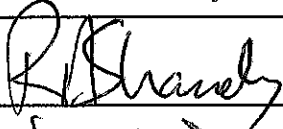
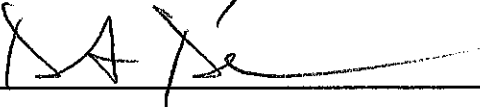


Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #1 Rev. 2	Determination of Activities that Constitute Human Subjects Research	Date Effective: 07/06/2022
Approved by IRB Chair		Date 7-6-2022
Approved by RP Director		Date 7-5-22

I. PURPOSE

To describe procedures for determining whether a project qualifies as human subjects research.

II. AUTHORITY

In accordance with federal regulations and ASU Policy 209, all research involving human subjects conducted by an agent of the University must be reviewed to 45 CFR 46 and approved by the Institutional Review Board (IRB), or determined to be exempt from IRB review by Research Protections staff, before it is conducted.

III. RESPONSIBILITY

1. Research personnel are responsible for submitting an application for IRB review, exemption, or not human subjects research (NHSR) determination, and for ensuring that no research procedures with human subjects are conducted prior to IRB approval or exemption.
2. Research Protections (RP) staff is responsible for determining whether a proposed project constitutes human subject research and for communicating the determination with the Principal Investigator (PI). If RP staff is unable to make this determination, the IRB Chair or designee is responsible for determining whether a proposed project constitutes human subjects research.

IV. DEFINITIONS

1. *Research* (see 45 CFR 46.102(l)), means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research for the purpose of this policy, whether or not they are conducted or supported under a program that is considered research for other purposes. For example, some demonstration and service programs may include research activities. For the purposes of this part, the following activities are deemed not to be research:
 - i. 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.
 - ii. Public health surveillance activities, including the collection and testing of information and 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, onset of disease outbreaks, or conditions of public health importance (including trends, signals, risk factors, patterns in disease, 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).
- iii. 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.
 - iv. Authorized operational activities (as determined by each agency) in support of intelligence, homeland security, defense, or other national security missions.
2. *Human subject, or participant*, (see 45 CFR 46.102(e)(1)) 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 private identifiable information or identifiable biospecimens.
 3. *Intervention* (see 45 CFR 46.102(e)(2)) includes both physical procedures by which information or biospecimens are gathered and manipulations of the subject or the subject's environment that are performed for research purposes.
 4. *Interaction* (see 45 CFR 46.102(e)(3)) includes communication or interpersonal contact between investigator and subject.
 5. *Private information* (see 45 CFR 46.102(e)(4)) 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 that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
 6. *Identifiable private information* (see 45 CFR 46.102(e)(5)) is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
 7. *An identifiable biospecimen* (see 45 CFR 46.102(e)(6)) is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
 8. *Clinical trial* (see 45 CFR 46.102(b)) means a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
 9. *Non human subjects research (NHSR)* is a project that does not constitute research and/or does not involve human subjects, as defined above. NHSR projects do not require IRB review or exemption, as these projects do not include research procedures with human subjects.
 10. *Electronic research administration system (eRA system)* refers to the system RP staff uses to receive applications for IRB review and exemption. Requests to rely on an external

IRB and requests for formal NHSR determinations are also submitted using the eRA system. A link to the current eRA system can be found on the Research Protections website.

11. Agent of the University is any individual who: (1) acts on behalf of the institution; (2) exercises institutional authority or responsibility; or (3) performs institutionally designated activities.

V. PROCEDURES

1. Research personnel complete and submit a request for initial review in Appalachian State University's eRA system.
 - a. The initial request may be an IRB submission, request for exemption, or request for a NHSR determination.
 - b. The eRA system may require that the Principal Investigator (PI), Faculty Advisor (FA), and any co-investigator certify the application before it is fully submitted (i.e. before it can be received by RP staff).
2. Class projects and student projects where the main outcome of the project is to provide an educational experience or learning opportunity for the student(s) involved do not require IRB review or exemption unless the findings of the project may be used to develop or contribute to generalizable knowledge. The responsibility for conducting ethical oversight for NHSR student projects rests with the course instructor or faculty advisor.
3. RP staff, or the IRB chair or designee, makes the final determination as to whether a project constitutes human subjects research (and therefore requires IRB review or exemption) and communicates the decision with the study's PI.
4. Human subjects research procedures are not permitted to begin until the project has received IRB approval or an official exemption determination.

VI. SUPPORT PROCEDURES AND PROCESSES

SOP #2

VII. REFERENCES

45 CFR 46

ASU Policy 209