Next

First, please answer the following three questions. These are required to generate a unique identifier. As such, very limited information is requested

✱1. 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.'

[   ]

✱2. 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.'

[   ]

✱3. 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. Please identify your employment status with DAIDS:

○ Federal government employee

○ Contractor employee (e.g., Henry Jackson Foundation employee)

5. Select your role with DAIDS:

[select dropdown]

6. If you selected "Other" in the previous question, specify here:

[text field]

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

[text field]

8. 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:

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

[text box]

12. What information or section are you referencing?

[text box]

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

[text box]

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17. 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

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

[ ]

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19. I regularly access additional Critical Events supplemental resources.

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

20. For what reason(s) do you access the Critical Events supplemental resources?

[ ]

21. What information or section are you referencing?

[ ]

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

◯ Strongly Disagree   ◯ Disagree   ◯ Not sure   ◯ Agree   ◯ Strongly Agree

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

◯ Strongly Disagree   ◯ Disagree   ◯ Not sure   ◯ Agree   ◯ Strongly Agree

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

◯ Strongly Disagree   ◯ Disagree   ◯ Not sure   ◯ Agree   ◯ Strongly Agree

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

[text box]

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

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32. 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

33. I regularly access/participate in Critical Event policy dissemination activities.

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

34. I can access/participate in Critical Event policy dissemination activities easily.

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

35. I am satisfied with the clarity and understandability of the Critical Event policy dissemination activities.

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

36. There are barriers that hinder my access/participation in Critical Event policy dissemination activities.

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

[text box   ]

[Prev]   [Next]

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

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

[   ]

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

- ( ) Yes
- ( ) No

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40. Where was this staff member located?

- ○ Program
- ○ OCSO
- ○ OPCRO
- ○ OD

41. Did you receive a response?

- ○ Yes
- ○ No

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

- ○ Yes
- ○ No

43. Did the response answer your question?

- ○ Yes
- ○ No

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

- ○ Yes
- ○ No

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

[   ]

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46. Have you ever been involved in communications regarding a Critical Event?

○ Yes

○ No

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47. What type of Critical Event did the communication entail? (please check all that apply)

☐ Unanticipated Problem

☐ Serious Noncompliance

☐ Continuing Noncompliance

☐ Suspension or Termination of IRB approval

48. Did you receive a response?

○ Yes

○ No

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

○ Yes

○ No

50. Were you able to apply the response you received to the Critical Event?

○ Yes

○ No

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

○ Yes

○ No

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

[text box]

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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:

53. 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

54. 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

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

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

56. 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

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57. DAIDS staff critical events trainings increased my knowledge of the Critical Events Policy and Manual.

○ Strongly Disagree   ○ Disagree   ○ Not sure   ○ Agree   ○ Strongly Agree

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

○ Yes

○ No

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

[text box]

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

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

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

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63. 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)

[ ]

64. 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)

[ ]

65. What recommendations do you have for Critical Events Policy Implementation improvement?

[ ]

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