Minutes
Institutional Review Board
February 10, 2011

Present: Mary Rose Lamb (Chair), Andrew Gardner, Anne James, Andrew Rife (community representative), Alexa Tullis, Lisa Ferrari

Meeting was called to order at 8:00 a.m.

Announcements: None

Orders of Business:

1. Approval of minutes: Minutes from 1/27/2011 approved

2. Review IRB Handbook

Alexa proposed a reorganization, which was presented and discussed, as follows:

POSSIBLE OVERALL OUTLINE

I. General Principles

II. Interested Parties: Definitions and their Responsibilities
a. Definitions:

- IRB
- Departmental IRB Designate
- Investigator (this is sort of obvious but should be included for completeness)

b. Responsibilities

- (this section would contain some of the information in the current "Procedures" part (Section 2)
- The Ethics Training stuff could be included in this section.

c. General Flow Chart of the Process (essentially of material in the first paragraph after D)

- I think that it would be helpful to have a general flow chart describing where the protocol goes, and what could happen at each point. Ex. Investigator drafts protocol according to guidelines, submits it to the Departmental IRB Designate, this person reviews it and determines if it warrants a full IRB review, then …

III. Type of Reviews Possible
a. Short descriptions of each type
b. Checklists and/or flow-sheets for determining which type of review an investigator's protocol needs.

- Examples of each kind could be included at the end of each checklist or the beginning? Or, as a way to streamline the document, examples could be provided in an appendix. Or, if the checklists are included, perhaps examples are not needed.
- The Dept of Health and Human Services has "decision trees" for helping identify which type of review is needed. They can be found at: http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html

IV. Guidelines for Preparing Research Project Proposals for Review
(possible organization)
a. A complete proposal includes the following components in the order given:
- Cover sheet
- Body of Proposal (5 pages maximum)
- Qualification of Investigators
- References
- Copies of Consent forms

b. Component Description and Specification
- This sub-section would then go on to give more details about each component & would include material like that which is currently in Section 4 but in a more linear presentation.
- I'd suggest including links to appropriate pages as needed. Having an example cover page directly following this material breaks up the Handbook and makes the material more difficult to follow.

It was suggested that there be a way to highlight common sticking points/pitfalls that can hold up proposals, particularly for applicants new to the process.
- Currently, much of this information is in the FAQ section, but those who do not have questions may not refer to it. It might be helpful to rename this section, e.g., "Common reasons for rejection or modification of proposals."
- The website would be a good place for this section, included as a link.

Andrew Gardener proposed an broader overall organization, as follows:
1. The IRB protocol/application
2. The larger policies, procedures, and guidelines document
3. Samples

Website
This led to a discussion of the need to revise the Web in a similar way so that the basic process and steps are clear and brief, with links to more detailed information and examples for those who need it.

Andrew Gardner suggested that the webpage could be distilled to five basic components.

1. A general overview of the IRB and its mission.
2. A very general overview of the IRB procedure. That should describe the role of delegates and the role of the full IRB committee.

3. A brief description of possible outcomes and brief definitions (exempt, expedited, full)
4. Links to documents
5. A list of delegates and IRB members.

Meeting dates that are currently on the webpage could be included if it is seen as valuable.

Departmental Delegates

- The delegate system was discussed, specifically whether or not all departments have/need to have one.
- Departments do not need to have a designate if they don't do research with human subjects. In some departments it falls to the department chair. It is also possible to use a delegate from another department.
- Currently, departmental delegates are not listed on the website.
- Revision of documents and website must include consideration of the current system, e.g.:
    - Remove language that says "department approval," which would enable some departments to group together and share a delegate.
    - Making sure all current delegates are listed on the website.
- Currently, delegates do not go through any training. There was some discussion re: this as it will likely be required if we add the ethics training for researchers.

IRB and Selected Disciplines

- There was also some discussion of concern from some disciplines (e.g., anthropology, specifically ethnographic research), that IRB guidelines are not well suited for their research traditions. Do we need to inform ourselves about how our programs at U of Puget Sound fit with policies of the IRB. Andrew Gardner offered to email materials to IRB members regarding this issue.

We concluded that many good ideas had been generated and that it is probably most efficient for sub-groups to address the components. The outline discussed and provided in these minutes will be used to determine how to best divide up the revisions.

Plan for next meeting: Develop an action plan/assign sections for writing revisions to the IRB guidelines and revising the IRB web page.

Meeting Adjourned: 9:00am

Respectfully submitted,
Anne James