



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-002-1	5/26/2021	HSO	HRPP Policy Committee	Page 1 of 6

## 1. PURPOSE

- 1.1. This policy explains how to the Human Research Protection Program (HRPP) differentiates between projects that are research involving human participants and those that are not. The Human Research Protection Program (HRPP) recognizes that the definitions of research and human subject are broad and it can be difficult to determine what research involving human participants is. This policy provides examples of projects and an assessment if they are research involving human participants.

## 2. DEFINITIONS

- 2.1. **Research (DHHS and HIPAA):** A systematic investigation including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge (45 CFR 46.102(l) and 45 CFR 164.501.)
- 2.2. **Human Subject (DHHS):** a living individual about whom an investigator (whether professional or student) conducting research: (i) Obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (ii) Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens. (45 CFR 46.102(e).)
- 2.3. **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.
- 2.4. **Clinical trial:** a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes (45 CFR 46.102(b).)
- 2.5. **Clinical Investigation (FDA):** The FDA has defined *clinical investigation* to be synonymous with *research, clinical research, clinical study, and study*. Any experiment that involves a test article (i.e., drug, medical device, food substance, biological product, or electronic product for human use), one or more human subjects, meets requirements for prior submission to FDA, or 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 56.102].
- 2.6. **Human Subject (FDA):** 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 individual or a patient [21 CFR 56.102(e)]. In addition, a human subject includes an individual on whose tissue specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR



<b>Number:</b>	<b>Date:</b>	<b>Author:</b>	<b>Approved By:</b>	<b>Page(s):</b>
UGAHRP-002-1	5/26/2021	HSO	HRPP Policy Committee	Page 2 of 6

812.3(p)].

- 2.7. **Systematic Investigation:** A predetermined and organized method of data collection, intervention and interaction, and/or analysis to study a specific topic, answer a specific question, test a hypothesis, or develop a theory. It is usually described in a formal protocol that sets forth an objective and a set of procedures to reach that objective.
- 2.8. **Generalizable knowledge:** Information that will expand the knowledge base of a scientific discipline or other scholarly field of study and can be expressed in theories, principles, and statements of relationships; Results that can be generalized to a larger population beyond the site of data collection or participants studied; or Results that may be replicated or transferrable to other settings.
- 2.9. **Secondary research:** research use of information or biospecimens originally collected for non-research purposes or for research studies other than the currently proposed one.
- 2.10. **Experimental subject:** An activity, for research purposes, where there is an intervention or interaction with a living individual for the primary purpose of obtaining data regarding the effect of the intervention or interaction [DoD Directive 3216.02.]

### 3. POLICY

- 3.1. A determination that a project is not research involving human participants must consider relevant regulations, laws, codes, and guidance and should be made by an individual with authority to represent the UGA HRPP and who has no direct involvement in the project being evaluated. The Human Subjects Office (HSO) Director, IRB Chairperson, or assigned designee familiar with regulations, UGA HRPP policy, and the nature of research make such determinations for UGA.
- 3.2. When activities are conducted or supported by the Department of Defense (DoD) they are evaluated according to DoD 5240.01, DoD 6025.13, DoD 6200.02, and 10 USC (see WORKSHEET 310.)
- 3.3. When activities are conducted or supported by the Department of Justice, they are evaluated according to 28 CFR 46.102 (see WORKSHEET 310.)
- 3.4. Graduate students must request a formal determination letter for any thesis or dissertation projects that may not be considered *research involving human participants*.
- 3.5. A project must meet either the definition of *research* (DHHS regulations) or *clinical investigation* (FDA regulations) and involve human subjects in order to be considered *research involving human participants*. All research involving human participants conducted by agents of UGA requires exempt determination or IRB approval before any activities may begin.
  - 3.5.1. **Examples of research involving human participants (this is not intended to be an all-inclusive list):**
    - 3.5.1.1. Clinical studies that utilize test subjects or their specimens for new devices,



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-002-1	5/26/2021	HSO	HRPP Policy Committee	Page 3 of 6

- products, drugs, or materials.
- 3.5.1.2. Research studies that collect data or specimens through intervention with individuals. Intervention may include physical procedures (e.g., drawing blood), or manipulation of a subject's environment (e.g., hot/cold stressors) even if these activities are conducted by collaborators at other institutions.
  - 3.5.1.3. Research studies that collect information about individuals through interaction such as surveys, interviews, questionnaires, and focus groups even if these activities are conducted by collaborators at other institutions.
  - 3.5.1.4. Secondary research studies using information or biological specimens linked to the participants by codes or other identifiers and the investigators has access to the identifier or code key.
  - 3.5.1.5. Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
  - 3.5.1.6. Studies that involve living individuals to evaluate environmental alterations, for example, weatherization options or habitat modifications to their living or working space, landscape design, or test chamber.
  - 3.5.1.7. Studies involving interaction or intervention with subjects that are designed to contribute to a field of study or theoretical knowledge.
  - 3.5.1.8. Pilot or feasibility projects that will be used to develop or evaluate research procedures or design for a research project that will involve human participants. For more information, see [HRP – 005 Pilot Activities](#).
- 3.6. When an activity does not meet either the definition of research or is research that does not involve human participants, exempt determination or IRB approval is not required.
- 3.6.1.Examples of projects that are not research or do not involve human participants (this is not intended to be an all-inclusive list):**
- 3.6.1.1. Data collection for internal departmental, school, or other University administrative purposes. Examples are teaching evaluations and customer service surveys.
  - 3.6.1.2. Benchmarking (measurement of an organization's policies, products, etc. and comparison with similar measurements of peer organizations) where the objectives are to analyze peer organizations' practices, determine whether improvements are necessary, and use this information to improve performance.
  - 3.6.1.3. Service surveys issued or completed by University personnel for the intent and purposes of improving services and programs of the University or its clients or for developing new services or programs for students, employees, or alumni. *Note: If at a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, exempt determination or IRB approval is required before the data may be used for the new project (See Secondary research in 3.5.1.4)*
  - 3.6.1.4. Information-gathering interviews where questions focus on practice, products, or
-



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-002-1	5/26/2021	HSO	HRPP Policy Committee	Page 4 of 6

policies. Examples include canvassing librarians about their libraries' inter-library loan policies or periodical purchases, or interviews with company engineers or managers about how a product is made.

- 3.6.1.5. Course-related activities designed specifically for educational or teaching purposes, where data are collected as part of a class exercise or course requirement. For more information, see [Guidance on Class Projects](#).
  - 3.6.1.6. Secondary Research involving only commercially available, de-identified cell lines or biological materials.
  - 3.6.1.7. Research involving cadavers, autopsy material or biospecimens from now deceased individuals. *Note: Some research in this category, such as use of protected health information and genetic studies involving the collection of information about living relatives, may need IRB review.*
  - 3.6.1.8. Innovative clinical practice is an intervention designed solely to enhance the well-being of an individual patient or client. The purpose of an innovative clinical practice is to provide diagnosis, preventative treatment, or therapy to individuals., even when the intervention or therapy is experimental. *Note: When innovative practice differs significantly from routine practice, appropriate safeguards must be in place to protect the rights and welfare of the patients, even when IRB oversight is not required.*
  - 3.6.1.9. Quality assurance or improvement projects and program evaluations without corresponding research questions or hypotheses or basis for inquiry in theoretical framework. Data are used internally and there are significant threats to external validity that will not be addressed by design. *NOTE: If a project involves introducing an untested clinical intervention for purposes which include not only improving the quality of care but also collecting information about patient outcomes for the purpose of establishing scientific evidence to determine how well the intervention achieves its intended results, that quality improvement project is also research involving human participants under the HHS regulations.*
  - 3.6.1.10. Case history or case study which is published and/or presented at national or regional meetings is not considered research if the case is limited to a description of the specific features/outcome of the case and do not contribute to generalizable knowledge.
  - 3.6.1.11. Research involving publicly available datasets or information. Examples: Inter-University Consortium for Political and Social Research (ICPSR), U.S Bureau of the Census, National Center for Health Statistics, National Center for Educational Statistics, U.S. Bureau of Labor Statistics, National Election Studies, National Crime Victimization Survey: School Crime Supplement, 2003, National Epidemiologic Survey on Alcohol and Related Conditions (NESARC), National Survey of America's Families (NSAF), PRAMS, Twitter feeds (tweets), Instagram. *Note: Investigators should contact the IRB if they are uncertain as to whether the data qualifies as*
-



Number:	Date:	Author:	Approved By:	Page(s):
UGAHRP-002-1	5/26/2021	HSO	HRPP Policy Committee	Page 5 of 6

*“publicly available.”*

- 3.6.1.12. Secondary research involving data or biological specimens that were not collected specifically for the currently proposed project and are labelled with a unique number or code that cannot be linked back to the participant by anyone.
- 3.6.1.13. Scholarly and journalistic activities (e.g., oral history, journalism, biography, literary criticism, legal research, and historical scholarship), including the collection and use of information, that focus directly on the specific individuals about whom the information is collected.
- 3.6.1.14. Public health surveillance activities, including the collection and testing of information or biospecimens, conducted, supported, requested, ordered, required, or authorized by a public health authority. Such activities are limited to those necessary to allow a public health authority to identify, monitor, assess, or investigate potential public health signals, onsets of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in diseases, or increases in injuries from using consumer products). Such activities include those associated with providing timely situational awareness and priority setting during the course of an event or crisis that threatens public health (including natural or man-made disasters).
- 3.6.1.15. Collection and analysis of information, biospecimens, or records by or for a criminal justice agency for activities authorized by law or court order solely for criminal justice or criminal investigative purposes.
- 3.6.1.16. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
- 3.6.1.17. When following DOJ requirements, research conducted within the Bureau of Prisons: Implementation of Bureau programmatic or operational initiatives made through pilot projects is not considered to be research per 28 CFR 512.10..
- 3.7. Requests pertaining to determination of human research must be made via the IRB Portal.
- 3.8. For projects that are not research involving human participants, investigators may propose to utilize a consent form or letter; however, no references to the project/ activity as “research” or IRB oversight should be included.
- 3.9. Follow adequate, discipline-appropriate guidelines to ensure that projects not subject to IRB review/oversight are conducted in a responsible, professional, and ethical manner (e.g., protect the privacy of the participants, maintain the confidentiality of individual responses.)  
*Note: There may be federal, state, local, or institutional laws and policies that may need to be considered even if the federal regulations for human research protections do not apply (e.g., FERPA, HIPAA.)*

#### 4. PROCEDURES: Investigators

---



## Determination of Human Research

<b>Number:</b>	<b>Date:</b>	<b>Author:</b>	<b>Approved By:</b>	<b>Page(s):</b>
UGAHRP-002-1	5/26/2021	HSO	HRPP Policy Committee	Page 6 of 6

- 4.1. Make an initial determination that the project is not research or does not involve human participants in response to IRB portal questions.
- 4.2. Describe the project in sufficient detail and provide adequate documentation including any data collection instruments that will be used (such as surveys or interview questions if there will be interactions with living individuals).
  - 4.2.1. If the project is secondary research, identify the source of data/biological specimens.
- 4.3. Maintain project records (e.g., correspondence, initial application, determinations) in accordance with the applicable record-keeping requirements.

### 5. PROCEDURES: HRPP Staff

- 5.1. If a project was submitted as research involving human participants, IRB staff must make an initial determination if the project meets criteria to be considered as such. Submissions that do not meet criteria to be considered research involving human participants will be assigned to the HSO Director or designee for determination.
- 5.2. The HSO Director or designee will utilize this policy, federal regulations and guidance, and supporting review materials (e.g., worksheets) to determine if the submission is research involving human participants.
- 5.3. A determination letter will be provided to the investigator indicating that the submission is not research involving human participants or, if the submission is research involving human participants, the investigator will be notified and additional information or changes requested to prepare the submission for exempt determination or IRB review.

### 6. MATERIALS

- 6.1. Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS) Decision Chart 01: Is an Activity Human Subjects Research Covered by 45 CFR Part 46?
- 6.2. Decision Tree - Research Involving Private Information or Biological Specimens
- 6.3. WORKSHEET – 310 – Human Research Determination
- 6.4. Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS) Guidance on Research Involving Coded Private Information or Biological Specimens
- 6.5. Template Letter – 513 – Not Human Research Determination
- 6.6. Guidance on Class Projects
- 6.7. Guidance on Pilot Activities

#### Revision History:

02/20/2015: REV0 New Document

05/26/2021: REV1