Attachment 4: NIAID DAIDS Focus Group Questions for Extramural Researchers

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Public reporting burden for this collection of information is estimated to average 2 hours 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.

1. For current DAIDS policies, which ones did you find required more clarification or explanation, and why? How did you go about getting the clarification?

2. How did you apply policies to design your research studies?
    a. How can the policies be more useful when you design your research studies?
    b. How did you apply policies to carry out your research studies?
    c. How can the policies be more useful when you carry out your research studies?

3. Did you find that the DAIDS policies effectively stated research staff roles and responsibilities?
    a. Was there anything unclear in the DAIDS policies about roles and the types of responsibilities or activities that need to take place?
    b. What additional information should be included in DAIDS policies to better communicate these roles and responsibilities?

4. How did you use policies to implement your research study? How did you implement your research study prior to development of policies?
    a. How did the DAIDS Policy on Storage and Retention of Clinical Research Records inform you about the requirements for record keeping? How did you develop requirements for record keeping prior to the development of this policy?
    b. How did the Human Subjects Protection and General Clinical Practice Policy inform you of all the training requirements necessary to be compliant with the policy? Were the Human Subjects Protection and Good Clinical Practice trainings taken by you or your staff before the policy was implemented?
    c. How did the Clinical Quality Management Plan Policy inform you regarding how to develop, implement and evaluate a CQMP plan at DAIDS? How did you develop, implement and evaluate a CQMP plan prior to the development of this policy?
    d. How did knowledge of these policies enhance your role in your research study?

5. What aspects of the policies enable you to implement your research studies?
    a. What are some of the resources required to put the policies in place?
    b. What affect did the policies have on implementing the research studies?

6. What aspects of the policies hinder the implementation of your research studies?
    a. If there are resource constraints, what are they?

7. To what extent are DAIDS policies consistently applicable to any research site or study?
    a. Are there any DAIDS policies in particular that are or are not consistently applicable to any research site or study?
    b. What are the organizational constraints that make it different between research sites or studies to implement DAIDS policies?

8. To what extent have the policies affected collaboration between sites?

9. Have you utilized policies to develop SOPs?
    a. Has the development of SOPs enhanced collaboration, and eased the process in starting a new research study or on-boarding a new research site?