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The SAGE Encyclopedia of Abnormal and Clinical Psychology

Institutional Review Boards

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Book Title: The SAGE Encyclopedia of Abnormal and Clinical Psychology
Chapter Title: "Institutional Review Boards"
Pub. Date: 2017
Access Date: May 18, 2017
Publishing Company: SAGE Publications, Inc.
City: Thousand Oaks,
Print ISBN: 9781483365831
Online ISBN: 9781483365817
DOI: http://dx.doi.org/10.4135/9781483365817.n731
Print pages: 1821-1823

Institutional review boards (IRBs) are committees established to oversee research conducted using human participants. Most IRBs are at colleges, universities, or other institutions where research is conducted with human participants, but some are independent or for-profit organizations. There are also committees that go by other names, such as Human Subjects Committee, though they function very similarly to IRBs. The main charge of these committees is to conduct reviews of research studies to ensure that the rights and welfare of human participants are being protected. Although this term typically refers to committees in the United States, other countries have comparable regulatory systems and/or bodies. This entry describes the structure and function of IRBs, provides historical context, and details the tasks of the IRB.

Structure and Function

In the United States, the treatment of human research participants is currently governed by the Federal Policy for the Protection of Human Subjects, known as the "Common Rule," which has been codified separately for separate government agencies. The rules for the Department of Health and Human Services are contained in Part 46 of Title 45 (Public Welfare) of the Code of Federal Regulations.

In general, IRBs comprise both men and women, scientists and nonscientists, and at least one member of the community who is not affiliated with the institution. Large institutions may have multiple IRB committees that function according to the same policy.

Research studies are determined by the IRB (a) to require a full board review, (b) to be exempt from review, or (c) to require an expedited review. Studies that require a *full board review* are read and discussed by a majority of IRB members, and feedback is then sent to the researchers as to whether the study is approved, not approved, or requires modification and then re-review. Studies that are determined to be *exempt* from IRB review contain low risk of harm to human participants (e.g., de-identified educational testing, studies using existing de-identified archival data). Institutions must have policies about who is eligible to determine whether a study is exempt; it is generally not left up to individual researchers to determine that their own research is exempt from IRB review. Between these two "poles" (full board review and exempt from review), studies may be eligible for *expedited review*, in which one IRB member may review the study, rather than the full board. Studies that are appropriate for expedited review must fall into one of several categories, and they may include no more than minimal risk to participants, or risks that do not exceed the risks encountered in everyday life. Unless determined to be exempt, research projects must also undergo an annual *continuing review* by the IRB. During the continuing review, the risk-to-benefit ratio is reevaluated by the IRB, given the study's results to date and the profile of any adverse events that may have occurred over the previous review period.

Historical Context

The need for human participant research to be regulated was widely recognized in the wake of World War II. Indeed, the history of research on human participants has some very dark moments, in which participants were treated horrifically, and current ethics codes reflect responses to these occurrences. Perhaps the most central of the regulations born of participant mistreatment is the necessity of informed consent. During World War II, prisoners in concentration camps were required to participate in medical research, including studies

with harmful consequences such as sterilization and intense pain—and they did not have the option to decline to participate. The Nuremberg Code (1948) thus established that informed consent was required for the conduct of research on human participants.

Current thinking regarding the treatment of human participants was also heavily influenced by the Tuskegee Study ("Tuskegee Study of Untreated Syphilis in the Negro Male"), in which participants with syphilis were tracked longitudinally for researchers to learn more about the natural course of the illness. The study was conducted from 1932 until 1972, and although treatment of syphilis with penicillin became standard care during the course of the study, participants were not informed of this fact and in some cases were prevented from getting treatment. This study is even more concerning given that the participants were all African American, and the researchers were predominantly White. It is now required that research on treatments and interventions (a) inform participants of alternative treatments at the start of the study and (b) update participants about any new developments in terms of promising treatments during the course of the study.

Other aspects of current research ethics were born of studies, such as the Milgram studies of obedience in 1963 (which led to regulations about the use of deception in research) and the Stanford Prison Experiment (1973), which led to a rethinking of how and when studies should be stopped, when they are deemed to be causing unforeseen harms. In 1979, the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research issued *Ethical Principles and Guidelines for Research Involving Human Subjects*, also known as the *Belmont Report*. Among other things, the *Belmont Report* outlined three principles that still govern the IRB's work today: (1) respect for persons, (2) beneficence, and (3) justice. Respect for persons emphasizes that people must be treated as having autonomy and agency; in other words, people must be seen as having the right to make decisions for themselves. Vulnerable populations, whose autonomy is compromised or limited in some way, are to be given extra protections (e.g., prisoners are provided extra protections because they may feel undue coercion to be in a research study; other vulnerable populations include children, pregnant women, and students). *Beneficence* refers to the notion that researchers should seek not only to "do no harm" but also to do good—to provide as many benefits to research participants as is practical. Finally, the principle of justice suggests that no one segment of the population (e.g., the poor) should bear a disproportionate burden of being research participants.

The Task of the IRB

In general terms, IRBs engage in complex cost-benefit analyses, weighing the risks to the human participants (cost) versus the potential benefit to society, in terms of knowledge gained. As such, the IRB considers questions such as, "Will participants give informed consent?" (including consideration of whether the information provided regarding risks is sufficient for the participant to be considered "informed" and whether or not the participant is likely to be in a state in which he or she can freely consent), and "What are the risks to the participants?" (in terms of physical risks, emotional distress, reputation, etc.). The IRB also considers the scientific soundness of the study but, generally, only to the extent needed to evaluate whether the potential knowledge to be gained outweighs the risks to participants.

The IRB's task may become complicated. For example, it is not always clear exactly what sorts of studies IRBs need to review. Many IRBs do not review projects that consist purely of oral histories (projects in which the memories of individuals and communities are collected in their own voices). The Common Rule defines *research* as "a systematic investigation,

including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge," and oral histories are often not intended to contribute to generalizable knowledge but rather to shed light on the experiences and perspectives of particular individuals or groups. Other research methods, particularly those used commonly in the social sciences, may pose particular questions as to how informed consent can be obtained without disrupting the research process, and what types of observations may be exempt from review. Participatory action research, in which the individuals being studied are often invited to join researchers in designing and conducting the research, poses particular challenges when considered with respect to the code, which was developed predominantly with conventional biomedical research methods in mind.

Research conducted abroad by U.S. researchers also poses particular challenges to IRBs, as other countries may have different standards (or no codified standards at all) for the treatment of human research participants, as does research that involves digital recordings, which may have a greater risk of having participants' confidentiality breached. Certainly, research on sensitive topics (e.g., sexual assault, suicidal ideation) must be considered carefully.

Conclusion

IRBs play an important role in protecting the rights and dignity of human research participants. No longer are researchers themselves solely responsible for determining whether or not their treatment of human participants meets basic ethical standards. That said, the IRB's application of the federal regulations is often fraught with complicated questions to which there are often no straightforward or easy answers.

See alsoBelmont Report; Ethics Codes

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Further Readings

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