Attachment 3: NIAID DAIDS Survey Question for Extramural Researchers

OMB#0925-XXXX
EXP. XX/XXXX

Public reporting burden for this collection of information is estimated to average 1 hour 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.

Please answer the following questions and select the appropriate category: Strongly Disagree-->Disagree-->Neither Agree nor Disagree-->Agree-->Strongly Agree or N/A

1. I learned about DAIDS policies in a timely fashion.

2. I am satisfied with the level of access to DAIDS policies.

3. I am satisfied with the information provided on how to access policies.

4. The content of the policies is easy to understand.

5. Policy training has been an effective means to help me understand the minimum DAIDS requirements.

6. I have found the DAIDS policy training on Storage and Retention of Clinical Research Records effective to better understand the requirements for maintaining clinical research records.

7. For all training received related to all DAIDS policies, I am satisfied with the additional refresher training I received to better understand policies.

8. After I took training, I gained an understanding of how to apply policies to my research studies and site operations.

9. When I submitted a question to DAIDS, the answer I received improved my understanding of the policies.

10. The answer I received was provided in a timely fashion.

11. For each communication mechanism listed in the table below, please indicate on the scale provided, whether the mechanism helped you recognize the policies that applied to your clinical research site or grantee. If other is applicable, fill in free text field.

Communication Mechanisms	***Scale***
OPCRO News Listserv alerts/Emails from PTQAB	(No extent-→Little extent-→ Some extent-→Great extent or N/A)
Discussions with PTQAB	No extent-→Little extent-→ Some extent-→Great extent or N/A)
Discussions with NIAID Program/Medical Officers	(No extent-→Little extent-→ Some extent-→Great extent or N/A)
Email from NIAID/Program Medical Officer	(No extent-→Little extent-→ Some extent-→Great extent or N/A)
Discussions with CRS Site Leader/Coordinator	(No extent-→Little extent-→ Some extent-→Great extent or N/A)
Discussions with CTU Principal Investigator	(No extent-→Little extent-→ Some extent-→Great extent or N/A)
Other	(No extent-→Little extent-→ Some extent-→Great extent or N/A)

Please answer the following questions and select the appropriate category: (Strongly Disagree-->Disagree-->Neither Agree nor Disagree-->Agree-->Strongly Agree or N/A)

12. I am able to apply DAIDS policies when conducting clinical research activities.

13. I am able to apply DAIDS policies when carrying out clinical research activities.

14. DAIDS policies effectively state who is responsible for activities related to those policies.

15. Clinical oversight roles and responsibilities are adequately described in DAIDS policies.

16. DAIDS policies provide a framework to implement my research studies.

17. Due to DAIDS policies, I am able to implement research consistently across my clinical research sites.

18. DAIDS policies enable me to facilitate the implementation of research consistently across more than one research protocol.

19. DAIDS policies have enhanced the ability for clinical research sites to collaborate.

20. How have you heard about DAIDS policies? (*check all that apply*)

□ OPCRO News Listserv alerts/Emails from PTQAB
□Discussions with PTQAB
□ Discussions with NIAID Program/Medical Officers
□ Email from NIAID Program/Medical Officer
□ Discussions with CTU Principal Investigator
□ Email from CTU Principal Investigator
□ Discussions with CRS Site Leader/Coordinator
□ Email from CRS Site Leader/Coordinator

□ Regional Training notifications
□ Other_____

21. What sources do you access for DAIDS policies? (*check all that apply*)

□ NIAID Web Site

□ HANC Web Site

□ NIAID Network Web Site (please specify network_____)

□ Study/Network Procedure Manuals

□ Other_____

22. What other mechanisms would you prefer for receiving notification of new and revised DAIDS policies?_____

23 a. In the table provided below, *please indicate for each policy, by checking yes or no, if there any barriers to accessing DAIDS policies.*

23 b. If there are barriers to accessing the policies, please provide a brief explanation as to why there is a barrier to accessing the policy.

Policy	**Are there barriers to accessing this policy?**	**If so, why?**
Human Subjects Protection/Good Clinical Practice	□Yes □No	
DAIDS Policy on Storage and Retention of Clinical Records	□Yes □No	
Clinical Site Monitoring Quality Management Policy	□Yes □No	
Other	□Yes □No	

24. How did you receive training? (*check all that apply*)

□ In person-classroom

□ Online

□ Via Teleconference

□ Other_____

25-28. If you have received training more than once for any of the following policies, *please place a check mark next to that policy and indicate the number of trainings you received.*

Name of policy	Have you received training? Yes/No	How many times have you received training?
Human Subjects Protection/Good Clinical Practice	☐Yes ☐No	
DAIDS Policy on Storage and Retention of Clinical Records	☐Yes ☐No	
Clinical Site Monitoring Quality Management Policy	☐Yes ☐No	

29. Who from DAIDS provided responses to your questions?

☐ DAIDS PO/MO (Program Officer, Medical Officer)

☐ PTQAB (Policy, Training, and Quality Assurance Branch)

☐ I don't know

☐ I didn't submit a question to DAIDS

☐ Other_____

30. Which of DAIDS policies helped inform the development of standard operating procedures for research studies at your institution, or for CRS, or for your protocol(s)? (*check all that apply*)

☐ Requirements for Human Subjects Protection and Good Clinical Practice Policy

☐ Requirements for Clinical Quality Management Plan Policy

☐ DAIDS Policy on Storage and Retention of Clinical Research Records

☐ N/A

☐ Other_____