Attachment 7: 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: Jeremy Braithwaite
Phone Number: 630-621-6031

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. Participating in this focus group will not affect your work or relationship with DAIDS. 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 U.S. dollars 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 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 Jeremy Braithwaite 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)