UI FACULTY-STAFF HANDBOOK
CHAPTER FIVE:
RESEARCH POLICIES

5200

HUMAN SUBJECT PARTICIPANT RESEARCH

PREAMBLE: This section outlines the considerations, legal and ethical, that need to be taken into account in any research that involves human subjects. It was original to the 1979 Handbook and was revised in July of 1995, and again in July 2003, to reflect changes in applicable federal law. In 2009 the Human Assurances Committee (HAC) was renamed to Institutional Review Board (IRB). In February of 2010 it has been rewritten in accordance with federal law and University policies. In 2018 changes were made to bring this policy into compliance with recent federal regulation changes. For further information, contact the Research Office (208-885-6651). [rev. 7-03, 1-09, 7-10, 1-18]

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A. GENERAL POLICY, LEGAL AUTHORITY AND ETHICAL PRINCIPLES

A-1. GENERAL POLICY. The University of Idaho, in the course of carrying out its teaching, research, and service missions, engages in human subject or participant research across a wide array of academic disciplines [and administrative functions]. Recognizing that engaging in research involving human subjects/participants imposes responsibility for safeguarding the rights and welfare of these persons, the University of Idaho (University) is committed to the protection of human research participants through compliance with applicable federal and state regulations and observance of ethical principles for the conduct of human research.

A-2. LEGAL AUTHORITY. All research subject to this policy shall be conducted in accordance with federal, state, and local law.

In fulfilling its commitment to protect the rights and welfare of human research participants, the University applies the regulations promulgated by the United States Department of Health and Human Services (HHS) for Protection of Human Subjects (45 C.F.R. 46) to all federally funded research. Under the approved federal-wide assurance (FWA) provided by the University to HHS, all federally funded human research participants are covered by applicable federal regulations enforceable by HHS at 45 C.F.R. 46. The University also complies with the applicable federal regulations established by the Food and Drug Administration for clinical investigations involving drugs, biologics, medical devices, and other test articles (21 C.F.R. 50, 56, 312, and 812).

By this policy, the University also requires that all non-federally funded and unfunded research comply with these regulations, unless otherwise specified by University policy, including but not limited to University of Idaho IRB Standard Operating Procedures (see Section F, below). [rev. 1-18]

A-3. ETHICAL PRINCIPLES. Consistent with its federal-wide assurance and this policy, the University shall...
be guided by the ethical principles governing the evaluation and conduct of research involving human participants, whether or not such research is subject to federal regulation, set forth in The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research on at the HHS www.hhs.gov website or contact Office of Research Assurances (see G below). While the principles announced in The Belmont Report serve to guide human participant research at the University, these principles are never held to or construed so as to supercede any local, state, or federal law or to supercede any regulations or policies promulgated by federal agencies. [Fed 1:18]

B. COVERED ACTIVITIES.

B-1. HUMAN PARTICIPANT-SUBJECT RESEARCH ACTIVITIES. Irrespective of funding source, all activities that meet the criteria for: (i) “research” involving “human subjects,” as defined in HHS regulations (45 CFR 46.102), or (ii) a “clinical investigation” involving “human subjects” or “subjects,” as defined in FDA regulations (21 CFR 50.3; 21 CFR 56.103; 21 CFR 312.3; 21 CFR 812.3), shall be subject to this policy. [Fed 1:18]

b. HHS Definition of “Research” Involving “Human Subjects:"

(1) “research” - a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge, (45 CFR 46.102(d)). This includes qualitative research methods such as constructivist, participatory, and action research that may not be considered generalizable. It also includes other methodologies that may not be considered generalizable but have the intent of adding to a body of knowledge.

--- Note: Certain activities by policy do not fall under the definition of research and are not subject to IRB review and approval. For example, projects carried out as part of coursework with the sole intent of teaching students research skills may be covered under the Course-Related Research Practica policy. Projects carried out as part of a University Quality Improvement or Quality Assurance project may be covered under the policy for such activities.

(2) “human subject”: a living individual about whom an investigator (whether professional or student) conducting research obtains (i) data through intervention or interaction, or (ii) identifiable private information (45 CFR 46.102(f)).

(iii) “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.

(ii) “Interaction” includes communication or interpersonal contact between investigator and subject.

(iii) “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 (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.

b. FDA Definition of “Clinical Investigation” Involving “Human Subjects” or “Subjects:"

(1) “clinical investigation” (deemed by the FDA to be synonymous with “research”): any experiment that involves a test article and one or more human subjects, and that either must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or need not meet the requirements for prior submission to the Food and Drug Administration under those sections of the act.
but the results of which are intended to be later submitted to, or held for inspection by, the FDA as part of an application for a research or marketing permit. [21 CFR 50.3(c); 21 CFR 102(c); 21 CFR 312.3(b); and 21 CFR 812(h)].

1. “Test article” is defined as 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 FDA regulation. [21 CFR 50.3(j) and 56.102(l)].

2. “human subject” or “subject:” an individual who becomes a participant in research, either as a recipient of a test article or as a control. [21 CFR 50.3(g) and 56.102(e)]; a human who participates in an investigation, either as a recipient of the investigational new drug or as a control. [21 CFR 312.3(b)]; or a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. (21 CFR 812.3).

B-2. EXEMPT HUMAN PARTICIPANT SUBJECT RESEARCH. Activities that meet the criteria for “human subject research” described in the HHS and FDA regulations above may nevertheless be exempt from compliance with federal human subject regulations, if the only involvement of human participants will be in one or more prescribed categories. For a list of “exempt” research categories see, [45 CFR 46.101(b)]. The IRB, or designee of the IRB, shall make the determination as to whether a particular research activity involving human participants is exempt. Even when research is determined by the IRB to be exempt, the ethical principles of The Belmont Report shall be applied by the investigator to the research activities. [ed. 1-18]

C. SCOPE OF AUTHORITY AND RESPONSIBILITY.

C-1. INSTITUTIONAL REVIEW BOARD (IRB) [see FSH 1640.54; ed. 1-18]

a. The IRB is the principle mechanism by which the University ensures that all human participant research activity is planned and conducted in a manner consistent with applicable law and policy and that the rights and welfare of human research participants are adequately protected. [ed. 1-18]

b. The responsibilities of the IRB include but are not limited to:

   (1) reviewing, approving, requesting modifications, as well as disapproving human subject/participant research. [45 CFR 46.109(a); [ed. 1-18]

   (i) research that has been approved by the IRB may be subject to further review and approval or disapproval by University officials. University officials may not approve research that has not been approved by the IRB. [45 CFR 112]; [ed. 1-18]

   (2) conducting continuing review of research approved by the IRB, according to federal regulations and at intervals appropriate to the degree of risk presented, but not less than once per year, including as necessary observing, or having a third party observe, the consent process and research activity; or requesting and inspecting information related to human participant subject research activity. [45 CFR 46.109(e); [rev. 1-18]

   (3) investigating instances of non-compliance, whether discovered during monitoring by the IRB or reported to the IRB, including unanticipated problems involving risks to research participants or others and serious or continuing noncompliance with this policy or the requirements or determinations of the IRB. [ed. 1-18]

   (4) suspending or terminating approval of research activity that is not being conducted in accordance with the requirements established by the IRB for a particular research activity or has been associated with serious

Commented [IC(7)] Changed to recognize that the RCR permits review periods to be established based on the degree of risk presented by the research and no longer requires annual review for all protocols.
harm to research participants or that is not otherwise in accordance with federal human subject research regulations or University policy. [45 CFR 46.103(a)(2)] [Fed. 1-18]

(5) reporting to appropriate University and, for federally funded research, federal government officials. [45 CFR 46.113] [Fed. 1-18]

(i) unanticipated problems involving risks to research participants or others and serious or continuing noncompliance; and [Fed. 1-18]

(ii) suspension or termination of IRB Approval [45 CFR 46.103(b)(5)]; [Fed. 1-18]

(6) developing and implementing administrative policies and procedures to implement this policy.

C-2. SIGNATORY OFFICIAL. The Signatory Official is the Vice President of Research and Economic Development or designee. This individual cannot be a voting member of the IRB and shall have the legal authority to represent the University in providing assurance to the federal government that the University will comply with federal human subject research regulations and shall be responsible for ensuring that all regulatory and programmatic requirements for the conduct of human participant research at the University are met. [Fed. 1-18]

[45 CFR 46.103(b)(2)(c)].

C-3. OFFICE OF RESEARCH ASSURANCES. The Office of Research Assurances shall provide administrative support necessary for the IRB to fulfill its duties. [45 CFR 46.103(b)(2)]. [Fed. 1-18]

C-4. UNIVERSITY INVESTIGATORS (FACULTY, STUDENTS, AND STAFF). Any person who engages in human participant research (See B. Covered Activities, above) under the auspices of the University (including faculty, students, and staff) shall comply with applicable federal, state, and local law, with University policy, and with the requirements of the IRB. [Fed. 1-18]

D. ORGANIZATION AND MEMBERSHIP OF THE IRB. The IRB shall be organized and its membership determined in accordance with federal regulations and University policy (45 CFR 46.107, 21 CFR 56.107, and FSH 1640.51). [Fed. 1-18]

E. REVIEW OF HUMAN PARTICIPANT-SUBJECT RESEARCH. [Fed. 1-18]

E-1. The IRB shall conduct initial and continuing review of human participant-subject research activity, following established procedures appropriate to the degree of risk involved in the research. IRB review of research shall be prospective, and no human participant-subject research activity may be carried out by an investigator without prior approval from the IRB. The IRB shall not provide retrospective approval of human participant-subject research. [Fed. 1-18]

E-2. The IRB, or its designee, shall review all research that meets the regulatory definition for human subject research but may be eligible for exemption from further review and oversight (see B. Covered Activities above). The IRB, or its designee, shall make the final determination as to whether a particular research activity involving human participants is exempt. For activities determined to be exempt, the IRB shall provide the investigator with a certification of exemption from continuing IRB oversight. [Fed. 1-18]

E-3. The IRB, or its designee, shall provide guidance to investigators as to what activities do not constitute human subject research and, therefore, do not require IRB oversight. The IRB shall provide, as necessary, certification to investigators that research activity is not human subject research.

F. UNIVERSITY OF IDAHO IRB STANDARD OPERATING PROCEDURES. The administrative policies, guidelines, and procedures developed to implement this policy shall be set forth in the University of Idaho IRB Standard Operating Procedures, which shall be maintained and made available to investigators by the Office of
Research Assurances. The University of Idaho IRB Standard Operating Procedures shall be reviewed and approved by the Signatory Official or designee in consultation with the IRB.

G. CONTACT INFORMATION. For further information regarding implementation of this policy, you may visit the IRB website or contact the Office of Research Assurances at 208-885-6340 or irb@uidaho.edu or visit the IRB website, fed. 1181