Mini Supporting Statement A For
"A Generic Submission for Formative Research, Pretesting, and Customer Satisfaction of NCI's Communication and Education Resources"
OMB No. 0925-0046-09, Expiration Date 05/31/2016

Title of Sub-Project: Customer Satisfaction Surveys of Participants in the New National Cancer Institute's Experimental Therapeutics Clinical Trials Network (ETCTN)

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Attachments

Attachment #1: Principal Investigator Online Customer Satisfaction Survey

Attachment #2: Research Staff Online Customer Satisfaction Survey

Attachment #3: Invite and Reminder Emails

Attachment #4: OHSRP Determination Letter

Section A.

A1. Circumstances Making the Collection of Information Necessary

Sec. 410. [285] of the Public Health Service Act (42 USC *§* 285) authorizes the collection of the information. The information will be collected within NCI's Investigational Drug Branch (IDB), Cancer Therapy and Evaluation Program (CTEP) within the Division of Cancer Treatment and Diagnosis (DCTD), National Cancer Institute (NCI). The focus of the online satisfaction surveys (**Attachments 1 and 2**) proposed in this application are to assess satisfaction of the external grantees participating in NCI's new Experimental Therapeutics Clinical Trials Network (ETCTN), which began in April 2014 and will continue for five years with an annual budget of $10 million. ETCTN's purpose directly supports a principal mandate of the NCI ("To assess the incorporation of state-of-the-art cancer treatments into clinical practice") and a key NIH goal ("To foster fundamental creative discoveries, innovative research strategies, and their applications"). Given the resources invested by NCI to advance cancer research via early phase clinical trials, it is critical to seek input from grantees (both Principal Investigators and their research staff) in a systematic, private manner to hear how the program is working and where corrections are needed.

This fits under the scope of NCI's, "Generic Submission for Formative Research, Pretesting and Customer Satisfaction" to "determine the level of customer satisfaction with products that help NCI identify strategies for improving the accessibility of materials/programs, their user-friendliness, and their relevance to the needs of NCI grantees committed to carrying out the processes to conduct early phase cancer treatment trials. Systematic formative research and pretesting has been widely adopted by health education program planners as an integral step in the development and targeted dissemination of messages and materials" (OMB No. 0925-0046 Expiry 5/31/2016; Supporting Statement A, Section A.2, p. 5). Specifically, the in-depth interviews would contribute to the Division's communication strategy by, "understand the characteristics of the target audience … determined the best promotion and distribution channels … and expend limited program resource dollar wisely and effectively" (OMB No. 0925-0046 Expiry 5/31/2016; Supporting Statement A, Section A.2, p. 6).

A2. Purpose and Use of the Information Collection

Two online surveys will be used. One will collect information from principal investigators (PI) who are oncologists and researchers at organizations that have received ETCTN grants and are responsible for developing and running the program's clinical trials. The PI survey serves to collect information about their satisfaction with the ETCTN's implementation and processes; their perceived quality of scientific protocols developed; their reactions and experiences to the team-science approach; and their belief on how the program has affected their level of collaboration with peers (**Attachment 1**). The other survey will collect information for the organizations' clinical research staff (i.e., grant and site administrators, clinical research associates and registrars) and ask them their satisfaction with ETCTN processes and resources involved to submit and administer protocols (**Attachment 2**). The data will assist NCI leadership in determining if and where mid-course corrections are needed (i.e., where satisfaction might be low), what areas are working well (i.e., high satisfaction) and where needs or resources are unmet and could be improved to increase the program's reach and effectiveness. The surveys also will provide important data to the NCI leadership to guide their decision making in their development and planning of the ETCTN's subsequent Funding Opportunity Announcement (FOA) for another five years (i.e., what components of the ETCTN might need to be changed or improved in the FOA before seeking applications).

A3. Use of Information Technology and Burden Reduction

The collection of information will be done via online customer satisfaction surveys (**Attachments 1 and 2**). The respondents will be invited by email (**Attachment 3**) and an on-line link will be available to link to the surveys. The NCI Privacy Act Coordinator has been contacted and a Privacy Impact Assessment (PIA) is being sought for the Information Technology system that is being used to collect, store and transmit the data to ensure that it provides a documented process to identify and safeguard the personally identifiable information being collected.

A4. Efforts to Identify Duplication and Use of Similar Information

No similar collection of information exists and because the program is new, no other past data collection efforts have been done that could help NCI in this effort.

A5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

A6. Consequences of Collecting the Information Less Frequently

CTEP requests OMB approval to field the ETCTN customer satisfaction surveys at the end of the first and second year of the program's implementation. The rationale for the end of the first year is to be sure that if any substantial concerns are uncovered, they will be identified early in the program's rollout and can be addressed sufficiently. A second year of data will help identify whether any changes made after the first year resulted in greater satisfaction; it also will give NCI a better understanding of audiences' perceptions and satisfaction after they have had two years to experience the new program and settle in and to help the planning for a subsequent FOA which will be written in grant years 3 & 4 of the program. Without data, NCI will have to assume that the program is working well and as planned. Without two years of data, NCI will not know if changes made after the first year have been addressed sufficiently. Finally, NCI and NIH have repeatedly requested that programmatic funding decisions be evidence-based: the online customer surveys are a mechanism to help NCI fulfill this obligation.

A7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This project will be implemented in a manner that fully complies with the Guidelines of 5 CFR 1320.5.

A8. Comments in Response to Federal Register Notice and Efforts to Consult Outside Agency

No efforts have made to consult with others.

A9. Explanation of Any Payment or Gift to Respondents

No payment or gifts will be given to respondents.

A10. Assurance of Confidentiality Provided to Respondents

Participation is voluntary and there are no penalties for not participating or withdrawing from the study at any time. The information collected in this study will be kept private to the extent provided by law. Names and other identifiers will not appear in any report of the study. Information provided will be combined for all study participants and reported as summaries by the contractor, User-Centered Design, Inc. NIH's Office of Human Subjects Research Protections (OHSRP) reviewed this project and determined that federal regulations for the protection of human subjects does not

apply to the activity proposed in this SSA, as the activities are not considered research but are being done as a measure of quality improvement/assurance (see **Attachment 4**). We also are in the process of requesting a Privacy Act Memo from the NIH Privacy Act Officer.

A11. Justification for Sensitive Questions

Personally identifiable information (PII) is being collected. in the form of the respondent's education level, name and contact information.. No sensitive questions are being asked.

A12. Estimates of Hour Burden Including Annualized Hourly Costs

It is expected that 250 participants will be surveyed each year (total N =500) with each survey taking no more than 15 minutes to complete on each occasion. The total burden time to complete the study is 63 hours annually (Table A12-1). Respondents will be asked to respond to the survey twice, once per year, so that changes made after the 1st survey can be reassessed the following year (for further detail, refer to Section A.6, above). Thus the total burden is estimated to be 126 hours over two years.

Table A12-1. Estimates of Hour Burden

Type of Respondent	Number of Respondents	Estimated Frequency of Response	Participation Time (in hours)	Annual Burden Hours
Principal Investigator	75	1	15/60	19
Research staff	175	1	15/60	44
Totals	250	1	15/60	63

The mean hourly wage rate for Principal Investigators was based on occupation code #29-1060 (Physicians and Surgeons; http://www.bls.gov/oes/current/oes_nat.htm) at $92.25/hour and for Research Staff was based on occupation code #29-1141 (Registered Nurses; http://www.bls.gov/oes/current/oes291141.htm) at $33.13/hour (based on the May 2013 National Occupational Employment and Wage Estimates in the United States). The annual respondent cost is estimated to be $3,210.47, and $6,420.94 over the course of two years (Table A.12-2).

Table A12-2. Cost to Respondents

Type of Respondent	Number of Respondents	Annual Burden Hours	Wage Rate	Respondent Cost
Principal Investigator	75	19	$92.25	1,752.75
Research staff	175	44	$33.13	1,457.72
Totals	250	63		3,210.47

A13. Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

There are no capital costs, operating costs, or maintenance costs to report.

A14. Annualized Cost to the Federal Government

The annualized cost to the Federal Government is estimated to be $45,248 (Table A14-1). The costs are primarily associated with the contractor ($29,832). The cost of the Federal employee is estimated to be $15,416 annually as the Task Leader of the contractor carrying out the survey tasks and responsibilities. This project is anticipated to have two surveys, both will be conducted one year apart, and thus over two years it is anticipated that the total cost will be $90,496. Salaries are based on the January 2014 General Schedule for the Washington, DC Metropolitan area (http://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2014/DCB.pdf).

Table A14-1. Cost to the Federal Government

Staffing	Task	Annualized Cost
NCI	Senior Behavioral Research Scientist (GS 15/8; $154,160/annually at 10% time for 12 months)	$15,416
Contractor	Development of Database, Collecting Data, Cleaning Data, Sending Email, Running Reports, and Managing Data Tables	$29,832
		$45,248

A15. Explanation for Program Changes or Adjustments

This is a generic sub-study under OMB No. 0925-0046.

A16. Plans for Tabulation and Publication and Project Time Schedule

Plans for statistical analysis include summary, descriptive and comparison analyses. Summary scores will be calculated from the item-responses measuring the key survey concepts. Descriptive statistics (mean, median, standard deviation) will be calculated for each survey item. Comparisons (t-tests, ANOVA) will be made within groups for each year to examine potential differences and across the two years to examine changes in perceptions and/or satisfaction.

The project time schedule is outlined in Table A16-1.

Table A16-1. Project Time Schedule

Activity	Months after OMB Approval
Field survey for Year 1	1
Data collected	2
Data analyzed and report generated	3-4
Field survey for Year 2	13
Data collected	14
Data analyzed and report generated	15-16

A17. Reason(s) Display of OMB Expiration Date Is Inappropriate

The OMB Expiration Date will be displayed on the survey.

A18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the Certification for Paperwork Reduction Act Submissions.