

Supporting Statement A for

Generic Clearance to Conduct Formative Research (NIAID)

OMB Control No. 0925-XXXX

NEW

Date: November 30, 2017

Name: Brandie Taylor

Address: 5601 Fishers Ln

Telephone: 240.669.2096

Email: taylorbr@niaid.nih.gov

Table of contents

- A. JUSTIFICATION
- A.1 Circumstances Making the Collection of Information Necessary
- A.2. Purpose and Use of the Information COLLECTION
- A.3 Use of Information Technology and Burden Reduction
- A.4 Efforts to Identify Duplication and Use of Similar Information
- A.5 Impact on Small Businesses or Other Small Entities
- A.6 Consequences of Collecting the Information Less Frequently
- A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5
- A.8 Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency
- A.9 Explanation of Any Payment of Gift to Respondents
- A.10 Assurance of Confidentiality Provided to Respondents
- A.11 Justification for Sensitive Questions
- A.12 Estimates of Hour Burden Including Annualized Hourly Costs
- A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record keepers
- A.14 Annualized Cost to the Federal Government
- A.15 Explanation for Program Changes or Adjustments
- A.16 Plans for Tabulation and Publication and Project Time Schedule
- A.17 Reason(s) Display of OMB Expiration Date is Inappropriate
- A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Attachments

Appendix 1- Sub-study application

Appendix 2 - Privacy Act Applicability (PAA) Memo

A. Justification

NIAID is requesting OMB approval for information collections to improve research approaches and final product development to identify emergent infectious disease threats and comorbidities related to the needs of diverse audiences. The National Institute of Allergy and Infectious Diseases is charged with the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases and disorders. The Evaluation Section of the Strategic Planning and Evaluation Branch (SPEB) at NIAID conducts various types of research, analyses, and assessments to identify and learn about target audience programmatic needs, and gaps. The activities conducted by the Evaluation Section of SPEB helps to ensure that NIAID communicates, educates, and disseminates appropriate, useful and effective resources. The information to be collected as part of this generic clearance will allow the agency to make appropriate adjustments in content and methods used in developmental and testing stages, including peer-review, in order to improve research approaches and final product development.

A.1 Circumstances Making the Collection of Information Necessary

NIAID is requesting OMB approval for information collections to improve research strategies and final product development in an effort to identify emergent infectious disease threats and comorbidities related to needs of diverse audiences. The authority to collect this information is under 42 USC 285f National Institute of Allergy and Infectious Diseases (NIAID). The National Institute of Allergy and Infectious Diseases is charged with the conduct and support of research, training, health information dissemination, and other programs with respect to allergic and immunologic diseases, disorders, and infectious diseases, including tropical diseases. To this end, NIAID conducts research and evaluations, including feasibility and evaluation design studies, needs assessments, process evaluations, and outcome and impact assessments.

The Evaluation Section of the Strategic Planning and Evaluation Branch (SPEB) at NIAID conducts various types of research, analyses, and assessments to identify and learn about target audiences, programmatic needs, and gaps. Specifically, SPEB conducts market, stakeholder, and user-centered research and evaluations to inform the design and development of NIAID resources to ensure they are effectively and appropriately reaching the intended audiences. These activities include, but are not limited to:

- Assessing audience trends utilizing various qualitative methodologies, including focus groups, interviews, and ethnographic studies.
- Assessing the relevance and appropriateness of resources and activities for target audiences via qualitative methods.
- Developing accurate metrics, materials, and resources based upon audience needs using qualitative methods and surveys.

The activities conducted and supported by the Evaluation Section of SPEB helps to ensure that NIAID communicates, educates, and disseminates appropriate, useful and effective resources. Results of these projects may not be disseminated beyond the institute as determined by programmatic need.

A.2 Purpose and Use of the Information Collection

The information to be collected as part of this generic clearance will allow the agency to make appropriate adjustments in content and methods used in developmental and testing stages, including peer-review, to improve research approaches and final product development. Outcomes will not be employed to influence or directly inform significant policy or determination/allocation of grant funding. Outcomes are primarily intended for internal agency use in the further development of materials, resources, and projects.

A full supporting statement part A and B, along with all accompanying instruments and documentation will be submitted for each information collection (IC) submitted under this generic.

A.3 Use of Information Technology and Burden Reduction

To the extent possible, data collection will employ automated or electronic methods. These collections may utilize electronic platforms such as Dedoose, Qualtrics, and Survey Monkey. Exceptions will include data collection methodologies which may not lend themselves to electronic data capture, such as focus groups, market research, and interviews.

On-line surveys represent an especially convenient option for eliciting feedback from consumers of Web-based products. Respondents complete online surveys regarding a product or topic under study and then submit the data electronically over the Internet. With online surveys, respondents can easily submit feedback during or immediately after using a Web-based product. They also allow participation from international audiences with virtually no additional costs.

This work may be conducted on IT systems owned, operated and controlled outside the NIH network by non-Government entities. **This data collection will not collect personally identifiable information (PII). A Privacy Act Applicability (PAA) memo is attached.** If any ICs submitted under this generic should collect PII, the package will include a thorough discussion of the applicability of the Privacy Act and associated privacy policies.

In accordance with HIPAA laws, and as appropriate, studies performed under this clearance may seek a waiver of consent to screen patient's medical records prior to enrollment for eligibility criteria when appropriate. This will reduce the burden of the researcher and streamline the process for identifying eligible patients.

If any information is collected subject to HIPAA, all participants will be appropriately notified of their rights under HIPAA, which will be documented in each IC submitted under this generic. After screening is completed, informed consent will be documented by all respondents who participate in any of the studies within this collection.

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

NIAID staff have searched clinical trials.org and reginfo.gov for similar studies and activities.

There are no other efforts to collect similar data. Assessments conducted under this generic clearance will not duplicate other studies because of the unique nature of the work conducted at and supported by NIAID.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved as respondents; therefore, there is no impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

NIAID must have timely information to ensure it is reaching the appropriate audiences and providing them with necessary materials, information, and products. Less frequent submissions would decrease the efficacy of resources, tools, and interventions. Research has illustrated that formative input and testing during development is crucial to the acceptance of materials and the delivery of services. In addition, this would decrease the chance that federal efforts are spent on approaches that stakeholders are not responsive to or cannot benefit from.

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

These data collections will be implemented in a manner fully consistent with 5 CFR 1320.5.

A.8.1 Comments in Response to the Federal Register Notice

NIAID published a 60-day notice for public comment in the FEDERAL REGISTER 25 of September 2017 (Volume 82, Number 184, page 44631). No public comments were received.

A.8.2 Efforts to Consult Outside Agency

In addition to public comments, NIAID solicits input from stakeholders through feedback mechanisms such as those already approved by OMB, reports, annual meetings and other venues.

A.9 Explanation of Any Payment of Gift to Respondents

The “default” for much of this work will be not to offer incentives. However, when deemed necessary, for instance, when individuals are recruited to travel to interviewing site, respondents may be eligible for an incentive. Some participants will receive a standard nominal incentive, number of follow-up visits required, etc. The decision to provide incentive and amount provided is in keeping with standard federal and institutional guidance.

Incentive levels will vary between \$15-75 USD per interaction, dependent upon the duration of the interaction (survey vs. IDI vs. home visits), target audience, geographic location, and number of visits. Inadequate respondent recruitment limits the effectiveness of the questionnaire evaluation. Requests and justification for incentives will be included in each individual collection submission.

If respondents participate remotely, via phone, or internet, any proposed stipend will be justified to OMB and will be adjusted to ensure they are less than those provided to respondents in in-person studies who have to travel to the agency or other facility to participate. Amounts and justifications will be determined on an individual basis. If such information collections include hard-to reach populations and non-standard stipend are planned, additional justification will be provided to OMB for those activities.

A.10 Assurance of Confidentiality Provided to Respondents

NIAID SPEB and contractors will follow procedures for assuring and maintaining privacy consistent with the Privacy Act during all stages of data collection. Participants will receive information about privacy in advance of the scheduled session or interaction. Participants in semi-structured in-depth interviews (both in person and on the phone) will receive privacy information prior to their interview. When appropriate, respondents will be informed that all information will be kept secure to the extent permitted by law.

A.11 Justification for Sensitive Questions

Since NIAID communications are concerned with the detection, diagnosis, treatment and prevention of infectious diseases, as well as allergies, some projects may involve asking questions about or discussion of sexual habits, practices, and how participants prevent his/her own risk for some diseases, religious beliefs, and other matters that are commonly considered private. This information is needed to gain a better understanding of the target audience so that messages, strategies, and materials will be appropriate and sensitive to their needs. Participants will be informed in advance about the nature of the activity and that their participation is voluntary.

Research Method	Number of Respondents	Number of Responses per Respondent	Average Burden Per Response (in hours)	Total Annual Burden in Hours
Focus Group Screeners	2000	1	15/60	500
Interview Screeners/Surveys	2000	1	15/60	500
Focus Groups	4000	1	2	8000
Pretesting	1000	1	1	1000
Dyad/Triad Interviews	4000	1	90/60	6000
In-depth Interviews (IDI)	6000	1	90/60	9000
Surveys	7,000	1	30/60	3500
Patient questionnaires	4,500	1	30/60	2250
Market research	300	1	4	1200
Peer review with adult scientific professionals – mail/telephone/email surveys	4500	1	30/60	2250
Peer review with adult scientific professionals – focus groups	250	1	90/60	375
Total	35550	35550		34575

A.12.1 Estimates of Hour Burden Including Annualized Hourly Costs

A variety of instrument's and platforms will be used to collect information from respondents. The annual burden requested is 34,575.

A.12-2 Annual Cost to respondent

No costs are anticipated except for the respondents' time to participate in these activities are anticipated. Estimates are based on both the historical numbers of respondents from past projects as well as projections of projects to be conducted over the next three years. The total cost burden over 3 years is estimated to be \$3,562,941. NIAID estimates the burden of this collection of information as follows:

Table 12-2 Annualized Cost to Respondents

Research Method	Type of Respondents	Annual Burden Hours	Total Annual Burden Hours	Hourly Respondent Wage Rate*	Total Wage
Focus Group Screeners	Healthcare Practitioners	250	500	\$38.06	\$9,515.00
	General public	250		\$23.86	\$5,965.00
Interview Screeners/Surveys	Healthcare Practitioners	250	500	\$38.06	\$9,515.00
	General public	250		\$23.86	\$5,965.00
Focus Groups	Healthcare Practitioners	4000	8000	\$38.06	\$152,240.00
	General public	4000		\$23.86	\$95,440.00
Pretesting	Healthcare Practitioners	500	1000	\$38.06	\$19,030.00
	General public	500		\$23.86	\$11,930.00
Dyad/Triad Interviews	Healthcare Practitioners	4000	6000	\$38.06	\$152,240.00
	General public	2000		\$23.86	\$47,720.00
In-depth Interviews (IDI)	Healthcare Practitioners	6000	9000	\$38.06	\$228,360.00
	General public	3000		\$23.86	\$71,580.00
Surveys	Healthcare Practitioners	2000	3500	\$38.06	\$76,120.00
	General public	1500		\$23.86	\$35,790.00
Patient questionnaires	General public	2250	2250	\$23.86	\$53,685.00

Market research	General public	1200	1200	\$23.86	\$28,632.00
Peer review with adult scientific professionals – mail/telephone/email surveys	Medical Scientists	4500	4500	\$38.72	\$17,4240
Peer review with adult scientific professionals – focus groups	Medical Scientists	250	250	\$38.72	\$9,680
Total		31950	31950		\$1,187,647

*Bureau of Labor Statistics: The General Public rate was obtained from the https://www.bls.gov/oes/2016/may/oes_nat.htm#00-0000

*Bureau of Labor Statistics: The Health Professionals wage rate was obtained from <https://www.bls.gov/oes/2016/may/oes290000.htm>

*Bureau of Labor Statistics: The Medical Scientists wage rate was obtained from <https://www.bls.gov/ooh/life-physical-and-social-science/medical-scientists.htm>

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

There are no other costs, including capital and start-up, or operation, maintenance, and purchase costs, associated with this generic.

A.14 Annualized Cost to the Federal Government

Information collections conducted under this generic clearance will in some cases be carried out under contract. Thus, the annualized cost burden for NIAID is \$1,025,112.

Table 14-1 Annualized Total

Cost Descriptions	Grade/Step	Salary	% of Effort	Fringe (if applicable)	Total Cost to Gov't
Federal Oversight					
Health science policy Analyst	GS14/5	\$126,958/annual	4%		\$5,078
Health Science analyst	GS13/6	\$110,595/annual	6%		\$6,635
Health Scientist Administrator	GS15/5	\$149,337/annual	2%		\$2,987
Medial officer	GS15/3	\$140,552/annual	2%		\$2,806
Medial officer	GS15/5	\$149,337/annual	2%		\$2,987

Deputy Program Director	GS15/10	\$161,900/annual	1%		\$1,619
Contractor Cost					\$1,000,000
Travel					\$3,000
Other Cost					
Total					\$1,025,112

A.15 Explanation for Program Changes or Adjustments

This is a new information collection request.

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

There are no publications or other schedules.

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

The expiration date and control number will be displayed on those forms that are part of this information collection.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

None