OMB #0925-xxxx Expiration Date: xx/xx/xxxx

NOTIFICATION TO RESPONDENT OF ESTIMATED BURDEN

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.

1: Background

Q: Tell me your role at your institution and, specifically, how you interact with the CIRB.

Note: Make sure the discussion is about their role in the organization and the types of things they need to do with the CIRB but NOT the procedures they do to get it done.

Probe on the following tasks:

- Initial submission (requirements, timing, feedback, status, etc.)
- Annual Maintenance
- Updating/modifying a study
- Updating institution information
- Updating personnel information
- Transferring a study?
- Closing a study
- Other (participant defined)

Q: Once you have IRB approval, do you interact with the local level institutions, and if so, how?

Q: An IRB package goes through multiple stages from the time it's initially submitted to the time the study closes. Can you describe in your terms what these stages are (e.g., an initial submission, pending review, initial review, completed review, etc.)

2: Tools

For each of the tasks, have them demonstrate as needed how they use the CIRB website and IRBManager.

Q: [For each task mentioned] Walk me through the process of accomplishing [task]. Specifically, what online tools, websites, or other resources do you use for [task]?

Note: Probe on their understanding of the role of CTSU, the CIRB Website, IRBManager, ePanel, and any other tools that they need to use (specifically related to working with the CIRB).

3: Training & Support

During the discussion, have them demonstrate as needed how they use the CIRB website and IRBManager for training and support.

Q: How did you learn the process that you use for these tasks?

Note: Probe specifically on help with the CIRB website and the IRBManager.

Q: What did you have the most difficulty learning, or what do you still need to get help on, in order to acocmplish your tasks with these tools.

Note: Probe specifically on help with the CIRB website and the IRBManager.

4: Document Types

Q: What's the difference between the terms quickguide, FAQ, checklist, and manual? Which do you use, and when?

Q: The website has forms and worksheets. Can you discuss the difference between those?

5: Website Content Review

Q: Here's a list of types of information. Tell me about your need (or lack thereof) for this information. For each item identified as important, is this currently available, and if so, where?

- History of the CIRB and how it operates (including SOP)
- How to become a signatory institution
- List of signatory institutions
- Information about component and affiliate institutions and their use of the CIRB
- List of CIRBs and their roles and responsibilities
- List of individual CIRB Members
- CIRB meeting dates and agendas
- List of studies currently under review
- Training material, FAQs, etc.
- Contact information for the CIRB

6: Related Sites

Q: Sometimes websites have links to other related sites or resources. Does the CIRB website need this, and if so, what links should be included?

Follow-up: After discussing this, show them the "Related Links" page and discuss which links are useful, if any.

Wrap up

OK, we're done. Are there any questions you would like to ask me about the site or about today's experience that I did not ask you about?

Thanks again for your participation.