Human Subjects in Research

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Introduction

The Institutional Review Board (IRB) is a federally mandated committee whose purpose is to ensure that 1) the rights, well-being, and safety of human subjects in research are protected; and 2) that Iowa State University research is compliant with applicable federal and state regulations as well as Iowa State policies and guidelines. To achieve these objectives, the IRB advises principal investigators in designing research projects that minimize potential harm to subjects, reviews all research involving human subjects prior to initiation of the research, approves research that meets established criteria for the protection of human subjects, and monitors approved research to confirm that subjects are being protected.

Definitions

Research means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l)).

Human subject means a living individual about whom an investigator (whether professional or student) conducting research (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or biospecimens.

> *Intervention* includes both physical procedures by which information or biospecimens are gathered (e.g., venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.
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> *Interaction* includes communication or interpersonal contact between investigator and subject.
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> *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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
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> *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
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> An *identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen (45 CFR 46.102(e)).

Clinical investigation means any experiment that involves a test article and one or more human subjects that is either subject to requirements for prior submission to the Food and Drug Administration under section 505(i) or 520(g) of the Federal Food, Drug, and Cosmetic Act, or is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act, but the results of which are intended to be submitted to, or held for inspection by the Food and Drug Administration as part of an application for a research or marketing permit (21 CFR 50.3(c)).

A *test article* means any drug (including a biological product for human use), medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food, Drug and Cosmetic Act or under sections 351 and 354-360F of the Public Health Service Act (21 CFR 50.3(j)).

Human subject (in a clinical investigation) means an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A subject may be either a healthy human or a patient (21 CFR 50.3(g)).

Policy Statement

Human subjects research (including clinical investigations) conducted by employees, students, or other agents of Iowa State University must receive IRB approval or determination of exemption prior to initiation of any human subjects research activities. Research must remain under IRB oversight until all human subjects research activities are complete.

Principal investigators (PIs) and supervising investigators (SIs) are ultimately responsible for protecting the rights, well-being, and safety of human research subjects as well as assuring compliance with all applicable regulations and requirements.

Resources

Links

- Office of Research Ethics
- Human Subjects Research Guidance and IRB Application Information
- Institutional Review Board (IRB)
- Research Participant Payments
- HHS – Office of Human Research Protection
- FDA – Protection of Human Subjects
- FDA – Institutional Review Boards