1. PURPOSE
This policy informs University of Georgia investigators on which activities may meet the definitions of human subjects research. Activities that are not human subjects research do not fall under the purview of the UGA IRB. The Institutional Review Board (IRB) recognizes that these definitions are broad and it can be difficult to determine what constitutes human subjects research. This policy, therefore, offers investigators examples of studies that typically do or do not qualify as human subjects research.

2. DEFINITIONS
2.1. Research (DHHS): a systematic investigation designed to develop or contribute to generalizable knowledge [45 CFR 46.102(d)].

2.2. Human Subject (DHHS): a living individual about whom an investigator conducting research obtains: (1) data through intervention or interaction with the individual or (2) identifiable private information [45 CFR 46.102(f)].

2.3. Clinical Investigation (FDA): the FDA has defined clinical investigation to be synonymous with research. 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].

2.4. 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 specimen an investigational device or control is used, even if the specimen is anonymous [21 CFR 812.3(p)].

2.5. Systematic Investigation: a systematic investigation is usually recognized by the fact that there is a predetermined and organized method [of data collection and 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.

2.6. Generalizable knowledge: to be considered “generalizable knowledge,” the activity includes one or more of the following:

- Information will expand the knowledge base of a scientific discipline or other scholarly field of study;
- Results are expected to be generalized to a larger population beyond the site of data collection or population studied; or
- Results are intended to be replicated in other settings.
Note: For Department of Defense-supported research, institutional oversight of the activity follows the definitions of “research” and “experimental subject” as defined by Department of Defense regulations [DoD Directive 3216.02].

3. POLICY

3.1. Only those activities that meet the definitions of research and human subject under the DHHS regulations and/or those that meet the definitions of clinical investigation and human subject under the FDA regulations will be considered human subjects research. All human subjects research that will be conducted under the auspices of UGA will require prior review and approval by the UGA IRB or one of the IRBs relied upon by UGA.

3.1.1. Examples of Human Subject Research (this is not intended to be an all-inclusive list):

- Clinical studies that utilize test subjects or their specimens for new devices, products, drugs, or materials.
- Research studies that collect data through intervention or interaction with individuals. Interaction may include surveys, interviews, questionnaires, and focus groups. Intervention may include physical procedures (e.g., drawing blood), or manipulation of a subject’s environment (e.g., hot/cold stressors).
- Research studies using private information or biological specimens where the investigators can readily ascertain the identity of the individuals to whom the information/specimens pertain, even if the information/specimens were not collected specifically for the currently proposed project.
- Studies that produce generalizable knowledge about categories or classes of subjects from individually identifiable information.
- 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.
- Pilot or feasibility projects that will be used to develop or evaluate research procedures or design for a project that will involve human subjects.

3.2. When an activity does not meet both definitions of research and human subjects, it is not considered human subjects research and no IRB review/approval is required.

3.2.1. Examples of Not Human Subjects Research (this is not intended to be an all-inclusive list):

- Observational studies of public behavior (including television and open internet chat rooms) do not involve human subjects if there is no intervention or interaction with the subjects, the behavior is not private, or there is no manipulation of the environment in order to stimulate certain types of behavior.
- Data collection for internal departmental, school, or other University administrative purposes. Examples are teaching evaluations and customer service surveys.
- 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.
- 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 a future date, an opportunity arose to contribute previously collected identifiable or coded survey data to a new study producing generalizable knowledge, IRB review may be required before the data could be released to the new project.
• Information-gathering interviews where questions focus on things, products, or policies rather than on peoples’ own personal thoughts, perceptions, feelings or ideas. 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.

• 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 IRB Guidance on Class Projects, https://research.uga.edu/docs/policies/compliance/hs/hs/Guidance-Class-Projects.pdf.

• Biographical research involving a living individual that is not generalizable beyond that individual.

• Research involving only commercially available, de-identified cell lines or biological materials.

• 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.

• Innovative therapies except when they involve "research" as defined by the above criteria. (An 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 particular individuals, or when the innovative therapy is investigational.) Note: When innovative therapies differ significantly from routine practice, it should be viewed and treated as such with appropriate safeguards in place to protect the rights and welfare of the patients.

Quality assurance or improvement projects and program evaluations are generally not considered research unless there is a clear intent to contribute to generalizable knowledge. If the data are re-examined or re-analyzed and new information surfaces that would contribute to generalizable knowledge, an application must be submitted to the IRB. See OHRP’s Quality Improvement Activities FAQs at https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/quality-improvement-activities/index.html. 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 may also constitute nonexempt human subjects research under the HHS regulations.

• 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.

• 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 “publicly available.”
• Research involving only analysis of data or biological specimens that are not individually-identifiable and were not collected specifically for the currently proposed project
• Oral histories which are NOT intended to draw conclusions, inform policy or generalize findings and for which the sole purpose is to create a historical record of specific personal events and experiences and provide a venue for people to tell their stories (See P&P – Oral History).

4. Authorization to Make Determinations
4.1. Each activity undertaken on behalf of UGA must be evaluated by the individual most familiar with the planning and development of the activity. Therefore, it is the responsibility of researchers to make appropriate determinations based on this policy. When an individual makes a self-determination that an activity does not constitute human research, the UGA IRB recommends that the individual document in writing how the determination was made and retain this with his/her study records.
4.2. The IRB has the authority to over-rule an investigator’s self-determination or the determination of other institutions or funding agencies. The UGA IRB determination that a planned activity is human subjects research will override an external determination unless the external determination is from the applicable human subjects regulatory agency.
4.3. If a determination cannot be made, the investigator must submit the activity/project to the IRB for determination. IRB members are the only UGA individuals authorized to make a formal determination that an activity is human subjects research or not.

5. Thesis or Dissertation Projects
5.1. Thesis and dissertation projects are usually conducted to develop or contribute to generalizable knowledge and, therefore, meet the definition of research. If these projects involve human subjects, IRB review and approval will be required.
5.2. Examples of theses and dissertations that involve interaction with human subjects but are not considered research are oral history projects, journalistic reporting, and biographical sketches.
5.3. Examples of theses and dissertations that are considered research but do not involve human subjects are interviews where questions focus on things, products, or policies rather than on peoples’ own personal thoughts, perceptions, feelings or ideas (see 3.2.1. above).
5.4. Graduate students must request a formal determination letter from the IRB for any thesis or dissertation projects that may not meet the definition of human subject or research or both.

6. PROCEDURE: Researchers
6.1. A researcher submits a request for determination through the IRB’s electronic application system.
6.1.1. The investigator will make certain assurances regarding the design and purpose of the proposed project.
6.1.2. The request should describe the activity in sufficient detail and provide adequate documentation for the IRB to make a determination including any data collection instruments that will be used (such as surveys or interview questions if there will be interactions with living individuals).
6.2. Follow adequate, discipline-appropriate guidelines in place to assure 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.

6.3. If a project is not human subjects research, and the investigator proposes to utilize a consent form for the study, no references to the project/activity as “research” or IRB oversight should be included.

6.4. The project records (e.g., correspondence, initial application, determinations) will be maintained appropriately in accordance with the applicable record-keeping requirements (see https://spguide.uga.edu/2017/04/20/record-retention/ for UGA’s record retention rules).

6.5. When funding agencies, administrators, or collaborators require documentation that the activity is not human subjects research, the investigator must submit the grant/project to the IRB for determination and obtain formal documentation.

7. PROCEDURES: Institutional Review Board

7.1. The IRB staff reviews the submission and makes the final determination if the submission meets the federal definition of human subjects research.

7.2. A determination letter will be provided to the researcher.

8. MATERIALS


8.2. Data/Specimen Decision Tree (Appendix A)

8.3. Office for Human Research Protections (OHRP) Department of Health and Human Services (HHS) Guidance on Research Involving Coded Private Information or Biological Specimens

9. REFERENCES

Research Involving Private Information or Biological Specimens

Are the specimens/data obtained* from living individuals?

NO; individuals are deceased.

Not human subjects research (NHSR); no IRB review needed.

YES; individuals are living.

Are the specimens/data?
- Human cell lines obtained from a commercial provider (e.g., ATCC);
- Human cells about which all information has been published; or
- Unidentifiable specimens/data obtained from a commercial provider; or
- Unidentifiable specimens/data obtained from a provider that is prohibited from releasing identifiers by established regulations or policies.

Were/Will the specimens/data (be) collected specifically for the proposed research through an interaction or intervention with living individuals?

NO

NHSR; no IRB review needed.

YES

Can the recipient link the specimens/data directly to identifiable living individuals?

CAN

Human subjects research (HSR); IRB review needed.

NO

Can the provider link the specimens/data, directly or indirectly, to identifiable living individuals?

NO

NHSR; no IRB review needed.

YES

Does the provider meet the definition of an "investigator" (by collaborating) in the recipient’s research?

NO; provider is solely providing.

YES; provider is collaborating** in recipient’s research.

Are the specimens/data provided with a code linking them to identifiable living individuals?

NO

NHSR; no IRB review needed.

YES

Can the recipient readily ascertain the identities of the individuals to whom the specimens/data pertain? Examples of firewall where the recipient cannot link the specimens/data to living individuals include:
- the key to decipher the code is destroyed before the research begins; or
- the investigators and the holder of the key to the code enter into an agreement preventing the release of the key to investigators under any circumstances; or
- there are IRB-approved written policies in place preventing the release of the key under any circumstances; or
- there are other legal requirements prohibiting the release of the key under any circumstances.

NO

NHSR; no IRB review needed.

YES

HSR; IRB review needed.

*Obtaining (per OHRP) means receiving or accessing identifiable private information or identifiable specimens for research purposes. This includes an investigator’s use, study, or analysis for research purposes of identifiable private information or identifiable specimens from any source or already in the possession of the investigator.

**Collaborating activities include, but are not limited to, (1) the study, interpretation, or analysis of the data resulting from the coded information or specimens; and (2) authorship of presentations or manuscripts related to the research.

Reference: NIH/OER