UPDATES TO FEDERAL GUIDELINES FOR PROTECTION OF HUMAN SUBJECTS IN RESEARCH

Relevant Change #1: Updates to the definition of "research" and "human subject" including identifying some specific activities that are NOT research per this definition.

"*Research*" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. … For purposes of this part, the following activities are deemed NOT to be research:

(1) **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

(2) **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) 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**.

(4) Authorized operational activities (as determined by each agency) in support of intelligence, **homeland security**, defense, or other national security missions.

"*Human subject*" means 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.

GC Impact Summary: Some investigations are research by all other accounts, but still do not qualify as research per the federal definition, thus placing them outside the purview of the GC IRB. If you have any questions about this, please email irb@gcsu.edu for clarification.

Relevant Change #2: Updates and revisions to the categories of research that qualify for exempt status.

Category 1 – normal educational practices

Research involving normal educational practices that are not likely to adversely impact students' opportunity to learn required education content or the assessment of educators who provide instruction.

Category 2 – low-risk and/or anonymous data and procedures

Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) when:

(i) Information recorded cannot be readily linked back to subjects, OR
(ii) Any information disclosure would place subjects at risk of harm; OR
(iii) Identifiable information is recorded, but IRB provides limited review for privacy and confidentiality protection

Category 3 – benign behavioral interventions

Research involving benign behavioral interventions (i.e., brief in duration; not likely to have adverse impact physically or psychologically) with the collection of information –verbal or written (including data entry) or audiovisual recording – from adults who prospectively agree when:

(i) information recorded cannot be readily linked back to subjects, OR,
(ii) any information disclosure would not place subjects at risk of harm, OR
(iii) identifiable information is recorded, but IRB provides limited review for privacy and confidentiality protection

In addition, if the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject is informed that they may be unaware of or misled about the nature of the research.

**If you are claiming exempt status under category 3, you MUST explain your justification in the "problem statement" in the exempt checklist in your application, including how your intervention is "benign" and your use of deception (if applicable).*

Note: If your research **involves children** in survey procedures, interview procedures, or observation of public behavior AND the investigator(s) participate in the activities being observed, you **DO NOT qualify for exempt status**.

Category 4 – secondary research

Secondary research use of identifiable private information or identifiable biospecimens for which consent is not required, if:

(i) Identifiable private information or identifiable biospecimens are publicly available; OR
(ii) Information is recorded in an unidentifiable manner, OR
(iii) Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health," OR
(iv) Research is conducted by, or on behalf of, a Federal department or agency using information collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards.

Category 5 – public benefit or service

Research and demonstration projects that are conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads, which are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including:

(i) procedures for obtaining benefits or services under those programs,
(ii) possible changes in or alternatives to those programs or procedures, or
(iii) possible changes in methods or levels of payment for benefits or services under those programs.

Category 6 – taste and food quality studies

Taste and food quality evaluation and consumer acceptance studies:

(i) If wholesome foods without additives are consumed, OR
(ii) If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Category 7 and Category 8 involve secondary research, storage, and maintenance of biospecimens which require broad consent and/or limited IRB review. If you feel your project qualifies for exempt status under category 7 or category 8 (see "exempt updates" document on Portal), please email irb@gcsu.edu for further guidance.

GC Impact Summary: More investigations for GC researchers are likely to qualify for exempt status than previously. If you have any questions about this, please email irb@gcsu.edu for clarification.