OHSR RESPONSE TO REQUEST FOR REVIEW OF RESEARCH ACTIVITY
INVOLVING HUMAN SUBJECTS

FAX:

Exempt: #: 12268

To: Lahl, Lyndi
NIAID
BG 6700B RM 4254

From: Office of Human Subjects Research (OHSR)

Nature of Research Activity:
Web-based surveys using Survey Monkey will collect data from DAIDS staff (FTEs and HJF contractor and extramural researchers/external stakeholders that receive support through NIAID/DAIDS. A pilot survey will be done to test the survey instrument (up to 10 DAIDS staff, and 8 extramural researchers/external stakeholders) to assess the understandability, reliability, and validity of the survey questions. After the pilot surveys are completed, the survey questions are finalized, and IRB approval and OMB clearance is obtained

Original Request Received in OHSR on: 1/12/2013

Responsible NIH Research Investigator(s): Lyndi Lahl, RN, MS NIAID

OHSR review of your request dated Mon, Jan 13, 2014 has determined that:

☒ Federal regulations for the protection of human subjects do not apply to above named activity. The OHSR determination of Not Human Subjects Research is based on the interpretation of 45 CFR 46 under "Research Involving Coded Private Information or Biological Specimens" (OHRP, Revised October 16, 2008) and Guidance on Engagement of Institutions in Human Subjects Research (October 16, 2008). NOTIFY OHSR VIA AN E-MAIL AMENDMENT OF ANY CHANGES THAT MAY ALTER THIS RESEARCH ACTIVITY.

☐ The activity is designated **EXEMPT**, and has been entered in the OHSR database. PLEASE NOTIFY OHSR OF ANY **SIGNIFICANT** CHANGES THAT MAY ALTER THE EXEMPT STATUS OF THIS RESEARCH ACTIVITY.

☐ **NOT EXEMPT**. OHSR recommends IRB review. Please forward your request to the Chair of your IRB, who may ask you to provide additional information in order to determine whether expedited or full review is appropriate.

☐ Confidentiality Agreement

☐ Reliance

☐ Amendment

☐ Other

Office Person TM Admin Assist. CB

Note:
1/28/2014: Program Evaluation

Takunda Matose

Takunda Matose	Program Analyst, OHSRP	1/28/2014
Signature	Title	Date

Domestic/International:
Domestic

Human Subjects Data: Yes
Biologic Material: No

OHSR Use Only
☐ 1 ☒ 2 ☐ 3 ☐ 4 ☐ 5 ☐ 6

Matose, Takunda (NIH/OD) [C]

From: OHSR (NIH/DDIR)
To: Lahl, Lynda (NIH/NIAID) [E]
Cc: Lohse, Pia (NIH/NIAID) [E]; Washington, Dione (NIH/NIAID) [E]
Subject: Determination for OHSRP 12268
Attachments: Request for Amendment OHSRP #___

Good afternoon, Lyndi, Pia, and Dione,

Attached is the OHSRP determination of **Excluded from IRB Review** per 45 CFR 46 and NIH policy for your project *Process Evaluation of the DAIDS Critical Events Policy Implementation (CEPI) Program.* You may proceed with the project.

Please retain this documentation as you would other research records. Amendments and or changes to the research must be submitted to OHSRP for review as changes may affect the determination. Please refer to **OHSRP #12268** for future amendments to this activity. To request future amendments, please use the attached email template modified to meet the specific changes needed for your project. If you have any questions or need further assistance, please feel free to contact us.

Best,

Takunda Matose
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

From: OHSR (NIH/DDIR)
Sent: Thursday, January 23, 2014 1:10 PM
To: Lahl, Lynda (NIH/NIAID) [E]
Subject: Req for Determination Rec'd_OHSRP 12268

Good afternoon Lyndi,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12268.** Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Process Evaluation of the DAIDS Critical Events Policy Implementation (CEPI) Program

****As per a new requirement for PIs, please fill in attached planned enrollment worksheet and return. We will need this before we can issue a determination. Please contact OHSRP with any questions.**

Thank you.
Sincerely,
OHSRP - National Institutes of Health

REQUEST FORM: OHSRP DETERMINATION FORSURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH

Date of Request: 01/13/2014

Requestor's name: Lynda Lahl e-mail: lahll@niaid.nih.gov

Role: __Administrative support _X_ Investigator Other, explain: _____

Name of NIH Senior Investigator: Lynda Lahl
(The investigator must be an NIH employee)

IC NIAID Laboratory/Branch DAIDS/OPCRO/ProPEP

Building & Room No. 6700 B Rockledge Dr. Tel. No. (301) 435-3756
FAX No. 301.402.1505

Is the NIH Senior Investigator an NIH employee (FTE)? _X_ Yes _____ No

Senior Investigator Signature: Lynda L Lahl
(Signature of Investigator who will conduct research)

Supervisor Signature: Judith Brooks
(Signature of official for IC, e.g., Lab/Branch Chief)

Name of NIH investigator conducting research if not the NIH Senior Investigator: *(i.e, junior investigator, contractor investigator, fellow, student)*
NA

Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination: Pia Lohse, lohsep@niaid.nih.gov; Dione Washington, washingtondi@niaid.nih.gov

1. **What role will the NIH investigator(s) have in this research project?** *(check all that apply)*
   - __ Conduct research activity
   - _X_ Analyze samples/data only
   - _X_ Consultant/advisor to collaborator(s)
   - __ Author on publication(s)/manuscript(s) pertaining to this research
   - __ Other, please describe: _____

2. **Title:** Process Evaluation of the DAIDS Critical Events Policy Implementation (CEPI) Program

3. **Describe in lay terms the research activity that will be performed:**

REQUEST FORM: OHSRP DETERMINATION FORSURVEYS, INTERVIEW PROCEDURES, PROGRAM EVALUATION, EDUCATIONAL TESTING AND RESEARCH

Date of Request: 01/13/2014

Requestor's name: Lynda Lahl e-mail: lahll@niaid.nih.gov

Role: __Administrative support _X_ Investigator Other, explain: _____

Name of NIH Senior Investigator: Lynda Lahl
(*The investigator must be an NIH employee*)

IC NIAID Laboratory/Branch DAIDS/OPCRO/ProPEP

Building & Room No. 6700 B Rockledge Dr. Tel. No. (301) 435-3756
FAX No. 301.402.1505

Is the NIH Senior Investigator an NIH employee (FTE)? _X_ Yes _____No

Senior Investigator Signature: _____
(*Signature of Investigator who will conduct research*)

Supervisor Signature: _____
(*Signature of official for IC, e.g., Lab/Branch Chief*)

Name of NIH investigator conducting research if not the NIH Senior Investigator: *(i.e, junior investigator, contractor investigator, fellow, student)*
NA

Please provide the name and e-mail of any others who should receive a copy of the OHSRP determination: Pia Lohse, lohsep@niaid.nih.gov; Dione Washington, washingtondi@niaid.nih.gov

1. **What role will the NIH investigator(s) have in this research project?** *(check all that apply)*
   __ Conduct research activity
   _X_ Analyze samples/data only
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   __ Author on publication(s)/manuscript(s) pertaining to this research
   __ Other, please describe: _____

2. **Title:** Process Evaluation of the DAIDS Critical Events Policy Implementation (CEPI) Program

3. Describe in lay terms the research activity that will be performed:

Web-based surveys using Survey Monkey will collect data from DAIDS staff (FTEs and HJF contractor)and extramural researchers/external stakeholders that receive support through NIAID/DAIDS. A pilot survey will be done to test the survey instrument (up to 10 DAIDS staff, and 8 extramural researchers/external stakeholders) to assess the understandability, reliability, and validity of the survey questions. After the pilot surveys are completed, the survey questions are finalized, and IRB approval and OMB clearance is obtained, DAIDS staff in the Protection of Participants, Evaluation, and Policy Branch will send emails to individuals in the target populations, inviting their participation in the survey. 100 DAIDS staff and 400 extramural researchers/ external stakeholders will complete the survey, up to two times over a 15-month period. With both the pilot survey and regular survey, all participants will be asked to read the informed consent statement; if potential participants wish to participate, they will be prompted to consent to complete the survey by clicking on the "agree" or "disagree" button at the conclusion of the informed consent statement. After agreeing to participate, participants will be prompted to enter their contact information. The evaluation contractor will manually create a unique link to the full survey for each participant, which will be emailed to individual participants. Survey data is coded and maintained separate from contact information, to protect the participant's privacy and maintain data confidentiality. Extramural researchers/external stakeholders will receive $15 for completing the pilot survey and $10 for each completed survey.

Nine 90-minute focus groups (two- DAIDS staff, seven- extramural researchers/external stakeholders) will be conducted with up to nine participants each. The extramural researchers/external stakeholders focus groups will be conducted during local (n=5), domestic (n=1), or international (n=1) DAIDS or Network meetings. DAIDS staff focus groups will be conducted locally. Emails will be sent to individuals in the target populations, inviting their participation in the focus groups. Persons scheduled to attend a focus group will be emailed the informed consent form. Written informed consent will be obtained from all focus group participants prior to their participation. Extramural researchers/external stakeholders will receive $30 for their participation in a focus group.

4. Proposed start date 01/15/2014 **Proposed completion date** 09/30/2016

5. Specify the nature of the data: *(select all that apply)*

__ Interview procedure
_X_ Survey
__ Educational Testing
__ Educational Research
__ Research on public benefit or service programs
_X_ Other, describe: _Focus group_____

6. What kind of human data (e.g., private information, responses to questionnaires, test results, recordings) will be collected in your research?
Online surveys and Focus groups will be used to collect data on awareness and accessibility, understandability, and applicability of the DAIDS Critical Events Policy. Name and contact information will be collected separate from the data collection survey and participant incentive distribution logs. The purpose for recording names is the confirm consent and verify the incentive amount given to each participant. Access to these names will be restricted to a limited number of SSI staff. Participant names will not be given to DAIDS.

7. Will human data be? (*select all that apply*)

Collected Yes X No ___
Received Yes _X_ No _X_
Sent Yes__ No _X_

Responses from participants will be obtained through online surveys (coded, no names). In addition, audio transcripts of participants in the focus group discussions will be collected.

8. If receiving or sending, list the collaborating investigator(s):
Name Institution/IC Address/e-mail FWA number*****
Social Solutions International, Inc., 8070 Georgia Ave, Su 201, Silver Spring, MD, 20910, FWA00008632

9. Where are the subjects of this research activity located? *(Provide a general description or complete the institutional information below)*

Institution: DAIDS staff (FTEs and contract employees) are local to the DC Metro area. Extramural researchers (e.g., domestic and international PIs, site coordinators), and external stakeholders (e.g., clinical site monitors, DAIDS Network leadership, Operations center staff, data management staff, protocol teams) are located around the world, including the U.S., sub-Saharan Africa, South America, and Asia. Surveys will be completed through the participants' computer. The extramural researchers/external stakeholders focus group interviews will be done at local (n=5), domestic (n=1), and international (n=1) DAIDS Network meetings. DAIDS staff focus groups will be conducted locally.
Contact Name: _____Lynda Lahl_____

Address: NIAID/DAIDS/OPCRO/ProPEP Phone: (301) 435-3756

10. Will NIH investigator(s) have direct contact or intervention with the subjects of the study? (For example, by interviewing, surveying or recording the subjects?)
Yes X__ No __

If yes, what is the age range of subjects involved in the research?
___ Children aged < 18 years
_X_ Adults aged ≥ 18 years

11. Who will collect the data or information?

(a) ___ NIH Investigator
(b) ___ non-NIH Collaborator
(c) __X_ NIH Contractor
(d) ___ Other, specify_____

If b or c, will an Honest Broker or data use agreement be used? Yes__ No_X_

If yes, complete and attach the Honest Broker Assurance or data-use agreement to this submission; e-mail ohsr_nih_ddir@od.nih.gov to request a form.

12. Select the best description that applies to the human data or information:

__ Data or information will not contain any identifiable information, nor can it be linked to individual subjects by you or your collaborators.
X__ Data or information will be recorded in such a manner that subjects can be identified directly or through identifiers linked to the subjects*
* All identifying information will be stored separate from study data. Any electronic data is encrypted and stored on a password protected computer in the SSI offices. Only Social Solutions' project staff with the appropriate security levels and completed security and privacy training are able to access the computer.

13. Per NIH guidance, are all conflicts of interest by NIH employees (sender or receiver), if any, resolved? _X____Yes _____No**

**A Federalwide Assurance (FWA) is issued by the U.S. Department of Health and Human Services (DHHS)/ Office of Human Research Protections (OHRP) to institutions which receive Federal funds/support to conduct human subjects research. To search for the FWA# for domestic or international institutions go to http://ohrp.cit.nih.gov/search/fwasearch.aspx?styp=bsc*

***If the answer is "No", note that OHSRP will be unable to make a determination and research may not proceed until all conflicts are resolved. For more information, see the October 2011, A Guide to Preventing Financial and Non-Financial Conflict of Interest in Human Subjects Research at NIH. For assistance review the list of Ethics Coordinators and find the contact for your IC: http://ethics.od.nih.gov/coord.pdf*

List of Attachments:

A- Pilot Survey Informed consent for DAIDS staff
B- Pilot Survey Informed consent for Extramural Researcher/External Stakeholders
C- DAIDS staff recruitment email for pilot survey
D- Extramural Researcher/External Stakeholders recruitment email for pilot survey
E- DAIDS staff recruitment email for potential survey participants
F- Extramural Researcher/External Stakeholders recruitment email for potential survey participants
G- Survey participants informed consent (all)
H- Email to participants with unique link to survey
I- DAIDS staff and PPD site monitor pilot survey questionnaire
J- Extramural Researcher/External Stakeholders pilot survey questionnaire
K- DAIDS staff survey
L- Extramural Researcher/External Stakeholders survey
M- Recruitment email for potential focus group participants
N- DAIDS staff focus group consent form
O- Extramural Researcher/External Stakeholders focus group consent form
P- Focus group details and preparations
Q- Focus group opening script
R- Focus group probes/questions

Attachment A: Landing Page with Study Details and Informed Consent Statement for Pilot Survey of DAIDS Staff

In order to register to take the pilot survey, participants will follow a link to Survey Monkey providing the following study details and informed consent statement. To provide consent, potential participants will click "Agree" or "Disagree" with the informed consent statement. If they disagree, they can exit Survey Monkey. If they agree, they will be prompted enter their email address and incentive distribution contact information. This information will be stored separately from any survey responses.

Social Solutions International, Inc. has been contracted by the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) to conduct a process evaluation of the Critical Events Policy Implementation (CEPI) program. Critical Events may occur during the conduct of clinical research that deviates from Institutional Review Board (IRB)/Ethics Committee (EC) – approved protocols and may adversely affect risks to research participants, or study outcomes and integrity. DAIDS created this policy to provide guidance on how to report critical events. Social Solutions is conducting this research in order to assess DAIDS staff, extramural researchers and external stakeholders' awareness of the policy and supplemental resources, as well as the accessibility, understandability, and applicability of the Critical Events policy and related documents. This research will also provide insight into the success of training efforts in increasing knowledge of the policy, and satisfaction with available training and support.

An important part of this research involves the collection of surveys from DAIDS staff, extramural researchers, and external stakeholders at two points throughout the next two years. We are asking for your participation in a pilot survey to determine the clarity of instructions, readability, understandability, reliability, and validity of the draft survey instrumentation, as well as the order and format of questions. Once you have completed the pilot survey, we are asking for you participation in a questionnaire on your opinions about the survey instrumentation.

The survey consists of a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and your related responsibilities. The information that you provide in this pilot survey will be used to improve and adjust the final survey instrumentation that will be sent to over 500 participants. Your opinions, experiences, and ideas are very important.

If you would like to participate, please read the informed consent statement below and select "Agree" to provide your consent to participate in the survey. You will then be prompted to enter your email address and if applicable, your mailing address so that we may send you a stipend for your time to complete the survey. DAIDS staff (including HJF-DAIDS staff) and Site monitors will not receive a stipend for their completion of the survey. All information collected will be kept confidential and secure. No personally identifiable information will be stored with your

responses to the survey. Your contact information will be used only to send you a unique link to the full survey and/or to provide your stipend.
Once you have consented to participate and provided your information, Social Solutions researchers will send you an email with a unique link to the Survey Monkey survey within 2 business days. No individual will participate in the focus group without prior completion of the consent form.

Informed Consent Statement

The survey consists of a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and your related responsibilities. The information that you provide in the survey may be used by NIAID/DAIDS to improve policy implementation and dissemination. Your opinions, experiences, and ideas are very important.

PROCEDURES
The survey will each take approximately 30-35 minutes to complete. You do not have to do anything to prepare for the survey. We will ask questions about the Critical Events policy, including how easy you find the policy to understand and apply to your work, your satisfaction with trainings on the policy, and recommendations for policy improvement.

PARTICIPATION AND WITHDRAWAL
Participation in this survey is completely voluntary. There is no consequence if you decide not to complete the survey.

POTENTIAL RISKS
We anticipate very few risks to you from participation in this survey. There is a small chance that you may feel uncomfortable with a question and not want to respond. If you do experience negative feelings as a result of the survey, a clinical psychologist will be available to discuss those feelings. In the unlikely event of physical or other injury resulting from the survey, emergency medical treatment will be provided, but financial compensation will not be available. Social Solutions will not provide compensation if you experience injury or other adverse effects, which are not the fault of the investigators.

ANTICIPATED BENEFITS
If you decide to participate in the survey, you may gain a better understanding of the Critical Events policy and resources and trainings available. This information may motivate you to obtain more information about the policy, about clinical research protocols, and/or change your behavior to positively improve clinical research and reporting. Additionally, the information that you provide will be used to improve the program's policy dissemination efforts.

PRIVACY AND CONFIDENTIALITY
To protect your identity, none of the information you provide will be associated with any statement or identified personally in any way. Other than the signed consent form, no personal

identifiable information will be collected. The consent form will be kept separate from the other information we collect to make sure that the data cannot be identified.

Any survey information collected by paper will be kept in a locked cabinet. Information transferred and stored electronically will be stored only on password-protected computers. Only specified researchers at Social Solutions will have access to this information, and all researchers are trained in secure and private research protocols. All files will be destroyed 7 years after the study concludes.

Information provided during the research will only be disclosed to others if necessary to protect your rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

QUESTIONS AND CONCERNS
If you have any questions about this project, you may contact:

Jenny Namur Karp	Kristen Stier
President and Principal Investigator	Project Coordinator/Research Associate
Social Solutions International, Inc.	Social Solutions International, Inc.
Email: jnkarp@socialsolutions.biz	Email: kstier@socialsolutions.biz
Phone: 202.491.4954	Phone: 202.870.2226

If you have any questions about your rights as a research participant, please call Karen Chen at 703-738-6684.

CONSENT
Informed consent shall be documented, as approved by the IRB, by your agreement with the informed consent statement. Agreement must be selected by the participant or the participant's legally authorized representative. The investigator should provide either the participant or the representative adequate opportunity to read the consent form and pose questions to the investigator prior to signing the form.

Please read and show that you understand what you have read by selected agree below.

I have read this form and understand all of the information about my involvement in the survey. By clicking below, I agree to participate.

Agree Disagree

Attachment B: Landing Page with Study Details and Informed Consent Statement for Pilot Survey of Extramural Researchers and External Stakeholders

In order to register to take the pilot survey, participants will follow a link to Survey Monkey providing the following study details and informed consent statement. To provide consent, potential participants will click "Agree" or "Disagree" with the informed consent statement. If they disagree, they can exit Survey Monkey. If they agree, they will be prompted enter their email address and incentive distribution contact information. This information will be stored separately from any survey responses.

Social Solutions International, Inc. has been contracted by the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) to conduct a process evaluation of the Critical Events Policy Implementation (CEPI) program. Critical Events may occur during the conduct of clinical research that deviates from Institutional Review Board (IRB)/Ethics Committee (EC) – approved protocols and may adversely affect risks to research participants, or study outcomes and integrity. DAIDS created this policy to provide guidance on how to report critical events. Social Solutions is conducting this research in order to assess DAIDS staff, extramural researchers and external stakeholders' awareness of the policy and supplemental resources, as well as the accessibility, understandability, and applicability of the Critical Events policy and related documents. This research will also provide insight into the success of training efforts in increasing knowledge of the policy, and satisfaction with available training and support.

An important part of this research involves the collection of surveys from DAIDS staff, extramural researchers, and external stakeholders at two points throughout the next two years. We are asking for your participation in a pilot survey to determine the clarity of instructions, readability, understandability, reliability, and validity of the draft survey instrumentation, as well as the order and format of questions. Once you have completed the pilot survey, we are asking for you participation in a questionnaire on your opinions about the survey instrumentation.

The survey consists of a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and your related responsibilities. The information that you provide in this pilot survey will be used to improve and adjust the final survey instrumentation that will be sent to over 500 participants. Your opinions, experiences, and ideas are very important.

If you would like to participate, please read the informed consent statement below and select "Agree" to provide your consent to participate in the survey. You will then be prompted to enter your email address and if applicable, your mailing address so that we may send you a stipend for your time to complete the survey. DAIDS staff (including HJF-DAIDS staff) and Site monitors will not receive a stipend for their completion of the survey. All information collected will be kept confidential and secure. No personally identifiable information will be stored with your

responses to the survey. Your contact information will be used only to send you a unique link to the full survey and/or to provide your stipend.

Once you have consented to participate and provided your information, Social Solutions researchers will send you an email with a unique link to the Survey Monkey survey within 2 business days. No individual will participate in the focus group without prior completion of the consent form.

Informed Consent Statement

The survey consists of a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and your related responsibilities. The information that you provide in the survey may be used by NIAID/DAIDS to improve policy implementation and dissemination. Your opinions, experiences, and ideas are very important.

PROCEDURES
The survey will each take approximately 30-35 minutes to complete. You do not have to do anything to prepare for the survey. We will ask questions about the Critical Events policy, including how easy you find the policy to understand and apply to your work, your satisfaction with trainings on the policy, and recommendations for policy improvement.

PARTICIPATION AND WITHDRAWAL
Participation in this survey is completely voluntary. There is no consequence if you decide not to complete the survey.

POTENTIAL RISKS
We anticipate very few risks to you from participation in this survey. There is a small chance that you may feel uncomfortable with a question and not want to respond. If you do experience negative feelings as a result of the survey, a clinical psychologist will be available to discuss those feelings. In the unlikely event of physical or other injury resulting from the survey, emergency medical treatment will be provided, but financial compensation will not be available. Social Solutions will not provide compensation if you experience injury or other adverse effects, which are not the fault of the investigators.

ANTICIPATED BENEFITS
If you decide to participate in the survey, you may gain a better understanding of the Critical Events policy and resources and trainings available. This information may motivate you to obtain more information about the policy, about clinical research protocols, and/or change your behavior to positively improve clinical research and reporting. Additionally, the information that you provide will be used to improve the program's policy dissemination efforts.

INCENTIVES
Participants (excluding PPD-DAIDS Site monitors) will receive $15 as a token of appreciation for their completion of the survey.

PRIVACY AND CONFIDENTIALITY
To protect your identity, none of the information you provide will be associated with any statement or identified personally in any way. Other than the signed consent form, no personal identifiable information will be collected. The consent form will be kept separate from the other information we collect to make sure that the data cannot be identified.

Any survey information collected by paper will be kept in a locked cabinet. Information transferred and stored electronically will be stored only on password-protected computers. Only specified researchers at Social Solutions will have access to this information, and all researchers are trained in secure and private research protocols. All files will be destroyed 7 years after the study concludes.

Information provided during the research will only be disclosed to others if necessary to protect your rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

QUESTIONS AND CONCERNS
If you have any questions about this project, you may contact:

Jenny Namur Karp	Kristen Stier
President and Principal Investigator	Project Coordinator/Research Associate
Social Solutions International, Inc.	Social Solutions International, Inc.
Email: jnkarp@socialsolutions.biz	Email: kstier@socialsolutions.biz
Phone: 202.491.4954	Phone: 202.870.2226

If you have any questions about your rights as a research participant, please call Karen Chen at 703-738-6684.

CONSENT
Informed consent shall be documented, as approved by the IRB, by your agreement with the informed consent statement. Agreement must be selected by the participant or the participant's legally authorized representative. The investigator should provide either the participant or the representative adequate opportunity to read the consent form and pose questions to the investigator prior to signing the form.

Please read and show that you understand what you have read by selected agree below.

I have read this form and understand all of the information about my involvement in the survey. By clicking below, I agree to participate.

Attachment C: NIAID DAIDS Staff Recruitment Email for Pilot Survey

[DATE]

DAIDS Critical Events Policy Implementation Program (CEPI) Pilot Survey

Please respond to this survey by January 29, 2014

Contact Us

Lyndi Lahl, Policy Health Specialist

Protection of Participants, Evaluation, and Policy Branch
OPCRO/DAIDS/NIAID/NIH

Lynda.Lahl@nih.gov

The use of a web-based survey will help to ensure survey responses are kept private . The survey will request no individual identifiers.

Welcome to the DAIDS Critical Events Policy Implementation Program (CEPI) Pilot Survey!

Why should you respond to this pilot survey?

As professionals who actively utilize DAIDS policies, we ask that you participate in the CEPI pilot survey so that we learn more about:

- Awareness, accessibility, understandability, and experience with the DAIDS Critical Events Policy and Manual
- Applicability of the DAIDS Critical Events Policy and Manual to clinical research
- Recommendations to improve the critical event reporting and question submission process
- Your experience taking the survey

- **The entire survey and questionnaire is voluntary and will take no more than 30-35 minutes to complete.** I encourage you to participate. Please click here to provide your consent to take the short, web-based, confidential survey by January 29, 2014. You be prompted to enter your email address and a unique link to the full, confidential web-based survey will be emailed to you within 2 business days.

Attachment D: NIAID Extramural Researcher and External Stakeholder Recruitment Email for Pilot Survey

[DATE]

DAIDS Critical Events Policy Implementation Program (CEPI) Pilot Survey

Please respond to this survey by January 29, 2014

Contact Us

Lynda Lahl, Policy Health Specialist

Protection of Participants, Evaluation and Policy and Branch
OPCRO/DAIDS/NIAID/NIH

Lynda.Lahl@nih.gov

The use of a web-based survey will help to ensure survey responses are kept private . The survey will request no individual identifiers.

Welcome to the DAIDS Critical Events Policy Implementation Program (CEPI) Pilot Survey!

Why should you respond to this pilot survey?

As professionals who actively utilize DAIDS policies, we ask that you participate in the CEPI pilot survey so that we learn more about:

- Awareness, accessibility, understandability, and experience with the DAIDS Critical Events Policy and Manual
- Applicability of the DAIDS Critical Events Policy and Manual to clinical research
- Recommendations to improve the critical event reporting and question submission process
- Your experience taking the survey

You will receive a small stipend as compensation for your time in completing this survey, excluding PPD-DAIDS Site monitors.

The entire survey and questionnaire is voluntary and will take no more than 30-35 minutes to complete. I encourage you to participate. Please click here to provide your consent to take the short, web-based, confidential survey by January 29, 2014. You be prompted to enter your email address and a unique link to the full, confidential web-based survey will be emailed to you within 2 business days.

Attachment E: NIAID DAIDS Staff Recruitment Email to Potential Survey Participants

[DATE]

Welcome to the DAIDS Critical Events Policy Implementation Program (CEPI) Survey!

Why should you respond to this survey?

As professionals who actively utilize DAIDS policies, we ask that you participate in the CEPI survey so that we learn more about:

- Awareness, accessibility, understandability, and experience with the DAIDS Critical Events Policy and Manual
- Applicability of the DAIDS Critical Events Policy and Manual to clinical research
- Recommendations to improve the critical event reporting and question submission process.

The entire survey is <u>voluntary</u> and will take no more than 30 minutes to complete. I encourage you to participate.

To Sign Up for the Survey:

- Click this link to read more about the study and consent to take the survey.
- You will then be prompted to enter your email address.
- A unique link to the full, confidential web-based survey will be emailed to you within 2 business days.

Attachment F: NIAID Extramural Researcher and External Stakeholder Recruitment Email to Potential Survey Participants

[DATE]

DAIDS Critical Events Policy Implementation Program (CEPI) Survey

Contact Us

Lynda Lahl, Policy Health Specialist

Protection of Participants, Evaluation and Policy and Branch OPCRO/DAIDS/NIAID/NIH

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The use of a web-based survey will help to ensure survey responses are kept private . The survey will request no individual identifiers.

Welcome to the DAIDS Critical Events Policy Implementation Program (CEPI) Survey!

Why should you respond to this survey?

As professionals who actively utilize DAIDS policies, we ask that you participate in the CEPI survey so that we learn more about:

- Awareness, accessibility, understandability, and experience with the DAIDS Critical Events Policy and Manual
- Applicability of the DAIDS Critical Events Policy and Manual to clinical research
- Recommendations to improve the critical event reporting and question submission process
  You will receive a small stipend as compensation for your time in completing this survey, excluding PPD-DAIDS Site monitors.

The entire survey is <u>voluntary</u> and will take no more than 30 minutes to complete. I encourage you to participate.

To Sign Up for the Survey:

- Click this link to read more about the study and consent to take the survey.
- You will then be prompted to enter your email address, and mailing address to receive your incentive.
- A unique link to the full, confidential web-based survey will be emailed to you within 2 business days.

Attachment G: Landing Page with Study Details and Informed Consent Statement

In order to register to take the survey, participants will follow a link to Survey Monkey providing the following study details and informed consent statement. To provide consent, potential participants will click "Agree" or "Disagree" with the informed consent statement. If they disagree, they can exit Survey Monkey. If they agree, they will be prompted enter their email address and incentive distribution contact information. This information will be stored separately from any survey responses.

Social Solutions International, Inc. has been contracted by the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) to conduct a process evaluation of the Critical Events Policy Implementation (CEPI) program. Critical Events may occur during the conduct of clinical research that deviates from Institutional Review Board (IRB)/Ethics Committee (EC) – approved protocols and may adversely affect risks to research participants, or study outcomes and integrity. DAIDS created this policy to provide guidance on how to report critical events. Social Solutions is conducting this research in order to assess DAIDS staff, extramural researchers and external stakeholders' awareness of the policy and supplemental resources, as well as the accessibility, understandability, and applicability of the Critical Events policy and related documents. This research will also provide insight into the success of training efforts in increasing knowledge of the policy, and satisfaction with available training and support.

As part of the evaluation, we will be conducting surveys and focus groups with DAIDS Staff, Extramural Researchers and External Stakeholders. Your involvement in the evaluation will be the key to our success. As one of those key stakeholders, on behalf of NIAID/DAIDS, we would like to request your participation in a survey. We are looking for participants who can complete the survey on 2 separate occasions – one during the months of October – December 2014 and another during the months of October-December 2015.

If you would like to participate, please read the informed consent statement below and select "Agree" to provide your consent to participate in the survey. You will then be prompted to enter your email address and if applicable, your mailing address so that we may send you a stipend for your time to complete the survey. DAIDS staff (including HJF_DAIDS staff) and Site monitors will not receive a stipend for their completion of the survey. All information collected will be kept confidential and secure. No personally identifiable information will be stored with your responses to the survey. Your contact information will be used only to send you a unique link to the full survey and/or to provide your stipend.

Once you have consented to participate and provided your information, Social Solutions researchers will send you an email with a unique link to the Survey Monkey survey within 2 business days. No individual will participate in the focus group without prior completion of the consent form.

Informed Consent Statement

The survey consists of a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and your related responsibilities. The information that you provide in the survey may be used by NIAID/DAIDS to improve policy implementation and dissemination. Your opinions, experiences, and ideas are very important.

PROCEDURES
The survey will each take approximately 25-30 minutes to complete. You do not have to do anything to prepare for the survey. We will ask questions about the Critical Events policy, including how easy you find the policy to understand and apply to your work, your satisfaction with trainings on the policy, and recommendations for policy improvement.

PARTICIPATION AND WITHDRAWAL
Participation in this survey is completely voluntary. There is no consequence if you decide not to complete the survey.

POTENTIAL RISKS
We anticipate very few risks to you from participation in this survey. There is a small chance that you may feel uncomfortable with a question and not want to respond. If you do experience negative feelings as a result of the survey, a clinical psychologist will be available to discuss those feelings. In the unlikely event of physical or other injury resulting from the survey, emergency medical treatment will be provided, but financial compensation will not be available. Social Solutions will not provide compensation if you experience injury or other adverse effects, which are not the fault of the investigators.

ANTICIPATED BENEFITS
If you decide to participate in the survey, you may gain a better understanding of the Critical Events policy and resources and trainings available. This information may motivate you to obtain more information about the policy, about clinical research protocols, and/or change your behavior to positively improve clinical research and reporting. Additionally, the information that you provide will be used to improve the program's policy dissemination efforts.

INCENTIVES
Non-DAIDS staff participants (excluding PPD-DAIDS Site monitors) will receive $10 as a token of appreciation for their completion of the survey.

PRIVACY AND CONFIDENTIALITY
To protect your identity, none of the information you provide will be associated with any statement or identified personally in any way. Other than the signed consent form, no personal identifiable information will be collected. The consent form will be kept separate from the other information we collect to make sure that the data cannot be identified.

Any survey information collected by paper will be kept in a locked cabinet. Information transferred and stored electronically will be stored only on password-protected computers. Only specified researchers at Social Solutions will have access to this information, and all researchers are trained in secure and private research protocols. All files will be destroyed 7 years after the study concludes.

Information provided during the research will only be disclosed to others if necessary to protect your rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

QUESTIONS AND CONCERNS
If you have any questions about this project, you may contact:

Jenny Namur Karp	Kristen Stier
President and Principal Investigator	Project Coordinator/Research Associate
Social Solutions International, Inc.	Social Solutions International, Inc.
Email: jnkarp@socialsolutions.biz	Email: kstier@socialsolutions.biz
Phone: 202.491.4954	Phone: 202.870.2226

If you have any questions about your rights as a research participant, please call Karen Chen at 703-738-6684.

CONSENT
Informed consent shall be documented, as approved by the IRB, by your agreement with the informed consent statement. Agreement must be selected by the participant or the participant's legally authorized representative. The investigator should provide either the participant or the representative adequate opportunity to read the consent form and pose questions to the investigator prior to signing the form.

Please read and show that you understand what you have read by selected agree below.

I have read this form and understand all of the information about my involvement in the survey. By clicking below, I agree to participate.

Agree Disagree

Attachment H: Email to Participants with Unique Link to Survey

Dear Participant,

Thank you for your participation in the DAIDS Critical Events Policy Implementation Program (CEPI) Survey. Please click the following link to complete the survey via Survey Monkey. This link is unique to you. Your survey responses will be kept secure and confidential. Once you have completed the survey, Social Solutions will mail your stipend [omitted for DAIDS staff, including HJF-DAIDS staff, and Site monitors].

Link

If you have any questions, please contact:

Jenny Namur Karp
President and Principal Investigator
Social Solutions International, Inc.
Email: jnkarp@socialsolutions.biz
Phone: 202.491.4954

Thank you for your time,

Social Solutions Researchers

Attachment I: DAIDS Staff and PPD-DAIDS Site Monitor Pilot Survey Questionnaire

Social Solutions International, Inc.

Now that you have completed the pilot survey, we ask that you reflect back on this experience. Please answer the following questions below.

1. Please rate the burden on your time to complete the survey instrument:
    a. Not at all burdensome
    b. Slightly burdensome
    c. Moderately burdensome
    d. Largely burdensome
    e. Overly burdensome

2. How long did it take you to complete the survey?
    a. 10-15 minutes
    b. 15-20 minutes
    c. 20-25 minutes
    d. 25-30 minutes
    e. More than 30 minutes

3. Please rate the clarity of instructions for the completing the survey instrument:
    a. Extremely clear
    b. Somewhat clear
    c. Unsure
    d. Somewhat unclear
    e. Extremely unclear

4. Please rate the clarity of questions in the survey instrument:
    a. Extremely clear
    b. Somewhat clear
    c. Unsure
    d. Somewhat unclear
    e. Extremely unclear

5. Please rate the readability of the survey questions:
    a. Extremely easy to understand
    b. Somewhat easy to understand
    c. Unsure
    d. Somewhat difficult to understand
    e. Extremely difficult to understand

6. If there was anything unclear about the survey instrument, please describe what was unclear in a couple of sentences below:

_____
_____
_____
_____

7. Please rate the logical order and flow of the questions:
    a. Extremely logical and coherent order
    b. Somewhat logical and coherent order
    c. Unsure
    d. Somewhat illogical and incoherent order
    e. Extremely illogical and incoherent order

8. What is your preference for question format?
    a. Likert Scale (participants rank their level of satisfaction or agreement with a statement)
    b. Multiple Choice Questions (participants select among alphabetized options)
    c. Multiple Selection Questions (participants checks all that apply)
    d. Open-ended questions (participants write full sentences)

9. Is there anything you would change about the survey? If so, please indicate below in a couple of sentences:

_____
_____
_____
_____

Attachment J: Extramural Researcher/External Stakeholder Pilot Survey Questionnaire

Social Solutions International, Inc.

Now that you have completed the pilot survey, we ask that you reflect back on this experience. Please answer the following questions below.

1. Please rate the burden on your time to complete the survey instrument:
    a. Not at all burdensome
    b. Slightly burdensome
    c. Moderately burdensome
    d. Largely burdensome
    e. Overly burdensome

2. How long did it take you to complete the survey?
    a. 10-15 minutes
    b. 15-20 minutes
    c. 20-25 minutes
    d. 25-30 minutes
    e. More than 30 minutes

3. Please rate the clarity of instructions for the completing the survey instrument:
    a. Extremely clear
    b. Somewhat clear
    c. Unsure
    d. Somewhat unclear
    e. Extremely unclear

4. Please rate the clarity of questions in the survey instrument:
    a. Extremely clear
    b. Somewhat clear
    c. Unsure
    d. Somewhat unclear
    e. Extremely unclear

5. Please rate the readability of the survey questions:
    a. Extremely easy to understand
    b. Somewhat easy to understand
    c. Unsure
    d. Somewhat difficult to understand
    e. Extremely difficult to understand

6. If there was anything unclear about the survey instrument, please describe what was unclear in a couple of sentences below:

_____
_____
_____
_____

7. Please rate the logical order and flow of the questions:
    f. Extremely logical and coherent order
    g. Somewhat logical and coherent order
    h. Unsure
    i. Somewhat illogical and incoherent order
    j. Extremely illogical and incoherent order

8. What is your preference for question format?
    a. Likert Scale (participants rank their level of satisfaction or agreement with a statement)
    b. Multiple Choice Questions (participants select among alphabetized options)
    c. Multiple Selection Questions (participants checks all that apply)
    d. Open-ended questions (participants write full sentences)

9. If you were provided with a $10 incentive to participate in a study that asked you to fill out this survey instrument on two occasions (for a total of $20), how likely would you be to participate?
    a. Definitely would participate
    b. More likely to participate
    c. Not sure
    d. More than likely NOT to participate
    e. Would not participate

10. Is there anything you would change about the survey? If so, please indicate below in a couple of sentences:

_____
_____
_____
_____

Attachment K: DAIDS Staff Survey

Social Solutions International, Inc.

Thank you for taking the time to complete this survey. The information you provide will help us to improve the program. Please answer each question as honestly as possible. Your name will not be linked to the answers you provide. The information you provide will be completely confidential.

Background Information - Please provide the following information about yourself:

Select your role with DAIDS (drop-down menu)

1. Clinical oversight staff (OCSO)
2. Program Officer (Non-Network PO)
3. Medical Officer
4. Other, please list: _____

Enter your number of years' experience with clinical research:

Please rate your current level of knowledge pertaining to the Critical Events Policy and Manual:

a. Extremely knowledgeable
b. Very knowledgeable
c. Moderately knowledgeable
d. Not very knowledgeable
e. Not at all knowledgeable

On a scale from 1 to 5 (1 meaning strongly DISAGREE and 5 meaning strongly AGREE), please indicate your level of agreement with the following statements:

1. I know where to find the Critical Events Policy and Manual.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***			***3***
4	***5***			

2. I regularly access the Critical Events Policy and Manual.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

3. For what reason(s) do you access the Critical Events Policy and Manual?

_____

_____

4. What information or section are you referencing?

_____

_____

5. I can access the Critical Events Policy and Manual easily.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3*** ***4*** ***5***

6. I am satisfied with the clarity and understandability of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3*** ***4*** ***5***

7. There are barriers that hinder my access to the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3*** ***4*** ***5***

a. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

8. I know where to find additional Critical Events supplemental resources, including the primer on Critical Events, supplemental Critical Events training aids, and the Critical Events Web Training Presentation Slides.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3*** ***4*** ***5***

a. If you circled Agree (4) or Strongly Agree (5), please list the supplemental resources that you know are available.

_____

9. I regularly access additional Critical Events supplemental resources.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3*** ***4*** ***5***

10. For what reason(s) do you access the Critical Events Policy and Manual?

_____

_____

11. What information or section are you referencing?

_____

_____

12. I can access additional Critical Events supplemental resources easily.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

13. I am satisfied with the clarity and understandability of the additional Critical Events supplemental resources.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

14. There are barriers that restrain my access to Critical Events supplemental resources

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

a. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

15. I know where to locate the DAIDS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

16. I have accessed the DAIDS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

17. I can access the DAIDS Online Critical Events Training easily.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

18. I am satisfied with the clarity and understandability of the DAIDS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

19. There are barriers that hinder my access to the DAIDS CRSS Online Critical Events Training.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***			***3***
4	***5***			

a. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

20. I know where to find information about Critical Events policy dissemination activities (webinars, network meeting information sessions, in-person staff trainings, etc).

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***			***3***
4	***5***			

21. I regularly access/participate in Critical Event policy dissemination activities.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***			***3***
4	***5***			

22. I can access/participate in dissemination activities easily.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

23. I am satisfied with the clarity and understandability of the dissemination activities.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***			***3***
4	***5***			

24. There are barriers that hinder my access/participation in dissemination activities.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***			***3***
4	***5***			

a. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

25. Did you receive any of the following communications describing the Critical Events Policy and Manual (please circle all that apply)?

a. HANC listserv email
b. HANC newsletter
c. HANC Conference Call
d. OPCRO email alert
e. DAIDS Training and Safety Branch email alert
f. Other _____

26. Have you ever emailed another DAIDS staff member with questions concerning the Critical Events Policy and Manual?

Yes ***No***

27. Where was this staff member located?
a. Program
b. OCSO
c. OPCRO
d. OD

28. Did you receive a response?

Yes ***No***

29. If so, did you understand the response received?

Yes ***No***

30. Did the response answer your question?

Yes ***No***

31. Could the response have been clearer or easier to understand?

Yes ***No***

32. What would have increased understandability and clarity of the response?

_____

_____

33. Have you ever been involved in communications regarding a Critical Event?
Yes ***No***

33. Did you receive a response?

Yes ***No***

34. What type of Critical Event did the communication entail (please circle all that apply)?
    a. Unanticipated Problem
    b. Serious Noncompliance
    c. Continuing Noncompliance
    d. Suspension or Termination of IRB approval

35. If so, did you understand the response received?

Yes ***No***

36. Were you able to apply the response you received to the Critical Event?

Yes *No*

37. Could the response have been clearer or easier to understand?

Yes ***No***

38. What would have increased response understandability and clarity of the response?

_____

_____

On a scale from 1 to 5 (1 meaning strongly DISAGREE and 5 meaning strongly AGREE), please indicate your level of agreement with the following statements:

39. I am satisfied with my ability to apply the Critical Events Policy and Manual to DAIDS clinical research studies.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***	***3***	***4***	***5***

40. I am satisfied that the supplemental resources and trainings improved my ability to apply the Critical Events Policy and Manual to DAIDS clinical research.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***	***3***	***4***	***5***

41. I view the Critical Events Policy and Manual as applicable to DAIDS clinical research.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1	***2***	***3***	***4***	***5***

42. I would benefit from additional training to improve my understanding and application of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3***

4 ***5***

43. DAIDS staff critical events trainings increased my knowledge of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree*** ***NA***

1 ***2*** ***3***

4 ***5***

44. Is there any policy or part of the Critical Events Policy and Manual that you do not view as applicable?

Yes ***No***

If 'Yes,' please identify what is not applicable.

_____

_____

45. What burdens exist in complying with the Critical Events Policy and Manual requirements?

_____

_____

46. What challenges or barriers exist in complying with the Critical Events Policy and Manual requirements?

_____

_____

47. What can be done to improve accessibility of Critical Events documents?

_____

_____

48. Which requirement(s) are the easiest to comply with? *(check all that apply)*

□ Notify PI within 24 hrs of becoming aware of incident
□ Determine type of Critical Event that occurred
□ Submit initial report to DAIDS within three reporting days after becoming aware of Critical Event
□ Reporting Critical Event to IRB/EC in accordance with institutional policies
□ Following corrective actions as directed by IRB/EC, DAIDS or other relevant entity
□ Provide update/final report to DAIDS within 15 calendar days
□ Other _____

49. Which requirement(s) are the most challenging to comply with? *(check all that apply)*
□ Notify PI within 24 hrs of becoming aware of incident
□ Determine type of Critical Event that occurred
□ Submit initial report to DAIDS within three reporting days after becoming aware of Critical Event
□ Reporting Critical Event to IRB/EC in accordance with institutional policies
□ Following corrective actions as directed by IRB/EC, DAIDS or other relevant entity
□ Provide update/final report to DAIDS within 15 calendar days
□ Other _____

50. What recommendations do you have for Critical Events Policy Implementation improvement?

_____

_____

Attachment L: Extramural Researcher/External Stakeholder Survey

Social Solutions International, Inc.

Thank you for taking the time to complete this survey. The information you provide will help us to improve the program. Please answer each question as honestly as possible. Your name will not be linked to the answers you provide. The information you provide will be completely confidential.

Background Information - Please provide the following information about yourself:

Select your role with DAIDS (*check all that apply*)

□ CRS Leader
□ CRS Coordinator
□ CTU Principal Investigator
□ CTU Coordinator
□ Clinical site personnel
□ Contracted site monitor
□ Network leadership
□ Operation center staff
□ Data management staff
□ Protocol team member
□ Other, please list: _____

If applicable, enter the DAIDS Network(s) you are affiliated with.

□ ACTG
□ HVTN
□ HPTN
□ IMPAACT
□ MTN

Are you involved with a non-network study?

Yes ***No***

Select the type of clinical research site you work at (*check all that apply*):

□ International (non-U.S. site)
□ Domestic (U.S. site)
□ Network
□ Non-Network
□ Pluripotent (a research site that conducts studies in more than one Network and may either be domestic and/or international sites)
□ New CRS Site (site not affiliated with DAIDS research before 2013)
□ Not Applicable

□ Other: _____

Are you a native English speaker? _____

Enter your number of years' experience with clinical research: _____

Please rate your current level of knowledge pertaining to the Critical Events Policy and Manual:

a. Extremely knowledgeable
b. Very knowledgeable
c. Moderately knowledgeable
d. Not very knowledgeable
e. Not at all knowledgeable

On a scale from 1 to 5 (1 meaning strongly DISAGREE and 5 meaning strongly AGREE), please indicate your level of agreement with the following statements:

1. I know where to find the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

2. I regularly access the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

3. For what reason(s) do you access the Critical Events Policy and Manual?

_____
_____

4. What information or section are you referencing?

_____
_____

5. I can access the Critical Events Policy and Manual easily.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

6. I am satisfied with the clarity and understandability of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

7. There are barriers that hinder my access to the Critical Events Policy and Manual.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

a. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

8. I know where to find additional Critical Events supplemental resources, including the primer on Critical Events, supplemental Critical Events training aids, and the Critical Events Web Training Presentation Slides.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

a. If you circled Agree (4) or Strongly Agree (5), please list the supplemental resources that you know are available.

_____

9. I regularly access additional Critical Events supplemental resources.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

10. For what reason(s) do you access the Critical Events Policy and Manual?

_____

_____

11. What information or section are you referencing?

_____

_____

12. I can access additional Critical Events supplemental resources easily.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

13. I am satisfied with the clarity and understandability of the additional Critical Events supplemental resources.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***

1 ***2*** ***3***
4 ***5***

14. There are barriers that restrain my access to Critical Events supplemental resources

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

b. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

15. I know where to locate the DAIDS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

16. I have accessed the DAIDS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

17. I can access the DAIDS Online Critical Events Training easily.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

18. I am satisfied with the clarity and understandability of the DAIDS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

19. There are barriers that hinder my access to the DAIDS CRSS Online Critical Events Training.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

b. If you circled Agree (4) or Strongly Agree (5), please describe these barriers.

_____

_____

20. How did you receive training? (*check all that apply*)
    - □ In person- DAIDS Regional Training Event (DRTE)
    - □ In person- Network meeting
    - □ Online- DAIDS Learning Management System (DLMS)
    - □ Online- HIV Clinical Research Support Services (CRSS) Contract website
    - □ Webinar
    - □ Other_____

21. I know where to find information about Critical Events policy dissemination activities (webinars, network meeting information sessions, in-person trainings, etc).

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

22. I regularly access/participate in Critical Event Policy dissemination activities.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

23. I can access/participate in Critical Event Policy dissemination activities easily.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

24. I am satisfied with the clarity and understandability of the Critical Event Policy dissemination activities.

Strongly Disagree	***Disagree***	***Not sure***	***Agree***	***Strongly Agree***
1		***2***		***3***
4	***5***			

25. There are barriers that hinder my access/participation in Critical Event Policy dissemination activities.

    Yes ***No***

26. Did you receive any of the following communications describing the Critical Events Policy and Manual (please circle all that apply)?
    a. HANC listserv email
    b. HANC newsletter
    c. HANC Conference Call
    d. OPCRO email alert

e. DAIDS Training and Safety Branch email alert

27. Have you ever emailed DAIDS staff with questions concerning the Critical Event Policy and Manual?

Yes ***No***

28. Who from DAIDS provided responses to your question(s)?
□ DAIDS PO/MO (Program Officer, Medical Officer)
□ ProPEP (Protection of Participants, Evaluation and Policy Branch)
□ I don't know
□ I didn't submit a question to DAIDS
□ Other_____

29. Did you receive a response?

Yes ***No***

30. If so, was the answer provided in a timely fashion.

Yes ***No***

31. If so, did you understand the response received?

Yes ***No***

32. Did the response answer your question?

Yes ***No***

33. Could the response have been clearer or easier to understand?

Yes ***No***

34. Did the answer you receive improve your understanding of Critical Events?

Yes ***No***

35. What would have increased understandability and clarity of the response?

_____

_____

36. Have you ever reported a Critical Event to DAIDS staff?

Yes ***No***

37. What type of Critical Event did you report?
    - □ Unanticipated Problem
    - □ Serious Noncompliance
    - □ Continuing Noncompliance
    - □ Suspension or Termination of IRB approval

38. Did you receive a response?

    Yes ***No***

39. If so, did you understand the response received?

    Yes ***No***

40. Could the response have been clearer or easier to understand?

    Yes ***No***

41. What would have increased response understandability and clarity of the response?

_____

_____

On a scale from 1 to 5 (1 meaning strongly DISAGREE and 5 meaning strongly AGREE), please indicate your level of agreement with the following statements:

42. I am satisfied with my ability to apply the Critical Events Policy and Manual to DAIDS research.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

43. I am satisfied with the supplemental resources and trainings on my ability to apply Critical Events Policy and Manual to my DAIDS research.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

44. I view the Critical Events Policy and Manual as applicable to my DAIDS research.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***

1 ***2*** ***3***
4 ***5***

45. I would benefit from additional training to improve my understanding and application of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree***
1 ***2*** ***3***
4 ***5***

46. Webinars increased my knowledge of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree*** ***NA***
1 ***2*** ***3***
4 ***5*** ***6***

47. Network meeting information sessions increased my knowledge of the Critical Events Policy and Manual.

Strongly Disagree ***Disagree*** ***Not sure*** ***Agree*** ***Strongly Agree*** ***NA***
1 ***2*** ***3*** ***4***
5 ***6***

48. Is there any policy or part of the Critical Events Policy or Manual that you do not view as applicable?

Yes ***No***

a. If 'Yes,' please identify what is not applicable.

_____
_____

49. Have there been changes made to your site's SOPs or routine activities to meet the Critical Events Policy and Manual mandates?

Yes ***No***

a. If 'Yes,' please identify what changes have been made:

_____
_____

b. How much additional time do these changes take to carry out?

c. If 'Yes,' please identify what changes have been made:

_____

_____

d. How much additional time do these changes take to carry out?

_____

50. What burdens exist in complying with the Critical Events Policy and Manual requirements?

_____

_____

51. What challenges or barriers exist in complying with Critical Events Policy and Manual requirements?

_____

_____

52. What can be done to improve accessibility of Critical Events documents?

_____

_____

53. Which Critical Events Policy and Manual requirement(s) are the easiest to comply with? (*check all that apply*)

□ Notify PI within 24 hrs of becoming aware of incident
□ Determine type of Critical Event that occurred
□ Submit initial report to DAIDS within three reporting days after becoming aware of Critical Event
□ Reporting Critical Event to IRB/EC in accordance with institutional policies
□ Following corrective actions as directed by IRB/EC, DAIDS or other relevant entity
□ Provide update/final report to DAIDS within 15 calendar days
□ Other _____

54. Which requirement(s) are the most challenging to comply with? (*check all that apply*)

□ Notify PI within 24 hrs of becoming aware of incident
□ Determine type of Critical Event that occurred
□ Submit initial report to DAIDS within three reporting days after becoming aware of Critical Event
□ Reporting Critical Event to IRB/EC in accordance with institutional policies
□ Following corrective actions as directed by IRB/EC, DAIDS or other relevant entity
□ Provide update/final report to DAIDS within 15 calendar days
□ Other _____

55. What recommendations do you have for Critical Events Policy Implementation improvement?

Attachment M: NIAID Recruitment Email to Potential Focus Group Participants

Dear DAIDS staff, Extramural Researchers, External Stakeholders [appropriate group will be selected before email is sent],

A review of the DAIDS Critical Events Policy Implementation (CEPI) Program is being conducted. The purpose of this review is to accurately gauge your perception with respect to the awareness, accessibility, understandability, applicability and experience with the DAIDS Critical Events Policy and Manual. DAIDS acknowledges that the ability to reliably and consistently access, understand, apply and harmonize the Critical Event Policy and Manual is essential to the adherence to the reporting requirements of certain U.S. regulations.

We are hoping you are able to participate in a focus group [during the time you're attending a Network/DAIDS meeting (for non-DAIDS participants), insert training name and date] [at this date and time (for DAIDS staff)] to get your thoughts, ideas, and opinions on how easily research the DAIDS Critical Event Policy and Manual may be accessed, understood, and applied in your day-to-day research activities. Your participation is kindly requested and is not compulsory. However, DAIDS encourages your engagement in these focus groups, which are an important part of determining how to improve the DAIDS Critical Events Policy Implementation Program. The input provided is fundamental to determining the effectiveness of the communication and dissemination of DAIDS research policies. While the program review team will capture each participant's name, organizational affiliation, and/or role, all identifiable information will be separated from participant response data. Furthermore, your identities will be kept private to the extent permitted by law, and all data and findings will be reported in aggregate for analysis purposes.

The focus group interview will be approximately 90 minutes in length. You will receive a small stipend as compensation for your time in participating in the focus group. Please send an email to [insert email address] to be scheduled for participating in the focus group. You will be emailed an informed consent form to be completed and brought with you to the focus group.

We thank you for your consideration with respect to participating in the scheduled focus group interviews. The ultimate goal is to derive a comprehensive assessment of whether the processes currently in place meets the needs of DAIDS staff, Extramural Researchers/External Stakeholders [appropriate group will be selected before email is sent] with the policies necessary to effectively and accurately conduct research. From the assessment, DAIDS aims to glean what has worked well to date, as well as where CEPI program improvements could potentially be made.

Thank you for your time and consideration,

Attachment N: DAIDS Staff Focus Group Consent Form

Social Solutions International, Inc.

TITLE OF STUDY: *Critical Events Policy Implementation (CEPI) Process Evaluation*

Principal Investigator: Jenny Namur Karp
Phone Number: 202-491-4954

Project Director: Kristen Stier
Phone Number: 202-870-2226

IRB Representative: Karen Chen
Phone Number: 703-738-6684

PURPOSE OF THE STUDY

Social Solutions International, Inc. (Social Solutions) has been contracted by the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) to conduct a process evaluation of the Critical Events Policy Implementation (CEPI) program. Critical Events may occur during the conduct of clinical research that deviates from Institutional Review Board (IRB)/Ethics Committee (EC) – approved protocols and may adversely affect risks to research participants, or study outcomes and integrity. DAIDS created this policy to provide guidance on how to report critical events. The CEPI program's goal is to increase policy awareness, accessibility, understandability, and applicability of the policy by target populations, including DAIDS staff, extramural researchers, and external stakeholders. Social Solutions is conducting research to assess DAIDS staff, extramural researchers and external stakeholders' awareness of the policy and supplemental resources, as well as the accessibility, understandability, and applicability of the Critical Events policy and related documents. This research will also provide insight into the success of training efforts in increasing knowledge of the policy, and satisfaction with available training and support.

An important part of this research involves the focus group discussions with extramural researchers and external stakeholders based at a different research sites domestically and internationally. We are asking for your participation in a focus group discussion with 8 other colleagues. The discussion will involve a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and related responsibilities. The information that you provide may be used by NIAID/DAIDS to improve policy implementation and dissemination. Your opinions, experiences, and ideas are very important.

PROCEDURES

The focus group will last approximately 90 minutes. You do not have to do anything to prepare for the discussion. We will ask questions about the Critical Events policy, including how easy you find the policy to understand and apply to your work, your satisfaction with trainings on the policy, and recommendations for policy improvement. We would like to hear as many

perspectives as possible, but you do not have to answer any questions that you do not want to answer. There are no right or wrong answers – only different points of view.
We will be recording the discussion on audiotape, and a staff person will be taking notes. We will not use your name during the audio recording, and no comments you make will be personally identifiable.

PARTICIPATION AND WITHDRAWAL
Participation in this focus group is completely voluntary. There is no consequence if you decide to leave the group. You do not have to respond to any questions that you do not want to answer. The investigator reserves the right to terminate your participation at any time if you are not following study protocol.

POTENTIAL RISKS
We anticipate very few risks to you from participation in this focus group. Although all participants have been asked to keep the discussions private, there is a small chance that other participants in the focus group may share personal information outside of the project. In addition, there is a small chance that you may feel uncomfortable with a question and not want to respond. Please remember that you do not have to answer any questions you do not want to. If you do experience negative feelings as a result of the focus group discussion, a clinical psychologist will be available to discuss those feelings.

In the unlikely event of physical or other injury resulting from the focus group, emergency medical treatment will be provided, but financial compensation will not be available. Social Solutions will not provide compensation if you experience injury or other adverse effects, which are not the fault of the investigators.

ANTICIPATED BENEFITS
If you decide to participate in the focus group, you may gain a better understanding of the Critical Events policy and resources and trainings available. This information may motivate you to obtain more information about the policy, about clinical research protocols, and/or change your behavior to positively improve clinical research and reporting. Additionally, the information that you provide will be used to improve the program's policy dissemination efforts.

PRIVACY AND CONFIDENTIALITY
To protect your identity, none of the information you provide will be associated with any statement or identified personally in any way. Other than the signed consent form, no identifiable information will be collected. The consent form will be kept separate from the other information we collect to make sure that the data cannot be identified.

Any information collected by paper or on the participant incentive distribution log will be kept in a locked cabinet. Information transferred and stored electronically will be stored only on password-protected computers. Only specified researchers at Social Solutions will have access to this information, and all researchers are trained in secure and private research protocols. All files will be destroyed 7 years after the study concludes.

Information provided during the research will only be disclosed to others if necessary to protect your rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

QUESTIONS AND CONCERNS
If you have any questions about this project, you may call Jenny Namur Karp or Kristen Stier at the phone numbers above. If you have any questions about your rights as a research participant, please call Karen Chen at 703-738-6684.

WRITTEN CONSENT
Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form. The investigator should provide either the participant or the representative adequate opportunity to read the consent form and pose questions to the investigator prior to signing the form.

Please read and show that you understand what you have read by signing your consent below.

I have read this form and understand all of the information about my involvement in the focus group. By signing below, I agree to participate.

_____ _____
Name (Printed) **Date**

_____ _____
Signature **Date**

_____ _____
Signature of Investigator **Date**

Attachment O: Extramural Researcher/External Stakeholder Focus Group Consent Form

Social Solutions International, Inc.

TITLE OF STUDY: *Critical Events Policy Implementation (CEPI) Process Evaluation*

Principal Investigator: Jenny Namur Karp
Phone Number: 202-491-4954

Project Director: Kristen Stier
Phone Number: 202-870-2226

IRB Representative: Karen Chen
Phone Number: 703-738-6684

PURPOSE OF THE STUDY

Social Solutions International, Inc. (Social Solutions) has been contracted by the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) to conduct a process evaluation of the Critical Events Policy Implementation (CEPI) program. Critical Events may occur during the conduct of clinical research that deviates from Institutional Review Board (IRB)/Ethics Committee (EC) – approved protocols and may adversely affect risks to research participants, or study outcomes and integrity. DAIDS created this policy to provide guidance on how to report critical events. The CEPI program's goal is to increase policy awareness, accessibility, understandability, and applicability of the policy by target populations, including DAIDS staff, extramural researchers, and external stakeholders. Social Solutions is conducting research to assess DAIDS staff, extramural researchers and external stakeholders' awareness of the policy and supplemental resources, as well as the accessibility, understandability, and applicability of the Critical Events policy and related documents. This research will also provide insight into the success of training efforts in increasing knowledge of the policy, and satisfaction with available training and support.

An important part of this research involves the focus group discussions with extramural researchers and external stakeholders based at a different research sites domestically and internationally. We are asking for your participation in a focus group discussion with 8 other colleagues. The discussion will involve a series of questions designed to help us better understand your awareness of the Critical Events policy and supplemental resources, as well as your opinion on the accessibility, understandability, and applicability of the policy and related responsibilities. The information that you provide may be used by NIAID/DAIDS to improve policy implementation and dissemination. Your opinions, experiences, and ideas are very important.

PROCEDURES

The focus group will last approximately 90 minutes. You do not have to do anything to prepare for the discussion. We will ask questions about the Critical Events policy, including how easy you find the policy to understand and apply to your work, your satisfaction with trainings on the policy, and recommendations for policy improvement. We would like to hear as many

perspectives as possible, but you do not have to answer any questions that you do not want to answer. There are no right or wrong answers – only different points of view.

We will be recording the discussion on audiotape, and a staff person will be taking notes. We will not use your name during the audio recording, and no comments you make will be personally identifiable.

PARTICIPATION AND WITHDRAWAL
Participation in this focus group is completely voluntary. There is no consequence if you decide to leave the group. You do not have to respond to any questions that you do not want to answer. The investigator reserves the right to terminate your participation at any time if you are not following study protocol.

POTENTIAL RISKS
We anticipate very few risks to you from participation in this focus group. Although all participants have been asked to keep the discussions private, there is a small chance that other participants in the focus group may share personal information outside of the project. In addition, there is a small chance that you may feel uncomfortable with a question and not want to respond. Please remember that you do not have to answer any questions you do not want to. If you do experience negative feelings as a result of the focus group discussion, a clinical psychologist will be available to discuss those feelings.

In the unlikely event of physical or other injury resulting from the focus group, emergency medical treatment will be provided, but financial compensation will not be available. Social Solutions will not provide compensation if you experience injury or other adverse effects, which are not the fault of the investigators.

ANTICIPATED BENEFITS
If you decide to participate in the focus group, you may gain a better understanding of the Critical Events policy and resources and trainings available. This information may motivate you to obtain more information about the policy, about clinical research protocols, and/or change your behavior to positively improve clinical research and reporting. Additionally, the information that you provide will be used to improve the program's policy dissemination efforts.

INCENTIVES
You will receive $30 as a token of appreciation for participating in the focus group, excluding PPD-DAIDS Site monitors.

PRIVACY AND CONFIDENTIALITY
To protect your identity, none of the information you provide will be associated with any statement or identified personally in any way. Other than the signed consent form, no identifiable information will be collected. The consent form will be kept separate from the other information we collect to make sure that the data cannot be identified.

Any information collected by paper or on the participant incentive distribution log will be kept in a locked cabinet. Information transferred and stored electronically will be stored only on password-protected computers. Only specified researchers at Social Solutions will have access to this information, and all researchers are trained in secure and private research protocols. All files will be destroyed 7 years after the study concludes.

Information provided during the research will only be disclosed to others if necessary to protect your rights or welfare, or if required by law. When the results of the research are published or discussed in conferences, no information will be included that would reveal your identity.

QUESTIONS AND CONCERNS
If you have any questions about this project, you may call Jenny Namur Karp or Kristen Stier at the phone numbers above. If you have any questions about your rights as a research participant, please call Karen Chen at 703-738-6684.

WRITTEN CONSENT
Informed consent shall be documented by the use of a written consent form approved by the IRB, and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form. The investigator should provide either the participant or the representative adequate opportunity to read the consent form and pose questions to the investigator prior to signing the form.

Please read and show that you understand what you have read by signing your consent below.

I have read this form and understand all of the information about my involvement in the focus group. By signing below, I agree to participate.

_____ _____

Name (Printed) **Date**

_____ _____

Signature **Date**

_____ _____

Signature of Investigator **Date**
(office use only)

Attachment P: Critical Events Policy Implementation Program Process Evaluation

Focus Group
Details and Preparations

Location
TBD

Arrival Time/Start Time
TBD

Preparation
Water
Name Tags
Markers
Incentives
Incentive Log
2 copies of Moderator's Guide
11 copies of consents forms

Moderation
Facilitator – Dr. Ami Lynch, Interviewer/IRB Director at Social Solutions International, Inc.
Notetaker – Kristen Stier, Project Coordinator/Research Associate at Social Solutions International, Inc.

Attachment Q: CEPI Process Evaluation DAIDS Staff/Extramural Researcher/External Stakeholder Focus Group Opening Script

Hello and welcome. Thank you for meeting with us today. My name is Dr. Ami Lynch and I am from Social Solutions International, Inc., a research and evaluation firm that works on a wide range of issues to improve the health and well-being for underserved populations and communities. Thank you for being here to share your thoughts and ideas. My role today is simply to guide our discussion and to make sure that everyone has an opportunity to share their experiences and opinions.

Opening Comments

Social Solutions is has been contracted by the National Institute of Allergy and Infectious Diseases (NIAID), Division of AIDS (DAIDS) to conduct a process evaluation of the Critical Events Policy Implementation (CEPI) program. We are researching how effective the program has been in notifying researchers and stakeholders of the policy and supplemental resources, and creating a policy that is accessible, easy to understand, and applicable to the work that you do. We are talking to researchers and external stakeholders associated with both domestic and international research sites and protocols. The purpose of this focus group is to understand your opinions and experiences with the Critical Events policy. We are specifically interested in your awareness of the policy, your view on its understandability and applicability to your work, your understanding of the policy itself and additional responsibilities it requires, and your satisfaction with supplemental policy resources, support from NIAID/DAIDS staff, and any trainings you may have participated in.

Confidentiality

The discussion should last for approximately 90 minutes. We would like to tape record the discussion so we can keep track of what you tell us. We will not record your names or connect them in any way to your answers so that we protect your confidentiality. When you wish to join in on the discussion and respond to a question, please raise your hand. What you say is very important and we do not want to miss anything. We are only audio-taping the discussion to make sure we don't miss any of the information you share.

We would like to ask everyone to keep the information that you hear from the discussion group confidential and not to discuss it outside of this room. We want you to feel comfortable sharing your personal opinions and experiences with the group so that we can learn from you.

Your participation in this group is entirely voluntary, and you are free to leave at any point if you find it necessary. I will be available after the session this evening to answer any questions you may have about the discussion or the project in general. If you need to get up and stretch, get

food or drink, and/or use the rest room during the focus group, please feel free to do so. We just ask that you do so quietly because of the recording.

Discussion Group Rules

First, since each and every person's comments are important, we ask that only one person speak at a time. This will help us to hear each other. There is no such thing as a right or wrong answer in this group. We have no expectations about what is going to be said. Tell us what you honestly think, and feel free to share whatever is on your mind. If you disagree with something that you hear, let us know. If you agree, don't just say, "I agree", but try to add your own perspective or opinions. We want to hear as many different opinions, ideas, and stories as possible.

Consent

Before we begin, I would like to make sure I have a consent form for all of you. When I call your name please let me know that you are here…. [Read names of participants from whom consents have been collected. Any participants that do not have the consent form will be asked to sign one at this time]

Does anyone have any questions at this time?
I am going to turn on the tape recorder now so we can get started…

Attachment R: CEPI Process Evaluation DAIDS Staff/Extramural Researcher/External Stakeholder Focus Group

Probes/Questions

Questions:

1. The critical events policy was implemented in June 2012. Did you receive any communication/information introducing the CE Policy and Manual? If so, what types of communications?

   1b. Were you satisfied with the communication surrounding how to access the CE Policy and Manual, supplemental resources, and trainings?

2. How many of you have tried to obtain additional information/resources re: the CE Policy and Manual?

   2b. How easy is it to access resources? Are the existing resources helpful/easy to understand?

3. What questions did you/do you have regarding the CE Policy and Manual?

4. What burdens exist in complying with CE Policy and Manual requirements?

5. Do you think the CE policy and Manual is applicable to your work?

   5a. Is there any policy or part of the CE Policy and Manual that you do not view as applicable? If so, please specify?

6. Have there been changes made to your site's SOPs or routine activities to meet CE Policy and Manual mandates? If so, please describe.

7. Are there any challenges/barriers to successfully meeting Critical Events reporting mandates? Why or why not?

8. Would you like more training on the CE Policy and Manual? If so, what content do you need and in what format would you like to receive the training?

9. What recommendations do you have for CE Policy and Manual improvements?

Thank You

Thank you again for taking the time to speak with us today. The information you have provided is very helpful. If you have any questions please feel free to contact me via email or phone. Thank you.

OHSR (NIH/DDIR)

From: Lahl, Lynda (NIH/NIAID) [E]
Sent: Sunday, January 12, 2014 5:37 PM
To: OHSR (NIH/DDIR)
Subject: application for survey, focus groups
Attachments: IRB submission_DAIDS evaluation 2013.pdf; CEPI Attachments NIAID IRB.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Categories: Yellow Category

Dear OHSRP staff,

Please see the completed the request form: OHSRP determination for surveys, interview procedures, program evaluation, educational testing and research, along with the accompanying attachment document. My Branch Chief and I are attending a local meeting on January 13 & 14, 2014. I have a printed copy of all documents and plan to obtain my Branch Chief's signature on pg 1. I will scan the signature page after I have the necessary signatures and will email your office tomorrow evening.

Thank you for your time. Please let me know if you have any questions.

Lyndi Lahl

Lyndi Lahl, RN, MS
Policy Health Specialist
Protection of Participants, Evaluation and Policy Branch (ProPEP)
OPCRO, DAIDS, NIAID, NIH, HHS
6700-B Rockledge Drive, RM 4254
Bethesda, MD 20892-7624
Tel. 301-435-3756
FAX 301-402-1506

OHSR (NIH/DDIR)

From: OHSR (NIH/DDIR)
Sent: Thursday, January 23, 2014 1:10 PM
To: Lahl, Lynda (NIH/NIAID) [E]
Subject: Req for Determination Rec'd_OHSRP 12268
Attachments: Intramural_planned_enrollment_report.pdf

Good afternoon Lyndi,

This email is to verify that OHSR has received your Request for Determination and it is currently being processed as **OHSRP #12268.** Please use this number in any future correspondence regarding this study. We will contact you via email if any additional information is needed. If you have not heard from OHSR within 7 business days, please contact us.

Protocol Title: Process Evaluation of the DAIDS Critical Events Policy Implementation (CEPI) Program

****As per a new requirement for PIs, please fill in attached planned enrollment worksheet and return. We will need this before we can issue a determination. Please contact OHSRP with any questions.**

Thank you.
Sincerely,
OHSRP - National Institutes of Health
Bldg 10, Suite 2C146
Bethesda, MD 20892
Office Telephone: 301-402-3444
Office Fax: 301-402-3443

The NIH is committed to maintaining the highest standards for the protection of human subjects.


Please consider the environment before printing this e-mail