Starting an Institutional Review Board at a PUI

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In recent years, federal oversight of research involving human subjects has become more extensive and more public than ever. While most psychology departments at PUIs have probably had an approval process for human subjects for some time, recent federal regulations are much more stringent about the composition, process, and purview of institutional review boards (IRBs). This new emphasis has the practical effect of formalizing what may have been an informal process at PUIs, and most likely extending involvement of IRBs to research in departments other than psychology. The first three authors have all been involved recently in the creation of a formal IRB process at Bucknell University: Halpern as a member of the psychology department, Rackoff as an administrator and the first chair of its IRB, and Cunningham as member of the physics department and currently an Associate Dean of Faculty serving on the IRB. Gaffield is an administrator at Wittenberg University and has served on its IRB since its creation in 1992. He has chaired it since 1995 and offers a perspective on the long-term operation of an IRB at Wittenberg. In this article, we offer some observations about the context in which we, and presumably other PUIs, have set up IRBs, and identify some specific issues that IRBs typically encounter during that process.

One important context is the set of federal rules governing IRBs, contained in the Code of Federal Regulations, Title 45, Part 46 (45CFR46 for short, found on the web at: **http://ohrp.osophs.dhhs.gov/humansubjects/guidance/45cfr46.htm**, which are written to apply only to federally funded research. It is very likely that many PUIs will want to broaden that purview. On Bucknell's campus, we discussed early in the process the ethical dilemma of extending different levels of human subjects protection depending on funding sources of the research. Equally troubling from the point of view of university liability was the potential of requiring less (or no) oversight for some research compared to other research. Bucknell decided that all human subject research would come under the jurisdiction of the IRB. It also recognized that because the definition of "research" in 45CFR46 requires the intent to contribute new knowledge, classroom exercises or lab projects designed primarily to learn lab skills might merit a lower level of attention from the IRB.

Wittenberg also did not consider limiting the authority of its IRB to only federally funded research. A Wittenberg faculty member was awarded a research grant by NIH that was contingent upon the college's establishing an IRB and filing an "Assurance of Compliance with HHS Regulations for the Protection of Human Research Subjects." Wittenberg chose simply to adopt a model assurance agreement provided by NIH, which obligated the college to apply 45CFR46 to all human subject research, regardless of its funding source.

Another relevant context is that 45CFR46 was originally intended to apply to biomedical research in large universities. However, most of us reading this article are in small or primarily undergraduate universities, and our institutions' human subject research will more likely occur in social science disciplines than in invasive medical research. Thus, 45CFR46 is not a perfect match for our needs, and requires some interpretation to fit PUIs better. For instance, because of the nature of some social science research, participants cannot always be fully informed about all the manipulations and hypotheses in the study.

A third important consideration in creating and operating our IRBs was to keep our educational mission in mind at all times. Thus, we viewed our mandate as not only the application of regulations, but to engage in dialogue with faculty and student researchers about the purpose of the system, and how to conduct research that is both ethical and scientifically valid. A further consideration in some

of the research we review is that participating in research is considered educationally valuable. Like many psychology departments, both Bucknell's and Wittenberg's introductory psychology courses have a research participation option as one means of fulfilling some course credit (a "subject pool"). It is important that students neither be required to serve as research participants nor be placed in a position in which they are not completely free to withdraw from participating without penalty or loss of benefits. Secondly, as a practical matter, despite the educational value of participating, schools might consider adopting Bucknell's policy prohibiting students younger than 18 from serving as research subjects, avoiding the need for parental consent.

Finally, we need to recognize the challenges that PUIs face in the practicalities of running an IRB in a small research community. Faculty members in many disciplines may not be familiar with IRBs, and will be hesitant to serve or even submit their research for review. Smaller institutions have a smaller pool to draw on for interested and competent IRB members. PUIs in small communities have a challenge in finding qualified members outside the university (a requirement as stated in 45CFR46) who are not related to university employees!

Composition of the IRB

Federal regulations specify only three of the member categories of an IRB: 1) a member from the community (typically a member of the clergy or a physician); 2) a non-scientist; and 3) members qualified to discuss the research under consideration. Who else should serve on an IRB, especially at a PUI? At both schools, the IRB includes a representative from psychology, representatives from other division "clusters," and the administrator who acts as the college contact person for faculty who submit federal grant proposals (the Associate Dean of Faculty at Bucknell; the Assistant Provost at Wittenberg, who also chairs). Divisional representation satisfactorily assures research expertise among the IRB members without requiring a faculty member from every interested discipline, which would enlarge the IRB to an unmanageable size.

Recruitment of IRB Members

Recruitment of IRB members both willing and able to serve can potentially be difficult. At most small institutions, faculty members are already burdened with administrative work, so faculty members may have to be enticed to become IRB members. On the other hand, many faculty members find ethical issues interesting, and IRB members will often have a vested interest in making the process work smoothly.

In fact, the workload on a typical IRB need not be burdensome at all. Most cases considered by our colleges' IRBs are managed through "expedited review," in which the chair or a designee alone can approve a proposed research project (45CFR46.110). The Department of Health and Human Services periodically produces a list of minimal risk research activities that are eligible for expedited review, which is available at the Office for Human Research Protection website at **http://ohrp.osophs.dhhs.gov/humansubjects/guidance/hsdc99-01.htm**. In addition, much of the research conducted at a PUI is exempt from extensive IRB review. The only caveat to bear in mind is that someone other than the researcher must decide whether a project is exempt. At Wittenberg, the IRB chair decides on exemptions. At Bucknell, each cluster has a faculty member who is not on the IRB serve as the initial reviewer. This reviewer and the IRB chair need to agree on the classification of each project. A list of exempted activities is found at 45CFR46.101(b)(1)-(6). Consequently, our PUIs have had few cases that have required full committee review.

The charter members of an IRB will have more demands on their time than subsequent members. The burden of developing a policies and procedures manual, for example, falls to the first members of a new IRB. Also, since all cases are new ground, there is no "case law" collective experience available to a new IRB to facilitate its discussions. However, in Wittenberg's experience, IRB decisions become fairly routine within a year or two.

A special burden falls on a chair of a new IRB. In Bucknell's case, the first chair is an administrator conducting institutional research who also has faculty experience. This has worked out well to ensure some continuity for the first few years, and to tap the expertise of someone experienced in interacting with government agencies and many campus constituencies. Wittenberg's first IRB chair was a member of the chemistry department who had never been involved in human subject research. The objective was to assure faculty ownership of the IRB at its founding. For the last half dozen years, the Assistant Provost has chaired. Management of the paper flow, the high volume of rulings on exemptions, the large number of expedited reviews, and the maintenance of IRB records may lead PUIs to choose an administrator as a chair, especially once the legitimacy of the IRB has been established.

Classroom Exercises and Lab Projects

One issue that Bucknell's IRB spent many hours discussing involved handling classroom exercises and lab projects involving human subjects. This IRB concluded that classroom exercises in which students use each other as subjects do not constitute research as defined in the CFR and, consequently, the IRB has no jurisdiction over them.

However, some laboratories, although designed primarily to teach lab skills, do in fact deputize the students into being experimenters for other, naïve students. Thus at Bucknell it was thought some level of IRB oversight is desirable. To limit the amount of time members of the IRB would spend on reviews, Bucknell decided that it would permit instructors to submit a general lab protocol that established boundary conditions for student projects (e.g., no use of students under 18). Lab instructors have the responsibility to make sure specific projects meet the general protocol guidelines. Instructors discuss the protocol with their classes, and student researchers fill out a form discussing their procedures, which is signed and kept by the instructor.

Wittenberg's IRB conducts individual reviews of every student research project (but, like Bucknell's IRB, not classroom exercises). It adopted this approach for two reasons: 1) It assures an independent review of all human subject research; and 2) by requiring students to petition the IRB, underscores for them the importance of ethics, the protection of human subjects, and the value of risk reduction.

Interfacing with the Campus

One of the major goals of the IRB is to provide communication to the campus community and individuals concerning policy issues on human subject research. This is particularly important with departments and individuals that only infrequently conduct research involving human subjects. Two of the main methods that Bucknell uses to communicate information about human subjects policy are via campus e-mail and via a thrice-weekly general campus publication that goes to all faculty and staff. So far these methods have been sufficient to spread the word about the IRB and the university's new human subjects policy, even from departments and individuals new to the review process. Bucknell has also begun to include IRB information as part of the new faculty orientation process.

Wittenberg's IRB is now well known to the faculty and a substantial number of those who conduct human subject research have served on the IRB during its ten-year history. Each fall, a reminder is sent to all faculty members, informing them of the IRB and its responsibilities and their obligation to submit human subject research to the IRB for its review.

Accessibility of Documents

Public access of forms makes the review process less tedious for faculty as well as students. At Bucknell, all of the review forms are available on our file server as word-processed documents and the policy document and paperwork will be translated into a web-friendly form once the policy is finalized. At Wittenberg, IRB documents are printed and distributed to all faculty members as part of the Faculty Manual.

Spirit of the IRB and Campus Politics

The IRBs at PUIs cannot see themselves as faceless committees that say "no" to proposals. Instead they need to be as helpful as possible to researchers using human subjects in order to make their projects both scientifically as well as ethically sound. A consequence of giving positive feedback has been that most researchers agree that the review process is a positive experience and that their research project is better as a result. So far, all projects that have been reviewed by our IRBs have eventually been approved, although several times they have insisted that procedures be modified as a condition of gaining approval.

Three other points should be kept in mind to make an IRB as user friendly as possible. Writing documents to facilitate the procedure is important. Students as well as faculty will get frustrated if they have to spend much time completing complicated forms or asking questions to clarify the review procedures. Quick turn around time for the review process is essential especially if the researcher's procedures must be modified. Finally, faculty and students will undoubtedly have questions about the review process and the human subjects policy. We have found that providing researchers samples of informed consent forms, for example, both helps them understand the components of informed consent and saves the time and trouble of creating new ones from scratch.

Other Issues

Several other considerations will be mentioned here only briefly. First, careful documentation of all IRB actions is essential if the institution is to be in compliance with federal guidelines. This includes detailed minutes of full-IRB reviews, a database to monitor the status of each active research project, and records of communications with the researcher when the IRB requires modifications of the research protocol. Both Bucknell and Wittenberg have found e-mail to be an effective way to facilitate such communications. To provide a suitable audit trail for any DHHS site visit, e-mail communication should be printed, dated and signed by the chair so that there is a complete paper file of each project.

Finally, one cannot discuss IRB issues without noting the significant challenges associated with the explosion of Internet and email-based research. Thorny ethical issues can arise in this arena, and there is often little in the way of precedent to assist the IRBs in arriving at a reasoned judgment. Some research universities have written policies on their Web sites that can be consulted for guidance. Class projects — which some colleges may decide is technically not research and thus not the province of the IRB — can nonetheless place subjects at significant risk when they employ e-mail or the Internet. Bucknell's IRB was forced to intervene when one class sent an e-mail survey to the whole campus community asking sensitive questions regarding medical conditions and family health history. Such data are transmitted via an insecure medium, and could be made public in the future, with negative consequences. The IRB permitted the students to use their e-mail message to recruit subjects, but required that the actual survey be administered and returned anonymously via campus mail. (At Wittenberg, the survey likely would have been considered research and subject to IRB review.)

In the end, the IRB must thus be prepared to be flexible in its interpretation and implementation of the federal regulations and its own policies so that the research and educational mission of the institution is supported without compromising the safety and autonomy of the human subject of research.

Resources

The following resources can help new and continuing IRBs in their work.

A. Print sources

Chastain, Garvin and R. Eric Landrum. 1999. Protecting Human Subjects: Department Subject Pools and Institutional Review Boards. American Psychological Association.

Protecting Human Research Subjects: Institutional Review Board Guidebook. 1993. Office for the Protection of Human Subjects of Research Risks, NIH. Available from Superintendent of Documents (017-040-00525-3).

Sales, Bruce D., and Susan Folkman. 2000. *Ethics in Research with Human Participants*. American Psychology Association, Washington, D.C.

Shea, Christopher. 2000. Don't Talk to Humans: The Crackdown on Social Science Research. *Lingua Franca* 10(6).

B. Videotapes from NIH

Evolving Concern: Protection for Human Subjects

Balancing Society's Mandates: Criteria for Protocol Review

The Belmont Report: Basic Ethical Principles and Their Application

C. Information on the web

Regulations in plain English:
http://obssr.od.nih.gov/IRB/protect.htm

IRB news tracked by the American Psychological Society:
www.psychologicalscience.org/newsresearch/irb/

For research involving children: Society for Research in Child Development:
http://www.srcd.org/about.html#standards

The Online Ethics Center for Engineering and Science:
http://onlineethics.org

Codes of Ethics of Professional Societies in the Social Sciences

American Psychological Association:
www.apa.org/ethics/code.html

American Anthropological Association:
www.aaanet.org/committees/ethics/ethcode.htm

American Sociological Association:
www.asanet.org/members/ecointro.html

For web-based IRB training: National Association of IRB Managers: **www.naim.org**

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— Andrea Halpern teaches and conducts research in the area of human cognition. She makes extensive use of human subjects in her research . She has overseen the subject pool in Bucknell's introductory psychology course.

— Jerome Rackoff has been at Bucknell University for twenty-five years — first as a member of the biology faculty, then in various administrative capacities in University Relations and Academic Affairs.