

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #1 Rev. 1	Determination of Activities that Need IRB Review	Date Effective: 1.21.2019
Approved by IRB Chair	<i>RAS</i>	Date 1/21/2019
Approved by RP Director	<i>Robin</i>	Date 1/21/2019

### **PURPOSE**

To describe policies and procedures for determining whether a project qualifies as human subject research and therefore requires prior Institutional Review Board (IRB) review and approval.

### **GENERAL DESCRIPTION**

In accordance with federal regulations and institutional policy, the IRB must approve all research involving human participants conducted by an agent of the University before it is conducted.

### *Definitions*

1. *Research* (see 45 CFR 46.102(I)), means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Activities that constitute 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* (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).
    - (5) *Identifiable private information* is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.
    - (6) *An identifiable biospecimen* is a biospecimen for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.
  6. *Clinical Trial* (see 45 CFR 46.102(b)) means a research study in which one or more participants who are prospectively assigned to one or more interventions (which may include placebo or control) to evaluate the effects of the intervention on biomedical or behavioral health-related outcomes.

For an activity to require IRB review, both the regulatory definition of “research” and “human subjects” must be met.

Projects that require FDA or EPA oversight, DoD projects, and NIH projects meeting the definition of a clinical trial require the application of additional regulations, including IRB review. Please contact Research Protections.

Student Research: The IRB supports the application of ethical principles and regulations for student projects, where they meet the definition of research per 45 CFR 46.102(1). Class projects that are not intended to contribute to generalizable knowledge do not require IRB review. Student research projects that are not designed to be generalizable (where the main outcome of the project is to provide an educational experience or learning opportunity for the student researchers) do not require IRB review. The responsibility for conducting ethical oversight for student projects rests with the faculty adviser or instructor.

### **RESPONSIBILITY**

Execution of SOP: Principal Investigator (PI)/Study Personnel, Research Protections (RP) Staff, IRB Chair.

### **PROCEDURES**

1. Each principal investigator (PI) is responsible for seeking IRB review and approval prior to initiation of any research involving participants or before conducting a clinical investigation.
2. PI completes and submits a request for initial review in IRBIS.
3. The Director of Research Protections, or the Chair of the IRB or their designees make the final determination as to whether scholarly activities meet the federal definition of research and of involving human subjects. If needed, the IRB or Research Protections may require the PI to complete a request for review (IRB application) in order to confirm whether the study needs review.
4. Research Protections communicates decision of Research Protections or IRB staff through IRBIS.

### **SUPPORT PROCEDURES AND PROCESSES**

SOP #2, Requesting IRB Review  
Guidance documentation for PIs