

Guidelines for the Review of Research Involving Human Subjects

TABLE OF CONTENTS

- I. Introduction:**
 - A. Institutional Review Board (IRB) Statement of Purpose**
 - B. Education in the Responsible Conduct of Research**
 - C. Student Research and Faculty Responsibility**
- II. The Institutional Review Board (IRB) and its Actions**
 - A. Introduction**
 - B. The Review Process**
 - C. Categories of Review**
 - 1. Exempt Research**
 - 2. Expedited Review**
 - 3. Full Board Review**
 - D. Procedures to Initiate Review**
 - E. Informed Consent Guidelines**
 - F. Compensation of Subjects**
 - G. Investigator's Right of Appeal**
 - H. Periodic Review of Research**
- III. IRB Membership**
- IV. IRB Meetings and Deadlines**
- V. GLOSSARY OF TERMS**

I. Introduction

A. Institutional Review Board (IRB) Statement of Purpose

The IRB is responsible for protecting the rights and welfare of human subjects participating in research projects. The IRB acts according to policies set forth by the United States Department of Health and Human Services Public Health Service Act as amended (45 CFR Part 46, also referred to as The Common Rule). Compliance with these federal regulations not only safeguards human subjects and the institution sponsoring the research project, but also protects the researcher.

Any research (defined in the glossary) that involves human subjects, whether funded internally or from extramural sources, or not funded, that is undertaken by an Appalachian State University faculty, academic staff or students, supported by or conducted at Appalachian State University, must be reviewed and approved by the IRB prior to soliciting subjects or collecting any data from any human subjects.

While the IRB is empowered to review and approve (or disapprove) research involving human subjects, the protection of research subjects from unnecessary or unacceptable risks is a university-wide responsibility. The primary responsibility for the responsible conduct of research falls on the investigators (faculty, faculty associates, academic staff, graduate students, undergraduates, technicians, etc.) who are conducting the research. However, other persons not involved directly (faculty colleagues, department reviewers, department heads, deans, etc.) 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.

B. Education in the Responsible Conduct of Research

It is the policy of Appalachian State University that all individuals engaged in research involving human participants must complete an educational program related to the responsible conduct of research prior to initiation of a research project. Effective July 1, 2008, the requirement can only be met by completing the [CITI IRB training program](#).

C. Student Research and Faculty Responsibility

Research conducted by students, such as thesis research and some class projects, may require the approval of the IRB prior to execution. It is the responsibility of faculty supervising research by students or staff to ensure that approval of the Board is obtained. Individual projects conducted primarily for instructional purposes within the context of a formal class, and **not designed to contribute to generalizable knowledge**, do not meet the definition of “research” as defined in the federal guidelines. Thus, they do not require review by the Board, provided the instructor is prepared to accept professional and ethical responsibility for all research projects conducted in conjunction with the class. Under these conditions, no IRB application need be made but it is the instructor’s responsibility to monitor the ethical propriety of these projects, applying the criteria listed in this document.

II. The Institutional Review Board (IRB) and its Actions

A. Introduction

In reviewing research proposals, the IRB has the authority to approve, require modifications in, defer, disapprove or terminate any research involving human subjects conducted under Appalachian State University's auspices.

If at any time, the Board becomes aware of:

1. unanticipated problems involving risks to subjects, or
2. other serious or continuing noncompliance with 45 CFR Part 46 or determinations of the Board, including ongoing human subject research which has not been reviewed by the Board,

it may request a meeting with the PI and/or suspend the research until the problem can be further evaluated. Under these circumstances, the Authorized Institutional Official (the Dean of Research and Graduate Studies and Research) must be made aware of the situation immediately, and he/she will be advised of any further sanctions subsequently recommended by the Board.

In these circumstances, the Board may impose sanctions on an individual by suspending the individual's right to conduct or supervise research involving human subjects, taking possession of the data collected by the non-compliant individual, withholding or revoking academic credit to a student researcher, and recommending discipline of a faculty member by the University. This list is provided by way of example only, and is not intended and should not be construed as exhaustive, in that individual situations may call for specific actions and remedies not identified herein.

B. The Review Process

The IRB reviews protocols for research in accordance with federal regulations governing research with human subjects. The Board may also apply such codes of professional ethics as it deems appropriate. These additional codes may or may not be addressed in federal documents. It is the policy of Appalachian State University that in order for any research protocol to be approved, the Board must determine that all of the following requirements are satisfied:

1. risks to subjects are minimized and are 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. appropriate informed consent will be sought 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 insure 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.

The IRB may process a protocol in one of three ways:

- By exemption certification
- By expedited review
- By full review

Any research protocol which does not fall under the category definitions of exempted or expedited research as outlined below, or any protocol as specifically requested by the Board, shall undergo full review.

Upon review by the Board, the IRB Administrator shall notify the PI by letter and/or email of the Board's decisions, and conditions which must be met, if approval is to be awarded. Approval will not be granted until all specified conditions are met. The letter shall also

1. advise the PI to notify the IRB if there are any subsequent changes proposed in the research protocol. No changes may be initiated without IRB review and approval.
2. indicate the period for which approval is valid (1 year, in most cases).
3. require the PI to make an application for annual review should the study extend beyond the initial approval expiration date.
4. direct that during the course of the research, should an adverse event occur which threatens the health, safety or emotional well-being of a participant, or which increases the risks to subjects from that described in the approval documents for the project, the PI must suspend the research immediately and report the incident to the IRB Administrator. The IRB administrator will investigate and determine the course of action to follow.

C. Categories of review.

1. Exempt Research

Certain categories of research protocols may be exempt from review by the full board. **Only the IRB Administrator is authorized to determine which protocols may be subject to limited review or may be exempt from review by the Board.** The IRB reserves the authority to require proposal modifications regarding human subject protection before approving the research as exempted from the requirements of the Common Rule.

Note that the exemption DOES NOT APPLY when the research activities include:

- a. the review of medical records when the information is recorded in such a way that subjects can be identified, directly or through identifiers linked to the subjects.
- b. surveys or interviews which include minors as subjects.
- c. techniques which expose the subject to more than minimal risk.
- d. the deception of the subject.

The federal categories of research eligible for exemption certification are as follows:

- a. Research conducted in established or commonly accepted educational settings, involving normal education practices, such as (a) research on regular and special education instructional strategies, or (b) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

The Board interprets this provision to exempt from review those research protocols in which subjects will consist exclusively of students in a faculty member's own classes. However, where the research requires using students in classes which are the usual responsibility of other faculty or staff members, the research protocol will require review and approval by the Board (unless the research is exempt under some other provision of law or University policy).

The Board makes this interpretation based on its belief that the phrase "normal educational practices" is intended to encompass only those situations in which a faculty member, or a student under a faculty member's supervision who is also an instructor, conducts research in his or her own classroom.

- b. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews or observation of public behavior, unless: (i) information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to the subjects; and (ii) any disclosure of an individual's response(s) outside of the research setting could reasonably place the subject at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.
- c. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), surveys, interviews, or observations of public behavior that are not exempt under (b) of this section, if: (i) the human subjects are elected or appointed public officials or candidates for public office; or (ii) federal statute(s) require(s) without exception that the confidentiality of the personal identifiable information will be maintained throughout the research and thereafter.
- d. Research involving the collection or analysis of existing data, documents, records, pathological specimens, or diagnostic specimens, if such sources are a matter of public record or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

- e. Research and demonstration projects which are conducted by or subject to the approval of, department or agency heads, and which are designed to study, evaluate, or otherwise examine: (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under such programs; (iii) possible changes in or alternatives to such programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under such programs.
- f. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed or (ii) if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U. S. Department of Agriculture.

2. Expedited Review

Federal regulations permit an expedited review procedure for 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 Board with the exception of disapproval. A research project may be disapproved only after full Board review as described in the next section. The Board shall be informed of all expedited reviews at its next full meeting.

Research activities that present no more than minimal risk (see glossary) to human subjects, and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure. The activities detailed below should not be deemed to be of minimal risk simply because they are included on this list. Inclusion merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, insurability, or reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

The expedited review procedure may not be used for classified research involving human subjects. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review used by the IRB — expedited or full. The categories in this list apply regardless of the age of subjects, except as noted. Categories one 1 - 7 pertain to both initial and periodic IRB review.

Expedited Categories

- 1) clinical studies of drugs and medical devices only when condition (a) or (b) is met.
 - a) research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
 - b) research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.
- 2) collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - a) from healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - b) from other adults and children, taking into consideration the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed 5 ml, or 3 ml per kg, whichever is less, in an 8-week period, and collection may not occur more frequently than 2 times per week.
- 3) Collection of data through noninvasive procedures, i.e., not involving general anesthesia or sedation, routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, nor are studies of approved medical devices being considered for new indications.)
- 4) Prospective collection of biological specimens for research purposes by noninvasive means.
- 5) Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis).
- 6) Collection of data from voice, video, digital, or image recordings made for research purposes.
- 7) Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

- 8) Continuing review of research previously approved by the full IRB as follows:
 - a) when (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects.
 - b) when no subjects have been enrolled and no additional risks have been identified.
 - c) when the remaining research activities are limited to data analysis.
- 9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Full Board Review

Full board review must take place for all protocols that do not qualify as above as “exempt” or “expedited”, or as otherwise specified by the Board.

D. Procedures to Initiate Review

Prior to the execution of any research involving human subjects, investigators shall have completed the mandated education described at the beginning of this document, and they shall have completed and submitted to the IRB Administrator copies of the protocol form along with copies of the proposed informed consent statement. The protocol form must provide the following information:

- Name(s) and department(s) of investigator(s)
- Title of the study
- Signature of responsible faculty member
- Whether or not external funding is proposed
- Purpose of the study
- Description of subjects
- Description of methodology, including a copy of any instruments used
- Potential benefits and risks to the subject
- Anticipated beneficial knowledge resulting from the study
- Description of any deception
- Procedures for protecting the anonymity/confidentiality of subjects
- A copy of any recruiting materials or scripts.
- Method for ensuring informed consent, including a copy of the proposed informed consent statement.

E. Informed Consent Guidelines

Obtaining the informed consent of a potential human subject for participation in any research (whether an experiment, survey, interview, or demonstration) is a federally mandated safeguard to insure the protection of the rights and welfare of all individual subjects, and, in fact, constitutes the very essence of protecting those rights. Therefore the IRB will review very carefully the method proposed for obtaining informed consent and the content of the document prepared for participants' signatures. When consent forms requiring signatures of research subjects and/or their parents or legal guardians are used, a copy of the fully signed form must be given to the subject/parent/guardian and a copy must be retained by the researcher for a minimum of three years after completion of the project.

Researchers must give subjects the following information in an informed consent form:

- 1) the title of the study, information on the purpose(s) of the research, a description of the method(s) and procedure(s) to be followed, including the intention to publish or disseminate the results of the study, and the amount of time the subject will spend in actual project participation.
- 2) a description of any reasonably foreseeable risks or discomforts to the subject, including expected total time of participation. If disguised or deceptive procedures are to be used, a plan to debrief participants must be explained to the IRB.
- 3) a description of any benefits to the subject or to others as a result of the information obtained from the research.
- 4) a disclosure of appropriate alternative procedures that may be advantageous to the subject when making an informed decision whether or not to participate in the research (this pertains primarily to medical research and drug trials).
- 5) A description of the measures to be taken to insure the confidentiality of data and the anonymity of individual subjects, if applicable, as well as any circumstances under which confidentiality CANNOT be guaranteed.
- 6) The name and phone number of a contact person(s) who will be available to answer any questions the subject or his/her legally authorized representative may have regarding the research (student investigators must include the name, address, and phone number of his/her faculty supervisor), and the statement "Questions regarding the protection of human subjects may be addressed to IRB Administrator, Research and Sponsored Programs, Appalachian State University, Boone, NC 28608, (828) 262-2130.
- 7) a clear explanation that participation is voluntary and that no penalty or loss of benefits to which the subject is otherwise entitled will occur should the subject either refuse to participate or decide to discontinue participation (at any time).
- 8) disclosure of costs to the subject, if any, because of his/her participation in the research; disclosure of compensation/reward to the subject, if any, for his/her participation in the research.

- 9) for projects of more than minimal risk to subjects, a statement must be included that describes how the costs of medical care or other therapies required as a result of injury or mishap incurred while participating in the research will be handled. The Consent Form should also include information about the availability and extent of on-site medical treatment should an injury occur.
- 10) The approval and expiration date for the consent form once approval of the project has been granted.
- 11) The consent form must not include a statement releasing the investigator, sponsor, institution or its agents from liability or negligence.

The consent form shall document that the subject understands the information contained therein, and has had an opportunity to have any of his/her questions answered. For survey research projects, informed consent is obtained by providing the potential subject/respondent a detailed explanation of the purpose for and the protocol of the research project. Completion of the survey instrument by the subject shall constitute informed consent, but this should be stated in the cover letter or survey instructions.

See Appendix A (Sample Consent Form)

F. Compensation of Subjects

- 1) If subjects are compensated less than \$20 for their participation, the PI shall maintain a list whereon subjects will sign their name and address, indicating receipt of compensation.
- 2) If compensation is great than \$20, the list shall also show SSAN (Social Security Number), recorded on individual forms to prevent disclosure to other participants.
- 3) Such lists shall be submitted to the Special Funds Accounting office.
- 4) The PI may petition the Board for a special “confidential” status, which applies only to disclosures of the subject’s name, address and SSAN, in cases where such disclosure, in the opinion of the Board, would constitute a special and undue risk to the subject. In this circumstance, only the number of subjects need be reported to the Special Funds Accounting Office.
- 5) Subjects should be informed of the collection of the above information in the Informed Consent Form.

G. Investigator’s Right of Appeal

It is the policy of Appalachian State University that the final decision regarding approval or disapproval of all protocols rests with the IRB. In accordance with federal regulations, no research involving human subjects may be conducted under Appalachian State University’s auspices without the prior and continuing

approval of the Board. Any investigator who disagrees with a decision of the Board may request a hearing before the duly-convened IRB to appeal its decision. Relevant arguments and/or witnesses may be presented on behalf of the investigator. The investigator may also request that the Authorized Institutional Official be informed of the appeal. However, final decision rests with the Board.

H. Periodic Review of Research

After a research protocol has been reviewed by the IRB, it is the investigator's responsibility to report to the Board any proposed changes in the research as well as any unanticipated problems that arise involving risk to subjects. If deemed necessary, the IRB Administrator may determine that reconsideration of the protocol by the full Board is warranted. If such a determination is made, the procedures governing initial review of protocols will be utilized.

In addition, federal regulations require that the Board conduct continuing review of approved expedited and full Board approved proposals at least once per year. Exempted protocols require no continuing review. It is the principal investigator's responsibility to initiate the request for continuation, which must include a summary of the protocol and a status report on the progress to date. In summary, the following must be submitted:

- 1) the number of subjects accrued,
- 2) a summary of any adverse events or unanticipated problems involving risk to subjects, and of any withdrawal of subjects or complaints about the research since the last review,
- 3) a summary of findings, and any amendments or modifications to the study, and
- 4) a copy of the current informed consent document.

Failure by the investigator to initiate this annual review prior to the expiration date of the approval shall result in immediate termination of the research.

Certain protocols may be reviewed more often than yearly, e.g.:

- 1) where protocols are considered to involve high risk, or have a high risk/benefit ratio.
- 2) where studies are complex involving unusual levels or types of the risks.
- 3) for projects conducted by investigators who previously failed to comply with the requirements of the IRB.
- 4) for projects where information has come to the attention of the IRB that protocol changes have been made without IRB approval.

III. IRB Membership

The Board shall consist of a minimum of five members, including

- 1) One member whose primary concern is in a scientific area
- 2) One member whose primary concern is in a nonscientific area
- 3) One member who has no affiliation with Appalachian State University
- 4) Additional members to insure ethical treatment of subjects

The regular members will be appointed by the Chancellor of the University for a term of three years and the Board will report to the Authorized Institutional Official. The Chancellor of the University shall designate the Chair of the IRB.

IV. IRB Meetings and Deadlines

Initial and continuing reviews of research will be conducted at full board meetings of the IRB. 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. Expedited reviews can be performed as described above in the absence of an IRB meeting.

Teleconferencing may be used for any members to participate in the meeting, and they shall be counted toward the quorum. Approval of research is by 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 has been restored.

Review of proposed protocol changes will be conducted at IRB meetings with a quorum present, except where expedited review is appropriate. Minor changes in previously approved research can be approved under an expedited review procedure as above. Any revisions to a protocol should be incorporated into the written protocol with the revision dates noted on the protocol itself.

All necessary review materials must be submitted to the office of the IRB Administrator at least two weeks before the meeting at which they will be considered. Complete copies of all materials to be reviewed will be distributed to the full Board at least one week in advance of the meeting at which they will be considered.

Minutes of each IRB meeting shall document the deliberations, actions, and votes for each protocol whether undergoing initial or continuing review. Votes shall be recorded as the number "For", "Opposed", and/or "Abstaining". Any unusual degree of risk or an approval period less than one year shall be documented explicitly in the minutes.

A copy of the minutes of each Board meeting will be forwarded to the Dean of Research and Graduate Studies. IRB records will be retained for at least three years, and records relating to research that is conducted will be retained for at least three years after completion of the research.

V. GLOSSARY OF TERMS

Anonymity-means that the identity of a subject cannot be matched to his/her response.

Confidentiality-refers to the treatment of individual information gathered during the conduct of the research. An individual discloses information to the investigator with the expectation that the information will not be divulged to others in a manner inconsistent with the understanding of the original agreement.

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

Exemptible Research-refers to human subject research activities that fall into one or more of the federally defined exempt research categories. Exempt research does not mean the research protocols are exempt from IRB review, only that the research may not require a full IRB review, and may not be subject to other IRB requirements, such as annual reviews or informed consent. It is strongly suggested that informed consent be used whether required or not.

Expedited Review-refers to the review by the IRB Chair or designate of research proposals which involve minimal risk or no-risk.

Full IRB Review-refers to the review of proposals conducted during an IRB meeting at which a quorum has been established.

Human Subject-refers to a living individual about whom a researcher obtains either identifiable private information, or data through intervention and/or interaction with the individual.

Informed Consent-refers to 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.

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.

Research-refers to a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. It is understood that such research may be disseminated by publication or in a public or professional forum.

Vulnerable Populations-refers to subjects such as children, prisoners, pregnant persons, or any population that may be relatively or absolutely incapable of protecting their interests through the informed consent process.

Summer 2009