Policy 216

1 Introduction

1.1 The University receives both internal and external research requests to recruit human subjects for research through University personnel, facilities, or University Digital Media.

1.2 Consistent with policies adopted by the Board of Governors of The University of North Carolina, this policy is intended to:

   1. provide appropriate oversight of the use of University facilities and University Digital Media in recruitment of human subjects for research;
   2. enable human subject research at the University to be conducted under consistent ethical and regulatory parameters; and
   3. provide guidance on the recruitment of Appalachian students, staff, or faculty for human subject research to the University community.

2 Scope

2.1 Unless otherwise exempted by the provisions hereof, this policy shall apply to any recruitment activity for human subject research that is conducted on behalf of the University or by an employee of the University. This policy applies to all individuals who assist with the recruitment of subjects for human subject research. It is applicable to activities that occur in University facilities as well as other locations whenever projects involve University funding, faculty scholarship or staff/student/agent effort as part of University activities. This policy shall be interpreted and applied in conformity with Federal, State, and UNC System Policies.

3 Definitions

3.1 Human Subject

   means a living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.

3.2 Research

   means a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.

3.3 University Digital Media

   means any University controlled electronic means of gathering responses from research subjects, including but not limited to e-mail, online surveys, web forms, and websites.
3.4 IO

means the institutional official as designated by this policy.

3.5 IRB

means the Institutional Review Board authorized by the National Research Act, Title 45 CFR part 46, and Title 21 CFR 56.

3.6 Research Protections

means the Office of Research Protections at the University.

3.7 PI

means the principal investigator.

3.8 Agent of the University

means any representative of the University conducting human subject research on behalf of or under the instruction of the University.

4 Policy and Procedure Statements

4.1 Roles and Responsibilities

4.1.1 The Chancellor of the University has designated the Chief Research Officer as the authorized IO with responsibility for the University program for the review of human subject research.

4.1.2 The Appalachian State University IRB is responsible for reviewing human subject research when Appalachian is engaged, as defined by the appropriate government agency, in the research unless the IO chooses to rely on the review of another IRB.

4.1.3 Research Protections administers the IRB and is responsible for managing IRB review processes; establishing appropriate procedures to protect human subjects and comply with local, state and federal laws and regulations; maintaining appropriate records; and serving as a liaison with the federal government on human subject research.

4.1.4 University personnel are responsible for confirming with Research Protections that the appropriate IRB approval is obtained prior to assisting an external researcher with the recruitment of human subjects for research.

4.2 Oversight

4.2.1 Recruitment for Human Subject Research

1. If the University is not engaged in human subject research and an external PI seeks to recruit human subjects through University personnel, facilities or University Digital Media, the University personnel responsible for the facility or University Digital Media must direct the PI to Research Protections to
confirm that the appropriate IRB approval is secured before assisting with recruitment.

2. If the University is engaged in human subject research, the PI must request Appalachian IRB review and obtain IRB approval prior to recruiting subjects. The PI must demonstrate to the University personnel responsible for the facility or University Digital Media that IRB approval has been obtained.

3. Human subject research recruitment through the use of facilities and University Digital Media must follow all appropriate University policies and procedures.

5 Additional References

Guidelines for the Review of Research Involving Human Subjects
Standard Operating Procedures, IRB

6 Authority

Federal Policy for the Protection of Human Research Subjects
Title 21 CFR Part 50

7 Contact Information

Director of Research Protections; 828.262.2130.
Office of Research Protections; irb@appstate.edu

8 Original Effective Date

November 30, 2012

9 Revision Dates