

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #3 Rev. 1	Continuing Review	Date Effective: 1.21.2019
Approved by IRB Chair	<i>[Signature]</i>	Date 1/21/2019
Approved by RP Director	<i>[Signature]</i>	Date 1/21/2019

PURPOSE

To describe the procedures for determining the need for and conducting continuing review of research involving human participants.

GENERAL DESCRIPTION

Principal Investigators are responsible for requesting continuing Institutional Review Board (IRB) review of research involving human participants in advance of the expiration of IRB approval for ongoing human subject research. In accordance with federal regulations and institutional policy, the IRB conducts substantive and meaningful continuing review.

PROCEDURES

Determining Need for Continuing IRB Review

Exempt studies do not require continuing review. Effective January 19, 2019, 45 CFR 46 does not require continuing IRB review (CR) for research that meets any of the following requirements:

1. Eligibility for expedited review; or
2. Research that has finished interactions/interventions and progressed to the point where it involves only one or both of the following:
 - a. Analyzing data, including identifiable private information or identifiable biospecimens;
 - b. Accessing follow-up clinical data from procedures that participants would undergo as part of standard care for their medical condition or disease.

The Appalachian State IRB has the authority to require CR for any research meeting the requirements above, provided justification is given and documented in the IRB record. The Principal Investigator will be informed of need for CR (and justification if CR is not mandated by the Final Rule) or other reports/check-ins in the IRB approval letter.

In order to maintain high standards for the protection of human participants in research, the Appalachian State IRB has determined the following types of research may require CR, even when not mandated by federal regulations:

1. Research under FDA or EPA regulation;
2. Pilot studies;
3. Funded studies where the sponsor may require or recommend CR;
4. Reliance agreement where Appalachian State is the relying institution, as we will defer to the primary IRB;

5. Studies where an adverse event or non-compliance is reported or identified;
6. Studies where other state, international or federal regulations may require CR;
7. Other studies for cause at the discretion of the IRB.

More than minimal risk studies will be subject to CR at a minimum frequency of 364 days from approval.

Continuing IRB Review (CR) Requests

1. Research Protection (RP) staff maintain a database that sends reminders of the expiration of IRB approval approximately 90 days, 60 days, and 30 days prior to expiration date.
2. The Principal Investigator (PI) must request CR in advance of IRB expiration when the research:
 - a. continues to enroll new participants and/or interactions/interventions with enrolled participants are ongoing;
 - b. is active for long-term follow-up (even when the research is permanently closed to enrollment and all participants have completed all research-related interventions); or
 - c. includes access to private identifiable information.
3. A complete CR request includes:
 - a. The PI must submit the CR request within 30 days of expiration date or the study will be closed by IRB Staff.
 - b. an application requesting CR which includes, when applicable, the number of participants enrolled and withdrawn from the study; summary of unanticipated problems/adverse events involving risks to the participants or others; complaints about the research; and any new, significant findings or recent literature that have implications for participation described;
 - c. revised sponsor protocol for externally funded research, if applicable;
 - d. data safety monitoring reports, if applicable; and
 - e. a copy of the informed consent document, if applicable.
4. Upon receipt of a CR request, RP staff:
 - a. For studies that were approved prior to January 21, 2019, the IRB staff will determine if the research meets the criteria to waive CR or be reclassified as exempt research. The IRB staff will process the request in compliance with the updated 45 CFR 46 and this SOP.
 - b. For studies that require CR, IRB staff will
 - i. confirm whether research personnel have completed any IRB mandated training; and
 - ii. confirm that the CR request is complete.
5. If a request for CR is incomplete, RP staff notifies the PI (and any research personnel designated to receive correspondence on the IRB application) via IRBIS that the request is incomplete. If the CR request remains incomplete after 45 days, RP staff notifies the PI that the request will be withdrawn in 7 days unless a complete CR request is submitted.
6. Modification requests and adverse event reporting should be submitted separately from CR requests.
7. An IRB administrator screens complete CR requests to determine the level of review: expedited or full board and follow appropriate review procedures. 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.

Expiration of Approval

1. If a PI fails to submit a complete CR request or the IRB has not completed a review by the end of the approval period, RP staff will notify the PI via email that IRB approval has expired. The notice of expiration states that human research cannot be conducted after expiration of IRB approval.
2. If the IRB determines that there is an overriding safety concern and/or ethical issue or that it is in the best interests of participants to continue the research activities, RP Staff or the IRB Chairperson will contact the PI through an email or letter to communicate that participants may continue in the study while the CR process is completed.
3. A PI can request CR for an expired study if the CR request is provided within 30 days of expiration of IRB approval. In all other cases, the PI must submit an initial request for review to obtain IRB approval for the study.

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#10, Post-Approval Monitoring

REFERENCES

45 CFR Part 46.109(e)(f)