

# Research Involving Human Subjects

Policy 209

## 1 Purpose

This policy provides authority to the Institutional Review Board (hereinafter "IRB") to provide ethical and regulatory oversight for research involving human subjects conducted by Appalachian State University, its faculty, staff, students and visitors.

## 2 Scope

This policy applies to all faculty, staff, students and any other individual engaged in research involving human subjects on the campus of the University, through funding provided by the University, on behalf of the University or in conjunction with University employees or students.

## 3 Definitions

### 3.1 Anonymity

Means that the identity of subjects cannot be matched to their responses either directly through identifiers or by "linked" or "coded" responses.

### 3.2 Confidentiality

Means not disclosing individually identifiable information received from a human subject to others in a manner inconsistent with the understanding of the original Informed Consent agreement.

### 3.3 Data Collection

Means any research procedure that is intended to elicit from or record the actions, reactions, attitudes, and/or behavioral manifestations of human subjects participating in a research project.

### 3.4 Exempt Research

Means human subject research activities which are minimal risk in nature and fall into one or more of the federally defined exempt research categories.

### 3.5 Expedited Review

Means a review by the IRB Chair or designee of research proposals which involve minimal risk or no-risk.

### 3.6 Full IRB Review

Means the review of proposals conducted during a convened IRB meeting at which a quorum has been established.

### 3.7 Human Subject

Means a living individual about whom a researcher (whether professional or student) conducting research that (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 bio-specimens.

### 3.8 Informed Consent

Means the voluntary agreement by an individual or an individual's legally authorized representative to participate in a particular study without any element of force, fraud, deceit, duress, or any other form of constraint or coercion. Valid consent requires voluntary action, competence, informed decision, and comprehension of terminology.

### 3.9 IRB

Means the University's institutional review board.

### **3.10 Minimal Risk**

Means that the probability and magnitude of harm(s) or discomfort(s) anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

### **3.11 Research**

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 purposes 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.

### **3.12 University**

Means Appalachian State University

### **3.13 Vulnerable Populations**

Means human subjects that are children, prisoners, pregnant persons, or any population that may be relatively or absolutely incapable of protecting their interests through the informed consent process.

## **4 Policy and Procedure Statements**

### **4.1 Roles and Responsibilities**

#### **4.1.1 Protection of Research Subjects**

The primary responsibility for the responsible conduct of research shall reside with the investigators who are conducting the research. However, other persons not involved directly share in the responsibility to establish and maintain an atmosphere where respect for the rights of individuals and compliance with applicable regulations is the standard.

#### **4.1.2 Vice Provost for Research**

The Chancellor has designated the University's Vice Provost for Research ("VPR") as the authorized Institutional Officer ("IO") with responsibility for the University's program for the protection of human subjects.

#### **4.1.3 Members of IRB**

4.1.3.1 The IRB shall report to the IO and consist of a minimum of five members, including:

1. One member from a scientific area; and
2. One member from a nonscientific area; and
3. One member unaffiliated with the University; and
4. Other additional members to provide expertise in research areas commonly employing human subjects, or expertise with unique or vulnerable populations to ensure ethical treatment of subjects; and
5. The IRB Administrator, as an ex officio non-voting member.

4.1.3.2 The Chancellor shall appoint all members of the IRB for a term of one to three years and shall designate a Chair.

#### **4.1.4 Office of Research Protections**

The Office of Research Protections provides administrative support and leadership to the IRB, and is responsible for the interpretation and implementation of this policy, as well as addressing non-compliance with this policy. The Office of Research Protection is responsible for:

1. Developing procedures to facilitate the review of human subjects research and to maintain compliance with federal regulations related to the protection of human subjects,
2. Developing procedures and guidelines for the IRB and University community related to the protection of human subjects under this policy,
3. Providing federal and state regulatory updates to the IRB and University Community, and
4. Acting as liaison with federal regulators when necessary.

## **4.2 IRB Oversight**

4.2.1 Any research involving human subjects, including internally funded, externally funded or unfunded research that involves University faculty, staff or students or is supported by or conducted on the University campus, must be reviewed and approved by the IRB prior to soliciting human subject participants or collecting any data from any human subject.

4.2.2 The IO has the authority to rely on another institution's IRB approval for collaborative activities where human subject protections are the responsibility of the collaborating institution's human subjects program.

## **4.3 Review Requirements**

4.3.1 The IRB shall only approve research protocols that satisfy all of the following requirements:

1. Any risk(s) to human subjects are minimal and reasonable in relation to anticipated benefits of the research;
2. Selection of subjects is equitable given the purposes and the setting of the research;
3. Researchers will seek Informed Consent appropriate to the research from each subject or the subject's legally authorized representative, and such consent will be appropriately documented (see Informed Consent Guidelines below);
4. The research plan makes appropriate provision for monitoring the data collected to ensure the safety of subjects;
5. Appropriate provisions are made to protect the privacy of subjects and to maintain the confidentiality of data; and
6. Where some or all of the subjects are likely to be vulnerable to coercion or undue influence, appropriate additional safeguards have been included to protect the rights and welfare of these subjects.

4.3.2 All proposals for research with human subjects will be processed by the IRB through an exemption letter, Expedited Review or Full Review. The IRB shall determine in its sole discretion which form of review is appropriate for each research protocol.

4.3.3 In reviewing research proposals, the IRB has the authority to approve as written, require modifications, defer review to a later date, disapprove or terminate any research involving human subjects conducted.

4.3.4 Research proposals approved by the IRB may be subject to further review by University officials as appropriate. However, those officials may not approve the research if it has not been approved by the IRB.

## **4.4 Levels of Review**

### **4.4.1 Exempt Research and Limited Review**

4.4.1.1 Certain categories of research protocols may be exempt from IRB review or may require limited IRB review. Research Protections staff, in consultation with the IRB Chair when necessary, shall make a determination regarding exemption or limited IRB review.

4.4.1.2 Research protocols involving the following will not be considered exempt from IRB review:

1. Prisoners as a specifically recruited population;
2. Children when the exemption category prohibits children as subjects;
3. Research which requires oversight by other federal regulations (e.g., HIPAA, FDA) where exemption is not permitted;
4. Research techniques which expose human subjects to more than minimal risk; or
5. The deception of the human subject without prospective agreement by the subject.

### **4.4.2 Expedited Review**

4.4.2.1 Federal regulations permit an expedited review procedure for research protocols that meet certain eligibility requirements. Such reviews may be carried out by the Chair of the IRB or by one or more experienced reviewers from among the members of the Board. In performing expedited reviews, reviewers may exercise all of the authorities of the IRB with the exception of disapproval. A research project may be disapproved only after a Full Review by the IRB. The IRB shall be informed of all expedited reviews at its next full meeting.

4.4.2.2 Classified research involving human subjects cannot be subject to an Expedited Review.

### **4.4.3 Full IRB Review**

Full IRB Review must take place for all protocols that do not qualify for an Exempt or Expedited Review or as otherwise specified by the IRB.

## **4.5 Full IRB Reviews**

4.5.1 The IRB shall engage in initial and continuing reviews of research protocols at their scheduled meetings. In order to conduct business, a majority of the members must be present, including at least one member who represents the nonscientific community. This constitutes a quorum.

4.5.2 Members may participate and be counted toward quorum in meetings via teleconferencing technology.

4.5.3 Approval of research protocols shall be via a majority vote of the quorum. Should a quorum be lost during a meeting, the IRB may not take further action or vote until the quorum is restored.

4.5.4 Minutes of each IRB meeting shall document the deliberations, actions, and votes for each research protocol whether undergoing initial or continuing review. IRB Chair shall record votes as the number of "For," "Opposed," and/or "Abstaining." Minutes shall include notation and explanation of any unusual degree of risk or an approval period less than one year for any research protocol.

4.5.5 IRB shall retain all records of its meetings and research protocols for at least three years after completion of the research or in accordance with the UNC System Record Retention Policy, whichever is longer.

## **4.6 Informed Consent**

### **4.6.1 Informed Consent**

Obtaining the Informed Consent of a potential human subject (or the subject's legally authorized representative) for participation in non-exempt research is a federally mandated safeguard to ensure the protection of the rights and welfare of all human subjects.

### **4.6.2 Complex Informed Consent**

For complex Informed Consent forms, the investigator must provide a concise statement of the possible risks and other key information regarding the research protocol to assist a prospective human subject or their legally authorized representative to make an informed determination to participate or not in the research.

### **4.6.3 Content of Consent Forms**

For research that is not exempt from IRB review, Informed Consent forms shall include at a minimum the following information:

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;
2. A description of any reasonably foreseeable risks or discomforts to the subject;
3. A description of any benefits to the subject or to others that may reasonably be expected from the research; and
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;
6. For research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
7. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject;
8. A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled; and
9. One of the following statements about any research that involves the collection of identifiable private information or identifiable bio-specimens:
  1. A statement that identifiers might be removed from the identifiable private information or identifiable bio-specimens and that, after such removal, the information or bio-specimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative; or
  2. A statement that the subject's information or bio-specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

### **4.6.4 Federal, State and Local Law Requirements**

Informed Consents shall also conform to all requirements of applicable federal, state, or local laws which require information to be disclosed in order to be legally effective. The consent form shall document that the subject understands the information contained therein, and has had an opportunity to have any of their questions answered prior to, during and after participation in the research.

#### **4.6.5 Alternation(s) of Informed Consent**

The IRB may approve a consent procedure which does not include, or which alters some or all of the elements of Informed Consent set forth above, or waives requirements to obtain Informed Consent if the IRB determines the following:

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the human subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the researcher will provide the human subjects with additional pertinent information after participation.

#### **4.6.6 Signed Consent Form(s)**

When an Informed Consent form requires the signatures of research subjects and/or their parents or legally authorized representative (LAR), a copy of the signed form must be given to the subject/parent/LAR and a copy must be retained by the Principal Investigator for a minimum of three years after completion of the project.

#### **4.6.7 Waiver to Obtain Signed Consent Form**

The IRB may waive the requirement for the Principal Investigator to obtain a signed consent form for some or all subjects if the IRB determines the following:

1. That the only record linking the human subject and the research would be the Informed Consent form and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject (or legally authorized representative) will be asked whether the human subject wants documentation linking the human subject with the research, and the subject's wishes will govern;
2. That the research presents no more than minimal risk of harm to human subjects and involves no procedures for which written consent is normally required outside of the research context; or
3. If the human subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, that the research presents no more than minimal risk of harm to human subjects and provided there is an appropriate alternative mechanism for documenting that informed consent was obtained.

#### **4.6.8 Written Statement**

In cases in which the Informed Consent requirement is waived, the IRB may require the investigator to provide subjects or legally authorized representatives with a written statement regarding the research.

### **4.7 Continuing Review and Post-Approval Monitoring**

4.7.1 Continuing review will generally not be requested for minimal risk research unless the IRB documents the justification for continuing review within local practices or regulatory requirements.

4.7.2 If continuing review is required, IRB approval may be for a maximum one-year period. The Principal Investigator ("PI") is responsible for requesting continuing review prior to the expiration of the approval period. Failure of the PI to initiate this annual review prior to the expiration date of the approval may result in termination of the IRB approval.

4.7.3 The IRB may conduct for cause and not for cause post approval monitoring of approved IRB research protocols in the following situations:

1. For cause monitoring may be the result of noncompliance, a reported incident, or other cause of concern identified by the IRB.
2. Not for cause monitoring will be regular, ongoing and randomly selected from all active, non-exempt studies.
3. Post approval monitoring may consist of record review, observing the consent process, or observing study procedures. One or more members of the IRB may participate in a monitoring event.

### **4.8 Payments to Human Subjects**

4.8.1 The Office of Research Protections, in conjunction with the Contracts and Grants Accounting, is responsible for maintaining procedures related to human subject research and compensation.

## 4.9 Noncompliance and Reportable Event

4.9.1 If at any time, the IRB becomes aware of unanticipated problems involving risks to human subjects, serious or continuing noncompliance with federal requirements, or terminations of the IRB, including ongoing human subject research which has not been reviewed by the IRB, the IRB shall request a meeting with the PI and suspend the research until the problem can be further evaluated.

4.9.2 In the event the IRB becomes aware of such noncompliance, the IO shall be notified of the situation immediately, and advised of any further sanctions subsequently recommended by the IRB.

4.9.3 Possible sanctions the IRB may impose for noncompliance include, but are not limited to, suspending the Principal Investigator's right to conduct or supervise research involving human subjects, taking possession of the data collected by the non-compliant PI, withholding or revoking academic credit to a student PI, and recommending discipline of a faculty or staff member to the Provost & Executive Vice Chancellor.

4.9.4 Principal Investigators will receive notice of any such sanction within 3 business days of the determination by the IRB, and such sanction shall be final.

4.9.5 As required by federal regulations, any decision of the IRB with respect to research involving human subjects is final. However, the convened IRB may review an investigator's request for reconsideration to a determination regarding noncompliance and/or corrective actions as warranted by the presentation of new information or unusual circumstances. All investigator petitions must be made within 30 days of the investigator's notification of the IRB's sanction. The IRB will review an investigator's request within 30 days, and the investigator will be notified in writing of the IRB's decision within 14 days of the review.

## 5 Related University Policies

[Appalachian State University's Human Subject Research Recruitment Policy](#)

## 6 Additional References

[Code of Federal Regulations, Title 42, Chapter 6\(a\) Public Health Service, Subchapter III Part H](#)

[Code of Federal Regulations, Title 45, Part 46 \(Protection of Human Subjects\)](#)

[U.S. Food and Drug Administration Regulations, Title 21, Parts 50, 56, 312, 812](#)

[North Carolina Statute on Practice of Medicine](#)

[Appalachian State University's Federal-wide Assurance](#)

[Appalachian State University's Standard Operating Procedures for Human Subjects Research](#)

## 7 Contact Information

Vice Provost for Research, (828) 262-7459, [irb@appstate.edu](mailto:irb@appstate.edu), [Office of Research](#)

## 8 Original Effective Date

May 18, 2010

## 9 Revision Dates

April 29, 2019

December 1, 2021

March 8, 2024