Supporting Statement A For:

Generic Submission for Technology Transfer Center (TTC)

External Customer Satisfaction Surveys (NCI)

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The Technology Transfer Center (TTC) of the National Cancer Institute (NCI) is part of the NCI Office of Management, which reports to the Office of the NCI Director. The TTC, formerly known as the Technology Development and Commercialization Branch (TDCB) and the Office of Technology Development (OTD), was established in January of 1988 to address the mandate set forth in the Federal Technology Transfer Act of 1986. Its current mission is to provide a complete array of services to support the technology transfer activities of NIH research scientists. The NCI TTC provides technology transfer services to NCI as well as to nine other NIH Institutes and Centers (I/Cs) under a Competitive Service Center (CSC) agreement.[1]

TTC activities include the following:

- Negotiate biomedical co-development research collaboration agreements between the NIH and outside parties, including universities, pharmaceutical and biotechnology companies;
- Review employee invention reports and make recommendations concerning filing of domestic and foreign patent applications;
- Facilitate collaborative research and technology transfer by conducting marketing campaigns for NIH researchers to help identify potential research co-developers; and
- Educate the NIH community about technology transfer, intellectual property, and other relevant regulations and processes.

[1] Center for Information Technology, Clinical Center, National Center for Complementary and Alternative Medicine, National Eye Institute, National Institute of Neurological Disorders and Stroke, National Institute on Aging, National Institute on Child Health and Human Development, National Institute on Drug Abuse, National Library of Medicine

In FY 2009, NCI technology transfer produced a total revenue stream of $57.1 million, which includes $51.6 million in royalties from licenses on NCI technologies (including inventors' shares) and $5.5 million from Cooperative Research and Development Agreements (CRADA). The funds received from CRADAs support a portion of NCI's research costs. Significant tangible and intangible benefits to NIH and public health can be realized through increased TTC efficiency in negotiating agreements and effectiveness in outreach efforts and communications.

Following a survey of NIH staff members in 1999, TTC established process improvements to improve the services it provides to its constituents. A second survey of researchers was conducted in 2006 for the NIH Office of Technology Transfer by Pursuant, Inc.[2] In 2008, NIAID surveyed NIH Clinical Center researchers for barriers to clinical research at the NIH[3]. These inputs continue to help TTC determine the extent to which changes made in 2000 achieved their goals, and to establish new goals.

Continuous improvement in services is critical, as this is a period of significant change in the biotechnology and pharmaceutical industries, driven by factors such as genomics, information technology, health economics, and globalization. Not yet fully understood is how this strategic, global trend in the market environment will affect the transfer of discoveries from NIH to the public. In contrast with the previous internally-focused survey efforts, the current study is designed to assess needs and attitudes of external customers (i.e., industrial biotechnology, pharmaceutical, and medical device companies) who are current and potential collaborators and licensees for NIH technologies and who have a strategic view of their needs

[2] Final Report "NIH Scientists' Role in Technology transfer: Findings from Qualitative and Quantitative Research," National Institutes of Health, Office of Technology Transfer, by Pursuant, Inc., June, 2006.

[3] Jorge Tavel (NIH/NIAID) and Betsey Herpin (NIH/NIAID) examined barriers to clinical research at the NIH via a survey commissioned by the Intramural Working Group and the MEC.

with respect to research collaborations. The TTC and the NIH technology transfer community have yet to conduct a comprehensive study to define its key external audiences and their critical performance needs, especially in terms of customer satisfaction, preferred communications channels, and the building of strategic alliances. This generic submission will enable the NCI TTC to update the process improvement goals it established following internally-focused surveys. Surveys of external customers will identify new priorities and allow formulation of goals based on customers' stated, rather than presumed, needs. Expected outcomes include higher performance obtained from greater efficiency and effectiveness in technology transfer, and therefore translation to the clinic, including:

- TTC workflow process improvements;
- Increased NCI TTC productivity in negotiating technology transfer agreements and in outreach efforts;
- More focused marketing of NIH discoveries to external customers;
- Better communication of industry needs to NIH scientists.

The 2007-2011 goals set forth in TTC's Business Plan include obtaining a better understanding of the needs of TTC's customers, and this is best attained by conducting a variety of surveys of the external customer segments of the NCI TTC. The purpose of the Technology Transfer Center (TTC) surveys is to gather critical information in three areas: (1) a detailed assessment of the biotechnology/pharmaceutical industry's strategic trends in establishing co-development partnerships, (2) its satisfaction with TTC's services, and (3) its expected and preferred communications channels. The universe of potential survey participants encompasses companies that conduct research and development in biomedical applications: pharmaceutical and biotechnology therapeutics, diagnostics, prognostics, medical devices, and software. The

survey universe (target population) will include companies who have utilized the services of the NCI TTC, “non-users” of TTC services, and those who have inquired about using TTC services. The results of the surveys will be used to strengthen the operations of the NCI TTC, including the Competitive Service Center. Specifically, new data on customer needs will be used to assess progress relative to existing process goals, revise them as necessary, and establish new goals and priorities for meeting customer needs.

Section 411 of the Public Health Service Act (42 USC 285a) authorizes the collection of the information and states:

> "The National Cancer Program shall consist of (1) an expanded, intensified, and coordinated cancer research program encompassing the research programs conducted and supported by the Institute and the related research programs of the other national research institutes, including an expanded and intensified research program for the prevention of cancer caused by occupational or environmental exposure to carcinogens, and (2) the other programs and activities of the Institute." And
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> "The Director of the Institute in carrying out the National Cancer Program—(4) shall encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research.” (Section 413, 42 USC 285a-2)

A.2 Purpose and Use of the Information

The objectives of the Technology Transfer Center External Customer Satisfaction Surveys are to:

- Obtain information on the satisfaction of TTC’s external customers with TTC customer services;
- Collect information of preferred and expected communications channels of TTC’s external customers; and
- Assess the strategic direction of companies engaging in collaborations and alliances with the NIH.

The Technology Transfer Center (TTC) has developed the first consent form and satisfaction survey (**Attachment 1)** for this generic submission, which will collect the following information:

- Respondent/company information: respondent's current position in the company; company type; location of parent company; number of employees.
- Strategic direction of the company: whether they develop strategic technology collaborations[4]; types of strategic technology collaborations; research collaborations formed in the last two years; research collaborations anticipated in the next two years; factors important to selecting a research partner; methods for finding new research partners; types of research partnerships developed within the past two years; state of research and development of research collaborations formed in the past two years; collaborations formed with off-shore organizations; and reasons for seeking off-shore collaborations.
- Experience with the NIH Technology Transfer services: level of familiarity with NIH Technology Transfer Services; how they learned about the NCI TTC; factors leading to not partnering with NIH researchers; factors leading to partnering with NIH; types of agreements completed; level of satisfaction with the length of time required to negotiate the agreement; feedback process; level of satisfaction with various aspects of the NCI technology transfer process; how they locate NIH research partners for potential collaborations; types of information the respondent would like to receive from the NCI TTC; preferred method of receiving NCI TTC information; additional TTC services that would be useful to meet the company's technology transfer needs.

[4] For the purpose of this survey, collaborations are defined as strategic alliances for co-development of technologies but not licensing or contractual relationships.

Subsequent surveys will be proposed based on the results of the initial survey. Additional surveys may include specific questions in one area and/or surveying a slightly different population that had not been initially envisioned.

The needs of external technology transfer customers and stakeholders have not been assessed systematically. Input from these groups is essential for defining workflow process improvements for services provided by the NCI TTC to the private sector research community. As stated in A1, the recent past has been a period of unparalleled change in the biomedical sciences, driven by technical factors such as genomics and information technologies as well as macroeconomic factors such as outsourcing and globalization. Taken together, these factors represent a fundamental change in the market environment. As the NIH is a principal supplier of basic science to "extend healthy life and reduce the burdens of illness and disability," the ability of the TTC to adapt to meet these market challenges is critical to the lifecycle development of the initial discoveries.

The results of this study will be reported in a comprehensive evaluation report that will summarize the findings and provide sufficient description of the study background and methodology. The results will be disseminated to multiple audiences including staff at the NCI Technology Transfer Center, the Technology Development Coordinators (TDCs) at NIH Institutes and Centers (I/Cs) that use the Competitive Service Center, technology transfer staff at non-client I/Cs, at the NIH Office of Technology Transfer, and to the Public Health Service Technology Development and Transfer Committee (TDTC) Marketing Working Group. Results may also be presented to the technology transfer community at a public conference and/or published as an article in a professional journal.

The results will be used to strengthen the operations of the NCI TTC, including the Competitive Service Center. Specifically, new data on customer needs will be used to assess progress relative to existing process goals, review them as necessary, and establish new goals and priorities for meeting customer needs. In addition, the TDTC Marketing Working Group can utilize the survey results to develop communications strategies for their ICs, since the external customer information will apply generically to their focus areas. The TDTC will also be able to infer workflow improvements from the customer-provided information on customer satisfaction since many of the processes are similar to the NCI TTC's.

A.3 Use of Improved Information Technology and Burden Reduction

This study will collect new information from external TTC customers primarily via web-based surveys. Subsequent surveys may be administered by other means, if deemed appropriate and cost-effective. In addition to results of the surveys, archival information sources such as NIH databases, commercial subscription databases, and corporate websites will be used to obtain additional background information about survey respondents and non-respondents.

For the first generic information collection (Gen IC) sub-study (included in this request), an advance notice ("announcement") (**Attachment 2**) will be sent via postal mail by the NCI Project Officer to the survey population six weeks after survey approval from OMB and two weeks prior to opening the survey web site to the survey population. One week later an e-mail version of the invitation will be sent (also **Attachment 2**). A second e-mail "invitation" (**Attachment 3)** will be sent by the Contractor to the survey population via e-mail one business day after the survey web site has been launched. An e-mail "reminder to participate" (**Attachment 4**) will be sent by the Contractor to all survey non-responders two weeks after the

web survey site goes into production. A second e-mail reminder will be sent by the Contractor to non-responders one week prior to the last day the survey will be available for use (**Attachment 5**). A final reminder will be sent to non-responders by the Contractor one day before the survey closes (**Attachment 6**). Details of the announcement, invitations, and reminders (if used) will be included in the justification memos for subsequent generic IC sub-studies under this clearance.

Most surveys will be administered electronically through a commercial web-based survey site (SurveyGizmo). The use of web-based technology for the first generic sub-study survey was selected to reduce respondent burden, reduce costs, and improve data quality. Answering a set of questions via web-based surveys requires half as much time as answering the same set of questions via telephone surveys[5]. Data collection using web-based technology can improve data quality since validation checks can be incorporated into the instrument. In addition, because data are entered electronically, errors in data entry and coding are avoided. Many consumers now prefer the convenience of web-based surveys because they can be completed at a comfortable pace and at a time convenient for the respondent.

Two disadvantages sometimes ascribed to web-based surveys are lower response rates and issues related to reliability and validity of data. Response rates for paper based and CATI surveys have been rapidly falling over the last two decades[6] . Conversely, response rates for web-based surveys have been growing with increasing internet usage among the general public[7]. Research comparing response rates among web-based, mail, and telephone surveys has traditionally found that response rates are generally lower for web-based surveys than for mail or

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[5] Van Gelder M.M.H.J., Bretveld RW, and Roeleveld N. (2010). Web-based Questionnaires: The Future in Epidemiology? American Journal of Epidemiology Advance Access published September 29, 2010, doi: 10.1093/aje/kwq291

[6] Curtin R, Presser S, Singer E. (2005). Changes in Telephone Survey Nonresponse over the Past Quarter Century. Public Opinion Quarterly 69(1):87-98.

[7] Kaplowitz M D*, Hadlock T D, Levine R. (2004). A Comparison of Web and Mail Survey Response Rates. Public Opinion Quarterly 68(1):94–101

telephone surveys; however, a meta-analysis of more recent studies has found that on average, web-based surveys yield only an 11% lower response rate compared to other modes (95% confidence interval 6%-15%) and that response rates are greatly increased when using targeted e-mail invitations[8]. In addition, response rates have been found to be greater among highly educated individuals such as our survey population[9]. With regard to the reliability and validity of data, web-based surveys are superior to computer assisted telephone interviews (CATI) in terms of their ability to moderate the effect of the interviewer on influencing social desirable responses[10]. Studies comparing methodologies have found that web-based surveys had the lowest rate of missing data items and CATI the highest[11]. Web-based surveys are noted by many studies for delivering better verbatim responses than CATI surveys. Several studies argue that the quality of data collected through web-based surveys is generally higher than through CATI due to the respondent's ability to re-read questions, elimination of time constraints or pressure, and completion at convenient times[12]. Studies using external data verification have found that web-based surveys have the highest levels of reporting accuracy and CATI the worst[13]. Based on the literature cited, we are confident that the response rate will be adequate and the data collected will be reliable and valid.

The survey websites will include an explanation of the purpose of the survey and will display a valid OMB control number. A Privacy Impact Assessment (PIA) has been entered into

[8] Manfreda, K L, Bosnjak, M, Berzelak, J, Haas, I, Vehovar, V. (2008). Web Surveys Versus Other Survey Modes: A Meta-analysis Comparing Response Rrates. International Journal of Market Research; 50(1):79-104.

[9] Braithwaite D, Emery J, De Lusignan S, et al. (2003). Using the Internet to conduct surveys of health professionals: a valid alternative? Fam Pract. 20(5):545–551.

[10] Kreuter F, Presser S, Tourangeau R. (2008). Social Desirability Bias in CATI, IVR, and Web Surveys: The Effects of Mode and Question Sensitivity. Public Opinion Quarterly 72(5):847-865; doi:10.1093/poq/nfn063

[11] ibid

[12] Kwak N, & Radler B. (2002). A Comparison Between Mail and Web Surveys: Response Pattern, Respondent Profile, and Data Quality. Journal of Official Statistics 18: 257-273.

[13] Tourangeau R, Yan T. (2007). Sensitive Questions in Surveys. Psychological Bulletin 133:859–83.

the electronic system, reviewed and completed at the NCI level and was promoted for NIH review on October 7, 2010. The full name of the IT system associated with the data collection is "NIH NCI Technology Transfer Center (TTC) Online Customer Survey" (**Attachment 11**). No Information in Identifiable Format (IFF) will be collected using this IT system. A secure URL and a password will be provided to respondents to access the online surveys. This website will not be available to the public. The survey instruments will comply fully with standards followed by Federal agencies when producing web pages and hardcopy surveys (e.g., Section 508 ref. http://www.section508.gov/ and NCI Web Policies on http://www.cancer.gov/policies/page3), and validated using accessibility testing tools and follow survey design best practices, for example as indicated in http://lap.umd.edu/survey_design/questionnaires.html.

A.4 Efforts to Identify Duplication and Use of Similar Information

The needs of external technology transfer customers and stakeholders have never been assessed systematically. Input from these groups is essential for defining workflow process improvements for services provided by the NCI TTC to the research community. These surveys will fill a critical knowledge gap between NIH's external customers and NIH researchers.

A.5 Impact on Small Businesses or Other Small Entities

The survey population consists of corporate managers and executives at small and large for-profit companies that conduct biomedical research and development in therapeutics, diagnostics, prognostics, medical devices, and software. Additionally, directors or managers at foundations and non-profit organizations will be surveyed. Although all the surveys require the full range of information from all respondents, several of the questions may not apply to small

companies and the respondent can therefore skip those questions. The information being requested has been held to the minimum required for the intended use.

A.6 Consequences of Collecting the Information Less Frequently

The proposed generic submission study will have different types of respondents complete the Technology Transfer Center External Customer Satisfaction Surveys over a three-year time frame. It is anticipated that initial data will result in areas where additional exploration of different types of respondents will want to be surveyed and analyzed and thus the reason subsequent rounds of currently, undetermined surveys.

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

No special circumstances are anticipated.

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

The 60-Day Federal Register notice soliciting comments on this study prior to initial submission to OMB was published on December 23, 2010 (75 FR 80830). No public comments were received. Additionally based on NIH's suggestion, a corrected Federal Register notice was published on during the week of February 14, 2010 to account for the proposed generic submission.

The Evaluation of the National Cancer Institute, Technology Transfer Center study was developed with consultation from a number of scientists throughout the development period (5/16/2007 to 03/01/2009) and throughout the course of the study. The initial survey

(Attachment 1) was reviewed by experts in qualitative data collection and cognitive psychology. It was pre-tested to ensure validity, usability, and functionality. The study maintains an Advisory Committee that will meet three times during the course of the evaluation to discuss the design, conduct, and analyses for the study; evaluate Contractor deliverables and progress in the study; and make recommendations for improvements and approve changes. The Advisory Committee consists of a Chairman from the NCI Technology Transfer Center who is also the Project Officer, a Technology Transfer Specialist from the NCI Technology Transfer Center; the Scientific Program Coordinator from the NCI Office of Science Planning and Assessment; a Mathematical Statistician from the NCI Division of Cancer Control and Population Sciences; a marketing specialist from the NCI Office of Communications and Education; and the Lead Public Health Advisor from the NCI Office of Communications and Education (list of members in **Attachment 7**).

A.9 Explanation of Any Payment or Gift to Respondents

Participants responding to this questionnaire will not receive remuneration for their participation.

A.10 Assurance of Confidentiality Provided to Respondents

The information collected in this study is not subject to the Privacy Act (see **Attachment 8 for NIH Privacy Act Officer's Letter**). The initial generic sub-study survey instrument includes a Consent Form (**Attachment 1**), and participants will indicate their consent in the completion and submission of their questionnaires. Subsequent requests will include a consent form with the survey.

The data from the web-based surveys will be placed on a secure server and will be password protected. This website will not be available to the public. All computerized data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Chapters 6-30 and 6-35. No reports or data files will contain personal identifiers.

All contract staff members working on the study are required to sign a statement pledging to maintain the confidentiality of all data. Access to study data is limited to the staff working on the study. All respondents are told their responses will be kept secure, to the extent permitted by law. The data from this study will be maintained until the completion of the study or until no longer required for the research. Data will be destroyed as required by NIH Manual 1743 - Keeping and Destroying Records.

The National Institutes of Health, Office of Human Subjects Research (OHSR) conducted a Review of Research Activity Involving Human Subjects and determined on July 21, 2010 that the Technology Transfer Center External Customer Satisfaction Surveys (NCI) were exempt, in accordance with 45 CFR 46 (Exempt No. 5301). A copy of the OHSR exemption approval is found in **Attachment 9**.

A.11 Justification for Sensitive Questions

The Technology Transfer Center External Customer Satisfaction Surveys (NCI) do not collect any personally identifiable information (PII) or ask any "sensitive" or company-confidential questions.

A.12 Estimates of Annualized Burden Hours and Costs

a. Annual Burden Hours. Table A.12-1 describes the estimates of the respondent burden for completion of the Technology Transfer Center External Customer Satisfaction Surveys. The initial survey contains 38 questions and depending upon the respondent's answers, and the skip patterns built into the survey, a respondent may be asked to answer between 10 and 34 questions. The burden to complete this survey is estimated to range from 15-20 minutes. It is estimated that subsequent surveys will be about the same length.

It is estimated that TTC will survey 4,000 respondents, which will take approximately 1,333 hours over a three-year approval period.

Table A.12-1: Estimates of Burden Hours for Generic Submission (3-year time frame)

Type of Respondents	Instrument	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Total Hour Burden
Executives, Managers, and Directors at Foundations, Non-Profits and For-Profit Organizations	Survey (Attachment 1)	4,000	1	20/60 (0.33)	1,333
Total		4,000			1,333

b. Annualized Costs to Respondents. At $69.08[14] per hour, the total estimated cost to respondents is $92,107 (Table A.12-2) over the three-year data collection period.

[14] http://www.bls.gov/oes/current/oes_nat.htm The hourly wage rate is the average of the mean hourly rate for Chief Executives ($80.43-Occupation Code 11-1011) and Marketing Managers ($57.73-Occupation Code 11-2021).

Table A.12-2: Cost to Respondents for Generic Submission (3-year time frame)					
Type of Respondents	Number of Respondents	Frequency of Response	Average Time per Response (Minutes/Hour)	Hourly Wage Rate	Total Respondent Cost
Executives, Managers, and Directors at Foundations, Non-Profits and For-Profit Organizations	4,000	1	20/60	$69.08	$92,106.66

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

There are no direct costs to record keepers or respondents other than their time to participate in the study.

A.14 Annualized Cost to the Federal Government

The total cost to the government for the services of the study Contractor for the initial survey is estimated to be $327,029 over a three year period (Table A.14-1). These costs include survey design and pre-testing (see Supporting Statement B, Section B4), preparation of the draft OMB Clearance package, fielding the survey (including response tracking, coding and processing the data, and delivery of final data files), and data analysis and reporting. Additional costs will be $90,000 after the first survey, since subsequent surveys exclude much of the preliminary labor associated with the first survey. Subsequent survey costs will consist of fielding the survey, data analysis, and reporting.

NCI staff time required to participate in planning and design activities, monitoring the study, and in analysis of this data is estimated to average .20FTE for scientific staff. The total

NCI labor corresponds to a total cost of $79,971, or an annualized cost of $26,657. The estimated annualized cost to the government to complete several surveys is $135,667 or $407,000 over a three-year period.

The overall government distribution is summarized in the following table:

Table A.14-1 Government Cost Distribution

	ANNUAL AVERAGE	TOTAL COST OVER 3 YEAR APPROVAL PERIOD
Contractor Costs	$109,010	$327,029
NCI Personnel Subtotal	$26,657	$79,971
Total	$135,667	$407,000

A.15 Explanation for Program Changes or Adjustments

This is a new data collection.

A.16 Plans for Tabulation and Publication and Project Time Schedule

The project schedule for completing data collection, processing, and analysis is presented in Table A.16-1.

A.16 - 1 Project Time Schedule	
Activity	**Time Schedule**
Advance notice letters sent from NCI to respondents	**1 - 4 months after OMB approval**
E-mail correspondence sent by the Contractor	**4 - 6 months after OMB approval**
Field questionnaire	**7 - 9 months after OMB approval**
Data Cleaning and Storage	**10 - 14 months after OMB approval**
Data Analyses	**15 - 18 months after OMB approval**
Semi-Final Report	**20 months after OMB approval**
Additional Surveys (following same activities as above)	**To start at approximately at 21 months after OMB approval**
Final Report	**36 months after OMB approval**

Data analysis will include quantitative and semi-quantitative (categorical) data analysis, including descriptive and analytical statistics as appropriate. Analyses performed by the Contractor will include:

1) Range and distribution of responses for each question.
2) Summary of external customer demographics (e.g. type of company; location of parent of headquarters; number of employees.
3) Cross-tabulation of demographics and instrument response variables.
4) Multivariate analyses to determine predictors of response.

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

The Technology Transfer Center External Customer Satisfaction Surveys (NCI) instrument will display the OMB expiration date.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

No exceptions to the Certification for Paperwork Reduction Act Submissions are requested.