Supporting Statement A for the Program Review of the Division of Acquired Immunodeficiency Syndrome (DAIDS) Policy Implementation Program

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A. JUSTIFICATION

A.1 Circumstances Making the Collection of Information Necessary

The National Institute of Allergy and Infectious Diseases (NIAID) recently restructured its HIV/AIDS Clinical Research Networks (Networks) in an effort to better address emerging domestic and international challenges to developing improved treatment and prevention strategies of HIV/AIDS to create a more integrated, collaborative, and flexible research structure. To support the facilitation of this restructuring, the Policy, Training, and Quality Assurance Branch (PTQAB), located in the Office of Policy in Clinical Research Operations (OPCRO), Division of Acquired Immune Deficiency Syndrome (DAIDS), National Institute of Allergy and Infectious Diseases (NIAID) was established.

In accordance with the legislative authority of NIAID as stated in 42 USC §285(f), PTQAB develops and maintains a coordinated set of policies, standard operating procedures, guidance, and other material to ensure that DAIDS funded and/or sponsored clinical research is conducted in agreement with applicable laws, regulations, guidelines, policies, and ethical standards.

The program to be reviewed is the DAIDS Policy Implementation Program (DPIP). DPIP consists of activities, such as communication, training and reporting, aimed at implementing and managing DAIDS policies and procedures which are used by extramural researchers, institutions, and other stakeholders when planning and conducting clinical research. When the Networks restructured in 2006, it was found that these policies contained a level of specificity that did not allow for sufficient flexibility in interpretation or implementation to maximize collaboration, efficiency, and accountability in DAIDS-funded/sponsored HIV prevention, vaccine, and treatment research.

The DPIP began in 2007 with an initial goal to develop and disseminate clinical research policies for DAIDS funded research to those managing and conducting the research. The DPIP has released 18 policies to date. To optimize the delivery, dissemination and training of the policies, DAIDS would like to obtain feedback from researchers to determine if any improvements should be made to the DPIP.

To guide this feedback, NIAID engaged a contractor (Booz Allen Hamilton) to develop the web-based survey and focus group questions, and collect and analyze the data. NIAID also established an Advisory Committee to review the data collection instruments, and provide recommendations to DPIP based on the analyzed data.

A.2 Purpose and Use of the Information Collection

The program review is designed to assess DPIP's progression to fulfillment of its program goals. The results of the review will provide DAIDS Office for Policy in Clinical Research Operations (OPCRO) staff and the DAIDS Site Oversight staff with information to guide optimal deployment of clinical research policies and procedures intended to harmonize, standardize and improve DAIDS funded/sponsored research. The program review will assess whether the DPIP program is implemented and functioning as intended to meet DPIP's program goals. The program goals for DPIP are: 1) Awareness & Accessibility - that extramural researchers (ERs) are aware of the policies and procedures (P&Ps), and can readily access them; 2) Understandability – the P&Ps are clear in their purpose and are written so that the content is easily understood; 3) Applicability – the ERs can correctly identify the P&Ps that apply to their research portfolios; and 4) Harmonization – the P&Ps facilitate collaboration and integration between DAIDS research programs.

Given the program goals for DPIP, the practical utility of the information from the program review is that it will provide DAIDS with information on the strengths of the current DPIP, and with areas that ERs think could use improvement. The use of this information will be used to determine how effectively DPIP meets extramural researchers' needs. By assessing the DPIP, DAIDS will determine how successfully it is reaching its goals - to facilitate and improve the quality of clinical research conducted.

The information collected will be based on nine research questions which were derived from the DPIP goals:

DPIP Program Goals	Associated Research Questions
Awareness & Accessibility - ERs are aware of new P&Ps and the P&Ps documents are readily accessible	1. How effectively does OPCRO make the target populations aware of policies?
	2. Are policies readily accessible?
Understandability - The P&Ps clearly articulate DAIDS expectations for P&P implementation by the ERs. The P&Ps are written so the content is easily understood.	3. Are the policies written so that the content is clear?
	4. Is there additional support to facilitate understanding of the new policies?
Applicability - ERs are able to correctly identify which P&Ps apply to the projects in their portfolios.	5. Does the target population understand which policies apply to the research projects in their portfolios?
	6. Do policies effectively communicate staffs' roles and responsibilities in projects?

DPIP Program Goals	Associated Research Questions
Harmonization - The P&Ps simplify the process to implement DAIDS-funded and/or sponsored clinical research (regardless of network or non-network status) by standardizing the minimum requirements. The P&Ps facilitate collaboration, efficiency, flexibility, and greater integration among DAIDS-funded clinical research programs.	7. Do policies simplify the implementation of DAIDS funded/sponsored research for ERs?
	8. Do policies apply broadly within networks and non-networks?
	9. Do standardized policies facilitate greater integration among DAIDS funded clinical research programs?

The collection of these data is fundamental to the conduct of the program review. While the program review does involve repeated data collections (via web-based survey), all collection of data is necessary. Also the first collection of data will serve as the baseline of the program review to be utilized in subsequent years.

Progress toward goals is defined by target population's perceptions of the DPIP including their satisfaction level with the communication of P&Ps, training about the P&Ps, and their ability to apply the P&Ps in clinical research. the Advisory Committee will be present the summary of the data and will work with DAIDS to develop one or more actionable recommendations for NIAID to consider.

A.3 Use of Information Technology and Burden Reduction

Data will be collected through a web-based survey and through focus groups. The web-based survey will reduce the time as well as the level of effort needed from respondents, because respondents can directly key in their responses to the survey. The survey will take approximately one hour to complete. Using a web-based survey will also reduce the amount of time and level of effort needed to analyze responses.

As increasing amounts of personally identifiable information (PII) is transmitted electronically, the possible dissemination of private PII threatens to create a considerable amount of harm to federal agencies and public citizens. Section 208 of the Electronic Government Act requires each agency to conduct and review a Privacy Impact Assessment (PIA) to examine the type of data an information system collects, maintains, or disseminates. Title II of the E-Government Act of 2002, Section 208, requires federal agencies to conduct PIAs prior to developing or procuring IT systems that collect, maintain, or disseminate information in identifiable form (IIF). The program review team is aware of the privacy impacts associated with the use of web-based surveys, and have developed strategies to mitigate these impacts including developing a PIA for the database housing survey results. The program review team will house all data collected in a database located within their secure facilities. They will ensure that no information is shared with any entities outside of NIAID, and will delete all individual identifiers prior to sharing any data outside of the program review team.

Respondents for each of the data collection instruments, including the web-based survey and the focus groups, will not include their name (only their CTU and CRS name). The use of a web-based survey will help to ensure survey responses for these two efforts are kept private to the extent permitted by law. It will allow respondents to key in their responses and submit them directly to the program review team. Once submitted, survey responses will automatically be uploaded into a database for analysis. No individual identifiers will be requested. Responses will be stored in a secure location for delivery to the program review team and then keyed into a database for analysis. For the focus groups, while the program review team will record the names of those who participated in each focus group, this information will be kept private to the extent permitted by law, and no information attributable to an individual will be reported to NIAID.

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

The DPIP has not retained any feedback. There is no other effort to collect like data that is being conducted within the Division.

A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this effort; therefore there is no impact on small businesses or other small entities.

A.6 Consequences of Collecting the Information Less Frequently

If this collection is not conducted, the program review of the DAIDS Policy Implementation Program cannot be executed. A web-based survey will be conducted three times, and respondents will also be part of one focus group. It is not possible to collect the information less frequently.

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

The proposed survey fully complies with all guidelines of 5 CFR § 1320.5 (d) (2). All guidelines of 5 CFR 1320.5 are met; therefore, there are not special circumstances in this program review.

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

a) The 60-day Federal Register Notice was published on July 16, 2009 on page 34580 in Vol. 74, No 135. To date, no comments have been received as a result of the Federal Register Notice.

b) In 2009, this program review was reviewed by Richard Gorman, Associate Director, Division of Microbiology and Infectious Disease 301.451.5291, Sarah

Glavin, Deputy Director for Science, Policy, Analysis and Communication, NICHD Office of the Director 301.496.7898, the members of the Policy, Training, and Policy Assurance Branch, NIAID , as well as members of the Strategic Planning and Evaluation Branch, NIAID.

A.9 Explanation of Any Payment of Gift to Respondents

There will be no payment, gift, or reimbursement given to respondents for time spent providing data.

A.10 Assurance of Confidentiality Provided to Respondents

Participation in this effort is entirely voluntary. The raw data will only be reported in the aggregate to DAIDS and the Advisory Committee. Furthermore, respondents for the web-based survey will not include their names. Prior to the survey, an e-mail will be sent to all potential respondents (See Attachment 1) The use of a web-based survey will help to ensure the privacy to the extent permitted by law of survey responses, allowing respondents to key in their responses and submit them directly to the contracted program review team. The program review team will have access to the individual data, which for the web-based survey are collected without the use if identifiable information. The program review team will solicit focus group participants from those who are planning on attending an existing DPIP training event or DAIDS research meeting. We will provide advance notification of the focus groups to potential participants via the DPIP listserv, the HIV/AIDS Network Coordination (HANC) website, and the DAIDS wide distribution list. Therefore the program review team will have each participant's name, job role, site location and network affiliation. This information is already known to NIAID based on their listserv information. After conducting the focus groups, any identifiable information (that is name or contact information) will be separated from other data and will be kept in a secure, password protected location. All other data and findings will be aggregated for analysis purposes.
Data will be kept secure to protect privacy. The focus group team will consist of a member from the contract team (Booz Allen) as the focus group lead and member of NIAID/DAIDS staff as focus group scribe who can provide any program background information to clarify focus group questions, if necessary. Prior to the focus groups, an e-mail will be sent to all potential respondents addressing who will be part of the focus group team privy to respondent data (See Attachment 2).

A.11 Justification for Sensitive Questions

There are no questions believed to be sensitive. If the respondent is uncomfortable, for any reason, responding to a question, he or she will not be forced to complete that question.

A.12 Estimates of Hour Burden Including Annualized Hourly Costs

Table 1 demonstrates the estimated burden for each data collection activity. 392 Extramural Researchers will participate in this effort. The estimated average response time is derived across all data collection (surveys and focus groups) over the course of two (2) years. Burden to respondents will be measured in time only (See Attachments 3 and 4). The annual reporting burden is as follows: the survey will be administered three times over two years and focus group will occur once; therefore, there are four total responses over the two year data collection period. In summary the *Estimated Frequency of Response for* the Survey and focus groups are therefore 1.5 and 1, respectively. The *Estimated Average Time per Response* for the survey is one hour and two hours for focus groups. In summary, one hour for the survey administered 1.5 times per year equals 1.5 hours, and 2 hours for the focus group convened 1 time per year equals 2 hours for a grand total of 3.5 hours. The *Estimated total annual* burden hours requested is 1,372.

There are no monetary annualized hourly costs for respondents.

Table 12-1. Estimates of hour burden /costs to respondents

Type of Respondents	Number of Respondents	Frequency of Response[1]	Average Time Per Response	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
Extramural Researchers	392[2]	1.5	1.0	588	15 [3]	20,580
		1	2.0	784		
Totals	392			1,372		20,580

[1] *Frequency of response reflects the number of times a person participates in a year. We are administering three surveys total over the life (two years) of the program review.*

[2] *A convenience sample approach will be used, drawing from Extramural Researchers in attendance at an existing training and who are willing to participate.*

[3] *Average hourly wages derived from Research scientist, Registered nurse, and Clinical researcher salaries from South Africa, India, Thailand, and the United States.* http://www.payscale.com/

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

Time and effort will be the only burden to respondents who participate in the program review. Respondents will incur no direct financial cost for responding to the data collection initiatives.

A.14 Annualized Cost to the Federal Government

The program review is for three years, and the total cost is $362,801.68; therefore, the annual cost to the Federal Government for research services from Booz Allen Hamilton is $120,934. Activities and associated costs included in research services include developing an Information Security Plan & clarifying issues related to the program review ($11,321), revising, updating and presenting Work Plan and Project Schedule ($21,644), identifying and refining target populations ($28,657), developing data collection instruments (DCIs), and the Office Of Management and Budget (OMB) ($37,043)Package, collecting archival and new data while ensuring data integrity, conducting data preparation /data analysis ($174,643), designing Program Review Standard Operating Procedures (SOPs) ($7,483) & program review templates, preparing and submitting monthly, quarterly and yearly reports ($17,415), conducting meetings with NIAID and the Advisory Committee ($25,239), preparing meeting summaries ($20,336), and developing Transition Plan ($9,021).

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

Tabulation: The result of the completion of this approach is a Program Review Summary which includes the findings and results from the program review and serves as a baseline for future program enhancements. It also suggests improvements needed to enhance the deployment of clinical research policies and procedures intended to harmonize, standardize, and improve DAIDS-sponsored/sponsored research. Study limitations are dependent upon response rates and data collected through the survey and focus groups. Since participation is not mandatory, ensuring a representative sample of extramural researchers may not be plausible. Gathering of focus group data depends on where an existing DAIDS research meeting/training is being held. This will limit the type of respondents who register and attend the meeting/training. Any documentation regarding the information found will state the limitations of the information gathered.

The Summary can also serve as a key communication tool that validates optimal policy and procedure dissemination and training efforts. The contractor will analyze the quantitative and qualitative data against the research questions posed. The quantitative data will be aggregated in frequencies or percentages, while the qualitative data will be reviewed for thematic analysis.

Project Time Schedule

Activity	Time Period
Submit Federal Register Notice and Obtain OMB Clearance	June – March 2010
Data Collection (Surveys and Focus Groups[1])	After OMB Clearance One month after (survey) One to two months after(focus group) Four to five months after (focus group) Seven months after (survey) Eight to 10 months after (focus group) 12 months after (survey) 12 to 13 months after (focus group) 19 – 20 months after (focus group)
Prepare Executive Summary and Final Program Review Report, summarizing three-year program	August 2011 (one-month prior to the end of the contract)

[1] *A respondent will participate in only one focus group.*

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

OMB expiration dates will be displayed on all materials.

A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement identified in item 19 "Certification for Paperwork Reduction Act Submissions," of OMB Form 83-I.

LIST OF ATTACHMENTS

Attachment 1: Email Communication to Extramural Researchers about Survey

Attachment 2 Focus Groups Communication to Extramural Researchers about Survey

Attachment 3: NIAID DAIDS Survey Question for Extramural Researchers

Attachment 4: NIAID DAIDS Focus Group Questions for Extramural Researchers