

Report of the Research Affairs Committee on the Status of the Reorganization of the Bloomington
Institutional Review Board.

Purpose

This report summarizes the status of the IRB reorganization on the Bloomington Campus. On September 23, 2008, the Research Affairs Committee of the Bloomington Faculty Council met with the Associate Deans for Research, and/or their designees from several of the Schools on the Bloomington Campus. Steve Martin from OVPRA, and Peter Finn and John Kennedy from the IRB also attended. The discussion concentrated on the current state of affairs and both short- and long-term approaches for addressing them.

Current Status:

1. OVPRA has invested substantial resources into the effort to improve the operation of the Bloomington IRB. Currently there are 3 full-time permanent employees 2 permanent part-time employees, and 11 experienced consultants working on the processing of protocols. In addition 4 employees from IUPUI are spending about 50% time (each) in the Bloomington office.
2. While this investment in resources appears to have led to improvements in responsiveness since the summer, there is a possibility that the extent of the remaining problems and the impact on future processing may be underestimated, It appears that many faculty and students appear to be waiting for things to get "better" before filing requests for review. Several individuals at the meeting mentioned this as a personal response, and not only a strategy adopted by colleagues.
3. Many protocols are still being processed based on individually tuned, priority driven processes. Thus, the Graduate School and OVPRA are working to minimize impacts on students, but often on a case by case basis. Similarly, the priority list distributed by OVPRA is still being used, which means many other forms of research are undergoing even longer delays.
4. The desire (and need) to attend to the compliance issue speedily led to the adoption of forms used by the IUPUI IRB's, which primarily deal with medical research. These forms appear to be more complex than needed, and this complexity may be contributing to the withholding of protocols. The IRB is providing training opportunities to all groups that request training. They are also collecting suggestions for improvements with the goal of revising the process during the Winter.

Longer Term Issues:

1. Research projects and perhaps even grant proposals are being delayed and even canceled by faculty. This can have long term negative impacts on the research effort at IUB. Similarly, student thesis topics are being redirected to areas which do not require human subjects research.

2. There is concern that the process is growing more complex than is needed. Issues such as the need to burden all research, including student research with the same compliance procedures required for federally funded research was questioned.
3. The balance between Institutional protection and communication with the human subjects on the consent documents is of concern. An informed consent document should be straightforward, and allow the potential participant to evaluate the known risks and benefits to participate in the research.
4. The rate at which protocols are approved on the first attempt is low which delays and discourages research.

Summary of Findings

The OVPRA and Bloomington IRB take the issues of delays very seriously. They are investing considerable resources to improve the processing of protocols. It is not clear that they could effectively use additional help right now, beyond filling vacant permanent positions.

The process that was introduced during the summer is not well tuned to the diversity of research on the Bloomington campus. Improvement of the process however should be done in a manner that does not further slow the processing of protocols, and therefore the proposal by the IRB chair to implement the process of improvement in stages is reasonable.

The severity of the problem is still unknown, but there is ample evidence that there are still major problems, the long term impact of which is not fully understood.

Interim Recommendations

1. Monitoring is still needed. Administration is urged to continue tracking the backlog, and have occasional formal meetings with faculty groups to gauge the true impact of any continuing issues.
2. The Research Affairs Committee recommends formation of a working committee, including input from administration and faculty. This committee will consider the most appropriate long term approach to dealing with compliance in regards to distinctions between federally funded and non-federal research.
3. The Research Affairs Committee should participate in appointing a committee to review the status of the IRB process for possible changes to be implemented beginning in January. Care should be taken to incorporate not only "senior researchers", but also users of the system who may not be as experienced with compliance forms (students, non-federal researchers, etc).
4. We recommend that before additional major reengineering of administrative support systems is undertaken, there be a beta trial period for a smaller group of individuals, to be followed by a staged implementation plan. While this was clearly not possible last summer, there are currently a number of plans for reorganization within OVPRA. Informal discussions with OVPRA have indicated their interest in working with the Research Affairs Committee to work with faculty on improving the implementation of new systems.