NIAID Critical Events Policy Implementation Process Evaluation Details and Informed Consent Statement for Extramural Researchers and External Stakeholders

OMB No. 0925-XXXX
Exp. Date: XX/XX/20XX

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 5 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA# 0925-XXXX. Do not return the completed form to this address.

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Study Details

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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.

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.

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. All information collected will be kept secure to the extent permitted by law. 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 stipends to eligible participants.

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 survey without prior completion of the consent form.

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Informed Consent Statement

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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. Participating in this survey will not affect your work or relationship with DAIDS.

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 the equivalent of $10 U.S. dollars as a token of appreciation for their completion of the survey.

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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 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, contact:

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

Jeremy Braithwaite
Survey Analyst
Social Solutions International, Inc.
Email: jbraithwaite@socialsolutions.biz
Phone: 630-621-6031

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

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Informed Consent Agreement

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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.

***1. 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

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Survey Distribution Information

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***2. Please provide your email address so that Social Solutions International, Inc. can send you the survey.**

Email Address:

Prev Done