

Overview

Guidance on Engagement of Institutions in Human Subjects Research
(As interpreted from the Office for Human Research Protection/U.S. Department of Health & Human Services)

Purpose

This document provides information for determining whether Fairmont State University is engaged in a non-exempt human subjects research project. Fairmont State University is engaged when its employees or agents for the purposes of the research project obtain:

1. data about the subjects of the research through intervention or interaction with them;
2. identifiable private information about the subjects of the research or;
3. the informed consent of human subjects for the research;

Examples

Fairmont State University Engaged in Human Subjects Research

1. Fairmont State University receives an award through a grant and all research activities involving human subjects are performed by employees or agents at another institution.
2. An FSU faculty member performs invasive or noninvasive procedures (collection of blood, utilizing physical sensors, implantation of medical devices) for research purposes.
3. An FSU staff member interacts with a subject through direct communication, such as administering a survey for research purpose.
4. An FSU medical resident, on behalf of the principal investigator, obtains informed consent of human subjects, for research that will be conducted at University Hospital.
5. An FSU student obtains private information or specimens from any source for research purposes. This includes, but is not limited to: observing or recording private behavior, using, studying or analyzing private information or specimens provided by another institution or already in the possession of the investigator.
6. FSU Faculty member is given a subcontract to assist on a funded project. FSU Faculty subawardee will help be a consultant as to provide expertise, will develop survey measures, will code and analyze identifiable data.
7. FSU Faculty member will help collect and measure air samples on a collaborative project looking at the quality of air/pollution in individuals' homes. FSU Faculty member will not be recruiting or consenting subjects but rather will collect samples, have access to data and will help with publications.
8. FSU Faculty member will help a colleague at another institution recruit students to participate on study looking at eating habits and keeping food diaries. The FSU faculty will help recruit/consent subjects. S/he will not administer the intervention but have access to de-identified data. S/he plans to publish separately.
9. FSU Faculty member worked on a project while completing their PhD at another university. Part of the study included therapy sessions to treating alcoholism among children of alcoholics. Study is an ongoing, multi-year project which s/he is no longer

involved with recruiting/consenting/administration of measures but has access to identifiable data. S/he wishes to help analysis data and publish with and separately from his/her colleagues.

Institutions Not Engaged in Human Subjects Research

1. Commercial service: A FSU student is hired to transcribe the audio recording of a focus group discussion conducted at health center. (Fairmont State University is not engaged in human subjects research).
2. Routine medical/clinical service: A private practice provides routine medical services and releases the data to the FSU investigator as a service. (The private practice is not engaged in human subjects research).
3. Administration of study interventions on a one time/short-term basis: A subject receives chemotherapy at a hospital as part of a clinical trial because the subject unexpectedly goes out of town; however, the hospital is not a research site. (The hospital is not engaged in human subjects research).
4. Distribution of research study information to prospective subjects: An FSU faculty member informs students about a research study being conducted at Marshall University. The FSU faculty member is not an investigator on that protocol. (Fairmont State University is not engaged in human subjects research).
5. Institutions that permit use of their facilities: An FSU investigator distributes a survey at a local community center. (The community center is not engaged in human subjects research).
6. Institutions that release identifiable private information or identifiable biological specimens: A high school releases student tests scores to an investigator from FSU School of Public Health. (The high school is not engaged in human subjects research).
7. Obtain coded private information from another institution while maintaining the link but are unable to discover the identity of the subjects: For example, the Department of Pathology receives coded specimens from a local hospital to analyze but has an agreement that the link will not be released to anyone within that department. (The Department of Pathology is not engaged in human subjects research).
8. Utilizing identifiable private information when visiting an institution engaged in research and approved by an IRB: An FSU resident visits a local medical center, a research site conducting a clinical trial, and accesses identifiable private information (as long as their research activities are overseen by the IRB of the institution that is engaged in the research). (Fairmont State University is not engaged in human subjects research).
9. Accessing identifiable information for auditing purposes: Patients' records from a local hospital are audited by the hospital for compliance purposes. (The local hospital is not engaged in human subjects research).
10. FDA reporting requirements: An employee of a local hospital obtains identifiable private information to satisfy the reporting requirements to the U.S. Food and Drug Administration. (The local hospital is not engaged in human subjects research).

DEFINITIONS

- Research: A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.
- Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information. Institution: Any public or private entity or agency (including federal, state, and other agencies) and agents of that entity.
- Federal Funding: An institution that is the direct (prime) recipient of federal funding for a research project is considered (by federal regulation) to be engaged in the entire research project, even when all activities involving human subjects are performed through subcontract or other arrangements by the employees or agents of other institutions.
- Employees or Agents: (1) act on behalf of the institution; (2) exercise institutional authority or responsibility; or (3) perform institutionally designated activities. “Employees and agents” can include staff, students, contractors, and volunteers, among others, regardless of whether the individual is receiving compensation.
- Interaction: Communication or interpersonal contact between investigator and subject.
- Private information: 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 (i.e., 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. Coded information is considered individually identifiable if a key to decipher the code exists, enabling linkage of the identifying information to the private information or specimens.
- Obtaining identifiable private information: Receiving or accessing identifiable private information or identifiable specimens for research purposes (OHRP interprets obtain to include an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens already in the possession of the investigator).
- Coordinating Center: A Coordinating Center is responsible for overall data management, monitoring and communication among all sites, and general oversight of conduct of the project.
- Assurance: An “Assurance” is a documented commitment by an institution to comply with the requirements in 45 CFR 46. All institutions “engaged” in research covered by the HHS regulations (45 CFR 46) that is conducted or supported by a Federal Department or Agency must either apply to OHRP for an Assurance or provide their Assurance number to NIH. If an institution will become engaged in human subjects research and does not have a Federal-wide assurance from OHRP , the institution must rely on an external IRB and be listed under that institution’s FWA through a collaborating investigator agreement.