

Minutes of the Institutional Review Board November 21, 2011

Present: Lisa Ferrari, Andrew Gardner, Anne James, Mary Rose Lamb, Julia Looper, Garrett Milam, Andrew Rife, Yvonne Swinth

As we have been working at revising the handbook, we have been trying to find ways to guide people unfamiliar with the process through writing and submitting a successful proposal. We have also been dealing with the wide range of disciplines that pursue research using human subjects.

In the meeting of 11/7/11, Ann James suggested that we look at a checklist used at Bay Path College as a potential model for our checklist. Andrew Gardner used three scenarios based on anthropological research done here or classic studies and attempted to use the checklist to figure out whether each research protocol required a full board review. Gardner noted that the checklist is eleven pages long on its own and it also directs the researcher to multiple links including extensive flowcharts. Gardner also found that the document is written for those engaged in biomedical research in the language familiar to researchers in those areas. It does not even mention the major research methods of the social sciences like participant observation. After running the scenarios through the check list, Gardner identified two major problems for a social scientist attempting to use the document: 1) How does one decide whether a protocol requires a full board review or qualifies for an expedited review? 2) How do we gauge the level of risk in a research project?

For instance, the first scenario was a project to look at the material objects students bring with them to college, the things they value as they make the transition to independent adult life. As a part of the project, the students would be photographed with their favorite things and those photographs would be used as part of an art project. Does this project require a full board review? The issues here are those of risk and legal liability. The students photographed with their objects are identifiable. What if the objects they value are illegal (the treasured family bong, for instance)? What if the photographs result in embarrassment to the students or their parents? While this study could be limited to students over 18, those able to make adult decisions about whether or not to participate, in our discussion we noted that the questions about risk would probably result in a full board review. Gardner noted that this analysis is an example of what the American Anthropology Association (AAA) has pointed out in its document on regulation of human research. Too much research is being directed to IRBs around the country because people will err on the side of caution and choose a full board review when the project may really be expedited. We noted that the decision to direct a protocol to the full board is made by departmental designates on this campus and is another reason for a way to train those designates to make good, consistent decisions about protocols.

The third scenario illustrated another problem for social science researchers: new opportunities may arise in the field that could not be predicted when the protocol was submitted to the IRB. If a researcher takes advantage of those opportunities and publishes the results of research not approved by the IRB, can that researcher be brought up for misconduct? Those conducting biomedical research cannot publish research that was not approved. But those doing

biomedical research are usually in a position to write a modification to a protocol and have it approved. How do you do that if you are in the Salvadoran jungle? Is there a way to write a protocol that is broad enough to account for opportunities that may arise in the field, to make changes based on what happens as you pursue your research? The AAA suggests that the term “research” is being used too broadly here and that IRB reviews should be limited to those projects involving biomedical research that includes a physical risk to human subjects or those studies that involve real psychological risk, like those that use deception. Those projects that involve neither type of risk can be registered in some way and researchers can proceed with their work.

We returned to our project to develop new materials for this campus. How does this discussion inform that project? Should we have two paths, two sets of guidelines and documents, one for biomedical research and a second for research in the humanities and social sciences? Can we do that or are we limited by federal requirements? We noted that the federal guidelines are usually adopted because they are the required format for those projects that receive federal funding. If we don't use the federal guidelines will we put either the University or the researcher at risk in our litigious society? For instance, if the student photographed with her treasured bong in the first project can't get into law school or be hired for a federal job after law school because that photograph is still available on an internet site, can the University or the researcher be sued? Is it the job of the IRB to protect either the University or the researcher from litigation? After this wide-ranging discussion, Garrett Milam noted that we will return to this in the spring as we try to find remedies for the problems of dealing with research in the humanities and the social sciences.

Milam then reviewed what we have accomplished toward the charges to the IRB:

- 1) The guidelines for addressing the discrepancies between the procedure in the Scientific Misconduct document and the Faculty Code have been submitted to the Professional Standards Committee.
- 2) A student member (graduate or undergraduate) would be a valuable addition to the IRB but could not be a voting member. Adding a student member would require a change to the by-laws, but in the interim we could have a student as an invited guest.
- 3) The presidential cabinet has accepted the version of the Memorandum of Understanding for institutional research that was approved by the IRB.

Respectfully submitted,

Mary Rose Lamb