
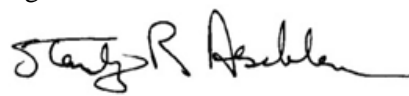


Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #2 Revision #	TITLE: Initial Review	Date Effective: 8/8/2012 Revision Date:
Approved By: RP Director	Signature 	Date: 8/15/2012
Approved By: IRB Chair	Signature 	Date: 8/15/2012

PURPOSE

To describe the procedures for conducting an initial review of human subject research.

GENERAL DESCRIPTION

In accordance with federal regulations and institutional policy, the IRB must approve—prior to implementation—human subject research conducted by Appalachian faculty, staff, student, or volunteer. Principal Investigators are responsible for requesting initial review of human subject research.

RESPONSIBILITY

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

PROCEDURES

1. Research Protections (RP) staff maintain an IRB website with instructions for requesting initial review of human subject research.
2. Principal Investigators (PI) or members of their research team request initial IRB review by sending a complete request to irb@appstate.edu. A complete request includes:
 - the appropriate IRB application,
 - a copy of any recruiting materials or scripts,
 - a copy of the informed consent document and any relevant assent forms, if applicable,
 - data collection instruments (e.g., survey, interview questions), if applicable,
 - permission forms from other institutions involved in the research, if applicable,
 - qualifications of investigators (e.g., a CV or experience in the specific research area), if applicable and not currently on record with RP staff,
 - the designation of a faculty advisor for research led by a student PI,
 - a copy of any associated grant or contract, and
 - the signature of the PI and faculty advisor (if the PI is a student).
3. Upon receipt of a review request, RP staff:
 - enter the request in an IRB management system,

Appalachian State University and Institutional Review Board Standard Operating Procedures		
SOP #2 Revision #	TITLE: Initial Review	Page: 2 of 3

- acknowledge receipt of the request through an email to all research personnel designated to receive correspondence on the IRB application,
 - confirm whether research personnel have completed any IRB mandated training,
 - confirm that the request is complete, and
 - follow procedures to determine that the activity meets the definition of human subject research.
4. If a request for review is incomplete, RP staff notifies the PI (and any research personnel designated to receive correspondence on the IRB application) via email that the request is incomplete. If the request remains incomplete after 45 days, RP staff notifies the PI that the request will be withdrawn if there is no response within 7 days.
 5. An IRB administrator screens complete review requests to determine the level of review: full board, expedited, or an exempt determination. If an IRB administrator is unable to determine the level of review (e.g., cannot determine if a study is minimal risk), the IRB Chairperson determines the level of review.
 6. Review procedures are followed.

RESEARCH PERSONNEL AND TRAINING

Research personnel who 1) obtain informed consent of participants; 2) interact with participants for research purposes; or 3) have access to identifiable private information for research purposes, must be listed on the IRB application.

All research personnel must complete IRB-mandated training as well as any University-mandated training (e.g., Blood Borne Pathogen training) before the study will be approved or determined to be exempt. RP staff maintain instructions for IRB-mandated training on the IRB website. Deviations from the training requirements will be considered on a case by case basis with the IRB Administrator and/or IRB Chair.

SPONSORED RESEARCH

For sponsored research, RP staff:

- consult and follow any sponsor IRB review requirements (e.g., the Department of Defense has additional review requirements that must be followed),
- associate the Sponsored Program number with the IRB request for review,
- conduct a congruency analysis of the IRB request for review with any associated contract/grant, and
- add Sponsored Programs to IRB correspondence.

OFF-SITE RESEARCH AND INTERNATIONAL RESEARCH

Appalachian State University and Institutional Review Board Standard Operating Procedures		
SOP #2 Revision #	TITLE: Initial Review	Page: 3 of 3

The term “off-site research” includes research conducted at sites that are not owned or operated by Appalachian State University (Appalachian), or at sites that do not fall under Appalachian IRB’s authority.

RP staff coordinates the review of off-site research to define the responsibilities of each IRB, communicate among the responsible IRB committees, and manage information obtained in off-site research to ensure the protection of human subjects. To coordinate off-site research review, the IRB Administrator, in consultation with the Chief Research Officer and General Counsel as needed, considers the source of the funding, federal regulations, specific sponsor regulations, and institutional policy. Appalachian may enter into formal agreement with other facilities, and/or personnel, which are not legal entities/employees of Appalachian to provide research review, to rely on other institutions for research review, or to cooperate in review. The IO, or designee, makes the final determination to rely on the review of another IRB and/or allow non-ASU entities/employees to rely on the oversight of the Appalachian IRB.

For IRB review of off-site research, the IRB Chairperson and an IRB administrator:

- consider whether the IRB has knowledge of local customs of the site of the research and can reasonably assess the risks of the research or whether an expert with knowledge of local customs is required to assess the risks of the research; and
- determine whether any non-U.S. regulations/laws apply to the research and must be considered in the review.

INSTITUTIONAL REVIEW

A research application may require institutional review in addition to IRB review (e.g., Institutional Biosafety Council; Radiation Safety Council; Conflict of Interest review). The PI is responsible for informing RP staff about the need for any other institutional reviews. RP staff coordinates additional required reviews to ensure that the research is not conducted until all required reviews have been completed and approved.

SUPPORT PROCESSES AND PROCEDURES

SOP #1 Determination of Activities that Need IRB Review

REFERENCES

45 CFR Part 46.103(b)(4)(i)