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.

Tasks/Questions

[Note: take user to the home page]

First take a few moments to get familiar with the new site design. Since some parts of it are not complete yet, don't worry about that. I just want you to feel comfortable with the layout and navigation before we start. Go ahead, and let me know when you're ready to start.

Home page (mission statement, main infographic, sample announcement to show the type that will be there, new logo, new footer, main nav., utility nav)

Task 1: What can you find about when the CIRB started and why it's used by NCI?

[About the NCI CIRB > History]

Task 2: How many boards are there and what type of studies does each board cover?

[The Boards]

Task 3: How does the CIRB process differ from a "normal" IRB process?

[About the CIRB > How It Works] *or* [Tutorials and Help > The CIRB Process – A Conceptual Overview]

[Infographics for the process(es)]

[Note: This data is at two levels. See which one they find. If they visit the general version, don't mention the detailed version to discuss the differences and who would be likely to want either or if one is good for everyone.]

Probe: What does the site tell you about why a Central IRB is a good thing?

Probe: What does the site say about the types of studies NCI uses the CIRB for?

Task 4: How many types of reviews are there in this CIRB process? And who does each type of review (probe on CIRB versus Subcommittee review).

Probe on information needs: Level of Detail, Time expectation, etc.

[Tutorials and Help > The CIRB Process – A Conceptual Overview]

[Infographics for the process]

Task 5: What if someone you knew was interested in using the CIRB for trials. What information can you find for them?

Probe: What do you call that? (Joining, Enrolling, etc.)

Probe: Level of Detail for the process

Follow up Task: If they don't notice the link, ask: What would a person do who actually wanted to get "enrolled."

Main Task: "Enrollment"

Follow up Task: [Tutorials and Help > For Signatory Institutions > Becoming a Signatory Institution]

Task 6: What is the process used to get a study protocol reviewed using the CIRB?

Probe: What do you think of this explanation" Is this process different from your previous understanding of the process? If so, how? Is this explanation complete? Missing anything?

Probe: What if someone was interested to know how far along their submission is in this review process?

[Tutorials and Help > For Study Chairs > Submitting a Study for Review]

Task 7: What is the process that occurs when someone would like to open a study (after the study protocol has been approved)?

Probe: What do you think of this explanation" Is this process differ from your previous understanding of the process? If so, how? Is this explanation complete? Missing anything?

Probe: What if someone was interested to know how far along their submission is in this review process?

Probe: See if they notice the statuses are steps and actual status names are defined.

[Tutorials and Help > For Signatory Institutes > Managing a Study > Opening a Study at Your Institution]

Task 8: What if you are interested in finding out if trial XYZ is going through the CIRB?

Probe on the new interaction design.

Probe: How do you refer to this list? Is this "studies under CIRB review" as it's called now, trails for which the CIRB is the IRB of record, studies using the CIRB, other?

Follow up: What if you were interested in finding documents for a study that has been closed. What would you do.

[CIRB Studies]

Post Test Interview Questions

Great, now I'd like to ask you a few questions.

1. Looking at the new design, what would you say is the purpose of this site? Is this different than the old site? *Alternately:* How would you describe this site to someone who has never seen it?
2. What are the things you liked most about the proposed design?
3. What are the things you liked least about the proposed design?
4. What surprised you the most today?

Wrap up

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

Thanks again for your participation.