The Institutional Review Board: Friend or Foe in a Graduate Student's Career

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Introduction

Graduate students face many challenges in their sojourn through the post-baccalaureate world of academia. One of the most important of these challenges is the development of an ability to understand and do research. They must master the skills and theories of their discipline; learn various methodologies and statistics for answering research questions; and then actually carry out an independent research project. It is in this latter task that many of these same graduate students will encounter the Institutional Review Board (IRB).[1] While not every graduate student engages in research that will directly or indirectly entail the use of human subjects, a very large proportion will. This is especially true for the social, behavioral and health sciences. So, the likelihood of facing a review process is very high, and that can have a major impact on one's success in seeking a graduate degree.

The IRB is a function of a university (or hospital or agency or whatever the entity) established under federal mandate. It is charged with reviewing and judging all research projects that involve human subjects, directly or indirectly, so as to safeguard the rights of those human subjects according to ethical principles and federal regulations. The IRB has the power to require changes in a research project or to even deny approval, thus preventing the research from taking place. Within the institution, there is no appeal of an IRB decision. Of course, while an IRB seldom operates in such a Draconian manner (even though many a researcher might think otherwise), the results of being lax in such review can lead to dire consequences for the institution. Numerous institutions have experienced the loss of federal funding across the board due to audits that showed laxity in the protection of human subjects.

Any researcher, graduate students included, must be certified as competent to do research with human subjects. In most cases, this certification involves the successful completion of some sort of education module. Once completed, the researcher submits a protocol that is a detailed description of the intended work and outlines its purpose, method and safeguards. The protocol is reviewed by the IRB, which may require changes and alterations in the research process so as to fit within federal and ethical guidelines. No research on human subjects may commence without the final approval of the IRB. Given the extent of information required and the seriousness with which an IRB must approach things, many researchers, particularly novices like graduate students, experience a high degree of stress during this process.

Anecdotally one hears how horrible, arbitrary and confusing the whole IRB process is, but is that truly the experience in academia today? The focus of this paper is on the novice researcher, the graduate student who is entering the world of scientific research. The paper looks at three descriptive questions. What is the knowledge level of such students in regards to human subject research and IRB regulations? What are the experiences of graduate students as they go through the process for the first time? Finally, what attitudes are formed concerning the IRB and the review process?

This information could be valuable for the institutions themselves, which must follow guidelines, yet not be seen as barriers to cutting edge research. Knowing how neophyte researchers think and feel can provide insights into how best to present the necessary materials for the successful completion of a research protocol. The goal for such institutions is, of course, to protect human subjects while supporting researchers in their striving to understand the "human condition." The importance of this goal and the IRB process at any research-based academic institution reinforces the need to have answers to the above research questions.

Review of Pertinent Literature

The need for regulation of medical research stems from historical events such as the human experimentation performed by Nazis during World War II and the Tuskegee study in which poor Black men suffering with syphilis were denied treatment without their consent (Dunn & Chadwick, 1999). The Nuremberg Code addressed the atrocities of the Nazi human experiments by covering issues such as the need for voluntary consent by subjects, freedom from any and all coercion by experimenters, a full understanding of the costs and benefits to subjects due to their participation in a medical study, qualified experimenters using relevant research designs, and that the individual has the right to withdraw at any time for any reason (Ferraro, et al., 1999; Oakes 2002).

The monitoring of human subject research came about in 1978 as a result of the Belmont Report (Belmont, 1979). At this time, Institutional Review Boards became

[1]These boards can have different names, such as "Human Subjects Review Board" or "Ethics Review Board" for example. Whatever the name, the function is quite similar in that they all review research involving human subjects so as to protect those subjects from harm due to the research.

a federal mandate. An IRB is a committee consisting of five or more individuals who review research protocols and monitor ongoing studies to ensure the protection of human research subjects. An IRB typically focuses on the research within its locality, such as the research within a specific university, and it is the IRBs themselves that have become a topic of discussion among researchers.

J.M. Oakes (2002) notes there are no writings that offer insights into the rationale of an IRB or prescriptive advice for researchers on how to work with an IRB. According to Oakes, recent increased scrutiny of social science research has caused researchers to become "increasingly frustrated, annoyed, and upset by IRB decisions, inconsistencies, delays, and misunderstandings" (p.445). Oakes believes that much frustration can be alleviated through proper education of IRB regulations and issues. Furthermore, institutional review boards need to learn from researchers and educate themselves regarding the issues involved in research.

A recent survey study of the IRB at the University of Dakota was designed to measure previous experience with the IRB, awareness of the purposes of the IRB, attitudes toward the IRB, and perceptions of and preferences regarding policies of the IRB (Ferraro, et al. 1999). This study found that 80% of the students felt that they were familiar with the purposes of the IRB. The majority stated that IRB request for proposal changes were "easy to understand or respectful." Some of the problems reported were an overly long approval process, conditions that were too restrictive and IRB members who assumed that they knew more about the subject than the investigator did. Some of the recommendations included: the IRB should speed up the process; there should be more training on completing (ambiguous and confusing) application forms; reviews should focus on issues related to human subjects rather than theory, hypotheses, methodology, or design; clear guidelines should be issued regarding what must be submitted to the IRB; and researchers should be made more aware of the purpose of the IRB.

We have all been privy to conversations in which students and faculty members have complained about the IRB process. With these conversations in mind, and the North Dakota study noting a lack of research regarding attitudes towards the IRB, this research focuses on discovering (1) how much graduate students know about IRB regulations, (2) how they find out about the IRB process and regulations, (3) how many have experienced frustration and delays, (4) how many have altered research plans in order to be able to use the short, exempt IRB protocol form, and (5) suggestions that graduate students might have regarding how the IRB could better help them as researchers.

Methods and Materials

A web-based survey was created for graduate students concerning the IRB and its workings. Using six point, Likert scale statements, the survey probed student knowledge, experience and attitudes. A total of 1,908 graduate students received an email inviting them to participate. As per the subject of this paper, the research was reviewed, approved and strengthened by the IRB.

All non-medical graduate students, at Saint Louis University, a private, Catholic university in St. Louis, Missouri, form the population for this study. It was noted that, among graduate students, those in the behavioral and social sciences do a large proportion of the human subjects research at the university. Medical students were excluded from the study because medical protocols are subject to review by a different group, and researchers assume a clearer need for oversight. Very few of these research projects involving human subjects have a graduate student as the principle investigator. Saint Louis University, until 2001, had only one central IRB. When the volume of protocols became so great, the committee was split into two freestanding units. One unit handles all medical school and hospital protocols. The second unit covers the non-medical protocols, most of which are in the behavioral and social sciences. It is under this IRB that one finds the vast majority of graduate students doing human subject research.

Based on the research questions, items were developed for the survey instrument. Item selection and refinement proceeded through a dialogic process and ultimately, 9 demographic and 22 attitudinal questions were formulated. In the judgment of the researchers these 22 attitudinal items sufficiently covered the five main research questions. The survey was constructed to be administered in a web-based format using the Test Pilot program available through the Information Technology department at the university.

Participants were contacted with a cover letter via their university e-mail accounts. The cover letter contained the URL of the survey instrument. Participants were informed that participation was voluntary, and that completion of the survey was expected to take approximately 20 minutes.

The overall response rate was low, with 160 surveys out of 1908 requests (8.4%) returned. Of these, 151 responses provided useable data (7.9%). It is believed that the low response rate was due to the fact that a large proportion of potential respondents resided in programs that do not normally perform research on human subjects. Within departments that normally perform human subjects research, the response rate was somewhat higher, though still low, for example, 25 out of 95 (26.3%) psychology students responded. It is also possible that the response rate was influenced by the format of the survey, since web-based surveys may still be seen as less legitimate by respondents.

Respondents to the survey were mostly female (63.6%). Fifty-one (34.2%) were in the first year of their programs, 32 (21.5%) in the second year, 30 (20.1%) in the third year, 17 (11.4%) in the fourth year, and 19 (12.6%) indicated that they were beyond the fourth year. Seventy-

three (50.0%) indicated that they were in programs terminating in a Ph.D., 34 (23.3%) were in MBA program, 22 (15.1%) in an Ed.D. program, and 17 (11.6%) were in Master's terminal programs.

Results

Descriptive statistics for the 22 attitude and perception measurement questions are shown in Table 1. A number of items were strongly endorsed by respondents to the survey. These included items 5 and 6, indicating that the IRB helps to improve the quality of research and is an important factor in protecting human subjects from ethical abuses. Responses to item 13 indicated that IRB does a good job of requiring changes to minimize risks to human subjects, and those to number 14 indicated that the IRB is perceived as being fair in its assessment of protocols.

On the other hand, subjects felt that the IRB approval process takes too long (item 15), and that its regulations are confusing (item 16). Interestingly, undergoing the ethics certification program did not alleviate this tendency - the mean for who had completed certification was 1.16, for those that had not it was 1.15.

In order to allow meaningful analysis, it was considered desirable to reduce the unwieldy number of items into a reasonable number of indices. The motivation behind this was to allow more accurate analysis of the constructs of interest.

To this end, a principal components analysis with Kaiser Varimax rotation was performed on those items measuring attitudes toward and perceptions of the IRB and its process. Missing scores were replaced by the mean for that variable. This produced 5 clearly interpretable factors. Seven of the items (items 5, 6, 8, 10, 11, 13, 14) loaded onto a factor that covers both the fairness of the IRB process and how well it performs its functions (such as ensuring compliance with relevant guidelines and protecting subjects) which has been named *perceived fairness*, 5 (items 4, 7, 15, 16, 17) measure confusion and *frustration* with the process, 4 (items 9, 12, 24, 25) measure attitudes toward *oversight limitation*, 3 (items 18, 19, 21) measure perceived *knowledge* of the process, and 2 (items 22, 23) measure perceived helpfulness of the IRB *certification* process. One item regarding the explanation of the IRB submission process on the IRB website did not load onto any factor and is considered separately.

Items loading onto each of the five factors were summed to produce the indices. Cronbach's alpha for each index and their intercorrelations are shown in Table 2. Responses to the *perceived fairness* questions indicated that the process is generally perceived as fair and successful in accomplishing its objectives, and a t-test indicated that the deviation from neutrality was significant (mean index score = 7.7, average item score = 1.1 – *agree somewhat*; $t(109) = 10.24$, $p < .001$). Responses to the *frustration* index items indicate that people are neutral to slightly frustrated with the process (mean index score = 2.5, average item score =.50 – *neutral to agree somewhat*; $t(115) = 4.12$, $p < .001$). Respondents indicated that they would like some *limitations to the oversight process* (mean index score = 2.9, average item score =.72 – *agree somewhat*; $t(129) = 6.54$, $p < .001$). Subjects were neutral regarding whether they had been made sufficiently *knowledgeable* about the process through classes and interactions with professors ($t(140) = 0.69$, $p > .05$), and those that had gone through the *certification* process felt that it was helpful to them (mean index score = 2.1, average item score = 1.05 – *agree somewhat*; $t(84) = 7.90$, $p < .001$).

Discussion and Conclusion

Overall, attitudes toward the IRB are relatively positive. This is especially true when it comes to perceptions of the effectiveness of the IRB in accomplishing its core mission and the fairness of the IRB, as measured by the *fairness* index. Only 23 of the 110 (20.9%) respondents scored in the negative range on this index, indicating that the perception that the IRB is unfair or inept is relatively rare. This perception was apparently aided by participation in the certification process, as those who had undergone certification considered the process to be considered more fair than those who had not (Certified: $M = 9.16$, $SD = 6.1$ – Uncertified: $M = 4.4$, $SD = 10.3$; $t(108) = 2.48$, $p < .01$). This probably indicates the effectiveness of the training process in educating researchers to the reasons for IRB oversight. In fact, a good certification experience seems to be crucial to overall attitudes toward the IRB. Those who reported that certification was helpful indicated that the process was fairer, they were less frustrated by it, and they were less likely to indicate that the IRB was overstepping reasonable bounds on its oversight (see table 2, intercorrelation of indices).

Despite the generally positive perception, 76 of 116 (66%) reported that they were confused or frustrated by the process. Subjects' major objection was that they felt that the IRB process takes too long, and that the regulations are confusing. In addition, they felt that the IRB should not require changes in research that have little relationship to protecting human subjects. The wording of this question leaves open the question of whether they felt that the IRB *actually does* require such changes. It seems reasonable to conclude that responses to this question were driven by frustration with the more pedestrian aspects of approval and this probably relates to confusion with the process. It is interesting to note that subjects who reported that they felt they had more knowledge of the process did not necessarily feel less frustrated and confused by it. In fact, there is no significant correlation between these indices for these subjects ($r(115) = -.156$, $p > .05$).

References

Belmont Report (1979). Ethical Principles and Guidelines for the Protection of Human Subjects. US National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. Found at http://www.hhs.gov/ohrp/humansubjects/guidence/belmont.htm.

Dunn, C.M. & Chadwick, G. (1999). *Protecting Study Volunteers in Research*. CenterWatch, Inc.: Boston.

Ferraro, R., Szigeti, E., Dawes, D. & Pan, S. (1999). A survey regarding the University of North Dakota Institutional Review Board: Data, attitudes, and perceptions. *The Journal of Psychology* 133 (3): 272-280.

Oakes, J.M. (2002). Risks and wrong in social research: An evaluator's guide to the IRB. *Evaluation Review* 26 (5): 443-479.

Table 1: Descriptive statistics for the 22 attitude and perception measurement questions

Item#	Label	N	Min	Max	Mean	SD
4	IMPEDED RESEARCH	128	-3.00	3.00	-0.77	1.89
5	IMPROVED QUALITY	137	-3.00	3.00	1.13	1.47
6	PROTECTS HUMAN SUBJECTS	145	-3.00	3.00	1.77	1.23
7	DO MORE RESEARCH	141	-3.00	3.00	-0.15	2.02
8	POSITIVE INTERACTION	114	-3.00	3.00	0.81	1.63
9	COURSE RESEARCH	146	-3.00	3.00	0.45	1.93
10	FAIR JUDGEMENT	130	-3.00	3.00	0.91	1.57
11	MONITORS COMPLIANCE	126	-3.00	3.00	0.68	1.60
12	NO CHANGE	142	-3.00	3.00	1.30	1.55
13	RISK ASSESSMENT	127	-3.00	3.00	1.09	1.37
14	FAIR ASSESSMENT	126	-3.00	3.00	1.09	1.31
15	TAKES TOO LONG	130	-3.00	3.00	1.53	1.57
16	CONFUSING	130	-3.00	3.00	1.15	1.58
17	CLEAR REQUIREMENTS	131	-3.00	3.00	-0.53	1.54
18	COURSES INFORMED ABOUT IRB	142	-3.00	3.00	-0.35	1.99
19	ADVISOR INFORMED ABOUT IRB	143	-3.00	3.00	-0.04	2.02
20	WEBSITE EXPLANATION	85	-3.00	3.00	0.32	1.57
21*	COMPLETED CERTIFICATION	150	.00	1.00	0.56	0.50
22	PROGRAM TAUGHT ETHICS	84	-3.00	3.00	1.17	1.44
23	PROGRAM TAUGHT REGULATIONS	84	-3.00	3.00	0.96	1.44
24	LEGAL ISSUES OVER ETHICS	130	-3.00	3.00	0.59	1.53
25	ONLY POTENTIALLY HARMFUL	142	-3.00	3.00	0.50	1.96

Note: * indicates that allowable responses for an item were dichotomous

Table 2. Intercorrelation and reliability of the five indices.

	Frustration	***Oversight***	***Knowledge***	***Certification***	**Cronbach's α**
Fairness	-0.306	-0.267	0.332	0.650	0.873
Frustration		0.566	-0.156	-0.394	0.812
Oversight Limitation			-0.106	-0.359	0.715
Knowledge				0.132	0.691
Certification					0.643