

Improving Information-Seeking Behaviors and Knowledge Bases for
Thesis Students in the Applied Behavior Analysis Graduate Program and
Students in the Rehabilitation and Mental Health Counseling Graduate Program

Video 8: The IRB as a Dynamic Process

Federal regulations and university policy require that human subjects' research must be reviewed and approved by a committee called the Institutional Review Board (IRB). An IRB is a committee designated by an institution to review, approve, and conduct periodic review of research involving human subjects. The IRB came about due to egregious unethical research that was conducted in the name of science.

In 1947, the **Nuremberg Code** was developed for the Nuremberg Military Tribunal as standards by which to judge the human experimentation conducted by the Nazis.

In 1966, the National Institutes of Health issued "Policies for the Protection of Human Subjects."

In 1974, the passage of the National Research Act established the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.

In 1978, The Belmont Report: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research" was published. It established three basic ethical principles for the acceptable conduct of research involving human subjects.

- **Respect for persons** involves a recognition of the personal dignity and autonomy of individuals, and special protection of those persons with diminished autonomy. This principle requires the researcher to obtain the informed consent of the study participant.
- **Beneficence** entails an obligation to protect persons from harm by maximizing anticipated benefits and minimizing possible risks of harm. This principle requires the researcher to perform a risk/benefit analysis and to minimize risks resulting from the study.
- **Justice** requires that the benefits and burdens of research be distributed fairly. This principle requires that subjects are fairly selected.

In 1981, the federal regulations were codified as Title 45 Part 46 of the Code of Federal Regulations. Since the purpose of the IRB is to inform and protect human subjects used in research, the IRB also acts as an advocate for the research subject. Hence, the role of the IRB is to foster high ethical standards in the conduct of research and to assure that uniform criteria are applied to protect the human subjects who take part in research. This means that the IRB reviews all university research projects, as well as the informed consent process. It is responsible to ensure that the research subject is fully informed of the procedures involved in the study as well as the risks.

Even research that may be exempt under the Code of Federal Regulations for Protection of Human Subjects (45 CFR 46) must be submitted so that an official determination can be made whether it is exempt. The following are criteria the IRB uses to foster high ethical standards in the conduct of research and to assure that uniform criteria are applied to protect the human subjects who take part in research.

1. Risks to subjects will be minimized. For example, the IRBs evaluate whether procedures to be performed on subjects a) are consistent with sound research design and do not unnecessarily expose subjects to risk, and b) whether they are already being performed for diagnostic or treatment purposes.
2. Risks to subjects will be reasonable in relation to any benefits that might be expected from taking part in a research study and to the importance of the knowledge that may result.
3. Selection of subjects will be fair and equitable. For example, the IRB seeks to determine that no eligible individuals are denied the opportunity to take part in any study, particularly those from which they may benefit, based on an arbitrary criterion such as gender, age or because they do not speak English.
4. Planned recruitment and consent procedures will result in voluntary participation and that informed consent will be obtained from each prospective subject or where appropriate, from the subject's legally authorized representative.
5. The research plan provides for monitoring the data collected to ensure the safety of subjects.
6. There are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data. An IRB may also serve as a privacy board, acting upon requests for waivers or alterations of the authorization requirement under the privacy rule for users and disclosures of PHI for research studies, in compliance with the privacy rules defined in the Health Insurance Portability and Accountability Act.

Now that we have an understanding of the role of the IRB, let's continue a quick review of the definitions of research and of human subject. The Code of Federal Regulations (CFR) is the codification of the general and permanent rules published in the *Federal Register* by the executive departments and agencies of the Federal Government. The CFR also contains the definitions used by the Federal Government.

Research, according to the CFR is defined as follows:

"Research is a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for purposes of this [45 C.F.R. 46] policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities."

(45 CFR 46.102(d))

A human subject is defined as follows:

"A human subject is a living individual about whom an investigator (professional or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information."

(45 CFR 46.102(f))

So, what constitutes human subjects research? Physical procedures; manipulation of the subject's environment; interviews, surveys, and other interpersonal forms of communication; gathering information about individuals that was collected for purposes other than a specific research study (e.g., medical or school records); obtaining bodily materials such as cells, blood or urine, tissue, organs, hair, and nail clippings even if the investigator did not collect these materials; access to medical records and data through medical information systems.

At the university, there are many individuals, departments, and organizations that play a role in the protection of human research subjects. Therefore, human subjects' protection is the responsibility of all individuals and organizations involved in the research. Not only does the IRB protect human subjects from harm and facilitate ethically responsible research, it plays a major role in an investigator's career.

The IRB is a dynamic process in that it does not end with the initial approval of the research project. Rather, it is a continuous process, requiring the researcher to reexamine his or her understanding of a project, of an intervention, of a population, with the intention to improve the research study in order to enhance the quality of life of the individuals engaging in the study.

The IRB sees the details as well as the big picture of a research project throughout the research project, from beginning to end. So is the communication between the IRB and you, the researcher.

An IRB is like a another pair of eyes whose only job is to ensure that all human subjects' considerations are met, which protects not only the subjects of the study but also you, as the researcher, and your institution. It is like a trusted colleague who acts as a critic, letting you know that this part needs to be explained better or that you should add this one step to protect your data.

An IRB can also be seen as a mentor, providing you with innovative ways of doing research. Because IRB members have different strengths, experience, and perspectives, their viewpoints can be a real asset to new and continuing investigators.

For example, an IRB might have concerns over the research methodology or recruitment. It might consider starting with a pilot or feasibility study, reducing the number of subjects, or breaking up the protocol into different stages. When the pilot is completed, the IRB can then assess risk and provide suggestions for the next IRB submission and review.

This type of interaction with an IRB builds the researcher's knowledge of the conducting of research as well as his or her confidence in creating a thoughtful, well-executed study.

Another reason to see the IRB as a colleague is for publication. Many journals now require authors to provide documentation of IRB review and approval. This encourages PIs to address the ethical implications of their research in design and implementation stages and improves the quality of the published results.

So, to sum this up, research is a dynamic process, requiring you, as the researcher, to interact with numerous individuals assigned to the protection of human subjects, from clerical staff to fellow researchers on the IRB.

The IRB is a **dynamic process** in that information is shared throughout the **IRB** to ensure that everyone in the organization is focused on the highest standards for the ethical conduct of research for which you, as PI, are responsible.

The IRB is there to help you. It's a good team to have on your side! For more information, see the Office for Human Research Protections (OHRP) IRB Guidebook [at http://www.hhs.gov/ohrp/irb/irb_guidebook.htm]. For information specific to USF, see the Office of Research, Research Integrity and Compliance.

For more information on the research process and tips for conducting literature reviews, please contact us at FMHILibrary@usf.edu.

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