Step 1. We admitted we were powerless—that our lives had become unmanageable.

—Twelve-Step Program (http://en.wikipedia.org/wiki/Twelve-Step_Program)

Even though Israel and Hay (2006) began their Research Ethics for Social Scientists with a pithy statement—“Social scientists are angry and frustrated”—at no time did Israel and Hay advocate throwing IRBs out. And they remained committed to ethics. “We behave in ways that are right and virtuous” (Israel & Hay, 2006, p. 10).

Likewise, throughout this book, we have held that ethical practice is vital and that IRBs are integral to planning and implementing ethically responsible research. At the very least, IRBs aid researchers in formulating the research protocol and channeling thinking about research ethics and one’s relationship with subjects. Labaree (2010, p. 192) claims:

The application process can help bring clarity to your research by requiring you to define the study’s purpose for an outside audience, stating clearly the specific methods used for gathering, recording and
archiving data and reporting findings, and helping reveal tangible benefits and study outcomes that may not have been obvious initially.

IRBs may indeed assist researchers in thinking through their research designs and give them a chance to reflect on core ethical issues, but IRBs could do more to assist researchers conduct ethical research with their subjects, and researchers could do more to solve ethical problems and collaborate with their IRBs. In this chapter, we outline ten simple and cost-effective suggestions to make the entire ethics review process a learning institution.

1. IRBs should build more accountability into the ethics review processes. Accountability is a common feature of academic institutions. For example, end-of-semester student evaluations allow a student to evaluate all aspects of the course inclusive of the teacher, the course topics, the textbook, the tutors, and so on. This occurs even though the student exists in a relatively powerless hierarchical position in relation to his or her teacher. Any teacher knows that a satisfactory score in these evaluations has a role in promotion decisions. Moreover, the student evaluation takes place as the student exits the class. The student’s evaluation does not benefit the student, but it may benefit students taking the class when next taught.

Could IRBs benefit from a similar evaluation system, requesting their client researchers to provide responses to a short multiple-choice questionnaire about the quality of the experience inclusive of the quality of the application form, the guidelines, the templates (consent form template), the communication with the committee, and timeliness of the process?

The Gunsalus et al. (2006) seminal white paper on the entrenched IRB debate claims the greatest irony is how little of the debate is informed by reliable research on the facts of the problem. A simple customer service questionnaire sent anonymously to researchers every six months would assess the relationships between researchers and IRBs. We conjecture that greater client satisfaction leads to better ethical outcomes for participants and greater satisfaction on the part of researchers and IRBs.

2. IRBs should use qualitative, open-ended questions, as well as multiple-choice questions, to understand how researchers experience the review process. They might ask researchers to describe the strengths and weakness of the process in their own words. They might also ask researchers, “What one change in the process would improve the IRB review?” Here, the IRB would treat the respondents as experts.

The authors are aware of IRBs that utilize customer service satisfaction surveys (i.e., http://humansubjects.stanford.edu/research/documents/survey_results_summary.pdf), but none collect both qualitative and quantitative data. To use a mix of techniques would demonstrate a genuine willingness to learn; it would reflect openness to critique and a willingness to improve their service to their clients. Why this absence of accountability exists is perplexing when public control techniques are
ubiquitous in most service sector encounters, allowing employers to have customers or clients evaluate the employees’ service. The trucking industry bumper sticker “How’s my driving. Call 800 CALL ME” encourages members of the public to notify a company if one of its drivers is driving erratically. Whom does a researcher call if an IRB acts erratically?

3. **Follow up on surveys.** An additional anonymous survey conducted a year or two after ethics approval would also be beneficial. Here, the IRB could ask the researcher a different set of questions to gauge how relevant, if at all, was the IRB review process to the research. Did the IRB review enhance the ethics practiced by the researchers? Was there some value added for the research subject? Related to this question is the assumption that researchers know their research better than any other party, enabling them to assess the relationship between the original ethics application and the ethical issues raised in the field. Were there any ways in which the ethics review procedures and outcomes proved harmful to the research or to the participants? Did new and more important ethical issues arise in the field, not predicted by IRB review? Or, were all ethical issues laid out in the IRB application? Answers to these questions provide accountability not yet realized. There is a possibility that IRBs need to learn that their reviews are only one part of ethics review. Ethical issues not considered by either the IRB or the researcher at the time of the original application may have confronted the researcher.

4. **Survey participants.** If IRBs were learning institutions, they would gather information from participants about the IRB review, for example, the consent form or how subjects define risk. Did the subject find the documentation useful, comprehensive, and understandable? Did parts of the study cause subjects distress? IRBs as learning institutions could research the research project by attaching self-addressed, prepaid questionnaires to the researcher’s consent form. This questionnaire could ask research subjects to assess the quality or readability of the consent form and other documents and request that they tell the IRB, in their own words, their thoughts on the process. These responses should be shared with the researcher and also feature in IRB member training. IRBs could also ask how subjects experienced taking part in the trial. The feedback could inform the IRB’s future reviews.

5. **Make all IRB meetings open to the public inclusive of researchers.** Allow researchers the opportunity to be active, not passive, participants in the ethics review process. Letter or e-mail communication between the IRB and the researcher must not be the sole means of communication. The researcher should have the right to appear before the IRB, and the IRB should account in person for their decisions. Imagine a society where all legal decisions were made behind closed doors. This obscuring of justice would be unacceptable in civil society.

In most academic institutions, IRBs render their opinions based solely on a paper trail. At a minimum, the researcher’s presence could answer any question the committee
had about the research and allow any misreading or miscommunication to be addressed. Thus, the researcher would learn the rationale for the IRB’s decision.

Many downstream benefits accrue from meetings open to all. Researchers’ attendance, especially for novice researchers, allows them to learn about the IRB process and its rulings. However, in the case of novice researchers, it would be desirable that either a supervisor or a mentor be present to support an applicant, if only to take notes. Support persons, especially those with more experience, may be able to negotiate with the ethics committee and provide an institutional memory on how the committee has assessed other projects in the past (Israel & Hay, 2006, p. 130).

6. IRBs should hold a colloquium or retreat with researchers on an annual or semiannual basis. This would be a means to bring together the best ideas on research ethics rather than a means of solely “educating” the researchers from the perspective of the prevailing IRB paradigm. For this event to maximize its success, it is imperative to have the discussion facilitated by someone not associated with the IRB or the institutional research culture. Within this neutral setting, genuine learning of each other’s perspectives could take place. Consider the following tale from the field by asking what was the value of the ethics review given to the researcher and how did this protect the research subject:

My ethics committee wanted me to give elderly rest home residents seven days between their reading the information sheet and their signing the consent form. I got the chair to agree to three days. When I turned up to get the consent forms, the residents had no memory of who I was, and invariably they asked their caregivers if they should take part in the study.

What would an IRB learn from this researcher’s account of her adhering strictly to the IRB’s decree?

7. IRBs should have a speedy appeals process. Access to a second opinion could provide a more appropriate solution to problems such as the one described in the case above. Yet, an appeals process, let alone a speedy one, is an ideal yet to be realized by most IRBs. A more robust or valid appeal process would seek a second opinion outside the IRB, perhaps from a sister IRB that might regularly provide second opinions on some applications. All IRBs should create partnerships with similar IRBs and routinely send original ethics applications on a reciprocal basis for blind review. This process makes each IRB accountable to the other. Moreover, this process creates a seamless appeals process such that any researcher could request a second opinion from the other IRB without the IRB being informed of any unresolved problem. A second opinion process enhances learning. IRBs should not consider their review a faultless science. Grady (2010, p. 1123) found widespread inconsistency in how IRBs apply regulations:

Practices and decisions vary from IRB to IRB, including determinations about whether full or expedited review is needed, whether risk is minimal or greater,
and the appropriateness of methods of recruitment and consent, often without justification for the variation. Despite these worrisome data and persistent concerns, remarkably little is known about how well IRB review protects human research participants. . . . To date, no published study of which I am aware has evaluated the effectiveness of IRBs in protecting research participants and few have investigated the nature, quality, or thoroughness of IRB deliberations.

8. *Nothing ethically justifies any research project being evaluated by more than one IRB.* (Second opinion, as described in Suggestion 7 above, is different from gaining separate approvals at each institution for multisite projects.) The justification for having each institution approve a multisite study is more political than ethical, involving more adherence to research governance than research ethics. How else can IRBs explain the cost of multiple reviews where the same project is submitted to multiple IRBs, usually on each IRB’s specific application form?

We examined the costs and effects of local IRB review of the consent and protocol in a multicenter clinical trial in Parkinson disease. Seventy-six percent of changes to the consent reflected standard institutional language, with no substantive changes to the protocol. The costs of this process exceeded $100,000. These findings support initiatives by the Office of Human Research Protections (OHRP) and the National Cancer Institute (NCI) to facilitate centralized reviews. This may be an opportune time for the National Institute of Neurological Disorders and Stroke (NINDS) to adopt a central review model. (Ravina, Deuel, Siderowf, & Dorsey, 2010, p. 259)

Such multiple reviewing does not constitute respect for persons, namely researchers. It is not unknown for a single project to be reviewed by 60 different ethics review committees, and at times, the committees contradict one another.

9. *When IRBs become learning institutions and understand the effects of their decisions on researchers and subjects, they may begin to confidently distinguish between high- and low-risk research.* For example, in Australia, Griffith University has developed a three-tiered classification of low, medium, and high risk for ethics review. For a project to receive Level 1 expedited review, the research must not raise any significant ethical issues or risks. An applicant applies via an online form accessed via the Internet. The ethics committee must ratify the outcome. A project that is eligible for Level 2 expedited review may raise some ethical issues or risks, but these have been appropriately dealt with in the design of the research; a small panel of the ethics committee considers applications for Level 2. Level 3 review is a full review. Griffith University’s system of three-tiered review has led to a 66% reduction of applications seen by full committee and for full review.

10. *Research administrations should create a learning environment for researchers.* The Macquarie University social science training website provides such a learning environment and explains its role as follows:
PLANNING ETHICALLY RESPONSIBLE RESEARCH

This free educational resource examines the particular ethical issues raised by social science and humanities research. The training module is divided into 6 basic parts. You can start and stop reading at any point in the module, and you can close it and return to it later. After you have reviewed the entire module, there is a quiz that tests your comprehension of the material. (http://www.mq.edu.au/ethics_training/)

IN CONCLUSION

There is a pressing need for human research ethics education, but IRBs are not and should not be the source of that education. Resources are required to educate researchers about matters far beyond what IRBs mandate, such as how to deal with big ethical moments that may confront researchers in the field. In addition, more useful education needs to be provided to help researchers focus on ethical problem solving as they design research and develop their ethics protocols.

Gunsalus et al. (2006) suggest gathering information in a national clearinghouse that supports IRBs and researchers alike. This would provide examples of good and poor practices rooted in disciplinary standards and help IRBs make priority determinations about what constitutes risk and harm in different human research settings. This could include researchers posting anonymously (to a website sponsored by an IRB) examples of big ethical moments, together with attempted, botched, and successful resolutions to ethical dilemmas, documenting stories from the field.

Posting examples of researchers’ successful and unsuccessful ethics applications allows prospective researchers to read how others explained and justified their research and traversed IRBs. Why should each novice researcher be forced to reinvent the ethics review process? The reason researchers do not learn is that they have few resources to guide their applications.

However, institutions need not wait for such a clearinghouse to come into existence. The learning environments of most institutions will probably reside on websites. Institutions can thus continually borrow the best and most effective resources from one another. There is much that both IRBs and researchers can do individually and collectively to make plans for more ethically responsible research.

A FINAL REFLECTIVE QUESTION

In what ways can the ethics review process become a learning institution? How can we measure its progress toward that goal?