RESEARCH INVOLVING HUMAN SUBJECTS

1. Overview

Federal regulations define when an activity is research involving human subjects. As described below, an activity is human subjects research (i.e., and subject to regulatory and institutional requirements) if it fits either the DHHS or FDA definitions. All research involving human subjects must be approved by an IRB before being performed unless the research has been determined to be exempt.

This policy describes applicable DHHS and FDA definitions, the scope of human subjects research for which The Ohio State University Human Research Protection Program (HRPP) has responsibility, and the process by which determinations are made that an activity is research involving human subjects.

2. Definitions for DHHS-Regulated Research

Generalizable Knowledge: Information from which one may infer a general conclusion; knowledge brought into general use or that can be applied to a wider or different range of circumstances. For example, publication and presentation are typical methods used to disseminate research findings, thereby contributing to "generalizable knowledge." However, not all information that is published or presented represents generalizable knowledge. Generalizable knowledge is also interpreted to include data intended for general use, regardless of its eventual distribution or acceptance.

Human Subject: A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or identifiable private information. *Note: See the FDA definition of human subject for FDA-regulated research.*

Individually Identifiable: The identity of the participant is or may readily be ascertained by the investigator or the investigator's staff, or is associated with the information. *Note: Individually identifiable for the purposes of HRPP policy may be similar to, but is not the same as, individually identifiable health information or protected health information as defined by the HIPAA Privacy Rule at 45 CFR Part 160. Limited data sets released from data repositories with IRB approval to release such data sets are not considered to be individually identifiable.*

Interaction: Communication or interpersonal contact between an investigator and participant.

Intervention: Physical procedure by which data are gathered, or manipulation of the participant or the participant's environment for research purposes.

Limited Data Set: Health information that excludes certain direct identifiers, but may include city, state, and ZIP code; elements of date; and other numbers,characteristics, or codes that cannot be used to identify an individual or the individual's relatives, employers, or household members. *Note: Limited data sets may be used or disclosed*

for purposes of research with a data use agreement as described by the HIPAA Privacy Rule at 45 CFR Part 164. For more information, including the list of identifiers that must be removed from health information in a limited data set, see HIPAA and Human Subjects Research*.*

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, or information that has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public. Examples of private information include medical or academic records or personal journals.

Research: A systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. *Note: See the FDA definition of research (clinical investigation) for FDA-regulated research.*

Systematic Investigation: A planned scientific or scholarly activity involving qualitative or quantitative data collection and/or data analysis that sets forth an objective(s) and a set of procedures intended to reach the objective(s), i.e., to acquire knowledge, develop a theory, or answer a question.

Treatment or Professional Practice: Interventions designed solely to enhance the well-being of a particular individual.

3. Definitions for FDA-Regulated Research

Clinical Investigation: Also: **research**, **clinical research**, **clinical study**. Any experiment that involves a test article and one or more human subjects that either:

- Meets the requirements for prior submission to FDA under sections 505(i) or 520(g) of the Food, Drug, and Cosmetic Act; or
- Need not meet the requirements for prior submission to FDA under the sections noted above, but the results of which are intended to be later submitted to or held for inspection by FDA as part of an application for a research or marketing permit.

Note: Non-clinical laboratory studies are not considered to be clinical investigations. See the DHHS definition of research for DHHS-regulated research.

Device: An instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part or accessory that:

- Is recognized in the National Formulary, United States Pharmacopoeia, or any supplement,
- Is intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body, and
- Does not achieve its primary intended purposes through chemical action within or on the body and is not dependent upon being metabolized to achieve its primary intended purposes.

Drug: Substance recognized in the United States Pharmacopoeia, Homeopathic Pharmacopoeia of the United States, or National Formulary (or any supplement to any of these), and is an article:

- Intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease or intended to affect the structure or any function of the body (other than food), or
- Intended for use as a component of any substance described above.

Experiment: Any use of a drug except for the use of a marketed drug in the course of medical practice or any evaluation of the safety and efficacy of a medical device.

Human Subject: An individual who is or becomes a participant in research, either as a recipient of a test article or as a control. A subject may be either a healthy human or a patient. For research that involves medical devices, a human subject also includes an individual on whose specimen an investigational device is used. *Note: See the DHHS definition of human subject for DHHS-regulated research.*

Test Article: Any drug (including a biological product) or medical device for human use, human food (including dietary supplements), food or color additive, infant formula, electronic product, or any other article subject to regulation by FDA.

4. Scope of Research Subject to the HRPP

A. The requirements of the Human Research Protection Program apply to research involving human subjects that is either of the following:

- ***Research*** that involves ***human subjects*** as defined by DHHS regulations
- ***Research (clinical investigation)*** that involves ***human subjects*** as defined by FDA regulations.

B. The HRPP is responsible for research activities involving human subjects when:

- Research is sponsored by The Ohio State University
- Research is conducted by or under the direction of any employee, staff, or agent of the university in accordance with university policy [Principal Investigator Status Appointments]
- Research is performed at university-approved performance sites in accordance with HRPP policy [Research Performance Sites and Collaborative Off-Site Research]
- Private information owned by the university is used for research or to identify or contact prospective participants, if Ohio State is engaged in the research.

C. All research involving human subjects under the jurisdiction of the HRPP will be reviewed by an Ohio State IRB, unless either:

- The research is determined to be exempt in accordance with HRPP policy [Exempt Research]

- The research is covered by a cooperative agreement (or other similar agreement) in which another appropriate IRB has agreed to serve as the IRB of record.

5. Human Subjects Research Determinations

A. Individuals seeking guidance about whether their intended activities are defined as human subjects research subject to the requirements of the HRPP should contact the Office of Responsible Research Practices (ORRP) staff for assistance. Investigators are asked to provide in writing (or electronically) sufficient information about the activity to determine whether it represents research involving human subjects.

B. When describing the proposed activity, the following information should be provided, as applicable:

- A brief description of the proposed activity and the potential participants to be involved
- The type of data/information to be collected and the process by which it will be collected
- An explanation of how the information and/or results of the proposed activity will be used; the description should include whether the results of the activity are to be published, presented, or shared outside the group involved in or supporting the work, now or at any time in the future (including thesis or dissertation projects)
- Whether the activity will involve access to data/specimens from established records, databases, or biological repositories; and if so, the source(s) of the data/specimens and whether these sources are privately held or publicly available.

C. Determinations about whether an activity constitutes research involving human subjects are made by designated ORRP staff who have no direct involvement in the proposed activity. ORRP staff may request additional information from investigators, as necessary, to ensure that there is sufficient information to make a determination about whether the activity is defined as research involving human subjects.

D. ORRP staff will assess whether the submission is subject to review and oversight by an Ohio State IRB in accordance with university policy as defined above. In making these determinations ORRP staff may consult the appropriate IRB Chair or other available reference (e.g., OHRP "Human Subject Regulations Decision Charts") for further guidance. ORRP staff will make one of the following determinations:

- The proposed activity is ***NOT*** research involving human subjects and may be conducted without IRB review or exemption
- The activity ***IS*** research involving human subjects and, before performed, must be submitted for IRB review or exemption.

E. Investigators will be notified in writing (or electronically) of the determination. Up to one week may be required for processing requests. Submission of the appropriate application and additional time will be required for IRB review or exempt determination for activities determined to be research involving human subjects.

6. Record Retention

Records of determinations about whether an activity is research involving human subjects, including materials submitted and related correspondence, are retained by the Office of Responsible Research Practices in accordance with HRPP policy [IRB Recordkeeping].

7. Applicable Regulations/Guidance

21 CFR 56.102, 21 CFR 312.3, 21 CFR 812.3, 45 CFR 46.102, OHRP "Human Subject Regulations Decision Charts" (02/16/16)

8. History

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Table 1.

Below is a list of activities that may (or may not) constitute research involving human subjects. The table is intended to provide examples and is not a definitive determination of whether a specific activity requires IRB review or exemption. For project-specific determinations, contact the Office of Responsible Research Practices.

Activity	Research Involving Human Subjects?
Scholarly or Scientific	
Intent to Publish – Activities that obtain data about individuals, systematically performed with the intent to generalize findings and to publish or present the results (regardless of eventual publication or presentation)	**Yes**
Pilot Studies – Development of research, including activities involving individuals that are performed to refine a data collection or study methodology	**Yes**
Viewing Identifiable Private Information – Identification of potential participants for a study or use of living individuals' data for research purposes, whether or not the data will be recorded in an identifiable manner	**Yes**
Coded Data – Study or use of data that cannot be readily associated with the living individual about whom the information relates	**No**, with some exceptions. Contact ORRP for assistance.
Deceased Individuals – Study of or use of data relating to individuals no longer living, when data do not also apply to living relatives	**No**, but there may be other requirements. Contact ORRP for assistance.
Quality Improvement – Activities involving individuals intended solely for internal use, performed to improve services or develop new services or programs, (e.g., satisfaction surveys) without plans for presentation or publication; audits (internal or external) performed as a part of organizational operations	**No**
Data Banking – Collection and storage of private information, if the data may be used in the future for research purposes, whether or not the data will be recorded in an identifiable manner	**Yes**
Social Science, Behavioral, Educational	
Survey, Interview, Observation – Collection of individuals' data using surveys, interviews, or observation with the intent to generalize findings	**Yes**
Audio- or Videotaping – Taping individuals for study in situations not normally expected to be recorded or when individuals can be identified from recordings	**Yes**
Honors or Master's Thesis or Doctoral Dissertation – Directed or independent activities involving individuals performed in support of or as part of a degree-granting program	**Yes**

Course-Related Activities – Classroom exercises or assignments that do not include medical procedures, when the purpose of the activity is to teach research methods or techniques, replicate accepted findings or provide research simulation, if data are used solely within the class and participants are informed of the instructional exercise	**No**
Biography or Oral History – Data reported as provided to document a specific event or experiences of individuals without broader conclusions by the reporter	**No**, except in certain situations. Contact ORRP for assistance.
Studies of Institutions, Policies, or Processes – Collection or analysis of data on "things," rather than information collected from individuals about themselves, their opinions, or attitudes	**No**
Ethnographic Research – Interactions with a group in a natural setting to create a broader understanding of that group or population	**Yes**
Internet Survey Research – Online collection of individuals' data with the intent to generalize findings	**Yes**
Medical or Biomedical	
Practice of Medicine – Standard diagnostic or therapeutic procedures performed for treatment purposes to benefit an individual, with or without associated research activities	**No**
Additional Procedures – Standard diagnostic or therapeutic procedures that would not otherwise be performed if not for the research (e.g., additional x-rays or blood draws)	**Yes**
Changes in Procedures – Alterations in patient care (including randomization between standard acceptable treatments) with the intent to generalize the results	**Yes**
Innovative Treatment – Changes in patient care or use of an innovative treatment (except for investigational use of drugs or devices) solely for clinical purposes and intended to benefit an individual	**No**
Clinical Investigation – Use of drugs or devices, except approved products used in the practice of medicine, including use of a human specimen with FDA-regulated devices	**Yes**
Retrospective Record Review – Review of existing personally identifiable records, including collection of historical controls for FDA-regulated studies, whether or not the data will be recorded in an identifiable manner	**Yes**
One or Two Case Reports – Description of clinical features and/or outcome of case(s) without additional evaluation, analysis, or review of others for comparison	**No** Note: Journals may have additional requirements.
Three or More Case Reports – Descriptions of clinical features and/or outcome of multiple cases, with or without additional evaluation; or fewer case reports	**Yes** (see also above)

requiring additional evaluation, analysis, or comparison	
Remnant Specimens – Collection or study of specimens generated from routine clinical procedures that would otherwise have been discarded	**Yes**
Emergency Use – Use of investigational drugs or devices in life-threatening situations	**Yes**, and specific requirements apply. Contact ORRP for assistance.
Specimen Banking – Collection and storage of human fluids or tissue regardless of whether individual identifiers are retained	**Yes**