

APPALACHIAN STATE UNIVERSITY

**Informed Consent for Participants in
Research Projects Involving Human Subjects**

<p>Institutional Review Board</p> <p>Approval Date: _____</p> <p>Expires On: _____</p> <p>Study #: _____</p> <p>Initials: _____</p> <p style="text-align: center;">Appalachian State University</p>

Title of Project _____

Investigator(s) _____

I. Purpose of this Research/Project

Subjects should be informed in clear, concise language about the nature of the study and the purpose for conducting the research. The total number of subjects involved and a brief description of the subject pool (age range, health status, etc...) should be given.

II. Procedures

The research procedures that involve human subjects should be explained in sufficient detail so that the subjects will be fully informed about their role, what activities or functions they will be expected to perform, for how long, the number of times they are expected to appear and over what period of time. They must be told where the research will take place, what instrumentation is to be used, if any, and conditions involved. At the end of this section, the subjects must have a clear understanding of what will be expected of them.

III. Risks

Any risks or discomforts to the research subject must be fully disclosed. Risks may range from physical danger such as muscle injury from strenuous exercise to emotional distress caused by remembering unpleasant experiences. Safeguards that are to be employed to reduce or minimize the risks must be described.

IV. Benefits

The tangible or intangible benefits, if any, to the subjects who participate must be described. If no benefits accrue to the subjects, what are the larger societal benefits for conducting the research? An analysis of the risks to benefits must clearly be on the benefits side.

A statement must be included to the effect that -- no promise or guarantee of benefits have been made to encourage you to participate.

At the option of the investigator, subjects may be informed that they may contact the researcher at a later time for a summary of the research results. If subjects are children, the parent/guardian must make the request.

V. Extent of Anonymity and Confidentiality

The extent to which subjects will be identifiable must be explained. If anonymity is promised (individuals cannot be identified), you need to explain how that will be accomplished. If confidentiality is promised (individuals can be identified, but the researchers promise not to divulge that information), you must explain how that will be accomplished. Social security numbers should not be used as identifiers in lieu of names. You may also say, "At no time will the researchers release the results of the study to anyone other than individuals working on the project without your written consent".

If taping (video or audio) is to occur, the subjects must be informed. You must state how the tapes will be secured and stored, under whose supervision, who will score or transcribe, who will have access and when they will be destroyed.

In some situations, it may be necessary for an investigator to break confidentiality. If child abuse is known or strongly suspected, investigators are required to notify the appropriate authorities. If a subject is believed to be a threat to herself/himself or others, the investigator should notify the appropriate authorities. The conditions under which the investigator may break confidentiality must be described in the Informed Consent.

VI. Compensation

There is no requirement that subjects are compensated, but if they are, they must be fully informed. If no compensation is to be earned, subjects must be so informed. Money or redeemable coupons or other currency may be given. Subjects must be informed about how much, when it will be paid, any bonuses for completing all the tasks, etc.

If extra credit in a course is the compensation, the subject must be informed as to how much credit is to be earned and the impact of that extra credit on their course grade. If extra credit is a form of compensation for participation in research involving human subjects, there must be alternate and equitable ways to earn the equivalent credit in the same course without participating as a subject in research. The subjects must be so informed. The course syllabus must describe the alternate ways to earn extra credit.

If as a result of a research project, the investigator determines that the subject should seek counseling or medical treatment, a list of local services should be provided. Also, a statement should be included indicating that no funds have been set aside for any injury or illness resulting from this project.

VII. Freedom to Withdraw

Subjects are free to withdraw from a study at any time without penalty. If they choose to withdraw, they will be compensated for the portion of the time of the study (if financial compensation is involved). If they choose to withdraw, they will not be penalized by reduction in points or grade in a course (if course credit is involved). Subjects are free not to answer any questions or respond to experimental situations that they choose without penalty.

There may be circumstances under which the investigator may determine that a subject should not continue as a subject. The subject must be compensated for the portion of the project completed.

VIII. Approval of Research

This research project has been approved, as required, by the Institutional Review Board of Appalachian State University and _____ (if others, i.e., school or school system, hospital, daycare center, multi-institutional project etc.).

IRB Approval Date

Approval Expiration Date

IX. Subject's Responsibilities

I voluntarily agree to participate in this study. I have the following responsibilities:

(List medical conditions to be reported, staying in place for a specific length of time after drawing a blood sample, consumption of alcohol, etc.)

X. Subject's Permission(May be modified in the case of minors or members of other vulnerable populations.)

I have read and understand the Informed Consent and conditions of this project. I have had all my questions answered. I hereby acknowledge the above and give my voluntary consent:

Subject signature

Date

Witness (Optional except for certain classes of subjects)

Date

Should I have any questions about this research or its conduct, I may contact:

Investigator(s)

Telephone/e-mail

Faculty Advisor(if applicable)

Telephone/e-mail

Robert L. Johnson **828-262-2692** **johnsonrl@appstate.edu**
Administrator, IRB Telephone e-mail
Graduate Studies and Research
Appalachian State University
Boone, NC 26608

Subjects must be given a complete copy (or duplicate original) of the signed Informed Consent.

EXPLANATION OF TERMS

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