

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

Appendix 19: Extramural Researcher External Stakeholder Survey Screenshots

OMB No. 0925-XXXX

Exp. Date: XX/XX/20XX

Burden Disclosure: Public reporting burden for this collection of information is estimated to average 30 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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1. Are you a PPD-DAIDS Site monitor?

Yes

No

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2. You have indicated that you are a PPD-DAIDS Site monitor. While you are eligible to participate in this study, you will not receive compensation (i.e. an incentive) for your participation. Do you still wish to participate in this survey?

Yes

No

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First, please answer the following questions three questions. These questions are required in order to generate unique identifiers. As such, we are asking for very limited information.

*** 3. Please enter the first two letters of your mother's first name. For instance, if your mother's name is Catherine, please enter 'CA.' If you do not know your mother's name, please enter 'NA.'**

*** 4. Please enter the first two letters of your father's first name. For instance, if your father's name is Frank, please enter 'FR.' If you do not know your father's name, please enter 'NA.'**

*** 5. Please enter the last two digits of your year of birth. For instance, if you were born in 1970, please enter '70.'**

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BACKGROUND INFORMATION

Please provide the following information about yourself

4. 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 specify)

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6. If applicable, enter the DAIDS Network(s) you are affiliated with (check all that apply):

- ACTG
- HVTN
- HPTN
- IMPAACT
- MTN

7. Are you involved with a non-network study?

- Yes
- No

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

- International (non-U.S. site)
- Domestic (U.S. site)
- New CRS Site (site not affiliated with DAIDS research before 2013)
- Not Applicable
- Other (please specify)

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8. Are you a native English speaker?

Yes

No

9. Enter your number of years' experience with clinical research:

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

Extremely knowledgeable

Very knowledgeable

Moderately knowledgeable

Not very knowledgeable

Not at all knowledgeable

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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:

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

14. What information or section are you referencing?

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

18. If you selected "Agree" or "Strongly Agree" in the last question, please describe these barriers:

19. 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

20. If you selected "Agree" or "Strongly Agree" in the last question, please list the supplemental resources that you know are available:

21. I regularly access additional Critical Events supplemental resources.

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

23. What information or section are you referencing?

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

27. If you selected "Agree" or "Strongly Agree" in the last question, please describe these barriers:

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

33. If you selected "Agree" or "Strongly Agree" in the last question, please describe these barriers:

34. 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 (please specify)

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

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

- Strongly Disagree Disagree Not sure Agree Strongly Agree

40. If you selected "Agree" or "Strongly Agree" in the last question, please describe these barriers:

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

- HANC listserv email
- HANC newsletter
- HANC Conference Call
- OPCRO email alert
- DAIDS Training and Safety Branch email alert
- Other (please specify)

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

Yes

No

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43. Did you receive a response?

- Yes
- No

44. 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 (please specify)

45. Did you understand the response received?

- Yes
- No

46. Did the response answer your question?

- Yes
- No

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

- Yes
- No

48. Did the answer you received improve your understanding of Critical Events?

- Yes
- No

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

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

Yes

No

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51. What type of Critical Event did the communication entail?

- Unanticipated Problem
- Serious Noncompliance
- Continuing Noncompliance
- Suspension or Termination of IRB approval

52. Did you receive a response?

- Yes
- No

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

- Yes
- No

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

- Yes
- No

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

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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:

56. 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

57. 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

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

Strongly Disagree Disagree Not sure Agree Strongly Agree

59. 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

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

Strongly Disagree Disagree Not sure Agree Strongly Agree Not Applicable

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

Strongly Disagree Disagree Not sure Agree Strongly Agree Not Applicable

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

Yes

No

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

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

Yes

No

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

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

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

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

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

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70. 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 (please specify)

71. 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 (please specify)

72. What recommendations do you have for Critical Events Policy Implementation improvement?[Prev](#)[Next](#)

74. For quality control purposes, please re-confirm your status as a PPD-DAIDS Site monitor.

- I am a PPD-DAIDS Site monitor
- I am NOT a PPD-DAIDS Site monitor

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Thank you for your participation in this important survey!

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Thank you for your participation in this important survey! In order to receive your incentive, please click the following link.

<https://www.surveymonkey.com/s/HF2WS3D>

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Done