DESIGNING AN EVALUATION SYSTEM FOR HUMAN BETTERMENT: THE CASE OF HUMAN PARTICIPANTS IN RESEARCH

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1. Introduction

Wherever humans are the subjects of research in the United States, those who use them are required to present their research procedures to an Institutional Review Board (IRB) who scrutinize them for their potential of aversive impact on human participants. The IRB represents a kind of human activity system that exists to look out for the welfare of human participants in research. Their review of a proposed research project involves a process of evaluative inquiry.

Human betterment is implicit in all activities of the IRB, though indirectly through the absence of detriment. It is generally accepted that some research with human beings is a necessary activity for the amelioration of the human condition. It is expected that researchers will take all necessary precautions to exercise research procedures without harm to their human participants. Aversive impact (harm) comes in many forms; it may be economic, physical, psychological, and social. Potential for harm weighs heavily in the IRB review process. Further, the potential benefits to humans should outweigh the potential risks, or in other words, human betterment should outweigh detriment.

The purpose of this paper is to discuss the case in design and development of an IRB for the author's institution. The paper is organized into several parts to present the choices of systems design considered, the design chosen and its implementation. The challenge of defining and assessing human betterment in the context of research with human beings, and evidence is presented pertaining to the case under development. Finally, some select issues are raised and discussed in regard to the IRB as an ethical and evaluative system for human betterment.

2. Systems Design of the IRB

The following design characteristics are considered central to the conduct of IRB review: a) the extent of involvement of the membership in a case review, b) synchronic to asynchronic review, c) the time period for review, d) the media to be used, e) the key elements of the system, and f) the key activity links among the elements that must be present to enable the review process to transpire.

Several existing models and institutional examples of IRBs were studied to become aware the range of systems design in action. The author also could tap four past periods of service on IRBs for public and private education institutions and the federal government. IRBs have tended to restrict operationalization of the design characteristics. The dominant form of IRB is a monthly meeting of the board of the whole to discuss research proposals and render a verdict on each one, as to whether

the project may be approved for use of human beings. But from the classic design, marked A below, there are several extensions and innovations, marked B through (9) to consider: A- group meeting (one day per week to month, in-person), B- group meeting (one day per week to month, conference call), C- panel meeting (one day per week to month, in-person), D- panel meeting (one day per week to month, conference call), E- virtual group meeting (week long period, email exchange with IRB chair), F- virtual group meeting (week long period, web site threaded discussion), G- virtual panel meeting (week long period, email exchange with IRB chief), H- virtual panel meeting (week long period, web site threaded discussion), I- combinations of the above, J- chair review with consultation as necessary from others, K- IRB certified independent reviewer, L- contract IRB review from outside the host institution, M- department oversight in lieu of IRB review, and N- course instructor review in lieu of IRB review.

3. The Design Chosen

It is important that the design of the IRB be as compatible as possible with the host institution. Given the import of technological advances to aid IRB activities and the fact that the author's IRB serves a distance education institution, the classic design, though used previously, is not the best fit. The author opted for Design E and soon after implementation began, Design G.

4. System Development

This case of IRB development involved describing the configuration of characteristics to be used. Guidelines passed in the United States Congress and published in the Congressional Record were consulted to delineate the chief parameters and boundaries for the IRB. Being an education institution, care was taken to include all constituencies on the board defined as such by the host institution. Persons were then recruited and the board constituted with recognized authority from the host institution. Given the geographical spread of the board, working through email became a natural medium for IRB communications and review of research proposals.

Once underway, the newly constituted IRB soon experienced a proliferation in the number of proposals to review. Two factors can account for the increase, which led the author to move from Design E to Design G.

First, the major influence was a coinciding pedagogical shift among the faculty. Pre-candidacy research courses in the doctoral programs were redesigned to more hands-on research activities and training exercises. Theoretical and term paper type course assignments were replaced with requirements to do pilot research projects. In other words, the emphasis moved away from reading and writing about research toward doing more research prior to the doctoral dissertation. The importance of research ethics and treatment of human participants became more evident in the research courses, since the pilot studies proposed usually involved human participants for purposes of recruitment, instruction, and data collection.

Second, the presence of the new board made the constituencies more aware of research ethics as a community concern. This visibility was also prompted by erecting the school web site, in which the IRB had its section. IRB policy and procedures, application forms, and related material became suddenly and instantaneously available to the entire distance education community.

Given the distance education nature of the programs and absence of residential based laboratories, classrooms, and subject pools under the supervision and control of campus based university

departments, the IRB felt compelled to review course research proposals. Whether human participants receive sufficient precautionary consideration for their protection in regard to research procedures to be used in research under the auspices of a distance education institution is unknown; therefore, the more conservative stance was taken. The pilot study for a course is considered with the same range and degree of human participant issues and risks as the dissertation, and the IRB began reviewing these projects in addition to theses, dissertations, and faculty research proposals. However, this places a tremendous workload on the IRB, when most universities allow departments to oversee and regulate research ethics without IRB review, namely, use of Designs M and N .

One response to these changes is the shift from Design E to G. Forming separate review panels headed by a chief reviewer allows several IRB reviews ongoing to occur autonomously; it distributes the workload across the board to accommodate the larger volume of research proposals to review.

5. Phases of Systems Development

The author had participated as a member of the IRB at his host institution a decade earlier when it operated according to Design A, as a review committee of the whole. This phase remained the design used at the institution until several years ago, when the IRB drifted into its second phase, which can be depicted as review by only one person, its chair, namely, the use of Design J. Certainly not in federal compliance, this design was replaced with Design E and later G during the author's term of office as chair. This latter period may be designated the third phase of IRB systems development.

6. Current Status and Future of the System

At present, this IRB is gaining experience in the use of Design G. It is postured to enter its fourth phase that will make use of a web site, in which researchers may post their applications and a virtual panel of the board will conduct a threaded discussion that constitutes its review of it. This "experiment" in IRB design has promise. However, it is the author's projection that some combination of designs will be the eventual answer for this distance education institution to review a variety of projects from three very different kinds of doctoral level graduate programs, as 1) internal pressures increase to seek outside grants and 2) external pressures mount toward stricter compliance with federal guidelines.

7. Case Discussion: Systems Design, Human Betterment, and the Efficacy of the IRB

This paper is a work in progress. To be developed preliminarily and after the Fuschl team work this April 2002 are subsequent sections that extend the above text to three areas of discussion.

First is the idea of assessing human betterment. Assessment tends to come from documenting the process of review, archiving the system, term evaluation reports, and feedback from users (principal investigators) on their experience of interacting and learning from the IRB.

Second, there needs to be concrete evidence of betterment through sources of evidence, analysis and synthesis of IRB reviews, and a study of the kinds and range of cases reviewed and experiences reported with the IRB. If betterment is only in the eye of the beholder, especially those working

closely as members of the conversation team, it may remain unconvincing to others who are outside the immediate membership. If a system is to be one that manifests betterment, it needs to be evident to others. However, this issue is one well worth exploring from both the insider and outsider points of view, because it leads to basic ethical imperatives, such as the notion that only those of the system can ethically design and benefit from their system.

Third, as a human activity system, the IRB has to remain open to the possibility that its policy and procedures may unintentionally lead to human detriment as well as betterment, and this notion needs exploration and study.

It is from the examination of the IRB activities that select issues, such as the three stated above, come to our attention. The above three issues may be epitomized as follows:: 1) the design of the IRB as an evaluation system, 2) design of the IRB as a system for human betterment, and 3) design of the IRB as a means to protect human participants in research. They are to be discussed before concluding the paper.