

What Research Needs to be Reviewed by the IRB

Generally, all “research” (as defined by the Code of Federal Regulations) involving human participants conducted by Huston-Tillotson University faculty, students, or staff must be reviewed by the IRB before data collection can begin. IRB approval cannot be given retroactively.

The Code of Federal Regulations (CFR) defines research as: “A *systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.*” Therefore, if the proposed study is not designed to develop or contribute to generalizable knowledge, then it is not subject to IRB review.

The revisions to the Common Rule, effective January 21, 2019, further specify activities that are not considered “research” under the CFR guidelines and are not subject to IRB review. These include the following:

- (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.
- (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.

Examples of projects that involve collection of data from human subjects but that do not meet the CFR definition of research and, thus, do not require IRB review include the following:

- Data collected by students or faculty for the sole purpose of a class assignment or teaching exercise.
- Data collected for the sole purpose of understanding Huston-Tillotson University’s students, their needs, or effectiveness of Huston-Tillotson University’s services.
- Data collected for the sole purpose of branding or marketing the College.

In all the above cases, the data are not intended to produce generalizable knowledge.

The CFR defines a *human subject* as “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.” *Intervention*, according to the CFR, “includes both physical procedures by which information or biospecimens are gathered (*e.g.*, venipuncture) and manipulations of the subject or the subject’s environment that are performed for research purposes.” Accordingly, if a researcher is analyzing de-identified secondary data for which they (and no member of their research team) can possibly make a link to identifiable information with the data in their possession, then it is not research with “human subjects” and not subject to IRB review.

Please note, IRB approval cannot be given retroactively, so data originally collected for non-research purposes (as defined by the CFR) cannot subsequently be approved to be used for research purposes. Accordingly, if one thinks that data involving human subjects may at some time be used for generalizable research—for example, as evidence in a report, publication, or presentation to analyze the effectiveness of utilizing a particular pedagogical approach or to describe the behavior of college students more broadly—then IRB approval should be sought **prior** to data collection with this potentiality clearly noted.

If you have any questions about whether your proposed study is research and/or involves human subjects, contact the Chair of IRB at cmcervantes@htu.edu.

Projects that do not meet the federal definition of research as outlined in the CFR should still heed ethical and disciplinary standards in collecting data from human subjects.