Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #2 Rev. 2	Requesting Initial Review of Human Subjects Research	Date Effective: 07/06/2022
Approved by IRB Chair		Date 7-6-2022
Approved by RP Director		Date 7-5-22

I. PURPOSE

To describe procedures for requesting initial review of human subjects research.

II. AUTHORITY

Federal regulations require that each IRB establish and follow written procedures for conducting initial review of human subjects research. ASU Policy 209 requires that all research involving human subjects conducted by an agent of the University must be reviewed to 45 CFR 46 and either approved by the IRB or determined to be exempt from IRB review.

III. RESPONSIBILITY

1. Research personnel are responsible for requesting initial review of human subjects research, for responding in a timely manner to requests for additional information, and for ensuring that no research procedures with human subjects are conducted prior to IRB approval or exemption.
   a. Research personnel are responsible for alerting Research Protections if the proposed project is subject to federal regulations other than 45 CFR 46 or if any of the research procedures will be conducted internationally.

2. Research Protections (RP) staff is responsible for receiving and screening requests for review, communicating with research personnel when additional information is needed, verifying that all research personnel have completed the required ethics training, determining the required level of review, and performing certain reviews.

IV. PROCEDURES

1. Research personnel request initial review by submitting an application through the electronic research administration (eRA) system. A complete request may include, but is not limited to:
   a. The appropriate IRB application;
   b. Copies of any recruiting materials or scripts;
   c. Copies of informed consent documents and any relevant assent forms;
   d. All data collection instruments (e.g. surveys, interview questions);
   e. Permission forms from other institutions involved in the research;
   f. Qualification of investigators (e.g. experience in the specific research area, certifications), if applicable and not currently on record with RP Staff;
   g. A faculty advisor (FA) if research is led by a student PI; and

h. The Sponsored Programs number of any associated grant or contract.

2. Upon receipt of review request, RP staff:
   a. Accepts the study for review in the eRA system;
   b. Confirms that all personnel have completed the required ethics training;
   c. Confirms that request is complete; and
   d. Follows procedures in SOP #1 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 via the eRA system or by email that the request is incomplete. If the request remains incomplete after 45 days, RP staff may notify the PI that the request will be withdrawn if there is no response within 7 days.
4. RP staff screens complete review requests to determine the level of review: full board, expedited, or exempt.
   a. If RP staff is unable to determine the level of review (e.g., cannot determine if a study is minimal risk), the IRB Chairperson or designee, may determine the level of review.
5. RP staff may perform a preliminary regulatory and technical review of review requests before scheduling further review.
   a. As part of this technical review, RP staff may return the application to research personnel with requests for clarifications and/or requests for revisions.
6. After the technical review process (if applicable) is complete, review procedures are followed in accordance with level of review.

V. RESEARCH PERSONNEL AND TRAINING

1. 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. Personnel who are not engaged in any of these three activities should not be listed on the IRB application, unless they are the FA for a student PI.
2. All research personnel listed on the IRB application must complete IRB-mandated ethics training as well as any University-mandated training (e.g., certifications, Blood Borne Pathogen training).

VI. SPONSORED RESEARCH

For sponsored research, RP staff consults and follows any sponsor IRB review requirements (e.g., the FDA, EPA, and DoD have additional review requirements that must be followed).

VII. OFF-SITE, INTERNATIONAL, AND COLLABORATIVE RESEARCH

1. Off-site research refers to research conducted at sites that are not owned or operated by Appalachian State University (ASU). Where appropriate, RP staff may request documentation that the site will permit ASU to conduct research.
2. For initial review of off-site or international research, RP staff and/or the IRB may:
   a. 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
   b. Confirm that the research team is aware of and will follow all non-U.S. regulations/laws that apply to the research.

3. Single IRB Review/IRB Authorization Agreements (Reliance Agreements): Collaborative projects involving exempt and non-exempt research with agents of other institutions under IRB oversight may require one institution to serve as the overseeing IRB. Appalachian may enter into formal agreements with other facilities and/or personnel which are not legal entities/employees of Appalachian to: provide research review or exempt determination, rely on other institutions for research review or exempt determination, or 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.
3. Collaborators with no affiliated IRB: Appalachian will not provide IRB oversight for a Principal Investigator who is not affiliated with the University (i.e., they are not listed in the Appalachian Directory). However, under certain circumstances and with IO approval, members of the research team who are unaffiliated with the University may be included in projects with IRB oversight. These personnel must complete the Individual Investigator Agreement and follow the same requirements as Appalachian State University personnel.

VIII. 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 as needed.

IX. SUPPORT AND PROCEDURES

SOP #1
SOP #5
SOP #6
SOP #9

X. References

45 CFR 46
ASU Policy 209