

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #2 Rev. 1	Requesting IRB Review	Date Effective: 1.21.2019
Approved by IRB Chair	<i>R. Brand</i>	Date 1/21/2019
Approved by RP Director	<i>Kevin S. McGovern</i>	Date 1/21/2019

PURPOSE

To describe 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, all research involving human participants conducted by an agent of the University. Principal Investigators are responsible for requesting initial review of human subjects research.

RESPONSIBILITY

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

PROCEDURES

1. Principal Investigators (PI) or members of their research team are responsible for Requesting IRB review by submitting an application through the IRB Information System (IRBIS), which can be accessed at:
<https://appstate.myresearchonline.org/irb/index.cfm>. A complete request includes:
 - The appropriate IRB application
 - Copies of any recruiting materials or scripts
 - Copies of informed consent documents and any relevant assent forms,
 - All data collection instruments (e.g. surveys, interview questions),
 - Permission forms from other institutions involved in the research,
 - Qualification of investigators (e.g. experience in the specific research area, certifications), if applicable and not currently on record with RP Staff,
 - A Faculty Advisor (FA) if research is led by a student PI,
 - The AGrants number of any associated grant or contract
2. Upon receipt of review request, RP Staff:
 - a. Accepts the study for review on IRBIS,
 - b. Confirms that all personnel have current CITI certification,
 - c. Confirms that request is complete, and

- d. Follow procedures to determine that the activity meets the definition of human subject research.
3. 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 the IRBIS system or 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 If the request remains incomplete after 45 days, RP staff notifies the PI that the request will be withdrawn if there is no response within 7 days.
4. An IRB administrator screens complete review requests to determine the level of review: full board, expedited, or an exempt determination.
 - a. 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.
5. Review procedures are followed in accordance with level of review.

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.

1. All research personnel must complete IRB-mandated training as well as any University-mandated training (e.g., certifications, Blood Borne Pathogen training) before the study will be approved or determined to be exempt.
 - a. IRB-mandated training consists of successful completion, within the last three years, of one of the approved CITI Program courses, found at: <https://about.citiprogram.org/>.
 - b. Only the following courses can be used to satisfy IRB-mandated training requirements: Biomedical Research Basic Course, Biomedical Research Refresher Course, Social/Behavioral Research Basic Course, Social/Behavioral Research Refresher Course.

SPONSORED RESEARCH

For sponsored research, RP staff:

- Consult and follow any sponsor IRB review requirements (e.g., the FDA, EPA and Department of Defense have 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, INTERNATIONAL, AND COLLABORATIVE RESEARCH

Off-site or international research: includes research conducted at sites that are not owned or operated by Appalachian State University (Appalachian). Where appropriate, the PI may be requested to provide documentation that the site will permit Appalachian to conduct research.

1. For IRB review of off-site or international research, the IRB Chairperson or an IRB administrator:
 - a. Considers 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
 - b. Determines whether any non-U.S. regulations/laws apply to the research and must be considered in the review.

Single IRB Review/Interinstitutional Agreements: Collaborative projects involving non-exempt research with agents of other institutions under IRB oversight require one institution to serve as the overseeing IRB. The default is the prime institution receiving the funding. In other cases the overseeing IRB may be determined by who is considered the Principal Investigator.

1. 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.
 - a. The Institutional Official (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.

Collaborators with no affiliated IRB: Appalachian will not provide IRB oversight for a Principal Investigator who is not affiliated with the University (e.g., they are not listed in the Appalachian Directory). However, under certain circumstances with IO approval, members of the research team may be included in projects with IRB oversight. The personnel must complete the Individual Investigator Agreement and follow the same requirements as Appalachian State University personnel for IRB 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

SOP #5 Expedited Review of Research

SOP #6 Full IRB Review of Research

SOP #9 Conducting Exempt and Limited Reviews

REFERENCES

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