

**Attachment 20: Focus Group
Opening Script and Questions**

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Attachment 18: Focus Group Opening Script and Questions

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~~secure your information to the extent permitted by law. 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 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 not respond to any questions you are not comfortable with and 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...

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.