Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 201.1	TITLE: Human Subjects Determination	Date Effective: 07/01/2021 Last Revision Date: 06/30/2021

I. Purpose

This procedure sets forth the process for determining whether the scope of a project meets the definition of human subjects research.

II. Definitions

The Common Rule/Department of Health and Human Services (HHS) (45 CFR § 46.102)

Biospecimen is a sample of material, such as urine, blood, tissue, cells, DNA, RNA, and protein from a human.

Human Subject means a living individual about whom an investigator conducting research:

1. Obtains information or biospecimens through intervention or interaction with the individual and uses, studies, or analyzes the information or biospecimens; OR
2. Obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

Identifiable biospecimen is a biospecimen where the identity of the subject is associated with the biospecimen or where the identity of the subject may readily be ascertained by the investigator.

Identifiable private information is private information where the identity of the subject is associated with the information or where the identity of the subject may readily be ascertained by the investigator.

Interaction includes communication or interpersonal contact between investigator(s) and subject.

Intervention includes both physical procedures by which information or biospecimens are gathered and manipulation of the subject or the subject's environment that is performed for research purposes.

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, as well as information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public.

Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

The following activities are deemed not 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 focuses directly on the specific individuals about whom the information is collected.

2. Public health surveillance activities, including the collection of information, the collection or testing of biospecimens – or both that is, 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.
5. Projects that involve human subjects but are conducted within a classroom, in order to achieve an educational learning objective, and where the results will not be shared or disseminated outside the classroom are not considered human subjects research. It is the responsibility of the faculty member overseeing these projects to use good ethical judgement to evaluate the appropriateness of these projects.

Food and Drug Administration (FDA)(21 CFR § 56.102)

If the research involves any of the following, FDA regulations 21 CFR §§ 50, 56 apply and require IRB approval prior to implementation:

- Any use of a drug in research other than the use of an FDA approved drug for standard medical practice;
- Any use of a medical device in studies where the purpose is to determine the safety or effectiveness of the device; OR
- Data will be submitted to or held for inspection by FDA as part of a marketing permit.

Clinical investigation means any experiment that involves a test article and one or more human subjects, and that either A) must meet the requirements for prior submission to the FDA under section 505(i) or 520(g) of the act, or B) need not meet the requirements for prior submission to the FDA under these sections of the act, but the results of that experiment 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.

The term "clinical investigation" does not include experiments that must meet the provisions of part 58, regarding nonclinical laboratory studies (21 CFR 56.102(c)). If the activities involve use of an FDA regulated test article (i.e. drug, device, food substance, or biologic under the purview of the FDA), WCU applies the FDA definition of "human subject."

Human Subject or "subject" means 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.

IV. Procedure

1. Investigators are responsible for assessing their own projects to determine whether they meet the definition of human subjects research. However, the IRB has the authority to overrule an investigator's self-determination.
2. Projects that do not meet the definition of human subjects research do not need be submitted to the IRB.
3. If an investigator is unsure as to whether their project meets the definition of human subjects research, they should consult with the IRB administrator, chair or other IRB representative informally by phone or email.

4. Investigators may request a formal letter determining a project is not human subjects research from the Office of Research Administration.
5. All projects that meet the definition of human subjects research must be submitted to the IRB, including collaborative project that may have also undergone review at another institution.

V. Responsibilities

IRB administrators, Investigators

VI. References

21 CFR 56.102
45 CFR 46.102