Welcome to the University of Findlay's Training for the Institutional Review Board (usually referred to as IRB). This video will provide a brief historical overview of what led to the development of IRB and why this governing body is required by Federal Law. The presentation will also explore the definitions of research, risk, and review level. The final section presents the process of documenting consent and examining specific policies for research at UF.

Please note that this information relates to research using human subjects (as defined in this presentation). If you are using animal subjects, research oversight is the responsibility of UF's Institutional Animal Care and Use Committee (often referred to as IACUC).

Historical Overview

The beginnings of IRB review of research dealing with human subjects can be found in early examples of disregarding the rights of subjects. One of the most well-known examples of this came to light internationally during the Nuremburg Trails (held between 1945 and 1946). During this time Nazis, government officials, and business executives involved in concentration camps were tried and sentenced. These decisions led to the Declaration of Helsinki in 1964 which outlines basic principles for human subject research. The central tenet being that concern for the human subjects must prevail over the interests of science and society.

As thoughts regarding safety for human subjects in research began to develop internationally, several studies in the United States also brought these issues to light. First was the 1966 study by Beecher which found research conducted at and published by prestigious institutions that presented risk to the subject without their knowledge or approval. This and other research helped inform the National Advisory Health Council Findings which outlined three priorities for research with human subjects.

Another clear example of the need for this type of oversight and review in human subject research is the 40 year Tuskegee Syphilis study. In this study African American men were told they received treatment for syphilis when they did not. Disregard for the safety of the human subjects in this research project gives just one example of why the establishment of the National Research Act was necessary. This act established requirements for the National Commission for Protection of Human Subjects of Biomedical and Behavioral Research. It also requires IRB at institutions that receive Health, Education, and Welfare support for human subject research – UF is one of these institutions. In 1979 the Belmont Report further defined the three basic ethical principles for IRB consideration.

IRB Basic Policies and Definitions

Filing for IRB approval takes time to complete before your research begins. The benefits to the researcher make the effort worthwhile. By submitting your project structure, research instruments, and consent documentation for approval you are indicating an awareness of care for the human subjects participating in your study, an understanding of research methods and principles that guide research intended for publication, and an establishment of accountability between you and UF (both ethically and legally). It is your responsibility to report your research

project and all required documentation in advance to ensure your study can begin in a timely manner.

At UF the review committee consists of 14 members – two members from each college at the university, an outside community member, and the IRB Research Officer. From the faculty members, a chair and vice-chair are elected. These positions are responsible for overseeing the governance of UF's IRB. The IRB Research Officer is responsible to act as the liaison between the committee and academic affairs.

This elected committee will assess your project structure, research instruments, and consent documentation with the ethical considerations explored in the historical overview section of this training in mind.

The first step in this process is to determine if the activity involves research at all. Research is defined as a systematic investigation designed to develop or contribute generalizable knowledge and includes some types of research you may not consider falling under this category.

The second step in this process is to determine if the activity involves human subjects. This category is broadly defined and application information will require the applicant to explain why the selected group is best suited to the study.

The third step in this determination process is to consider if the research will fall into the exempt category of research. There are many situations that fall into exempt research, the final determination will be made during the application process. It may seem easier to not apply for IRB review of a project you do not think will be publically disseminated. However, it is better to have approval and to not need it, than to not have it and want it after the research is complete.

The fourth step in the research determination process is to ensure your application contains all the required information for IRB approval. This detailed list is explained more fully in a separate IRB Application Training Tips video. One specific aspect researchers need to consider is the definition of vulnerable subjects. While most UF students will fall under non-vulnerable, some types of research questions or unforeseen student populations may require special consideration.

Human Subject Flow Chart

The IRB review process follows different steps based on the level of examination required as determined by risk, participant type, and level of review. The first step of this process is started when a complete application is submitted to the IRB Research Officer. Note that at this time research for class purposes only do not require IRB review – and will be discussed in detail later in this video. However, if there is any possibility of the research being used for public dissemination (outside of UF), it is better to apply for IRB approval than to not have the documents when you want to publish your research later.

The next step is to determine the level of risk present to human subjects in the project. Risk is defined as the degree to which participants are at risk for incurring physical, emotional,

psychological, or economic risk. This is noted by the researcher applicant on a scale of less-than-minimal to greater-than-minimal.

Another aspect of review is to define the type of participant – as explored earlier, the options are either non-vulnerable or vulnerable. Both level of risk and type of participant help determine the final level of review. This is another aspect of the application that the researcher will indicate, but the final determination is made by the IRB committee.

A study that is identified as exempt will be reviewed by one IRB committee member.

Studies that are identified as expedited are reviewed by two reviewers (at least one of whom is outside of the department of the applicant).

All other studies fall under full review and will be submitted during the next possible meeting to the entire committee for review.

Consent Procedures

All studies require consent from human subjects. Full (sometimes called informed) consent explains in detail specific aspects of the research project to allow participants to understand completely the research project and risks being a part of the project may expose them to. A full consent form template is provided to make this process understandable for applicants. Filling out the complete IRB application first is recommended, as the information required for the consent form MUST match the application information. Any changes made to the main application should be reflected on these forms as well.

Research applicants may ask for a waiver or alteration of the full consent form for specific purposes in the study. A template for this type of consent is also provided and filling out the full application first is also recommended as this information should match the application as well.

The most important aspect of understanding consent is that the project must allow for consent to be an ongoing process – and indicate how subjects can withdraw from the study without repercussion (if possible).

In addition to these basic considerations some types of studies (case studies in health professions research typically), may require use of data that falls under the Health Insurance Portability and Accountability Act (also known as HIPPA). Studies that fall under these areas should follow the appropriate guidelines for the research project being conducted.

UF Specific Procedures

As a conclusion to this historical overview and definition of terms and process, there are several UF specific procedures applicants must understand when applying for IRB review.

The first is that the principal investigator (also referred to as the PI) listed on the application must be a full time faculty/staff member at UF. This applicant must provide proof of IRB training when the application is made and when proposals are renewed. The PI will monitor all aspects of the application, study, and completion; in addition this person is responsible for securely maintaining documents for the minimum three years required by IRB protocol. Student

researchers work with the designated PI and are called secondary investigators (SIs). There may also be other co-investigators that are other full time faculty/staff members, but a PI must be designated for communication throughout the IRB process.

The submission process for UF is to submit appropriate documentation as noted in the application and required by the study. (See Application Training Tips video for specifics).

As mentioned before, IRB review is only needed for projects that will be disseminated publically (beyond UF). The annual symposium for scholarship and creativity is considered an internal method of dissemination – however, if there is any chance the researcher will use the information outside of that space, IRB review of the project is required.

If the project will remain internal and falls under one of the common categories for instructional/class projects, then the instructor of that course is responsible to ensure the project is carried out within principles of ethical research. IRB does provide a brief consent statement that should be used in these cases after the instructor has carefully reviewed the instrument.

At the end of the application process, once the committee has reviewed all provided documents and research instruments, the PI will receive notification of one of four IRB committee decisions. Approved means the study may move forward. Pending requires minor revisions that are communicated to the PI by the IRB Research Officer. The PI and SIs will be required to make changes and no research can be performed until these changes are made. Tabled means that there are more than minor revisions to be made and the project may not move forward until these are addressed. Denied indicates that the questions about the rights and welfare of the subjects are so significant that the approval of the study is unwarranted.

Projects that last beyond one calendar year must have a project status report. The study is automatically suspended if approval is not received before prior approval runs out. NOTE: Any public dissemination of research requires annual renewal. For example, if a publication is in-press, the PI should submit this document annually until publication is finalized.

Once a study is complete, the PI is responsible to submit a certificate of compliance to the IRB Research Officer. Once the form has been approved the project is closed.

Conclusion

Thank you for taking the time to understand the historical importance that IRB review plays in protecting human subjects during research. For specific details on how to fill out the application, please see the Application Training Tips video. If you have any further questions feel free to contact your college's IRB representative (current members can be found on the IRB Blackboard site) or the IRB office directly (irb@findlay.edu).