Supporting Statement A for:

PROCESS ASSESSMENT REVIEW OF THE DIVISION OF ACQUIRED IMMUNODEFICIENCY SYNDROME (DAIDS) CRITICAL EVENTS POLICY IMPLEMENTATION (CEPI) PROGRAM

OPCRO, DAIDS, NIAID, NIH, HHS

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A.1 Circumstances Making the Collection of Information Necessary

All National Institute of Allergy and Infectious Diseases (NIAID)/ Division of AIDS (DAIDS) –supported and/or –sponsored clinical research falls under the reporting requirements of applicable U.S. regulatory agencies, including HHS's Office for Human Research Protections (OHRP) and the Office of Research Integrity (ORI). DAIDS has named events that are reportable to these HHS agencies "Critical Events". Institutions are responsible to report critical events that occur under covered research to, amongst others, DAIDS. DAIDS developed a policy and a manual to provide guidance to DAIDS staff, extramural researchers, and external stakeholders on DAIDS and relevant regulatory agency requirements for reporting critical events.

In accordance with the legislative authority of NIAID as stated in 42 USC §285(f), the Protection of Participants, Evaluation and Policy (ProPEP) Branch develops and maintains a coordinated set of policies, standard operating procedures, guidance, and other material to ensure that DAIDS -supported 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 Critical Events Policy Implementation (CEPI) Program. CEPI consists of activities, such as communication, training, and reporting, aimed at implementing the DAIDS Critical Events (CE) policy and manual which is used by DAIDS staff, extramural researchers, institutions, and external stakeholders when identifying and managing reportable events. The purpose of the CEPI Program assessment is to gauge the successes of the CEPI Program. A previous assessment, the DAIDS Policy Implementation process (DPIP) evaluation, laid the foundation for the proposed CEPI Program assessment.

The DPIP provided a baseline of program performance that can be used to gauge the impact of the program over a longer period of time. Key recommendations emphasized the need to maintain the program's success and sustainability by continuing training, clarifying changes to policies, enhancing outreach to the target population and clarifying the target population's roles and responsibilities. The outcomes of the DPIP identified several next steps necessitating the need for the CEPI Program Assessment.

The CEPI Program began in 2012, with the release of the Critical Events policy and manual. To optimize the delivery, dissemination and training of the policy documents, DAIDS would like to obtain feedback from DAIDS staff, extramural researchers and external stakeholders to determine if any improvements should be made to the CEPI Program.

To guide this feedback, NIAID engaged a contractor (Social Solutions International, Inc.) to develop the web-based survey and focus group questions, and collect and analyze the data. NIAID has also identified an Advisor to review the data collection instruments and provide recommendations to CEPI based on the analyzed data.

A.2 Purpose and Use of the Information Collection

The process assessment review is designed to assess CEPI's progression to fulfillment of its program goals and will assess whether the CEPI program is implemented and functioning as intended to meet CEPI's program goals. The program goals for CEPI are: 1) Awareness & Accessibility - The target populations (i.e., DAIDS Staff, extramural researchers, external stakeholders) are aware of the DAIDS CE policy and manual and associated documents and whether the policy and associated documents are readily accessible.; 2) Understandability – The Critical Events policy and manual clearly articulate DAIDS expectations for CE policy implementation by the target populations. The CE policy and manual should establish a common base of understanding and promote positive attitudes towards event reporting; and 3) Applicability – Target populations are able to correctly identify which Critical Events have occurred at their sites and are able to apply the CE policy and manual to their events.

The results of this assessment will be used to inform DAIDS and Protection of Participants, Evaluation and Policy (ProPEP) leadership regarding further policy deployment decisions. In addition, the CEPI Program assessment will determine whether previously recommended improvements included in the DPIP were successfully incorporated into the policy rollout process. The results of this assessment may be used as a model for policy development to facilitate compliance in reporting certain incidents and implementation in other National Institutes of Health (NIH) Institutes and Centers (ICs) and will be shared with all interested divisions and institutes within the NIH. There are no plans to share this information with the public.

Given the program goals for CEPI, the practical utility of the information from the process assessment is that it will provide DAIDS with information on the strengths of the current CEPI Program, and with areas that extramural researchers think could use improvement. This information will be used to determine how effectively the CEPI Program meets extramural researchers' needs. By assessing the CEPI Program, 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 12 research questions which were derived from the CEPI Program goals:

DPIP Program Goals	Associated Research Questions
Awareness & Accessibility - The target populations (DAIDS Staff, extramural researchers, external stakeholders) are aware of the DAIDS Critical Events (CE) policy and manual and associated documents and whether the CE policy and associated documents are readily accessible.	1. How were the Critical Events policy and manual communicated to target populations?
	2. Are target populations aware of Critical Events trainings and resources?
	3. Are they able to participate in trainings and locate resources?
	4. What barriers exist in preventing participation in trainings by the target population?
Understandability - The Critical Events policy and manual clearly articulate DAIDS expectations for CE policy implementation by the target populations. The CE policy and manual should establish a common base of understanding and promote positive attitudes towards event reporting.	5. What are the target populations' perceptions of the CEPI Program?
	6. Are the Critical Events policy and manual written and formatted so that the content is clear?
	7. What facilitated NIAID/DAIDS staff, extramural researchers, and external stakeholders understanding of the regulatory reporting requirements and Critical Events policy and manual requirements?
	8. How have the target populations' awareness, knowledge, attitudes, and behaviors been affected by the CEPI Program?
Applicability - Target populations are able to correctly identify which Critical Events have occurred at their sites and are able to apply the CE policy and manual to their events.	9. Are the target populations able to successfully meet critical events reporting mandates?
	10. What burdens are created from the CEPI Program?
	11. What, if any, recommendations do the target populations have for program improvements?
	12. What are the challenges or barriers to complying with the regulatory reporting requirements and CE policy and manual?

The collection of these data is fundamental to the conduct of the process assessment. While the process assessment 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 process review to be utilized in subsequent years.

Progress toward goals is defined by the target population's perceptions of the CEPI Program including their satisfaction level with the communication of CE policy documents, training on the CE policy documents, and their ability to apply the CE policy documents in clinical research.

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 25-30 minutes 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 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 CEPI process assessment team is aware of the privacy impact 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 CEPI process assessment 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 CEPI assessment team.

Respondents for each of the data collection instruments, including the web-based survey and the focus groups, will not include their name. The use of a web-based survey will help to ensure survey responses for these two efforts are kept secure to the extent permitted by law. It will allow respondents to key in their responses and submit them directly to the CEPI process assessment team. Once submitted, survey responses will automatically be uploaded into a database for analysis. Responses will be stored in a secure location for delivery to the process assessment team and then keyed into a database for analysis. The CEPI process assessment team will record the names and email addresses of those who participated in web-based surveys; web-based survey participants who choose to receive an incentive will also have their mailing address recorded. Participant names and email addresses will be recorded for focus group

participants. This information will be kept secure 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

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 as respondents; 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 process assessment of the DAIDS CEPI program cannot be executed. A web-based survey will be conducted two times over the course of two years, with respondents able to complete the survey a maximum of two times, to assess potential changes in respondents' perceptions and attitudes regarding CEPI over time. Respondents may 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 process assessment.

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

No comments were received during the 60-day Federal Register notice, published April 9, 2014, Document Citation 79 FR 19633, Document Number 2014-07960 pages 19633-19632, Shortened URL https://federalregister.gov/a/2014-07960.

A.9 Explanation of Any Payment of Gift to Respondents

Social Solutions (SSi) intends to provide modest remuneration for Extramural Investigators and External Stakeholders (excluding DAIDS-PPD site monitors) survey respondents and focus group participant's time, travel, and incidentals to recruit and retain survey and focus group participants. Web-survey participants will receive $10 and focus group participants will receive $30. Incentives will primarily serve to compensate

participants for their time, and the energy and effort it requires to complete the survey at two time collection points and/or to participate in an in-person focus group. The survey will take approximately 30 minutes; the focus group will take 90 minutes. Both activities entail efforts outside of participants' typical job functions. The survey must be completed online, with an appropriate computer setup, electricity, and Internet connection. Focus groups will occur during previously arranged meetings, potentially keeping participants from participating in other meeting-related activities.

In order to serve NIAID's mission to improve data quality and pursuant to the CEPI project work plan to ensure data integrity, three primary issues become apparent regarding survey data: response rate, representativeness, and item-response (i.e., the rate of completed questions). Research by Olson, Abelson, and Olsen (2013) demonstrated that the provision of financial incentives on a questionnaire not only increased the response rate and improved the representativeness of the sample taking the survey, but also reduced item non-response.

The success of including an incentive for the survey in SSI's work in this study could hinge on a balanced connection between the size of an unconditional gift and the effort needed to complete the relatively lengthy questionnaire and the provision of an immediate reward as opposed an internal future prize drawn up by survey researchers. For this reason, the incentive values for the survey and focus group activities have been set at $10 and $30, respectively. Pilot survey data indicate that potential participants may be enticed to participate in the two-wave survey with the provision of a $10 incentive at both time points.

Furthermore, longitudinal survey is often wrought with problems related to tracking, locating and follow-up with survey participants. Work by Grossman, Calhoun, Farabee, and Veliz (2014) demonstrated that incentives significantly increased response rates to follow-up surveys. Given that SSI's work involves follow-up with participants at least one year following the baseline assessment, the provision of incentives will be necessary to increase data validity and enhance generalizability of findings.

The provision of incentives for focus group participation may also serve as a mechanism through which to increase response rates (i.e., sufficient number of individuals in the focus groups) and item-response (i.e., thoughtful answers to focus group questions). Providing financial incentives for focus groups may be problematic for the representativeness of the focus group sample (i.e., those who are motivated by a financial incentive may be in some way different from those who are not motivated by such incentives), SSi does not anticipate this as an obstacle for its work. SSi's sample of focus group respondents will be drawn from previously arranged professional meetings where the entire universe of potential respondents already meet the requirements for inclusion in the focus group sample. In other words, SSi does not see motivation for financial incentive as serving as source of external noise that will bias focus group data.

References

Grossman, J., Calhoun, S., Farabee, D., & Veliz, R. (2014). Keeping substance abusers engaged in longitudinal studies: Do immediate incentives matter? Poster presented at the Western Society of Criminology Meeting, Honolulu, HI.

Olsen, F., Abelsen, B., & Olsen, J. A. (2012). Improving response rate and quality of survey data with a scratch lottery ticket incentive. *BMC Medical Research Methodology, 12,* 52-58.

A.10 Assurance of Confidentiality Provided to Respondents

The CEPI Program assessment activities was submitted to the NIH Institutional Review Board (IRB) and the SSi IRB for review. The NIH IRB determined that the CEPI assessment project was excluded from IRB review, under the applicable HHS regulations and NIH policy. The NIH Office of Human Subjects Research (OHSR) gave permission for the CEPI project to proceed (See Attachment 1). The SSi IRB reviewed and approved the project, effective January 25, 2014 (See Attachment 2), and following the completion of the pilot survey, approved minor changes to the project on March 8, 2014 and May 7, 2014.

Participation in this effort is entirely voluntary. The SSi IRB approved informed consent forms and processes will be used to obtain informed consent from web-based survey and focus group participants. DAIDS will send an e-mail to all potential survey respondents that provides select information for persons interested in participating in the survey (See Attachments 3 & 4). Persons interested in additional information on the survey will click on a link embedded in the email to access an online document with study details and informed consent (See Attachments 5a and b); each potential respondent must agree to participate in the survey before being allowed to access the survey questions. Written informed consent will be obtained from focus group participants prior to the focus group discussion (See Attachments 6 and 7). Within two business days after a potential respondent agrees to participate in the study, SSi will send an email with a unique link for respondents to complete the study (See Attachment 8). At the end of the survey, extramural researchers and external stakeholders will be prompted to click on a link that opens a separate webpage in order to select how the incentive will be delivered and complete the incentive distribution form (See Attachment 9).

Web surveys will be collected from the sample 500 participants twice (Time 1 and Time 2) during the project period. The raw data will only be reported in the aggregate to DAIDS. Furthermore, respondents for the web-based survey will not include their names. Prior to the survey, DAIDS will send an e-mail to all potential respondents for T1 (See Attachments 3 & 4). The use of a web-based survey will help to secure survey responses to the extent permitted by law, allowing respondents to key in their responses and submit them directly to the contracted CEPI assessment team. DAIDS will send follow-up reminder email communications at three points following the initial invitation

(at two to four -week intervals) (See Attachments 10 & 11). In the event potential respondents have not responded or completed the survey following the second follow-up message, additional attempts to verify email addresses will be made. Each follow-up and the initial invitation will include a number of means (phone and email) by which participants may contact the survey administrators in order to get clarification about the assessment or the survey and to troubleshoot any technical issues. Web-survey respondents that read the informed consent and agree to participate will be sent an email with a unique link to complete the survey (See Attachment 8). SSi will send an email invitation to web-survey participants from T1, so they can complete the survey at T2 (See Attachment 12) and will send follow-up reminder email communications at three time points following the T2 invitation (at two-week intervals) (See Attachment 13).

Survey data will undergo a stringent anonymization process whereby unique identifiers will be assigned to all individuals. The unique identifiers allow linking survey data to execute a composite longitudinal analysis. The process assessment team will have access to the individual data, which for the web-based survey are collected without the use of identifiable information. Data from each survey will be securely collected in Survey Monkey – with all information transfers encrypted. The SSi evaluator will transfer the secure responses to the STATA or Dedoose software package (for either quantitative or qualitative responses), without the tracked participant email address, for statistical analysis and qualitative coding. The CEPI assessment team will solicit focus group participants from those who are planning on attending an existing DAIDS training event or DAIDS Network meeting. DAIDS staff will provide advance notification of the focus groups to potential participants via the OPCRO News listserv, the HIV/AIDS Network Coordination (HANC) website, and the DAIDS-wide distribution list and will register individuals for focus group participation. The process assessment team will be give the focus group participant's name, job role, site location and network affiliation in advance of the focus group session. 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.

While the SSi CEPI assessment team does not anticipate collecting any personal identifying information during electronic/web-based data collection, in order to receive their incentives, participants will be asked to provide a limited amount of personal information. Web-survey participants who wish to receive the incentive will be required to complete an incentive distribution form (IDF) (See Attachment 9) with their name and mailing address for incentive distribution. Once the survey has been completed, participants will receive their incentive per their preferred method (e.g., PayPal deposit, Western Union Transfer, Money Order). International participants who cannot receive their incentives via PayPal or Western Union will see a prompt that asks participants to describe a method through which they are able to receive funds. They will also be prompted to enter their email in the event that their proposed method is not feasible. If this occurs, Social Solutions will contact these individuals via email to coordinate a possible delivery mechanism. One possible delivery mechanism is an international wire transfer. An international wire is a bank-to-bank transfer, in which the participant will

provide their bank details (e.g., name, address, routing and account number). Social Solutions' bank will initiate a transfer to the recipient's bank. Other delivery mechanism options will be explored on a case-by-case basis. All web-survey incentives will be in the amount of $10 U.S. dollars (or equivalent).

SSi staff that are analyzing survey data will not work with the incentive distribution contact information directly. A list of participants that have completed the survey will be drafted using only the unique links that were manually created and emailed to participants. The list of unique links that have completed the survey will be given, on paper and by hand, to another SSi staff member. The SSi staff member will coordinate the mailing of incentives, manually verifying the email associated with the unique link, and then manually addressing incentives with information connected to each email address. All contact information will be stored on paper documents in an SSi locked cabinet. No document connects survey responses to personally identifiable information, and no document connects the unique link to the individuals' full contact information. Such information will be kept separately from any other paper documentation collected from the study. Therefore, no staff member will be able to electronically or physically, connect survey responses with participant contact information for incentive distribution.

Focus group participants will be required to sign a sign-in sheet that documents their participation and doubles as an incentive distribution log (See Attachment 14). If they prefer, the participants may initial the sign-in sheet rather than providing their full name. Cash incentives of $30 U.S. dollars (or equivalent) will be provided at the end of each focus group. Following conclusion of each focus group, the sign-in sheet and signed informed consent form (if needed) will be locked in a separate storage cabinet with the data from the focus groups. Only the interviewer and IRB Institutional Officer will have access to these files. Focus group data and reports will not include any reference to personal identifying information.

Data will be kept secure. The focus group team will consist of a member from the contract team (SSi International) 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. In addition, another SSi project staff member will manage audio-recordings of the focus group discussions. 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 15).

In an effort to maintain the highest levels of research integrity, all research facilitated at Social Solutions (SSi) is conducted in accordance with the standards for involvement of human subjects. As such, when the provisional performance measures, and data collection tools and templates were finalized, Social Solutions prepared and submitted an Institutional Review Board (IRB) package to its IRB.

Social Solutions has an Institutional Review Board (IRB No. 00004885, FWA No. 00008632). As necessary with all HHS-supported research involving human subjects, Social Solutions' research protocol, performance measurement documents, and consent

forms were reviewed and approved by the Social Solutions' IRB. The IRB holds researchers to the highest standards and ensures the protections of human subjects. As a condition of employment, all Social Solutions staff and consultants involved in research must complete the required NIH Internet training course on the protection of human subjects.

All study data collected for projects and assessment data are housed at the SSi office. Hard copy data are kept in a locked filing cabinet in a locked office. All identifying information is maintained in a secure manner by the SSi CEPI assessment team; the data are kept separate from identifiers, but linked using a unique number. Only specified SSi staff have access to the identifiers. For electronically collected information, SSi will employ the latest firewall protection, intrusion detection systems, SSL encryption and proprietary security products. Data are stored in this office for seven (7) years after the completion of a study or assessment and destroyed in accordance with the American Psychological Association standards, including personally identifying information. To the extent possible, individual level data are de-identified using unique identifies so that names, addresses, or other personal information is not transferred to databases or final report write-ups.

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 12- 1 demonstrates the estimated hours of burden to respondents for each data collection activity. Up to 118 DAIDS staff members (including DAIDS contractors) plus 463 Extramural Researchers (ER) and external stakeholders (ES) will participate in this effort. DAIDS staff consists of contractors and FTEs. There is no way to initially differentiate between DAIDS FTE and contract staff; therefore the burden hours assume that all DAIDS staff respondents are contractors (i.e., non FTEs).

The estimated average response time is derived across all data collection (surveys and focus groups) over the course of two and one-half years. Burden to respondents will be measured in time only. The survey burden hours include review of the informed consent and completing the survey. Since the focus group informed consent is sent to participants prior to the focus group, the burden hours are listed as a separate line item. The annual reporting burden is as follows: the survey will be administered two times over two years and focus groups will be done nine times over a two-year period; therefore, there are 11 total responses over the two-year data collection period. In summary the Estimated Frequency of Response for the Survey, the informed consent review, and the focus groups are therefore 1, 1, and 1, respectively. The Estimated Average Time per

Response for the survey informed consent review and survey reminders are 5 minutes, completing the survey 30 minutes (including the option to receive incentives- attachment 9), focus group informed consent review 10 minutes, incentive distribution log for focus group participants 2 minutes, and focus group participation 90 minutes. The Estimated total annual burden hours requested is 470.

Table 12-1. Estimates of hour burden to respondents

Type of Respondents	Form Name	Number of Respondents	Frequency of Response	Average Time Per Response	Annual Hour Burden
DAIDS staff surveys IC review	Webpage Study Details and Informed Consent DAIDS Staff screenshots	100	1	5/60	8
DAIDS staff surveys	DAIDS Staff Survey screenshots	100	1	30/60	50
ER/ES- web surveys IC review	Webpage Study Details and Informed Consent for Extramural Researchers and External Stakeholders screenshots	400	1	5/60	33
ER/ES- web surveys	Extramural Researcher External Stakeholder Survey screenshots	400	1	30/60	200
DAIDS staff - web survey reminder	Reminder email to T2 web-survey participants	100	1	5/60	8
ER/ES- web survey reminder	Reminder email to T2 web-survey participants	400	1	5/60	33
DAIDS staff focus group IC review	DAIDS staff focus group consent form	18	1	10/60	3
ER/ES- focus group IC review	Extramural researcher external stakeholders focus group consent form	63	1	10/60	11

ER/ES- focus group	Incentive distribution log for focus group participants	63	1	2/60	2
DAIDS staff focus groups	Focus group opening script and questions	18	1	90/60	27
ER/ES- focus groups	Focus group opening script and questions	63	1	90/60	95
Totals		1162			470

Table 12- 2 demonstrates the estimated cost to respondents for each data collection activity. See Attachments 16 and 17 for table with researcher salaries and Bureau of Labor Statistics, Occupational Employment and Wages news release. The estimated cost to respondents was based on the average hourly wages derived from Research scientist, Registered nurse, and Clinical researcher salaries in South Africa, India, and the United States and is available at http://www.payscale.com/.

Table 12-2. Estimates of costs to respondents

Type of Respondents	Number of Respondents	Annual Hour Burden	Hourly Wage Rate	Respondent Cost
DAIDS staff, ER/ES survey IC review	500	41	$16.63	$682
DAIDS staff, ER/ES survey reminders	500	41	$16.63	$682
DAIDS staff, ER/ES- web surveys	500	250	$16.63	$4158
DAIDS staff, ER/ES- focus group IC review	81	14	$16.63	$233
DAIDS staff, ER/ES- focus groups	81	122	$16.63	$2,029
ER/ES- focus group	63	2	$16.63	$33.26
Totals	1725	470		$7817.26

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 process assessment. Respondents will incur no direct financial cost for responding to the data collection initiatives.

A.14 Annualized Cost to the Federal Government

Table 14-1 lists the annualized cost to the Federal Government for the proposed data collection effort, and is estimated to be $87,048.

Item	Salary	Fringe Rate	% Effort	Annualized Cost
NIH Project Oversight Officer - GS14-6	123,970	0%	3%	$3,719
SSi Project Director	$342,136	0%	5.5%	$18,817
SSi Survey Analyst	$155,351	0%	18.5%	$28740
SSi Interviewer	$295,006	0%	5%	$14,750
SSI Writer/Editor/Research Associate	$97,133	0%	5%	$4,857
Operational Costs for Data Collection Activities – Printing, equipment, overhead), non-labor				$1020
Other Contractual costs for data collection, non-labor				$9,000
Travel costs associated with data collection				$4,157
Indirect on ODCs & travel				$1,988
Total				$87,048

The program assessment is for three years, and the total contractor award is $249,523; therefore, the annual cost to the Federal Government for research services from Social Solutions International is $87,048. This amount does not include other NIH staff cost. Please note that the contractor rates are fully loaded.

Table 14-1 Annualized cost to the Federal Government

Table 14-2 Three-year budget with associated tasks

Work Task	Three Year Budget
Revise work plan and logic model	$1200
identify and refine target populations	$968
Develop data collection instruments	$10,181
Collect archival and new data/data integrity/ data analysis	$187,753
Design process assessment SOPs & templates	$6,344
Monthly, quarterly, and yearly reports	$12,948
Meetings with NIAID staff	$20,131
Meeting summaries, updated work plan, logic model and project timelines	$9,358

Table 14-2 includes the three-year budget for the tasks associated with the process assessment.

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 Process Assessment Summary which includes the findings and results from the process assessment 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 standardize and improve DAIDS-supported/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 to those who register and attend the DAIDS 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, and will be analyzed for potential changes in respondents' perceptions and attitudes regarding CEPI. The qualitative data will be reviewed for thematic analysis. Table 16-1 lists the planned CEPI activities with the projected time schedule.

Table 16-1 Planned activities and projected time schedule

Activity	Time Period
Submit Federal Register Notice and Obtain OMB Clearance	March – October 2014
Data Collection (Surveys and Focus Groups)	After OMB Clearance One-three month after (survey) Four to 16 months after (focus groups) 13-15 months after (survey)
Data Integrity and preparation	One to 23 months after
Data Analyses	Two to 24 months after
Executive Summary and Final Report, summarizing three-year program, Transition plan	August 2016 (one-month prior to the end of the contract)

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.