



UALR Graduate Council

Sunday, November 22, 2009

Dr. Joel Anderson
Chancellor

Dear Dr. Anderson:

On behalf of the UALR Graduate Council, I would like to thank you for the opportunity to respond to the new, proposed **IRB Policies and Procedures Manual**.

We recognize that you will be receiving comments about the new manual from many parties, including responses from most, if not all, of the colleges represented at the Graduate Council. This letter, therefore, is intended to address some of the concerns raised by the Graduate Council's representatives that transcend specific concerns that these parties have individually. The issues raised below primarily concern the impact that we perceive these policies and procedures will have upon the research environment at UALR. We all recognize the very important need that an Institutional Review Board fulfills within a university setting, including but not limited to the ethical treatment of research participants, an unbiased assessment of proposed research protocols, being in compliance with all federal and state regulations, and maintaining the highest standards of ethical behavior in practice and in appearance.

The concerns that the Graduate Council have regarding the new manual fall into two primary categories:

1. The manual seems to go well beyond federal guidelines focused on assessing probable risk to human subjects.
2. The manual is very inaccessible in terms of both length and language.

In addition, a third category relates to long-standing issues with the implementation of the current IRB process, which we believe will be exacerbated by these new policies and procedures. Then we will conclude with a couple philosophical perspectives.

Probable Risk

Federal guidelines clearly state that an institution such as UALR has responsibilities in assessing probable risk of research affecting human subjects. However, the tone of the proposed manual appears to go well beyond this focus, even to the point of assessing the research design and the importance of the results of this research; this extension of the role of the IRB does not seem justified and we feel it should be left to the researchers to determine within their collegial framework and professional standards as well as those required by funding sources. Even with

broad representation on the IRB, how could there be sufficient expertise to make these determinations on all research activities that might fall under the IRB's jurisdiction?

Many have commented within the Graduate Council and public forums that the model, upon which our proposed manual apparently is based, may not be the most appropriate model. Applying a framework from a university that includes a medical school where the risks to human subjects may be catastrophic is not consistent with the majority of the research conducted at UALR where the potential hazards are much less severe in a majority of situations.

Probable risk, for an institution such as UALR, might better be defined by generic guidelines and enhanced training rather than by case-by-case evaluations. Certainly some research projects need an in-depth evaluation, but in most cases, general guidelines should more than suffice. Consider, for example, the IRB workload at the beginning of a semester just for class projects embracing our new emphasis of integrating research into undergraduate education.

Perhaps the most important point that the Graduate Council would like to make is that clear guidelines need to be established for projects that do *not* require IRB review. A checklist plainly exempting whole categories of research would go a long way in unburdening a host of researchers from preparing materials for review and thereby allowing the review process to focus on those projects that do require an unbiased perspective (see, for example, the University of Southern California guidelines on exempt projects at <http://wagner.nyu.edu/irb/files/USCguidelines.pdf>).

Accessibility

It's hard to believe that anyone would assert that a 188-page document describing human subject policies and procedures is accessible. Many other institutions with more of a research focus than UALR (e.g., Louisiana State University in Baton Rouge) have documents about 10% or less in size, and many of these are written in plain English rather than the more formal/legalistic language of our proposed manual.

This point is particularly germane for our students. If they are unable to understand human research requirements and/or view the process as too cumbersome, their enthusiasm and interest in pursuing original research may be compromised.

Implementation Issues

Many have commented on the length of time that it takes to get IRB approval under the current set of guidelines; imagine how this might be extended with much more rigorous reviews and a much bigger net potentially drawing in research projects that might not have been under review before. There is a concern that *all* research projects must be submitted to the IRB since apparently only the IRB, under the new guidelines, can determine whether a project is subject to review. We know of at least one UALR program that has stopped requiring students to do original research due to the length of time experienced in getting IRB approval. This is a sad situation, especially in light of the importance that UALR places on research.

Additionally, there seems to have been very little transparency in how these proposed policies and procedures have come about, how the IRB membership is determined, whether there is adequate representation on the IRB from the various colleges and programs, the terms of IRB membership (perhaps term limits should be instituted?), and the mechanisms by which the IRB relates and communicates with other parts of the university. On a practical matter, IRB meetings probably need to be much more frequent (perhaps even weekly) and meeting times published well in advance. And, maybe, this would justify two IRBs – one dealing with cases that require a high level of scrutiny (e.g., biomedical research) and another for projects more of the norm for UALR. Patricia Mark and Jeanne McPherson in **Institutional Review Boards and Public Relations/Mass Communication Research: Furthering the Conversation** recommend:

- Separate review boards for medical research and non-medical research
- Separate review boards for quantitative and qualitative research
- A special committee for expedited class practice projects

Philosophical concerns

In addition to the issues raised above, there is a general concern that the proposed policies and procedures are establishing an adversarial relationship between the IRB and researchers at UALR. If this is perceived to be adversarial by student and faculty researchers, it will undermine the research objectives that UALR promotes, even to the point of discouraging research (at least in areas involving human subjects).

Furthermore, the protection of human subjects including informed consent, confidentiality, and respect for the person are values that should be promulgated to all individuals conducting research. Rather than severely burdening a few individuals with a tremendous caseload, we should invest in the ethical training and responsible choices of all of our students, faculty and staff and distribute this decision-making process as much as feasible. When the opinion of the on-campus experts is needed, the IRB can play an important role. But in most cases, we should support researchers in making this determination within their own collegial, departmental, and/or professional context through excellent training and college-level review panels.

Again, thank you for the opportunity to respond. We all understand the necessity and importance of having sound, accessible, and appropriate human subject research oversight. We look forward to addressing the issues we've raised with you in the future.

Sincerely,



Steven F. Jennings, PhD, MBA
Chair, UALR Graduate Council