

# Ethics Review Process as a Foundation for Ethical Thinking

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The Institutional Review Board process, while not perfect, has been fairly effective in balancing the progress of research and protection to human subjects. I see two key benefits of the Institutional Review Board process in ensuring ethical human subjects research. The obvious one is the review - getting outside eyes who are not heavily invested in the project and outcome to look for issues. The problem is (hopefully) not a lack of ethics among researchers, but that the excitement over the project and outcomes blinds researchers to the potential risks. The second benefit is forcing researchers to think about issues before beginning research, *and giving them the tools to do so*.

The Institutional Review Board Process has led to standard training in research ethics. Best practices for Institutional Review Boards have long involved training programs in human subjects research for the investigators; this is typically a prerequisite for Institutional Review Board approval of a project (or for working on an IRB approved project.) This has led to at least a basic understanding of the issues among investigators conducting human subjects research.

As time has progressed, the training programs have evolved. In 2000, a Collaborative IRB Training Initiative (CITI) Human Subjects Training program was created to standardize and reduce the administrative overhead. Initially CITI provided basic human subjects research training, with biomedical and social science specializations. Many Universities have adopted this training, initially as an online supplement to their programs, and more frequently now as the sole training approach. With the growing adoption, the offerings have expanded, with many modules offering a wide variety of specialized training in ethical conduct of research.

The widespread availability of such training has led to broader adoption; in 2010 Responsible Conduct of Research training became a requirement for students and postdoctoral fellows supported by new National Science Foundation and National Institute of Food and Agriculture grants, and many types of National Institutes of Health grants. This requirement applies to all grants, not just those doing human subjects research. This is more general research ethics training, not just human subjects, but ensures at least a level of human subjects research training for most Ph.D. students. While some places require only online training, this has served as the impetus for classroom ethics training at others, and in fact the NIH requirement cannot be satisfied solely with online training.

Research involving Big Data brings up somewhat different issues; typically such research does not involve the direct intervention with subjects typically anticipated in both biomedical and social science research. While there are exception (e.g., A-B testing on web sites is a form of direct intervention), the risks are generally quite different. As a result, I do not advocate direct application of the existing IRB regulations. While perhaps adequate for academic research, corporate research introduces new issues (e.g., risks to corporate image) that are not a part of the existing framework.

My concern is that the attempt to address these risks will become an attempt to develop standards and even regulations that control uses of data, neglecting the need for (ongoing) education

of those using the data. Such an approach will lead to a culture of “am I compliant?”, rather than “is what I am doing ethical?”. This will lead to failures where the data uses, and the risks, are not foreseen by those developing the standards, and compliant projects causing significant harm. A second type of failure, perhaps more insidious, is controls that prevent minimal risk innovations; e.g., data use that protects data subjects using methods not foreseen by those writing the standards.

The alternative is a process that ensures that users of Big Data think about the ethical issues involved, and are given appropriate education to analyze the risks. This will of necessity be different for different types of data, industries, and data uses. This demands a flexible and evolving process for ensuring appropriate use of Big Data.

I suggest that we look not at what the current Institutional Review Board Process is, but how it came to be, as a model for broader ethical review of use of Big Data. We should start with a requirement for ethical review from a group whose mission is ethics review, and broad guidelines:

- Protecting individuals who the data is about,
- Protecting those who use what is developed from the use of the data,
- Protecting the organization doing the work, and
- Enabling work where the rewards are worth the risks.

The ethics review panel should be distanced from the work being proposed, but should have flexibility to determine appropriate rules and process for that organization.

Existing training for Institutional Review Board members likely provides a good start, and some Big Data ethical review boards may find existing training appropriate for their data users and researchers. However, by providing a high level of flexibility, best practices will emerge, and be adopted not by fiat, but as the most cost-effective way to accomplish ethical review for use of Big Data.

While this model may be difficult for some (e.g., a startup company may not be able to have an “arms-length” review panel), it allows for innovation. For example, an external partner (perhaps associated with venture capital) could offer ethics review as a service for startups, or small companies could partner to review each other’s work (much like the Community Research IRB that reviews all research, both biomedical and social sciences, conducted between Purdue and one or more of our community partners: IU Health Arnett, Franciscan St. Elizabeth Health, and Horizon Oncology Research, Inc., and has membership from all organizations).

This approach will not prevent all ethical lapses, but over time should lead to workable and effective methods covering the majority of cases. Furthermore, it will lead to a culture of ethics training and awareness that is appropriate for different industries, is cost effective, and appropriately balances the risks and rewards of using Big Data.