

DEPARTMENT: INSTITUTIONAL REVIEW BOARD
POLICY NUMBER: 002
SECTION: IRB AUTHORITY AND COMMITMENT
REVIEW RESPONSIBILITY: IRB
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REVISION DATE:
LAW IMPLEMENTED: 45 CFR 46.101,102,103

SUBJECT: Institutional Review Board Jurisdiction/Applicability

1. The IRB is an administrative body established to protect the rights and welfare of human research subjects recruited to participate in research activities conducted under the auspices of the Institution with which it is affiliated.
2. At Florida State University, the appointed University Human Subjects Committee serves as the IRB, and has the authority to approve, require modifications in, or disapprove all research activities that fall within its jurisdiction as specified by both the federal regulations and University policy.
3. All research or clinical investigations involving human subjects regardless of funding source or sponsorship must be reviewed and approved by the IRB. No intervention, investigation, or interaction with human subjects in research, including recruitment, may begin until the IRB has reviewed and approved the research protocol. Specific determinations as to the definition of “research”, “clinical investigation”, or “human subject” and their implications for the jurisdiction of the IRB under Florida State University policy are made by the IRB.
4. Florida State University’s Assurance with the federal government specifies that all research activities involving human subjects, and all other activities which even in part involve such research, regardless of funding source or sponsorship, must be reviewed by the IRB (Human Subjects Committee) if one or more of the following apply:
 - a) the research is sponsored by Florida State University, or
 - b) the research is conducted by or under the direction of any employee, faculty, staff, student, or agent of FSU in connection with his or her institutional responsibilities, or
 - c) the research is conducted by or under the direction of any employee, faculty, staff, or agent of FSU using any property or facility of this institution, or
 - d) the research involves the use of Florida State University’s non-public information to identify or contact human research subjects or prospective subjects.

5. Definition of “Human Subject”: Pursuant to federal regulation, “human subject” is defined as “living individual(s) about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual, or identifiable private information.” Therefore, only research activities involving data obtained through intervention or interaction with a living individual or involving identifiable private information regarding a living individual must be reviewed by the IRB.
 - a) Intervention includes both physical procedures by which data are gathered (for example venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.
 - b) Interaction includes communication or interpersonal contact between Investigator and subject.
 - c) Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (the identity of the subject is or may readily be ascertained by the Investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects. This may include identifiable private information obtained from a primary subject regarding a third party.

6. Definition of “Research”: Only certain activities involving human subjects qualify as “research” subject to the jurisdiction of the IRB. The federal regulations define “research” to mean “a systematic investigation (i.e. the gathering and analysis of information) designed to develop or contribute to generalizable knowledge”.
 - a) A major factor in determining whether an activity is research subject to IRB review depends upon the Investigator’s intent to “contribute to generalizable knowledge”, and whether there is a systematic design in advance, generally utilizing a scientific approach or protocol, for the defined purpose of contributing to generalizable knowledge.
 - b) If the Investigator intends to publish or disseminate the results, the activity will be viewed as intending to contribute to generalizable knowledge, and to be research subject to the IRB’s jurisdiction. Activities that may result or be included in a theses, dissertation, journal article, poster session, public speech or presentation, or project report must be reviewed by the IRB.
 - c) Thus, if there is any possibility that the Investigator may want to publish or disseminate the resulting data in the future, then the protocol must be submitted for IRB review.
 - d) The determination as to whether an activity involving human subjects can be defined as “Research” is the sole responsibility of the IRB, and not the Investigator.

7. Definition of “Clinical Investigation”: A “clinical investigation” is an experiment using a test article on one or more human subjects that are regulated by the Food and Drug Administration or support applications for research or marketing permits for products regulated by the Food and Drug Administration. Products regulated include food and color additives, drugs for human use, medical devices for human use, biological products for human use, and electronic products.
8. Standard Diagnostic or Therapeutic Procedures: The distinction between research and treatment can become blurred in patient care settings, as well as in some educational and training settings. An established and accepted diagnostic or therapeutic procedure that is performed only for the benefit of a patient or student is generally not subject to the jurisdiction of the IRB. If, however, there is a collection of data about a series of such procedures or treatments for dissemination or generalization, then such activity would constitute research within the purview of the IRB. Also, if patient care or assignment to intervention is altered for research purposes in any way, the activity must be submitted for IRB review. Similarly, a diagnostic procedure for research purposes that is added to a standard treatment would also require IRB review.
9. Innovative Treatments or Procedures: Innovations in diagnosis, therapy, or treatment are generally not subject to IRB review if they are applied to a patient for the sole purpose of aiding that individual, although such innovations are governed by professional ethics (i.e. obtaining informed consent). IRB review is required, however, when a systematic investigation of such innovations is considered.
10. Emergency Use of an Investigational Drug or Device: Research activities may not be commenced, even in an emergency, without IRB review and approval. If emergency care is commenced without prior IRB review and approval, then the patient may not be considered as a research subject; such emergency care may not be claimed as research, nor may any data regarding such care be included in any report of a research activity. When emergency care involves investigational drugs, devices, or biologics, the U.S. Food and Drug Administration (FDA) requirements must be met. However, nothing in these policies is intended to limit the authority of a physician to provide emergency medical care for patients who need such care. Rather, the use of information collected about that treatment for research purposes is prohibited.
11. Human Cell or Tissue Repository: Human cell or tissue research typically involves repositories that collect, store, and distribute human tissue materials for research purposes. Tissue repository activities involve the collectors of tissue samples, the repository storage and data management center and the recipient investigators. Human cell or tissue repositories do not qualify as human subject research if the material submitted to the repository satisfies both of the following conditions:
 - a) the material, in its entirety, was collected for purposes other than submission to the repository (the material was collected solely for clinical purposes, or for legitimate but unrelated research purposes, with no additional material collected for submission to the repository); and

- b) the material is submitted to the repository without any identifiable private data or information (no codes or links of any sort may be maintained, either by the submitter or by the repository, that would permit access to identifiable private data or information about the living individual from whom the material was obtained).
12. Florida State University PI Initiated Research/Clinical Investigation: Research which is conducted by a FSU Investigator who initiates and/or conducts a clinical investigation, alone or with others, is considered to be FSU PI Initiated Research. In such a case, it is the Investigator's responsibility to keep the IRB Office informed of any unanticipated problems involving risks to subjects or adverse events that were serious or unanticipated, and resulted in a change to the risk/benefit ratio, even if the event occurred at a location for which the FSU IRB is not the IRB of record.
13. Student- Conducted Research: All activities that meet the definition of research with human subjects and that are conducted by students for a class project or for work toward a degree must be reviewed by the IRB. For example, activities that must be reviewed and approved by the IRB include all master's theses and doctoral dissertations that involve human subjects and all projects that involve human subjects and for which findings may be published or otherwise disseminated.
14. Research Practicums/Research-Methods Classes: Courses of study at FSU which are designed to train students and provide them with an opportunity to practice various research methods differ from research activities that would generally require IRB review in that the primary intent of the classroom project is for the student to become more knowledgeable about the research process. Additionally, such projects typically do not lead to generalizable knowledge and are not undertaken with that goal in mind. Therefore, simulations of research using human subjects and course-assigned data collection are not deemed to be research that is subject to IRB review so long as the activity meets the following requirements:
- a) the activities are designed for educational purposes only,
 - b) the data will not be generalized or published outside the classroom,
 - c) the data will not result in an article, master's thesis, doctoral dissertation, abstract, other publication or presentation, and
 - d) the student volunteers or other participants are clearly informed that the activities are an instructional exercise and not actual research. Instructors are encouraged to become familiar with each student's project, and to discuss it with the student. If the instructor determines that there is a possibility that the student's proposed project may result in a formal presentation or publication, then he or she should recommend that the student submit the project for IRB review before beginning the study.
15. Case Studies: The use of a single human subject in research activities can constitute research that is subject to IRB review and approval when there is a clear intent before recruiting or interacting with the subject to use systematically collected data that would not ordinarily be collected in the course of daily life in reporting and

publishing a case study. As a general rule, when a series of subject observations are compiled in such a way as to allow possible extrapolation or generalization of the results from the reported cases, that activity constitutes research that must be reviewed by the IRB. This type of activity must always be reviewed by the IRB when there is an intent to publish or disseminate the data or findings.

16. **Defining a Project as Research after the Project has Commenced:** If an investigator commences a project and later finds that the data gathered could contribute to generalizable knowledge or that he or she may wish to publicize the results, the investigator must submit a proposal to the IRB office for review as soon as possible. Investigators who attempt to circumvent FSU policies regarding human subjects research by collecting data as non-research and then applying to use them as existing data will face the possibility of their research not being approved. It is in the investigator's best interest to consider carefully the likelihood that he or she will want to use the data for research purposes in the future, and to err on the side of inclusion and seek IRB approval prior to commencing the work.
17. **Failure to Submit Project for IRB Review:** If an investigator knowingly engages in activities that qualify as research that is subject to IRB review without obtaining prior approval by the IRB, the data that are collected and the results may be deemed as not usable by the IRB. This would depend on the kind of research engaged in, the risks, the appropriateness and the intent of the investigator. Possible outcomes may include, but not be limited to, frequent reviews of the ongoing research, not allowing the research to be published, or not allowing the data to be used for thesis or dissertation requirements.