Applying to the IRB

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Applying to the Institutional Review Board (IRB) is often seen as one of the most intimidating and nerve-wracking aspects of implementing a research project. The protection of research subjects is a vitally important consideration in the planning and preparation of a project and the IRB validates and ensures these protections. Fortunately, IRB experiences can be rewarding and mutually educational. As with any potentially daunting experience, being knowledgeable of the why's and how's of the process can alleviate anxiety and help in gaining the rubber stamp of approval.

The IRB process in the United States owes a great deal to a 1979 government commission which prepared the Belmont Report. The report made clear the ethical concerns in research, namely the importance of respect for persons, beneficence and justice. The report represents multiple measures aimed at assisting in the development of guidelines for an IRB. It is no accident that extensive private and public sector attention has been given to the issue of research subject protection in light of grave ethical errors committed by everyone from the Nazi's to well-intentioned graduate students and highly esteemed research universities. A review of this quintessential and short report can help researchers reframe their paradigms of informed consent, subject recruitment and the assessment of risks versus benefits.

Institutional review boards consist of a committee of five or more individuals from the community representing many walks of life and may include nurses, physicians, lawyers, and laypeople. They are charged with reviewing research proposals and monitoring ongoing projects with the single goal of protecting the human subjects in the studies. In recent years high profile legal and ethical concerns coupled with high stakes financial and scientific gains have made Institutional Review Boards all the more important and in some cases even stricter than they have historically been. By understanding that the IRB has one objective in mind, researchers can narrow gaps in confidentiality, subject protections and consider cost-benefit arguments in the face of varying risk levels.

Following the instructions and meeting the requirements for IRB proposals can be an easy pitfall to avoid for both novice and expert researchers. Every institution will have varying requirements and submission guidelines, but all will require thorough discussion of ethical concerns, study design and protections for participants. The review process may take four to six weeks and can require multiple submissions of proposals or visits to the board itself. Planning far ahead and being patient with the process are required when working with an IRB.

IRB proposals will usually require some of the following elements and can assist researchers in preparing to actually defend a proposal or in the design of the research methodology itself. Peer-reviewed journals require IRB approval for publication consideration and many IRB forms and policies can be found on the internet or are available from institutional IRBs upon request. Studies that are carried out for an extended period of time may be subject to continuing review. Higher risk situations may require more frequent reviews; otherwise reviews must occur once a year.

Proposal checklist: a listing of considerations and items to be turned into the IRB. This checklist might also be used to help a researcher determine if the project needs a full review, an expedited review (a type of review that is shortened and generally less thorough because of the lower risk to subjects) or if it is exempt altogether (the IRB can help decide this).

Project description: Describing the project itself and how it will be carried out may actually more than one section. Generally the applicant will need to include the name of the researchers, purpose of the study (or abstract) including the research questions, time frame for the study, research and data collection methods and level of risk to the participants. A plain-language discussion of the research procedure is generally also requested. Increasingly, IRBs are being asked to look at the value and validity of studies. It is important that the researcher will be able to defend whether or not the study has value for the future and whether the methodology will support findings and make it worth the risk to subjects (Casarett, Karlawish & Moreno, 2002).

Subject Participation and Recruitment: This section should include the sample to be studied, methods of recruitment and retention. Special attention is given to groups that are considered particularly vulnerable such as pregnant women, prisoners, children, those with development delays or who are unable to consent for themselves, non-Caucasian subjects and impoverished participants. A discussion of inclusion and exclusion criteria should cover the above considerations.

Informed Consent: Consent forms and procedures are a big part of the IRB review process and many times feedback from an IRB is focused on consent gathering or modifications to consent forms. It is essential to keep in mind that informed consent is not just a piece of paper the participant signs or a onetime event but is an ongoing process of education and commitment between the researcher and participant. All consent forms are required to be attached to proposals.

Maintenance of Confidentiality: A top concern directly stemming from informed consent and a sacred protection that is scrutinized by the IRB. Confidentiality protection might include coding of questions, eliminating participant's names or identifying features or encrypting data. HIPPA requirements must be also be met or exceeded.

Risks/Benefits to Subjects: The general rule of thumb when it comes to discerning risks (actual or foreseeable) and benefits are to overestimate the risks and underestimate the benefits. It is unethical to promise things to subjects that cannot be delivered or substantiated. Risks may be classified as physical, psychological, social and economic.

Conflicts of Interest: Increasingly, disclosures of the researcher's conflicts of interest are being requested by IRBs to validate the potential impact on the protection of subjects.

References: This can help the IRB determine how the researcher substantiated research methods, decisions to examine the particular problem and to assist in determining the full risks versus benefits for the study itself.

Being able to conduct research is not a right, but rather a privilege and one that requires careful attention to the individuals who are at the center of the study itself. Institutional Review Boards in collaboration with the researcher have a singular goal of protecting these individuals and ensuring that they are exposed to minimal risk in the face of potential benefits (Arford, 2004). Following proposal guidelines, being informed about the IRB process and putting ethical concerns for subjects at the top of your priority list will assure a smooth and painless IRB preparation and approval process.

References/Bibliography

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National Cancer Institute: Human Participant Protections Education for Research Teams accessed November 9th, 2006 from http://cme.cancer.gov/clinicaltrials/learning/humanparticipant-protections.asp (this is a web tutorial often required by graduate schools and research programs that must be completed to meet institutional and government education requirements).

National Institutes of Health: Web Site listing Regulations and Ethical Guidelines including: The Belmont Report, the Nuremburg Code, Protection of Human Subjects (45 CFR 46),World Medical Association Declaration of Helsinki and the NIH's Research Guideline. Accessed November 9th, 2006 from http://ohsr.od.nih.gov/guidelines/belmont.html

U.S. Department of Health and Human Services: Office for Human Research Protections (OHRP). The quintessential site for information on research and IRB's, regulation and education. Accessed November 9th, 2006 from http://www.hhs.gov/ohrp/. See especially the IRB Guidebook at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm

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