Institutional Review Board (IRB) Planning and Considerations

Introduction

Evaluation of programs and services often requires engaging individuals in research activities. When this occurs, the individual is defined by federal regulation as a "human subject." Before any research involving human subjects is conducted, there are steps that need to be taken in order to ensure that these individuals are protected in regards to risk, privacy, consent, and other aspects of their participation.

What is an IRB?

An Institutional Review Board (IRB) is an objective, independent, administrative body, established to protect human subjects from physical and psychological harm. The creation of IRBs is a response to unethical research that caused great harm to unwilling study participants in the Nazi experiments during the Holocaust and the Tuskegee Syphilis Study. In 1974, the National Research Act was signed into law and the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research was created. The Commission was charged with identifying the basic ethical principles that should guide human subjects research, which resulted in the Belmont Report. The three principles of the Belmont Report include:

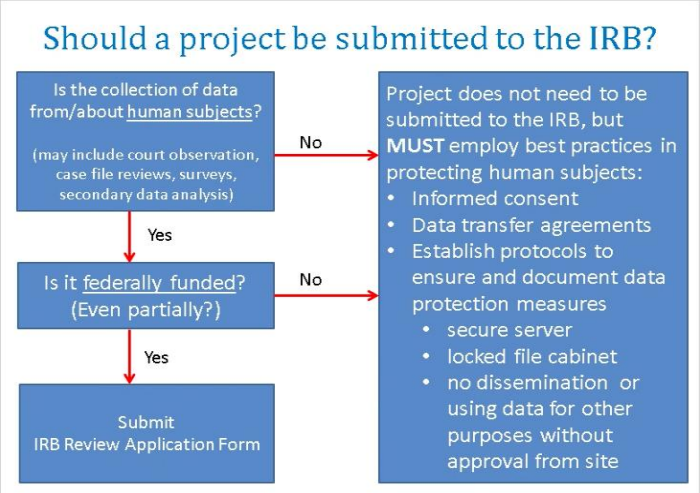
1. **Respect for Persons** - individuals should be treated as autonomous agents and that individuals with diminished autonomy are entitled to protection;
2. **Beneficence** - the potential benefit of research must outweigh the risk of harm; and
3. **Justice -** risks must be fairly distributed in society, and vulnerable populations should not be exploited.

There are hundreds of IRBs in the United States and each is required to register with the Office of Human Research Protections (OHRP), overseen by the Department of Health and Human Services (HHS). The function of IRBs today is to review original research protocols that are submitted, including any modifications to protocols, renew

those that are expiring, and notify participants when **adverse events** occur during the study in order to ensure that federally funded research does not expose subjects to undue or unnecessary harm or risk as a result of their participation. IRBs have ultimate authority over all approvals of research activities.

When is an IRB required?

An IRB is only needed for **federally funded research projects** that include **human subjects**. **Research** is defined as those projects that **systematically collect data** to contribute to **generalizable knowledge.** For example, systematically collecting data can include surveys, focus groups, case file reviews, court proceedings observations, and **secondary analysis** of files. Human subject research includes any study in which a principal investigator obtains data about living individuals through direct interaction or through the access of identifiable private information pertaining to an individual. Even if a project does not fall under the auspices of the IRB, ethical considerations such as **informed consent** and **data protections** should be in place.



IRB Submission Considerations Chart

What does the IRB process look like?

Federally funded, human subjects research requires the institution to register its own IRB or designate another institution's existing IRB as their IRB of record. Once this is completed, the institution can obtain a Federalwide Assurance (FWA) from the OHRP, which is required for organizations to receive support from the HHS.

After an organization establishes or designates an IRB, a **principal investigator** for the project must be chosen and listed on the IRB application. The principal investigator of a study is the person that is primarily responsible for the research and their duties entail:

- protecting the rights and welfare of the participants;
- ensuring the research conducted is approved by the IRB and conducted according to the protocol that was submitted and approved;
- ensuring the research is properly designed and will yield valid results ;

- participants meet the eligibility requirements ;
- informed consent is appropriately attained; and
- changes to the protocol and adverse events are reported to the IRB and other appropriate authorities.

Once a principal investigator is chosen, investigators participating in human subjects research must complete and submit an IRB application describing their project. Researchers can request exemptions from review, expedited reviews, or full reviews.

- **Exemptions** can be approved for projects that involve minimal risk to participants, do not include deception, do not include sensitive information, and do not involve a protected group of people such as **vulnerable populations** (e.g., inmates, children, those with reduced mental capacity). The IRB decides which projects are exempt, so an application must be submitted even if the investigators believe their project falls into an exempt category.

- **Expedited reviews** include a review of the IRB application by the IRB chair and at least one other IRB member. Similar to exempt research, expedited review includes only those projects in which there is minimal risk to participants, there is no deception, and no use of vulnerable populations. Expedited review can also be used to renew a project's IRB approval or make amendments to the application. Even though this category of review is named "expedited," it does not mean that the review will be done quickly.

- **Full reviews** are the most stringent of the review processes, and they are reserved for those projects that include risk to participants, sensitive information, deception, and/or vulnerable populations. During full review, the full IRB panel (or a quorum) reviews the application materials, which include research protocols, consent forms, and any research instruments, and take a vote on whether or not the project is approved or if modifications need to be made (e.g., changes in protocols, consent forms, changes in project scope). Some IRB panels may have the principal investigator present before the vote to answer any questions they may have. Some panels also require a representative of vulnerable populations to be a part of the panel.

Glossary

- **Adverse events** - events that can in any way cause harm to participants, such as a breach of privacy or other mistake
- **Data protection** - efforts to keep the data you receive from human subjects safe; asking questions like, "How long will you keep the data? Can it be used for other purposes? When and how will the data be destroyed?," are an important part of this process

- **Generalizable knowledge** - If you use data you have gathered to advance theories in the field, write scholarly articles, make presentations on the findings, or promote the effectiveness of a program to other sites you are creating generalizable knowledge
- **Human subject** - a living individual about whom an investigator conducting research obtains data either through intervention or interaction with the individual, or through access to identifiable private information about the individual
- **Informed consent** - the process of providing all relevant information about the purpose, risks, benefits, alternatives, and procedures to a potential participant.
- **Principal investigator** - the investigator has the primary responsibility for protecting the rights and welfare of human subjects.
- **Protected/vulnerable populations** - include children, individuals with questionable mental capacity to consent, and prisoners
- **Research** - a systematic investigation (including development, testing, and evaluation) designed to discover or contribute to a body of generalizable knowledge
- **Systematically collected data** - Systematic research can include focus groups, surveys, case file reviews, court observations, checklists, interview protocols, or secondary analysis of automated data files
- **Secondary analysis** - analysis of data collected by another entity for another purpose

Additional Resources:

Office for Human Research Protection: IRB Education Materials

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