Generic Information Clearance for CDC/ATSDR

Formative Research and Tool Development

Assessment of task-based exposures that may affect reproductive health in nail salon employees

Supporting Statement A

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Table of Contents

Section

- **Goals of the project:** The goal of this information collection is to field test and determine the feasibility of a data collection instrument to help NIOSH study adverse reproductive health outcomes in nail salon technicians.

- **Intended use of the resulting data:** The resulting data generated from the online questionnaire and paper feedback form will be used to benefit the federal government in future studies and interventions both by better understanding the health effects faced by this population and by allowing NIOSH to refine data collection instruments for use in future epidemiologic studies with much larger sample sizes.

- **Methods to be used to collect data:** Respondents will fill out the questionnaire using RedCAP with the assistance of a NIOSH researcher. Questions will be multiple choice. A feedback form containing three open-ended questions will be verbally administered by a NIOSH researcher to collect participants' feedback on the questionnaire.

- **The specific subpopulation to be studied:** Respondents are persons employed as nail technicians in nail salons who choose to participate in this study.

- **How data will be analyzed:** Quantitative data will be analyzed using descriptive and inferential statistics. No personal identifiers will be included.

A. JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Centers for Disease Control and Prevention (CDC) National Institute for Occupational Safety and Health (NIOSH) requests approval of a Formative Research and Tool DevelopmentGenIC entitled "Assessment of Task-Based Exposures That May Affect Reproductive Health in Nail Salon Employees". A literature review indicates that limited data exists on the relationship between work as a nail technician and adverse reproductive health outcomes. Field testing of this data collection instrument using the formative research GenIC is being requested to occur as part of a current NIOSH exposure assessment study that will allow for the refinement and optimization of study enrollment, materials, instructions, and participant experience to reduce the burden of future data collections that will occur as part of a larger epidemiologic study on the same population. The information collection includes a questionnaire that will allow NIOSH to further understand the relationship between work in this industry and potential health outcomes and refine the data collection instrument for deployment in future studies with a larger sample size across the country and a feedback form that will collect input from participants on improving the data collection instrument. This information collection activity will be beneficial in ensuring future NIOSH research is specific to the needs of the study populations and improving the relationship between interested parties and NIOSH researchers.

Background

The Centers for Disease Control and Prevention (CDC) conducts surveillance and prevention research projects as part of its response to current public health issues. Many of these projects provide the basis for the recommendations and guidelines that CDC provides. Since its inception in 1970, the National Institute for Occupational Safety and Health (NIOSH), Centers for Disease Control and Prevention (CDC), has been one of the leading federal agencies developing workplace exposure assessment methodologies and conducting studies to identify and evaluate worker exposures and hazards. Exposure Assessment is a multi-disciplinary field that identifies and characterizes worker and workplace chemical, particulate, and physical hazards; develops estimates of exposure for dose-response and risk assessment studies; and evaluates the significance of exposures and effectiveness of intervention strategies. The exposure assessment studies and methods developed by NIOSH are necessary to first identify the exposure or hazard and then determine whether an injury or illness can be associated with the specific exposure/hazard.

NIOSH has explored the relationship between work as a nail technician and adverse reproductive health outcomes previously (Siegel et al., 2021); however, the data was used retrospectively from birth records and was not paired with exposure data. The data collection instrument included as part of this exposure study and this GenIC will address factors such as work history and frequency of job tasks that provide a more nuanced look at a nail technician's exposures beyond just occupation while simultaneously measuring their actual exposures to reproductive toxicants. This study will also determine the feasibility of estimating chemical exposures through self-reported work history, which is being collected with this instrument.

The purpose for developing and field testing this instrument is to better understand the exposures faced by nail technicians during work in salons, reproductive health outcomes they experience, and their concerns about their health due to their work. This information is critically important to the design of future studies on this topic. Due to the limited amount of current research in this area, understanding the scope of exposures to reproductive toxicants nail technicians face and workplace practices and behaviors will aid in planning future epidemiologic studies and reducing workplace exposures.

The Information Collection Request (ICR) for this project is to conduct field testing of a questionnaire that will link work history to reproductive health outcomes and allow researchers to estimate exposures based on work activities and collect participant feedback on the questionnaire. Conducting field testing with a small sample size in this study will allow for the refinement and optimization of the data collection instrument to reduce the burden of future data collections prior to large-scale use (future OMB submission). This ongoing data collection activity benefits the Federal Government by providing CDC with data supporting research on understudied health outcomes in this study population.

No personally identifiable information will be collected. The questionnaire will not ask open-ended questions; rather, multiple answer choices will be offered for most questions. In some cases, such as when selecting controls in place, an "Other" option will be provided as it may be difficult to include an exhaustive list of all applicable options. Responses to the questionnaire will be collected electronically as participants will enter responses into REDCap, a secure internet-based survey software system that has been approved by NIOSH Office of the Director Information Technology (ODIT). REDCap provides enterprise-grade security features including data encryption, redundancy, continuous network monitoring, and Single Sign On (SSO). The feedback questions are open-ended, but they will be asked verbally by researchers who will record participants' answers. No PII will be recorded by researchers while collecting feedback.

2. Purpose and Use of the Information Collection

The purpose of this information collection request is to field test a newly developed questionnaire on a limited scale to understand if the data collected from the study population produces the desired information to correlate work history with health outcomes, and to assess the feasibility of estimating workplace exposures based on work history and frequency by creating a Job Exposure Matrix (JEM).

The data collection instrument will address the following topics:

- Demographic information
- Work history
- Reproductive health and pregnancy outcomes
- Tasks performed during work hours

For this proposed information collection, field testing of the newly developed instrument will allow for the refinement and optimization of study enrollment, materials, instructions, and participant experience to reduce the burden of future data collections prior to its full-scale use. Without field testing the information now, planning future epidemiological studies will be more difficult for NIOSH and likely result in increased burden on participants due to lack of refinement of the questions. The questionnaire will be administered electronically with assistance from NIOSH researchers to ensure comprehension of the questionnaire by the study population and improve information collection in future studies with this study population. A three-question feedback form will be administered verbally by researchers following completion of the questionnaire to collect participant feedback on the questionnaire being field tested to improve it further.

In addition, the questionnaire data will allow for a better understanding of the exposure data collected in this study. One goal of this study is to construct a job exposure matrix (JEM), which seeks to link tasks performed with the associated exposure. Due to the wide variety of nail products used in different services that nail technicians offer clients, the research team hypothesizes that performing different

services may result in different exposures to the technician performing the task. The exposure data collection in parallel with field observations will provide much of the basis for the JEM, but the questionnaire data will provide more information about the work being done in salons than the observations of the research team alone and allow the research team to validate the JEM using self-reported data on tasks performed by nail technicians.

This generic information request is not intended to produce results that can be generalized beyond the scope of this study. The objective of this request is to field test a data collection instrument that will allow NIOSH to respond to the needs of this unique study population in a timely manner and validate a method of estimating exposures that will facilitate collecting data with a larger sample size in future research. Following field testing and collecting feedback from participants, NIOSH will continue to improve the content of the data collection instrument to ensure wide comprehension and response rates among this study population.

3. Use of Improved Information Technology and Burden Reduction

All data for the questionnaire will be collected using REDCap, a secure internet-based survey software system that is approved for use by NIOSH. REDCap provides enterprise-grade security features including data encryption, redundancy, continuous network monitoring, and Single Sign On (SSO).

The instrument and survey software will use computer generated skip patterns to reduce the respondent's overall burden, so they only see questions that are relevant to them. Participants will take the questionnaire electronically using a government laptop with assistance from NIOSH researchers to ensure comprehension. The estimated time to complete the questionnaire is approximately 15 to 20 minutes.

The feedback form will be collected using paper forms where answers are recorded by researchers after asking the three questions verbally. Researchers will not record any PII or sensitive information on the paper forms, and they will be kept secure by the project officer. The estimated time to complete the feedback form is approximately 5 to 10 minutes.

4. Efforts to Identify Duplication and Use of Similar Information

This effort is not duplicative. NIOSH is the only federal entity that conducts research to improve occupational safety and health. Within NIOSH, there are no other currently funded projects approved addressing the research area of reproductive health in nail technicians, and no similar information has been gathered by or maintained by NIOSH or other Federal agencies, nor is the information available from other known sources.

5. Impact on Small Businesses or Other Small Entities

Almost all nail salons are small businesses employing fewer than 10 employees (Sharma et al. 2018). The results of this study and use of the data collection instrument will primarily benefit small nail salons, which are often owned by nail technicians, and their employees. Data collection will be performed with the needs of small salons in mind in order to reduce burden on these small businesses and their employees. Participation in this information collection request is voluntary and does not impose an ongoing burden to small businesses. The average burden for any stakeholder will not exceed 20 to 30 minutes.

6. Consequences of Collecting the Information Less Frequently

This information request is for a one-time data collection from each individual and will be time-limited and conducted only over the two-day period of exposure assessment. No follow up information will be collected. The data collection activities will not take longer than 3 years to complete from inception of information collection to the conclusion of data collections and development of the Job Exposure Matrix (JEM). There are no legal obstacles to reducing the burden.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances with this information collection package. This request fully complies with the regulation 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A. A Federal Register Notice was published for the generic information collection The Federal Register notice was published for this collection on July 22, 2022, Vol. 87, No.140, pp. 438360. No public comments were received.

B. The project concept has been shared and discussed with multiple external partners, including VietLead, a Vietnamese community-based organization in Philadelphia, PA; the University of Michigan; and Drexel University. The data collection instrument was developed with feedback from other researchers within NIOSH and the University of Michigan.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts for completing either data collection.

10. Protection of the Privacy and Confidentiality of Information Provided by Respondents

ISSO determined in conjunction with the CDC Privacy Office that Privacy Act is not applicable. The collection contains PII with demographic information in the survey (i.e., Age, Race, Ethnicity and Gender).

Research Electronic Data Capture (REDcap) and Modernization Platform for NIOSH (MPN) include the in-place technical, physical, or administrative controls (safeguards).

Research Electronic Data Capture (REDcap) and Modernization Platform for NIOSH (MPN) System Security Plan (SSP) defines the process for handling security incidents. The system's team and the Cybersecurity Program Office (CSPO) share the responsibilities for event monitoring and incident response. Direct reports of suspicious security or adverse privacy related events to the component's Information Systems Security Officer (ISSO), CDC helpdesk, or to the CDC Security Incident Response Team (CSIRT). The CDC CSPO reports to the HHS Computer Security Incident Response Center (CSIRC), which reports incidents to US-CERT as appropriate.

The information collected for the project will be maintained or stored locally under strict access controls limited to the local project leader/manager or his/her designate. Under no circumstances will an individual be identified using a combination of variables such as gender, race, birth date, and/or other descriptors. Once the targeted number of respondents is reached or the data collection period is

completed, the questionnaire and feedback form will be closed so that the number of respondents will not exceed the target number of respondents specific to each study.

Participation in the activities is strictly voluntary. Participants will be informed of their right to refuse to participate, end the questionnaire and/or feedback form at any point, or skip questions. They will also be informed of the purpose of the study and potential uses of the data. The participants will not be asked to disclose any private business information.

Electronic data collection and data management systems used for these activities will comply with the current encryption security standards from National Institute of Standards and Technology (NIST) Federal Information Processing Standards (FIPS), which meet or exceed Advanced Encryption Standards (AES).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

IRB Approval
The proposed data collection was reviewed and approved by the NIOSH Human Research Protection Program (Attachment 4).

Sensitive Questions
Due to the focus of this study on reproductive health outcomes among nail technicians, this questionnaire will collect potentially sensitive information on race and ethnicity as well as reproductive health topics such as past pregnancy outcomes and practices such as breastfeeding. 81% of nail technicians are female, yet reproductive health outcomes in this population have only been studied anecdotally or retrospectively, with no contextual or exposure assessment data collected in this area.

The questionnaire also asks about whether participants were born in the United States, whether participants are currently pregnant, and current marital status. Participants are given the option to select "Prefer not to answer" for these three questions. These questions are included because this information is relevant to guide this study and future research on the topic, as 76% of nail technicians are Asian and 79% are immigrants (Sharma et al. 2018).

Because over two-thirds of nail salon workers are of Asian descent, questions pertaining to race/ethnicity are asked with the minimum categories for all options except Asian to reduce burden to participants. For those respondents who select Asian as an answer, more detailed categories will be available as choices due to the large fraction of nail salon employees who are specifically of Vietnamese descent. Although SPD 15 guidance typically requires an all-or-nothing approach, the study population is unique in that the majority of workers are women of Asian descent who are either immigrants or children of immigrants, and within the broader category of Asian as a race, ethnicity (e.g., Vietnamese, Filipino, etc.) has been shown to be a determinant of both exposure and health in the nail salon worker population. Most nail salon workers in the United States are Vietnamese, and this information is essential for researchers to adequately characterize and analyze results. According to the Bureau of Labor Statistics, in 2023, 65% of manicurists and pedicurists were Asian, 24% were white, 6% were Black, and 14% were Hispanic or Latino. This study has a small sample size of about 40, so among the participants enrolled in this study, we don't anticipate having enough participants who do not identify as Asian to conduct any statistical analysis based on racial data collected at a more granular level than the minimum categories. Not collecting this information is also supported by existing research on salons, which has found disparities in nail salon workers by the minimum categories of race (white, Black,

Asian, etc.) and between different categories within Asian (Vietnamese compared to other categories), but not within different categories for other races. For this reason, to reduce the burden to participants and to avoid collecting data that will not be used in analysis, more detailed race information will only be collected for participants of Asian descent.

All personally identifiable information collected in this study is protected by a Certificate of Confidentiality under the Public Health Service Act. All sensitive information collected during the study will be safeguarded by CDC in a secure manner and will not be disclosed, unless otherwise compelled by law.

12. Estimates of Annualized Burden Hours and Costs

The annualized response burden is estimated at 6 hours for the study population to complete the instrument with an estimate of 12 respondents per year. It is estimated that it will take approximately 15-20 minutes for each respondent to complete the questionnaire and 5-10 minutes for the feedback form. All respondents will complete both instruments once during the site visit.

Exhibit A.12 Annualized Burden Hours

Type of Respondent	**Form Name**	**No. of Respondents**	**No. of Responses per Respondent**	**Average Burden Per Response (in hours)**	**Total Burden (in hours)**
Nail Technician	Questionnaire	12	1	20/60	**4**
Nail Technician	Feedback Form	12	1	10/60	**2**
Total					**6**

A.12.B Estimated Annualized Costs

The annualized cost to the respondents is segmented in Exhibit A.12.B, with total respondent cost estimated at $64.56. The Bureau of Labor Statistics National Occupational Employment and Wage Estimates for May 2022 was used to estimate the average hourly wage rate for Occupational Code 39-5092: Manicurists and Pedicurists (https://www.bls.gov/oes/current/oes_nat.htm).

Exhibit A.12.B. Annualized Cost to Respondents

Type of Respondent	**Form Name**	**Total Burden Hours**	**Hourly Wage Rate**	**Total Respondent Cost**
Nail Technician	Questionnaire	4	$16.14	$64.56
Nail Technician	Feedback Form	2	$16.14	$32.28
Total				$96.84

13. Estimates of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no other costs to respondents or record keepers. There will be no direct cost to the respondents other than their time to participate in the data collection activity.

14. Annualized Cost to the Government

Exhibit A.14 presents the personnel costs of federal employees involved in program management, data collection, and analyses to the government. The annual cost is estimated at $10,276 for 3 years.

Exhibit A.14. Annualized Cost to The Government

Expense Type	**Expense Explanation**	**Annual Costs (dollars)**
Direct Costs to the Federal Government		
	CDC Project Officer (GS-11, 0.10 FTE)	$7,198
	CDC Epidemiologist (GS-13, 0.03 FTE)	$3,078
	Subtotal, Direct costs	$10,276
	TOTAL COST TO THE GOVERNMENT	**$10,276**

15. Explanation for Program Changes or Adjustments

This is a new generic information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Individual data collections under this generic approval will be time-limited and conducted only once. Final results will not be published and will be used internally to improve future data collection instruments.

Exhibit A.16. Project Time Schedule

Activity	Time Schedule
Site Visit #1	2-3 months after OMB approval
Site Visit #2	14-15 months after OMB approval
Site Visit #3	26-27 months after OMB approval
Analyses of Exposure Data and Review of Questionnaire Responses; Construction of Job Exposure Matrix	34-35 months after OMB approval

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

References

Siegel, M. R., Rocheleau, C. M., Broadwater, K., Santiago-Colón, A., Johnson, C. Y., Herdt, M. L., . . . Lawson, C. C. (2022). Maternal occupation as a nail technician or hairdresser during pregnancy and birth defects, National Birth Defects Prevention Study, 1997–2011. *Occupational and Environmental Medicine*, *79*(1), 17. doi:10.1136/oemed-2021-107561

Sharma, P., Waheed, S., Nguyen, V., Stepick, L., Orellana, R., Katz, L., . . . Lapira, K. (2018). *Nail Files: A Study of Nail Salon Workers and Industry in the United States* Retrieved from https://www.labor.ucla.edu/publication/nail-files/