification number, numbers of vials collected, and dates for collection and shipping. Add any comments regarding the collection, storage and shipment that might impact the analytical testing of the samples, i.e., inadequate blood draw (QNS), hemolysis, lipemia, specimen freeze/thaw cycles, etc.

SHIPPING PROCEDURE

Supplies needed:

- Styrofoam lined shipping container with outer cardboard container
- Saf-T-Pak 95kPa leak-proof shipping bags with absorbent material or Biohazard Bags
- Filled specimen storage boxes
- 10-15 lbs dry ice per shipping container
- Packing material or newspaper to fill extra space
- Completed FedEx air-bill
- Dry Ice label
- Tape for sealing shipping boxes
- Completed collection log

1. Storage boxes are provided for each vial/tube type. Place each of these boxes inside one of the plastic Saf-T-Pak or biohazard bags along with an absorbent pad, snap the bag shut.
2. Place the bagged specimen boxes inside the styrofoam shipping container. Add 10-15 lbs of dry ice to the shipper and place extra packing material around the specimens (newspaper, paper towels, etc.)
3. Prepare the proper documents needed for shipping and mark the appropriate boxes including the one for **dry ice** shipment and priority delivery.
4. Place the following labels on the outside of the shipping container.



Shipping address:

CDC Warehouse,

3719 N Peachtree Road

Chamblee, GA 30341

ATTN: Sample Logistics- Makeda Kay

Chamblee Building 109, Room 1312B

TEL: 770-488-4289/7227

FAX: 770-488-4301

EMAIL: NCEHSampleLogistics@cdc.gov

Please phone, fax or email to the above numbers to inform the day the package is shipped. Ship only on Monday - Thursday to insure that the package will arrive during a regular work day and not over a weekend day or on a Federal Holiday.

Appendix K: Preparation of Proposed Bioaccessibility Testing Fluids

Bioaccessibility Testing of Metals and SVOCs in Tire Crumb Rubber Materials

Preparation of Proposed Artificial Fluids

For the accessibility testing, simulated bio-fluids will be used to mimic oral ingestion and dermal exposure pathways. The document describes proposed formulations for the artificial bio-fluids.

1. Oral ingestion pathway – artificial saliva, gastric and intestinal fluids

For the oral route, tire crumb rubber materials will briefly come into contact with saliva followed by gastric and interstitial fluids. The residence time of metals in the mouth is usually short; therefore, dissolution in saliva is often considered negligible. Rather, most bioaccessibility studies aim to mimic dissolution in the stomach, where material is subjected to pepsin at pH values of 1 to 4, and in the small intestines at pH values of 4 to 8 (Marques et al., 2011).

1.1. Artificial saliva

The proposed artificial saliva formulation is adopted from CPSC.

Prepare 1 L of CPSC formulation artificial saliva using the recipe below. Dissolve the potassium and sodium salts in 0.900 L di water then add the calcium and magnesium salts. Adjust the solution pH to 6.8 with HCl, dilute to 1.000 L with di water.

Constituent	Formula	Mass (g)
Magnesium chloride hexahydrate	$MgCL_2 \cdot 6H_2O$	0.1667
Calcium chloride dihydrate	$CaCl_2 \cdot 2H_2O$	0.1470
Dipotassium hydrogen phosphate	K_2HPO_4	0.5748
Potassium carbonate	K_2CO_3	0.5252
Sodium chloride	NaCl	0.3272
Potassium chloride	KCl	0.7454

1.2. Artificial gastric fluid

The proposed formulation for the artificial gastric fluid, developed by NIOSH (Stefaniak et al., 2010b), is given below.

Constituents	Mass (g/L)
Primary electrolytes and ionic constituents	
Calcium Chloride Dihydrate ($CaCl_2 \cdot 2H_2O$)	0.2646
Magnesium Chloride Hexahydrate ($MgCl_2 \cdot 6H_2O$)	0.1525
Potassium Chloride (KCl)	0.8647
Sodium Chloride (NaCl)	2.8559
0.04 M Hydrochloric acid (HCl)	1.4263
Sodium bromide (NaBr)	0.0008
Copper (II) Chloride Dihydrate ($CuCl_2 \cdot 2H_2O$)	0.0003
Sodium fluoride (NaF)	0.0009
Phosphorous Pentachloride (PCl_5)	0.4707
Organic acids and carbohydrates	
D(+)-Fucose ($C_6H_{12}O_6$)	0.1380
D(+)-Glucose ($C_6H_{12}O_6$)	0.3500
D(+)-Glucuronic acid, sodium salt, monohydrate ($C_6H_9NaO_7 \cdot H_2O$)	0.0241
Sialic acid ($C_{11}H_{19}NO_9$)	0.0731
Amino acids	
DL-Alanine ($C_3H_7NO_2$)	0.0287
L-(+)-Arginine ($C_6H_{14}N_4O_2$)	0.0330
L-(+)-Aspartic acid ($C_4H_7NO_4$)	0.0170
L-Cystine ($C_6H_{12}N_2O_4S_2$)	0.0180
L-(+)-Glutamic acid ($C_5H_9NO_4$)	0.0200
Glycine ($C_2H_5NO_2$)	0.0130
L-Histidine ($C_6H_9N_3O_2$)	0.0130
L-Isoleucine ($C_6H_{13}NO_2$)	0.0070
L-Leucine ($C_6H_{13}NO_2$)	0.0120
L-(+)-Lysine Monohydrochloride ($C_6H_{14}N_2O_2 \cdot HCl$)	0.0175
L-Methionine ($C_5H_{11}NO_2S$)	0.0080
L-Phenylalanine ($C_9H_{11}NO_2$)	0.0080
L-(-)-Proline ($C_5H_9NO_2$)	0.0170
DL-Serine ($C_3H_7NO_3$)	0.0160
L-Threonine ($C_4H_9NO_3$)	0.0150
L-(−)-Tryptophan ($C_{11}H_{12}N_2O_2$)	0.0140
L-Tyrosine ($C_9H_{11}NO_3$)	0.0100
Nitrogenous Substances	
1 M Ammonium hydroxide (NH_4OH)	0.1996
Urea (CH_4N_2O)	0.0840
Uric acid ($C_5H_4N_4O_3$)	0.0080
Vitamins	
L-(+)-Ascorbic Acid ($C_6H_8O_6$)	0.9500
Cobalamine concentrate ($C_6H_9N(AO_7) \cdot H_2O$)	0.000006
Histamine Dihydrochloride ($C_5H_9N_3 \cdot 2HCl$)	0.0002
Pepsin	
Pepsin	3.2000

1.3. Artificial intestinal fluids

The proposed formulation for the artificial intestinal fluid at fasted-state is given below (Marques et al., 2011).

Table 6. Fasted-State Simulated Intestinal Fluid (FaSSIF)

Composition	**FaSSIF**
sodium taurocholate (mM)	3
lecithin (mM)	0.2
maleic Acid (mM)	19.12
sodium hydroxide (mM)	34.8
sodium chloride (mM)	68.62
Properties	
pH	6.5
osmolality (mOsm/kg)	180 ± 10
buffer capacity (mmol/L/pH)	10

2. Dermal pathway - artificial sweat and sebum

The surface of the skin is coated with a co-solvent of mainly aqueous sweat and oily sebum. To simulate the dermal exposure route, both artificial sweat and artificial sebum will be used in the *in vitro* bioaccessibility testing procedure. Since 1940, there has been at least 76 different acritical sweat formulations and 27 different acritical sebum formulations reported. The proposed formulations for artificial sweat and artificial sebum are developed by NIOSH.

2.1. Artificial sweat

Human sweat is known to contain at least 61 different chemical constituents at varying concentrations. The proposed artificial sweat formulation is listed in the table below (Harvey et al., 2010).

Sweat Constituent	**Mass (g/L)**	**Volume (µL/L)**
Primary electrolytes and ionic constituents		
Sodium Sulfate (Na_2SO_4)	0.0583	---
Sodium Iodide (NaI)	---	53.2
Sodium Fluoride (NaF)	---	923.6
Sodium Bromide (NaBr)	---	788.8

Sweat Constituent	Mass (g/L)	Volume (µL/L)
Cadmium Chloride Anhydrous ($CdCl_2$)	---	16.5
Copper (II) Chloride Dihydrate ($CuCl_2 \cdot 2H_2O$)	---	801.3
1M Ammonium Hydroxide (NH_4OH)	---	5200.0
Sulfur (S)*	0.0737	---
Iron Sulfate Heptahydrate ($FeSO_4 \cdot 7H_2O$)	0.0027	---
Lead (Pb)- Reference Solution 1000ppm	---	24.9
Manganese (II) Chloride ($MnCl_2$)	---	692.1
Nickel (Ni)- Reference Solution 1000ppm	---	24.6
Zinc (Zn)- Reference Solution 1000ppm	---	850.3
Sodium Bicarbonate ($NaHCO_3$)	0.2520	---
Potassium Chloride (KCl)	0.4547	---
Magnesium Chloride Hexahydrate ($MgCl_2 \cdot 6H_2O$)	0.0167	---
Sodium Phosphate Anhydrous Monobasic (NaH_2PO_4)	0.0484	---
Phosphorous Pentachloride (PCl_5)	0.0027	---
Sodium Chloride	1.5519	---
Organic acids and carbohydrates		
1M L(+)-lactate solution ($CH_3CH(OH)COOH$)	---	14000.0
Pyruvic acid ($C_3H_4O_3$)	---	12.7
Butyric acid ($C_4H_8O_2$)	---	0.22
Acetic acid ($C_2H_4O_2$)	---	7.4
Hexanoic acid ($C_6H_{12}O_2$)	---	5.7
Propionic acid ($C_3H_6O_2$)	---	0.26
Isobutyric acid ($C_4H_8O_2$)	---	3.7

Sweat Constituent	Mass (g/L)	Volume (µL/L)
Isovaleric acid ($C_5H_{10}O_2$)	---	6.0
D(+)-Glucose ($C_6H_{12}O_6$)	0.0306	---
Amino acids		
DL-Alanine ($C_3H_7NO_2$)	0.0511	---
L-(+)-Arginine ($C_6H_{14}N_4O_2$)	0.1359	---
L-(+)-Aspartic acid ($C_4H_7NO_4$)	0.0453	---
L-(+)-Citrulline ($C_6H_{13}N_3O_3$)	0.0701	---
L-(+)-Glutamic acid ($C_5H_9NO_4$)	0.0544	---
Glycine ($C_2H_5NO_2$)	0.0293	---
L-Histidine ($C_6H_9N_3O_2$)	0.0807	---
L-Isoleucine ($C_6H_{13}NO_2$)	0.0223	---
L-Leucine ($C_6H_{13}NO_2$)	0.0275	---
L-(+)-Lysine Monohydrochloride ($C_6H_{14}N_2O_2$·HCl)	0.0274	---
L-(+)-Ornithine Monohydrochloride ($C_5H_{12}N_2O_2$·HCl)	0.0253	---
L-Phenylalanine ($C_9H_{11}NO_2$)	0.0215	---
L-Threonine ($C_4H_9NO_3$)	0.0536	---
L-(–)-Tryptophan ($C_{11}H_{12}N_2O_2$)	0.0112	---
L-Tyrosine ($C_9H_{11}NO_3$)	0.0308	---
L-Valine ($C_5H_{11}NO_2$)	0.0293	---
Nitrogenous Substances		
Ammonium[1]	---	---
Uric acid ($C_5H_4N_4O_3$)	0.0099	---

Sweat Constituent	Mass (g/L)	Volume (µL/L)
Urea (CH_4N_2O)	0.6006	---
Creatinine ($C_4H_7N_3O$)	---	989.8
Creatine Monohydrate ($C_4H_9N_3O_2 \cdot H_2O$)	---	559.3
Vitamins		
Thiamine Hydrochloride ($C_{12}H_{17}ClN_4OS \cdot HCl$)	---	33.7
Riboflavin ($C_{17}H_{20}N_4O_6$)**	---	24.5
Nicotinic Acid ($C_6H_5NO_2$)**	---	1785.1
D-Pantothenic Acid Calcium Salt ($(C_9H_{17}NO_5)_2Ca$)	---	548.0
Pyridoxine Hydrochloride ($C_8H_{11}NO_3 \cdot HCl$)	---	6.4
Folic Acid ($C_{19}H_{19}N_7O_6$)	---	35.3
L-(+)-Ascorbic Acid ($C_6H_8O_6$)	---	978.5
Dehydroascorbic Acid[2]	---	100mL
Inositol ($C_6H_{12}O_6$)	---	720.6
Choline Chloride ($C_5H_{14}NOCl$)	---	181.5
p-Aminobenzoic Acid ($C_7H_7NO_2$)	---	12.3

[1] Added as ammonium hydroxide with primary electrolytes and ionic constituents

[2] If necessary, prepare dehydroascorbic acid solution by mixing 0.0352g ascorbic acid in 2L water then add 0.200mL ascorbate oxidase enzyme and incubate solution at 37°C for 30 minutes

Procedures:

Prepare 1 L artificial sweat according to the recipe above and buffer to pH 5.3

The amounts of some chemical constituents in the table are too small to be weighed accurately on the balance. Prepare the following stock solutions first:

Sodium Iodide: make concentrated solution by dissolving 0.010g NaI in 0.050L water; pipet appropriate volume into beaker

Sodium Fluoride: make concentrated solution by dissolving 0.025g NaF in 0.050L water; pipet appropriate volume into beaker

Sodium Bromide: make concentrated solution by dissolving 0.015g NaBr in 0.050L water; pipet appropriate volume into beaker

Cadmium Chloride Anhydrous: make concentrated solution by dissolving 0.010g CdCl2 in 0.050L water; pipet appropriate volume into beaker

Copper Chloride Dihydrate: make concentrated solution by dissolving 0.010g CuCl2•2H20 in 0.050L water; pipet appropriate volume into beaker

Manganese Chloride: make concentrated solution by dissolving 0.010g MnCl2 in 0.050L water; pipet appropriate volume into beaker

Hexanoic Acid: make concentrated solution by pipetting 1.0mL hexanoic acid in 0.050L water; pipet appropriate volume into beaker

Isobutyric Acid: make concentrated solution by pipetting 1.0mL isobutyric acid in 0.050L water; pipet appropriate volume into beaker

Isovaleric Acid: make concentrated solution by pipetting 1.0mL isovaleric acid in 0.050L water; pipet appropriate volume into beaker

Creatinine: make concentrated solution by dissolving 2.400g creatinine in 0.250L water; pipet appropriate volume into beaker

Creatine monohydrate: make concentrated solution by dissolving 1.000g creatinine monohydrate in 0.250L water; pipet appropriate volume into beaker

Thiamine Hydrochloride: make concentrated solution by dissolving 0.010g thiamine hydrochloride in 0.050L water; pipet appropriate volume into beaker (if cloudy, add drop of 5N NaOH to clear solution)

Riboflavin: make concentrated solution by dissolving 0.010g riboflavin in 0.050L water; pipet appropriate volume into beaker (if cloudy, add drop of 5N NaOH to clear solution)

Niacin: make concentrated solution by dissolving 0.010g niacin in 0.050L water; pipet appropriate volume into beaker (if cloudy, add drop of 5N NaOH to clear solution)

Pantothenic acid: make concentrated solution by dissolving 0.010g D-pantothenic acid calcium salt in 0.050L water; pipet appropriate volume into beaker (if cloudy, add drop of 5N NaOH to clear solution)

Pyridoxine Hydrochloride: make concentrated solution by dissolving 0.010g pyridoxine hydrochloride in 0.050L water; pipet appropriate volume into beaker

Folic Acid: make concentrated solution by dissolving 0.010g folic acid in 0.050L water; pipet appropriate volume into beaker (if necessary, add drop of 5N NaOH to clear folic acid stock solution)

Ascorbic Acid: make concentrated solution by dissolving 0.090g ascorbic acid in 0.050L water; pipet appropriate volume into beaker

Inositol: make concentrated solution by dissolving 0.015g inositol in 0.050L water; pipet appropriate volume into beaker

Choline Chloride: make concentrated solution by dissolving 1.000g choline chloride in 0.050L water; pipet appropriate volume into beaker

p-Aminobenzoic Acid: make concentrated solution by dissolving 0.010g p-aminobenzoic acid in 0.050L water; pipet appropriate volume into beaker

2.2. Artificial sebum

The artificial sebum formulation is given below (Stefaniak et al., 2010a). Prepare 300 mL of artificial sebum by dissolving the lipids in the table below in a 2:1 co-solvent mixture of chloroform (200 mL) and methanol (100 mL).

Constituent	Chemical	Mass (g)
Squalene	Squalene, 99+%	0.5151
Wax esters	Palmityl palmitate, 98%	0.9718
Wax esters	Oleyl Oleate, ≥99%	0.2430
Triglycerides	Tristearin	1.0690
Triglycerides	Triolein	0.5345
Free Fatty Acids	Stearic/Palmitic, 96%	0.6876
Free Fatty Acids	Oleic Acid	0.6876
Cholesterol Esters	Cholesteryl Oleate	0.0972
Free Cholesterol	Cholesterol	0.1944

REFERENCES:

Harvey CJ, LeBouf RF & Stefaniak AB (2010) Formulation and stability of a novel artificial human sweat under conditions of storage and use. *Toxicol In Vitro* 24, 1790-1796

Marques MRC, Loebenberg R & Almukainzi M (2011) Simulated Biological Fluids with Possible Application in Dissolution Testing. Dissolution Technologies August, 15-28

Stefaniak AB, Harvey CJ, Wertz PW (2010a) Formulation and stability of a novel artificial sebum under conditions of storage and use. *International Journal of Cosmetic Science*, 32, 347–355

Stefaniak AB, Virji MA, Harvey CJ, Sbarra DC, Day GA & Hoover MD (2010b) Influence of artificial gastric juice composition on bioaccessibility of cobalt- and tungsten-containing powders. Int J Hyg Environ Health 213, 107-115

Appendix L: Considerations for the Protection of Human Subjects

Introduction

The U.S. EPA is dedicated to the protection of human subjects who participate in their observational human exposure studies. To ensure the protection of human subjects, the EPA's National Exposure Research Laboratory (NERL) has developed state of the science information to help research scientists address specific elements when developing and implementing their observational human exposure studies. The Scientific and Ethical Approaches for Observational Exposure Studies (SEAOES) document developed by NERL (EPA 600/R-08/062, U.S. EPA, National Exposure Research Laboratory, Research Triangle Park, NC, 2008) provides information on regulatory requirements and ethical issues to consider when performing human subjects research. EPA researchers use the information and guidance in the SEAOES document in the design of observational human exposure research studies. Key elements in the SEAOES document considered when designing observational exposure research studies include: study conceptualization and planning; ensuring protection of vulnerable groups; privacy, confidentiality, and other concerns related to observational human exposure studies; creating an appropriate relationship between the participant and researcher; building and maintaining appropriate community and stakeholder relationships; and designing and implementing strategies for effective communication.

As described in Section 8 of this research protocol, the study will be performed in accordance with human subject protections and procedures under federal regulations and according the policies of CDC/ASTDR and the U.S. EPA. The CDC Institutional Review Board (CDC IRB) will be responsible for review of the human subjects research conducted under this research protocol. The study protocol, consent and assent forms, and the questionnaire will be submitted for review and approval by the CDC IRB. Following CDC IRB approval, the protocol and IRB materials will be submitted to the U.S. EPA Human Subjects Research Review Official (HSRRO) for review and approval. No participant recruitment or human subjects data collection will proceed until the CDC IRB and EPA HSRRO approvals are obtained.

The following sections describe Considerations for the Protection of Human Subjects in this research protocol addressing key elements described in the SEAOES document. The elements described below generally follow the outline of the SEAOES document. Preceding sections of this research protocol are referenced as appropriate.

1.0 Elements to be considered in study conceptualization and planning

The research protocol for the details the elements to be considered in study conceptualization and planning in Sections 1 – 3.

1.1 Justification for the Proposed Study

Concerns have been raised by the public about the safety of recycled tire crumb rubber used in playing fields and playgrounds in the United States. Limited studies have not shown an elevated health risk from playing on fields with tire crumb rubber, but the existing studies do not comprehensively evaluate the concerns about health risks from exposure to tire crumb rubber. Because of the need for additional information, the U.S. Environmental Protection Agency (EPA), the Centers for Disease Control and Prevention/Agency for Toxic Substances and Disease Registry (ATSDR), and the U.S. Consumer Product Safety Commission (CPSC) are launching a multi-agency action plan to study key environmental human health questions. This coordinated federal action includes outreach to key stakeholders, such as athletes and parents, and seeks to fill important data and knowledge gaps, characterize constituents of recycled

tire crumb rubber, and identify ways in which people may be exposed to tire crumb rubber based on their activities on the fields. The Federal Research Action Plan includes numerous activities, including research studies. While additional research questions may require evaluation beyond this year, the information will help answer some of the key questions that have been raised.

The mission of the U.S. Environmental Protection Agency (EPA) is to protect public health and safeguard the environment. Children's environmental health protection is included in the Agency's strategic plan and in the Office of Research and Development (ORD) children's environmental health research is a cross-cutting topic for the National Research Programs. Research conducted in ORD develops the information and methods that decision makers need to assess how the natural and built environments affect children's health and well-being. In addition to addressing an issue of national concern, the research aims to support the needs of the ORD National Programs by addressing whether and how adults and children are exposed to chemical and microbiological agents when they use synthetic turf fields with recycled tire crumb rubber.

1.2 Justification for Including Human Subjects in the Research

Adults and children may be exposed to chemicals from tire crumb rubber material used on synthetic turf fields. There is currently uncertainty about activity factors that may influence exposures as well as the amount, frequency, and duration of exposures. Research with human subjects will collect activity information and exposure measurements needed to reduce uncertainties and better understand whether there are potential risks to people that use synthetic turf fields with tire crumb rubber infill material.

1.3 Ensuring Scientific Validity of the Research Study

This research protocol describes the technical approach for the characterizing recycled tire crumb rubber and exposure characterization for users of synthetic turf fields. It was developed by a team of researchers in the Office of Research and Development and at ATSDR. This research protocol describes what data will be collected and how it will be analyzed to meet the study objectives. To help judge and ensure the scientific validity of the study, the research protocol will be subjected to an external expert peer review.

1.4 Ethical Issues in Ensuring Fair Subject Selection

CDC/ATSDR and EPA will ensure fair research subject selection for the exposure characterization study through IRB-approved procedures that limit the potential for coercion and identify participant activity categories most relevant for assessing appropriate exposure scenarios.

1.5 Ensuring a Favorable Risk-Benefit Ratio

While there are no direct benefits to research participants in the exposure characterization study, the risks of participation are considered to be minimal.

1.6 Scientific and Ethical Reviews

This research protocol will be externally peer reviewed by three reviewers who are recognized experts in the field of exposure science and/or other scientific disciplines and understand the complexities and

sensitivities associated with conducting observational exposure measurement studies. The research protocol will be reviewed by the CDC IRB and by the U.S. EPA HSRRO.

1.7 Conflicts of Interest
The researchers at EPA and CDC/ATSDR are not aware of any conflicts of interest related to this study.

1.8 Considerations for Ensuring that Participant Behaviors are not Changed Adversely Because of Being in the Study
The SEAOES document discusses how changes in participant behavior may affect the study outcome. The Hawthorne Effect, for example, is well-recognized and in some cases is difficult to both minimize and assess in some research activities. The exposure characterization study will monitor participants engaged in physical sports or training activities on synthetic turf fields. A small passive VOC sampler will be attached to participant clothing during an activity session. A subset of participants will be videotaped. These research activities may unintentionally influence participant behavior. Research teams will emphasize with the participants the importance of following their usual activities during the study. Participants will not be asked to perform any scripted activities or asked to alter their routine activities during the study other than to participate in the sample collection activities described in this protocol.

1.9 Proposed Approaches for Monitoring Scientific and Ethical Issues During the Study
CDC/ATSDR and EPA will follow IRB guidance and mandates for monitoring scientific and ethical issues during the study.

2.0 Ensuring Protection of Vulnerable Groups
Concern for the protection of vulnerable groups is fundamental to modern ethical thought and guidelines. The Common Rule requires IRBs to assure that “additional safeguards have been included in the study to protect the rights and welfare of these [vulnerable] subjects”. Researchers have to justify the involvement of vulnerable populations in the research study and include appropriate safeguards for protection of their safety and welfare.

2.1 Identification of Vulnerable Groups in the Study
The Common Rule identifies children as an example of a vulnerable group. EPA (40 CFR 26) and HHS (45 CFR 46) both extend additional protections to children when participating in observational exposure measurement studies. CDC/ATSDR and EPA will ensure the protections of the children who participate in the study through IRB-approved procedures. No active duty military personnel and/or their families will be considered for participation. No prisoners will be included in the research.

2.2 Justification for Involving Vulnerable Persons in the Study
One of the primary public concerns regarding synthetic turf fields with tire crumb rubber infill is the potential for children’s exposure to toxic chemicals. Because children may have different activity patterns than adults, they may be exposure to constituents in different amounts and through different pathways. The main objective of the exposure characterization study is to obtain information to better understand activity patterns and exposures through inhalation, dermal adsorption, and ingestion for adults and children.

2.3 Consideration of Special Requirements for Vulnerable Groups
Children have long been recognized as a vulnerable group in research studies. EPA (40 CFR 26) and HHS (45 CFR 46) both extend additional protections to children when participating in observational exposure measurement studies. The participation of children in this observational human exposure study is critical to characterizing children's exposures to synthetic turf field constituents. Children will not be asked to perform any scripted activities or other tasks outside of their normal routines that might change their activities and exposures. Active duty military service members and their families will not be recruited or included as research participants in this study.

3.0 Privacy, Confidentiality, and Other Concerns Related to Observational Human Exposure Studies
Considerations for this element are described in the research protocol Sections 5 and 8.

3.1 Privacy Issues
Considerations for this element are described in the research protocol Sections 5 and 8.

3.2 Confidentiality of Information and Participation
Considerations for this element are described in the research protocol Sections 5 and 8.

3.3 Non-Study Hazards with Mandated Reporting Requirements
CDC/ATSDR and EPA will follow IRB requirements and guidance on procedures to identify, address, and report non-study hazards when national, state, or local reporting requirements exist (e.g. child abuse).

3.4 Other Non-Study Hazards
CDC/ATSDR and EPA will follow IRB requirements and guidance on procedures to identify, address, and report non-study hazards that do not have mandatory reporting requirements.

3.5 Third Party Issues
Third party issues need to be considered as part of this research protocol. The research will involve participants engaged in activities on synthetic turf fields that are owned, operated, and/or managed by third parties. Much of the exposure characterization measurement work involves collecting samples of facility air and surfaces. Permissions to collect samples and conduct research activities will need to be obtained from the field owner/manager. The research team will ask the IRB for specific guidance in managing third party issues and concerns as part of this research. One question, for example, is about reporting measurement results back to the facility/owner manager.

3.6 Plans for Data and Safety Monitoring and Oversight
CDC/ATSDR and EPA will follow IRB requirements and guidance on data and safety monitoring and oversight as part of this research study.

4.0 Creating an Appropriate Relationship between the Participant and Researcher
CDC/ATSDR and EPA will strive to maintain and appropriate relationship between researchers and participants during recruitment, discussing informed consent, during participation in research activities, and in any post-research communication. Because the research involves children, it is important that research staff not have interaction with the children without other adults present and should not spend

time with children in a private, unobserved setting. Personal sample collection may involve collecting wipe samples from the hands, arms, and legs of adults and children and collecting blood samples. Researchers should discuss what will be done in advance of sample collection, and ensure that the participant agrees to the personal contact that will occur. Sample collection should only be performed in the presence of another adult.

4.1 Informed Consent Process
Considerations for this element are described in the research protocol Section 8.

4.2 Reimbursement to Research Participants
Considerations for this element are described in the research protocol Section 8. The researchers believe that the amount of reimbursement being offered will be commensurate with the time and effort research participants will expend. Any and all proposed payment levels will be discussed with and approved by the CDC/ATSDR IRB.

4.3 Research Rights and Grievance Procedures
CDC/ATSDR and EPA will follow IRB-approved requirements and guidance for addressing research rights and grievance procedures.

4.4 Recruitment Strategies
Recruitment strategies are described in the research protocol Section 4.

4.5 Retention Strategies
The study design does not include longitudinal data collection, therefore, retention strategies are not a key element of the research protocol.

5.0 Building and Maintaining Appropriate Community and Stakeholder Relationships
CDC/ATSDR and EPA will implement outreach and communication to numerous stakeholders under the Federal Research Action Plan. The research will be implemented at a small scale in numerous locations across the United States. As such, community-based research will not be performed in this research. Regardless, information will be provided about the research and discussions will be held with local field owners/managers, governments, organizations, and other stakeholders when and where interest is expressed.

6.0 Designing and Implementing Strategies for Effective Communication
CDC/ATSDR and the EPA have developed an outreach plan that includes development of communication materials, identifies numerous potential stakeholders, and is arranging discussions or webinars with state and local governments, the public, and other stakeholders as part of the outreach process. Additional communication material will be developed for sharing with facility owner/managers and potential participating organizations and field users.