Research Ethics in Action: Cybernetic, Praxiological, and Systemic Perspectives in An Evaluation System

Arne Collen

Saybrook Graduate School and Research Center
450 Pacific, San Francisco, California 94133 USA
email: acollen@saybrook.edu

Abstract

Cybernetic and systemic aspects in one kind of evaluation system are described. A conceptual system of ethics based heavily on praxiology is introduced. The convergence of the three perspectives is illustrated in a social system, whose primary purpose is the examination of risk to and protection of human beings to be used for research purposes. It is argued that this kind of evaluation system manifests research ethics in action.

1 Purpose and Overview

The purpose of this paper is to apply three perspectives to describe a particular kind of social system that has as its purpose the evaluation of research proposals for impact of research procedures on human beings. Each perspective is articulated in turn and then integrated by means of discussion of some representative case illustrations. In this endeavor, questions of a critical nature to the evaluation of this system arise, and it is at this meta level that the paper concludes.

2 What (and Who) Is the IRB?

Where human beings are the objects and subjects of research, the projects that use them require prior scrutiny by a panel of evaluators, known in the United States as the Institutional Review Board (IRB). The domain of the IRB encompasses any matter in regard to the potential for aversive impact of research procedures on human participants [Stanley et al., 1996]. The IRB exists chiefly to evaluate potential impact, explicitly for the presumed protection of those participants, and there are secondary benefits of IRBs beyond the review of research proposals [Chastain and Landrum, 1999].

IRBs are an expected part of any research institution using human participants in the United States. They are mandated through guidelines of the federal government. Research involving humans requires an IRB review consisting of a panel of evaluators. On the average, the typical IRB meets monthly, has sixteen members, and reviews close to 300 proposals per year [Hayes et al, 1995]. However, IRBs may vary in design, for example, a proposal may be assigned to a subgroup of its membership. IRBs and the review panels seem to range anywhere from one to two dozen members. As much as possible, the evaluators are chosen for their expertise and experience with research ethics and the problems and issues relevant to the project under review, but at the same time the IRB is to represent a variety of stakeholders and constituencies of the institution, and even the public interest, the so-called public-at-large members. In recent years, IRBs make increasing use of distance technology, such as conferencing, email, and the World Wide Web. The perspectives presented in this paper rest upon the author's experience over the past 3 years as the principal designer, developer, and chair of the IRB of his institution.

3 Multiple Perspectives

The IRB represents one kind of human activity system [Checkland, 1981]. It is a social organization where evaluation is center stage in any description of its purpose and activity. Each case coming before the IRB for review necessitates the application of research ethics and many concepts and principles of research design and execution. The chief concern is always the adverse impact any procedure may bring to the human participants, and the IRB panel expects a convincing argument that the potential benefits of doing the research outweigh the potential detriments. The IRB process of review is readily construed as a form of evaluation research as well as human systems inquiry. Highlighting ideas of activity, evaluation, humaneness, inquiry, and ethicality communicate some of the key perspectives or lens one can use to study and describe the IRB. In short, the IRB can be studied and described from multiple perspectives. With these emphases in mind, for this paper, we proceed to examine the IRB from the perspectives of first systemics, second cybernetics, and third praxiology. The IRB familiar to the author will be used to illustrate them.

4 Systemic Aspects

With regard to the systems view [Buckley, 1968; Jackson, 1991; Minati and Collen, 1997], the IRB has its set of elements that when interacting makes it a human activity system. There are the boundary conditions, relationships, and configuration of key entities that comprise the IRB as a social system, which is also a body nested within the larger human organization it

serves. There is the IRB membership comprised of persons who may be called upon to serve on a review panel. There is the head or chair of the IRB operation with at least one staff support person. At any one time, there may be several review panels conducting a review of research proposals, and each proposal has one or more principal investigators who communicate with the chief evaluator or chair of the review panel, the chair of the IRB and staff support person. Alternatively, the IRB may meet periodically, for example weekly or monthly, as one large panel of 15-25 members to discuss all proposals received since the last meeting.

The activities of this social system is documented through the flow of paperwork among the participating persons. This paper work involves IRB applications and accompanying materials, such as consent forms, research proposals, instruments, instructions to participants, and solicitations for participation. It also entails communications between the IRB and the principal investigators, all of which become archived in a review file to be housed at the host institution for a 3 year period before being destroyed. This IRB archive also becomes a conduit with other elements of the system, specifically, administrators of the host institution and outside regulatory agencies, such as a funding source or federal government body that may audit the IRB in regard to its policy and procedures. In the author's case, the IRB chair also maintains the IRB portion of the institutional web site that is a resource of IRB policy, procedures, forms, and links to resource documents. Given their importance to the system, the IRB archive and web site maybe defined as two key elements in addition to the persons who delineate the system.

Boundary conditions imposed on the IRB usually come in three forms. First, the purview of the IRB may be delimited to certain kinds of research domains, for example, medical research, social science research, or research in education, or these categories need not be applied. Members are chosen whose experience applies to the research domain. How serious the restrictions depend on the size and volume of research projects of the host institution as well as the sets of guidelines employed. Research in medical and laboratory settings carry certain research procedures and ethical issues that may not come in the same form found in education and community research settings, and vice versa. Furthermore, institutions that do research using human beings are not restricted to one IRB. It is up to the institution to determine how many IRBs are needed to cover the review of research in the various research domains.

Second, the IRB has to be cautious in its review to not get into matters tangential to impact of research procedures on human participants. There are often multiple choices of research design, participant selection, instruments, and data processing that have negligible to benign impact on participants. The researcher may prefer one instrument, for example, and an IRB reviewer who is also a veteran researcher, prefers

another instrument. The IRB cannot be drawn into such decisions, unless it is clearly evident there is potential for aversive impact on participants, and even then, if the researcher can show adequate precautions are in place, the risker procedure may still be defensible.

Third, a review is usually conducted as a confidential process. It is proper those who serve on the review panel are free of outside influence and able to converge on their points of critique without concerns and pressures from other elements of the system. The outcome of the review is to stand as an IRB position independent of other possibly vested parties, namely the principal researcher, administrators and peers of the host institution, employers, sponsors, and funding sources. In this sense, for the brief time period required to conduct the review and formulate its communication to the principal investigator, the IRB panel itself may be considered temporarily a closed system. However, in practice, there are often communications back and forth between the chief of the IRB panel and the principal investigator as revisions to research procedures may be requested and made after the initial review. Also, many IRBs permit the principal researcher to attend the review session when his or her proposal comes before the board for review, thus permitting some dialog between both parties, which often expedites the review process.

5 Cybernetic Aspects

In terms of cybernetics [Buckley, 1968; Jackson, 1991], the IRB has a number of feedback loops and the feedforward steering function that compels the IRB to follow its course of review, which is to adhere to legal regulations of due process and humane concern for human participants, comply with stated guidelines from governmental bodies and codes of ethics adopted by professional associations. There are three kinds of activity that can be described to convey the cybernetic aspects of the IRB.

First, at the center of activity is the reciprocal link between the IRB chair and staff support person. This team initiates, monitors, and closes all basic processes of the IRB. Within each review panel the members form a close knit group whose internal communications occur to conduct a review, in conjunction with the reciprocal relation linking the chief reviewer of the panel with the chair of the IRB. The chair initiates the review process with the chief, and the chief terminates the process with the chair. Not only does the process of panel review have to progress smoothly under the guidance of its chief reviewer, but also the IRB chair must oversee several simultaneous panels through their process to a timely conclusion. Additionally, the IRB chair maintains reciprocal communication links with administrators of the host institution, others who inquire about IRB policy and procedures, and persons from outside the host institution referred by administrators.

The process of a panel review brings to life the heart of activity of the IRB. Following this process offers the

second example of the interplay among several cybernetic loops of the IRB as a sociocybernetic system. At the author's institution, typically the principal investigator obtains the IRB application form and up to several models, such as consent form and letter of permission, off the institution web site. The researcher completes and sends them with all accompanying materials to the staff support person, with one copy sent also to the IRB chair. The chair constitutes the review panel, designates its chief, and informs the staff support person, who then distributes the applications to panel members. As the author's institution specializes in distance education, the IRB membership reflects this character, and in lieu of face-to-face monthly meetings, the IRB panel conducts its review by email discussion with the chief reviewer. The panel chief summarizes the position and points of feedback from the reviewers, and communicates them to the principal researcher. A back and forth may ensue between the researcher and the chief reviewer until the chief is satisfied that the researcher has meet all conditions stipulated by the review panel to enable the researcher to use human participants for research purposes. If there are complex points and unresolved issues that necessitate intervention by the IRB chair to resolve, that happens to bring closure to the review. All communications are archived, along with the application and accompanying materials, as the IRB file of that review.

A third kind of IRB activity is worth mention. Besides the reviews, communications occur among the IRB membership on a regular basis, usually between the membership and the IRB chair. The IRB chair maintains an email listserv with the membership to keep all members informed of IRB developments, reviews in progress, changes in policy and procedures, and contemporary issues outside the IRB that may impact on the work of the IRB, such as new publications, national debates, and changes in federal guidelines. Finally, there are always a small number of question and answer, personal discussion, and information email exchanges ongoing between the IRB chair and individual members. In effect, these cybernetic loops continue, while several active panels conduct their reviews. Thus, all members are involved with the IRB at some level, even when a particular member is not serving on a specific review panel at any given time.

6 Praxiological Aspects

Given the description of the cybernetic and systemic aspects, it should be clear that the conduct and practice of review are salient to the description of the IRB. It is essential to IRB review that review procedures be conducted efficiently and effectively, and that guidelines and due process be upheld. Just as the IRB would expect of those whose research proposals it reviews, it is imperative for the IRB to be both efficacious and ethical as a social system.

Praxiology is general methodology [Alexandre,

2000; Gasparski, 1993; Kotarbinksi, 1965] that can focus explicitly on IRB matters. The author coined the phrase "the Es of praxiology" in regard to human inquiry [Collen, 1993]. In conducting IRB review, evaluators can apply such a conceptual framework for research ethics to determine whether the benefits of the proposed project sufficiently outweigh the risks to justify the use of human participants for research purposes. It is from this reference point that this paper considers the praxiological aspects of the IRB.

The praxiological perspective brought to inquiry aids the researcher to examine the doability and manageability of human inquiry. The emphasis can nicely be acquired and applied through the mnemonic device termed "the Es of praxiology." From classical praxiology [Kotarbinski, 1965], the Es refer to efficiency, effectiveness, and efficacy. In more contemporary contexts, we may add to these the Es of ethicality, effort, evaluableness, evaluability, expendability, executability, and expensiveness. The set of constructs bring of course an immense increase in the complexity to human inquiry, once again, both for the researcher who proposes the project as well as the IRB evaluators who must review it.

The set of Es of praxiology in its extended version constitutes a fuller conceptual system. This scheme may be applied to the IRB in regard to its cybernetic and systemic aspects described earlier. We can term this application "praxiological decision making." Such decisions preoccupy much of human inquiry, not only for the principal researcher, but also for the panel reviewers. For example, although some research procedures may be more expedient, they may be more adversely impactful and hence more ethically questionable.

The conceptual scheme is particularly useful to propose as well as scrutinize research. For example, to obtain financial support for a research project requires a tough rationale and sound logic to justify the expenditure of material and information resources, tax payer money and venture capital, and time of research participants. Further, there is always some level of risk to participants who are usually volunteers. The risks may be economic, physical, psychological, and social in consequence. The benefits to participation compared to drawbacks are to be considered to justify implementing the research. Statements in the proposal that cover the Es are increasingly expected in the frequently fierce competition for funding.

In contrast to the fundability of a proposed project is understanding the contributions of the project once completed, because it often leads to further funding requests and sometimes attempts to apply the findings. The detection of the strengths and value as well as shortcomings and limitations of research methodology and findings can come through use of the Es in critique of published research. This activity is as important as fundability. Researchers are expected to be accountable to their funders, research participants, and society at

large. Accountability also holds for the IRB, in that use of the Es in case review provides a means to cover more comprehensively as many aspects as possible to protect the participants as much as possible from potential harm.

To move from a specific principal investigator engaged with a specific review panel, a subsystem within the IRB, to a more superordinate level, in which we may consider the design of the IRB as a socio-cybernetic system, praxiological decision making also becomes prudent. Whether the particular IRB is better designed to conduct reviews by face-to-face, email, or their complement, the designer has to consider the technological infrastructure, organization, and admin-istrative processes of the host institution. One con-figuration (design) may be a more efficacious means of conducting reviews than another. For example, at the author's institution, use of email and the web has essentially replaced the more traditional face-to-face weekly-to-monthly meetings at the institution.

Another illustration of this application at a more meta level may be IRB policy implications of cybernetic loops set in motion when, unknown to the IRB chair and chief reviewer, a panel reviewer is personally related to or a supervisor of the principal investigator of the project, or is vested in the funding source of the project. Such entanglements broach the ethicality of IRB review in terms of potential conflicts of interest, and they can usually be readily resolved through disclosure and reclusion.

In bringing to bear the praxiological scheme of Es on a case before the IRB, the review panel frequently finds certain key questions of an ethical nature surface. These questions may be classified as zero order, that is the most basic of questions, in that they concern a specific E in relation to a specific research procedure. For example, "Which procedure is the more efficient for data collection?" Other questions raise the complexity of the evaluation, in that two Es interact in weighing the ethicality of a research procedure. For example, "In the course of executing the research procedures, what assessment (monitoring), if any, is to be made of human and ecological impact?" These latter questions are of a higher order. First order would mean that two Es converge in considering whether a specific research procedure has potential for aversive impact on human beings. Naturally, one could continue to generate higher orders of complexity of question asking, however, this line of reasoning is rather academic for purposes of IRB review. Suffice it to note the initial two levels of question asking can easily flood the review panel with considerable set of questions to consider. The task becomes one of targeting quickly those zero and first order questions most germane to the case.

The basic questions, like all others generated through this scheme, are always implicitly related to ethicality, because this praxiological scheme, as a conceptual system of ethics, is applied directly to the domain of research ethics. Ethicality sits at the center of the conceptual system and every element is tied to it. All questions raised by IRB reviewers must be about the research ethics of the case.

7 IRB as an Evaluation System

Bringing together the three main perspectives discussed in this paper, looking through three lens, we see research ethics in action, when the salient aspects of a case clarifies for us the interplay of these perspectives to witness, and for those participating, to experience the IRB as an evaluation system. The IRB of the author's institution faces a wide variety of ethical issues and practices in its evaluation of graduate student projects. These projects almost always involve student research required to fulfill research requirements of the masters and doctoral programs.

One basic question pertinent to most projects is, "Is the participant being provided with truly informed consent?" The main elements (marked parenthetically) of the system interface to address this question. The researcher (1) makes use of the model or template (2) available in the institution web site (3). This model is fashioned to the researcher's consent form, an expected appendix to the application (4) submitted to the IRB for review. There is typically dialog among the members of the review panel (5) as to clauses present and absent, and their expressed clarity. The researcher may be required to resubmit to the chief reviewer (6) a revised consent form to meet the conditions necessary to clear the project for implementation. The main cybernetic loop here becomes evident in the exchanges between the researcher and chief reviewer. The praxiological scheme provides a framework to communicate reasons of feedback to the researcher as to the importance and necessity to have clauses include certain phrases and be stated in particular forms to provide an acceptable informed consent document. Often researchers are not fully informed about basic rights participants have in being used for research purposes, such as being able to withdraw at any time without stating a reason, refusing to answer any question, being informed of known side effects of a procedure, and being given a copy of the signed consent form for their records. In contrast, sometimes researchers exclude clauses known to be directly relevant for fear participants will not want to participate, intending to debrief participants after the research procedures are completed, which they attempt to justify in their application to the IRB. Whether it be naive or intentional exclusion, the ethicality of the informed consent is a matter of central concern for IRB reviewers.

An example of a derivative question common to all IRB reviews is, "Do the benefits, either specific or general, of the proposed research outweigh the risks of applying the research procedures to the human participants?" The same elements and cybernetic loop apply. The focus of discussion becomes that particular section of the IRB application where the researcher is

472

asked to make a cogent argument to the IRB that the project is worth doing, despite the risks. Surprisingly, many researchers have not thought through carefully the benefits-to-risks relationship (ratio), even though they have become well versed in justifying their work to their peers, mentors, colleagues, coworkers, and funders. This emphasis asks researchers to give some such attention to their participants. To illustrate, in many of the student projects making use of the semi-structured research interview, the choice of some words and phrases in questions asked of participants may be provocative, demeaning, emotionally laden, and even inflammatory. The researcher may not realize subtle instances for the kind of participants targeted, until conducting the interview on a pilot basis. In its feedback, the IRB helps to raise the researcher's sensitivity in this area of concern for the impact of such question asking on the participants. Certainly there is little-to-no benefit to upset participants in the researcher's justification and quest to obtain the answers sought to the questions asked in the interview.

One further illustration of an ethical issue common to many of the projects evaluated is found in the question, "On the participants behalf, does the researcher adequately safeguard the data collected?" Researchers are expected to lock securely the consent forms and raw data in separated locations, especially if it is possible for anyone to connect the two documents for a given participant. Restrictions of access are to be limited chiefly to the principal researcher, no one else, and especially not to third parties whose interest has little if anything to do directly with the research.

What is common to the above illustrations is the manner in which IRB review makes visible the cybernetic, systemic and praxiological aspects of the system. For the author, the saliency of the questions and ethical issues are abstract representations underlying the convergence of these three aspects. Conducting a panel review engages those who define the human elements of the system. It brings to life, so to speak, the evaluation system, which they experience through the process of review.

8 IRB as a Subordinate System

In stepping back from the review of any particular case, we discover some common themes, expressed as institutional issues, that run through or typify the process of review. They also reveal the dynamics of the IRB as a whole, a convergence that fosters a more wholistic comprehension of the IRB as an evaluation system in its broader context. In the IRB currently familiar to the author, three institutional issues are discussed: first, the application that makes the review possible; second, the time necessary to review; and third, the consequences of review on those whose work is reviewed.

Preparation of the application to be reviewed by the IRB requires some familiarity with research ethics,

application forms, and appropriate appendices. Researchers may expend considerable time and energy to make their presentation detailed, clear, and complete for IRB review. Whether they view this activity as educative and necessary, or bothersome, in part depends on their past experience with IRB review and the present manner of feedback and treatment by the IRB. Thought needs to be given periodically to the improvement of IRB materials to be as user friendly as possible. Chair of the IRB must more than welcome critique and suggestions for improvement, but must act to make them happen. At the author's institution, an inherent part of the IRB as a sociocybernetic system is a continuous openness and ongoing solicitation of feedback and suggestions for improvement from researchers and IRB members.

The time it takes for an IRB review process to transpire has always been one of controversy in an institution. Reviews range widely in the extent of scrutiny necessary. On the one hand, projects classified as "Exempt" involve rather benign research procedures, where those that will employ sensitive, questionable, and high impact procedures will involve "Full" review; those in between are termed "Expedited" review. As one would expect, the Full panel review generally takes the longest to complete. Once the proposal is funded and project staffed, understandably, researchers are anxious to begin. Waiting typically a month for IRB review is often disconcerting for many researchers, especially if IRB feedback comes with conditions to obtain its approval. In short, the time period of IRB review interfaces with other time bound processes of its host institution. They have to be understood and taken into account if the IRB and other subsystems of the institution interacting with the IRB are to run smoothly.

The after effects of review on the principal researcher and supervisor are critical to the acceptance of the IRB. These persons will likely have to work again with the IRB in the future, for example, further IRB applications in the case of programmatic research and expected institutional service on the IRB. Those who come into contact with the IRB take with them a critical learning experience. It will set for them their attitude and disposition toward the domain of research ethics and review of research. With each case, the IRB not only has a duty to perform in the protection of human participants, but also an opportunity to educate and convey to researchers a respectful and caring concern toward those who will provide them with the information and data required to meet the objectives of the research.

These issues are only three of many that enable us to reflect upon the IRB as an ethical social system. It has to be an operation with integrity and maintain the respect of other entities of the larger institution. IRB actions affect the work and attitudes of others, making public relations a constant concern in its communications with others in its host organization.

These issues also leave the IRB open as a system to critique and improvement. IRB review certainly involves presumptions that scrutiny of research procedures benefits participants by lessening the potential for aversive impact on human beings, in that researchers are more cognizant of the ethical issues and practices involved as a result of IRB review. Like an insurance policy, IRB approval is thought to mean more measured protection for the human participants, and IRB demands on principal investigators to change procedures to make them more benign will in fact lessen negative impact. However, these notions have yet, to the author's knowledge, been put to systematic test, and they are increasingly debated in the United States for various kinds of research procedures. Therefore, the IRB must negotiate its place in its institution. On the one hand, IRB review holds researchers accountable for compliance with federal guidelines and professional codes of conduct relevant to their research projects. On the other hand, it educates and influences those within the institution it serves that IRB review is a vital service of the institution, in which the activities of the IRB raise general consciousness and ethical competence systemswide, concerning the treatment of human beings as subjects of research.

When the purpose of the institution is education, the balance between accountability and caring is of critical concern, because the IRB is one important means by which the ethos of research ethics passes to the next generation of researchers. Part of this balance comes by membership service on the IRB, whereby the members of the institution have first hand experience through IRB review of research ethics in action. It is vital, therefore, that the researchers, namely the graduate students and their faculty, in the author's institution are recognized, adequately represented, and serve as primary constituent members of the IRB.

9 Summary and Conclusion

Cybernetic, systemic, and praxiological perspectives converge to provide a more wholistic comprehension of the IRB as an evaluation system. The Es of praxiology form a scheme for question generation that can facilitate IRB review. Questions posed are always linked to ethicality, and as a set, they form a complex conceptual ethical system. The questions not only serve reviewers to examine specific research practices and procedures, but also they often lead to reflective evaluation as to whether the IRB is an effective, efficient, and ethical system.

The convergence of perspectives fosters an appreciation of the challenges, issues, place, functions, and contributions of the IRB embedded in a research institution. As a member doing the work of, and as a principal researcher working with, the IRB is research ethics in action that should enable a more informed grasp of the complexity and systemicity of the IRB. In principle, such a comprehension should enhance the principal investigator's ability to maneuver through this system to obtain approval of proposed research, and further, it should in a complementary fashion foster greater efficiency and effectiveness among IRB members to conduct the process of review. These more speculative contentions invite continued study.

References

[Alexandre, 2000] Victor Alexandre, editor. *The Roots of Praxiology: French Action Theory from Bourdeau and Espinas to Present Days*. Volume 7 of Praxiology: The International Annual of Practical Philosophy and Methodology. Transaction Publishers, New Brunswick, New Jersey, 2000.

[Buckley, 1968] Walter Buckley, editor. *Modern Systems Research for the Behavioral Scientist: A Sourcebook*. Aldine Publishing Company, Chicago, Illinois, 1968.

[Chastain and Landrum, 1999] Garvin Chastain and Eric Landrum, editors. *Protecting Human Subjects: Departmental Subject Pools and Institutional Review Boards*. American Psychological Association, Washington, DC, 1999.

[Checkland, 1981] Peter Checkland. *Systems Thinking, Systems Practice*. John Wiley & Sons, New York, 1981.

[Collen, 1993] Arne Collen. *Human Science Research, A Systemic Approach to Disciplined Inquiry, Seminar Supplement*. HSR Seminars, Walnut Creek, California, 1993.

[Hayes et al., 1995] Gregory Hayes, Steven Hayes, and Thane Dykstra. A survey of university Institutional Review Boards: Characteristics, policies, and procedures. *IRB: A Review of Human Subjects Research*, 17(3):1-6, 1995.

[Kotarbinski, 1965] Tadeusz Kotarbinski. *Praxiology: An Introduction to the Sciences of Efficient Action*. Translated. by Olgierd Wojtasiewicz. New York: Pergamon Press, New York, 1965.

[Jackson, 1991] Michael Jackson. *Systems Methodology for the Management Sciences*. Plenum Press, New York, 1991.

[Minati and Collen, 1997] Gianfranco Minati and Arne Collen. *Introduction to Systemics*. Eagleye Books, Walnut Creek, California, 1997.

[Stanley et al., 1996] Barbara Stanley, Joan Sieber, and Gary Melton, editors. *Research Ethics: A Psychological Approach*. University of Nebraska Press, Lincoln, Nebraska, 1996.

CYBERNETICS AND SYSTEMS 2002

VOLUME I

Proceedings of the Sixteenth European Meeting on
Cybernetics and Systems Research,
organized by the Austrian Society for Cybernetic Studies,
held at the University of Vienna, Austria, 2–5 April 2002

Edited by

ROBERT TRAPPL
University of Vienna
and Austrian Society for Cybernetic Studies

CYBERNETICS AND SYSTEMS 2002
Proceedings of the 16th European Meeting on
Cybernetics and Systems Research