NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

1. Are you a PPD-DAIDS Site monitor?

- ○ Yes
- ○ No

Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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.'**

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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)

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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)

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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?

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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:

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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?

Prev Next

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

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:

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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:

Prev Next

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

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

Prev Next

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

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)

Prev Next

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

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

- ○ Yes
- ○ No

Prev Next

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

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?

Prev Next

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

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

- ○ Yes
- ○ No

Prev Next

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

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?

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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

Prev Next

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

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:

Prev Next

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

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?

Prev Next

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

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

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

Thank you for your participation in this important survey!

Prev Next

NIAID Critical Event Policy Implementation Extramural Researcher/External Stakeholder Survey

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

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

Prev Done