



Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #1 Revision #	TITLE: Determination of Activities That Need IRB Review	Date Effective: 4.3.2012 Revision Date:
Approved By: IRB Chair	Signature 	Date 4/3/2012
Approved By: RP Director	Signature 	Date 4/3/2012

## **PURPOSE**

To describe policies and procedures for determining whether a project qualifies as human subject research or a clinical investigation 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, prior to implementation, human subject research conducted by an Appalachian faculty, staff, student, or volunteer.

An activity that meets either the Department of Health and Human Services (DHHS) definitions of "research" and "human subjects"; or the Food and Drug Administration (FDA) definitions of "clinical investigation" and "human subjects" requires review and approval by the Appalachian IRB or a decision to rely on the review of another IRB.

### *Definitions*

#### *DHHS/Common Rule*

1. *Research*: A systematic investigation designed to develop or contribute to generalizable knowledge [45CFR 46.102(d)]. Activities which meet this definition constitute research, whether or not they are conducted or supported under a program which is considered research for other purposes. For example, some demonstration and service programs may include research activities. Some research development or testing and evaluation may also meet this definition.
2. *Human subjects (DHHS)*: A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.
3. *Intervention* includes both physical procedures by which data are gathered (for example, venipuncture) and manipulations of the subject or the subject's environment that are performed for research purposes.

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4. *Interaction* includes communication or interpersonal contact between investigator and subject.
5. *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, and information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). Private information must be individually identifiable (i.e., the identity of the subject is or may readily be ascertained by the investigator or associated with the information) in order for obtaining the information to constitute research involving human subjects.

*FDA*

1. *Clinical investigation*: Involves use of a test article (i.e., drug, device, food substance, or biologic), one or more human subjects, meets requirements for prior submission to the FDA (involves drugs or medical devices other than the use of FDA approved drugs or medical devices in the course of medical practice), or results are intended to be part of an application for research or a marketing permit.
2. *Human subjects (FDA)*: An individual who is or becomes a participant in research either as a recipient of a test article or as a control or as an individual on whose specimen a device is used. A subject may be either a healthy individual or a patient [21 CFR 56.102(e)] (Drug, Food, Biologic).
  - a. 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), Appalachian applies the FDA definitions of "human subjects."
3. *Human subjects (FDA for medical devices)*: A human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control. A subject may be in normal health or may have a medical condition or disease [21 CFR 812.3(p)] (Medical Devices). This definition includes the use of tissue specimens even if they are unidentified.

**RESPONSIBILITY**

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

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## **PROCEDURES**

1. Each investigator is responsible for seeking IRB review and approval prior to initiation of any research involving human subjects or before conducting any clinical investigation.
2. The investigator is responsible for making a preliminary decision regarding whether his/her activities meet either (a) the Department of Health and Human Services (DHHS) definitions of both "research" and "human subjects" or (b) the FDA definitions of both "clinical investigations" and "human subjects." (If the sponsor applies other regulations, these must be considered in the determination of whether the activity is human subject research.) The section listed below, "Determining Human Subject Research," may guide the investigator in making this decision.
3. The investigator may contact RP staff or the IRB Chair for an authoritative decision and/or advice on the application of the federal regulations and Appalachian policy for human subject research.
4. In cases where it is not clear whether the study requires IRB review, RP or the IRB may ask the investigator to send a memorandum to the IRB/RP by e-mail or hard copy detailing the proposed research. In complicated cases, RP or the IRB may ask the investigator to complete and submit an application to the IRB for a decision. The Director of RP or IRB Chair or their designees make the final determination whether the activities meet the federal definitions using the section below, "Determining Human Subject Research" as a guide. The IRB or RP may require the investigator to contact the applicable regulatory agency to assist in making the determination.
5. RP communicates the decision of the IRB or RP staff to the investigator via phone, e-mail, or hard copy.

## **DETERMINING HUMAN SUBJECT RESEARCH**

1. To be classified as research, a project must comprise a systematic investigation designed to develop or contribute to generalizable knowledge. This means that a project or study is research if it:
  - a. is conducted with the intention of drawing conclusions that have some general applicability and
  - b. utilizes a commonly accepted standard research methodology.
2. If a project meets the definition of research, the next step is to determine whether human subjects are involved. Human subjects are involved if the research obtains information about living individuals either by 1) an intervention or interaction with the individual or 2) accessing individually identifiable private information. (See flowchart <http://www.hhs.gov/ohrp/policy/checklists/decisioncharts.html#c1>)

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- a. The FDA definition of human subjects includes the use of tissue specimens even if they are unidentified.

*Examples*

The following types of projects generally meet the definition of research: master’s thesis or doctoral dissertation, epidemiological research, behavioral and social science research, pilot studies, retrospective medical reviews, research involving subject pools, and clinical research.

Quality Assurance and quality improvement projects that attempt to measure the effectiveness of programs and services may constitute human subject research if the purpose of the project is to contribute to generalizable knowledge. In cases where the project is limited to local improvement, any published materials should not refer to the project as “research”.

Class projects involving collection of data from human subjects may or may not meet the definition of research. Class projects conducted for instructional purposes that are not designed to contribute to generalizable knowledge do not meet the definition of “research”. Course instructors are responsible for making the decision whether the project meets the definition of “research”. For assistance, please contact RP staff.

The following types of projects generally do not meet the definition of research: a survey to evaluate the performance of faculty, staff and students for internal purposes; an oral history of a particular artist; and secondary analysis of publically available de-identified data, such as reviewing US census data.

**SUPPORT PROCEDURES AND PROCESSES**

Initial Review of Human Subject Research SOP

**REFERENCES**

- 21 CFR 56.102
- 45 CFR 46.102