Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #4 Rev. 2	IRB Review of Modifications and Addendums	Date Effective: 1.21.2019
Approved by IRB Chair	[signature]	Date 10/24/19
Approved by RP Director	[signature]	Date 10/24/19

PURPOSE

To describe the procedures for conducting reviews of modifications and addendums for approved human subject research.

GENERAL DESCRIPTION

Principal Investigators (PI) are responsible for requesting IRB review of proposed changes to approved human subject research. Changes in research procedures or consent/assent forms may not be initiated without IRB approval, except when necessary to eliminate apparent immediate hazards to the subject. Research procedures currently approved by the IRB may be conducted while the IRB reviews a modification request. In accordance with federal regulations and institutional policy, the IRB conducts substantive and meaningful review of proposed changes to an IRB approved study.

RESPONSIBILITY

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

PROCEDURES

Modification and Addendum IRB Review (MOD) requests

1. The Principal Investigator (PI) must submit a MOD request for proposed changes to an approved research protocol and/or informed consent form/process prior to implementing changes, except when necessary to eliminate apparent hazards to subjects. In cases where changes are made to eliminate apparent hazards to subject(s), the PI must inform the IRB Chairperson or Director of RP as soon as possible and request IRB review of the MOD request.
    a. Minor personnel changes (not a change in PI, overseeing MD, or other significant role) may be requested via email to irb@appstate.edu, with a reference to the IRB number. All personnel must complete applicable required training before they can be added to the study.
2. A complete MOD request includes:

   a. Request for Modification in IRBIS which explains the nature of the modification (i.e., change that impacts overall protocol), exception (i.e., change that impacts individual subjects and does not change the overall protocol), or deviation (i.e., a departure from the protocol),
   b. revised sections of the application, revised consent forms, and other applicable materials with proposed changes highlighted, and
   c. data safety monitoring reports, if applicable.
3. Upon receipt of a review request, RP staff:
   a. Verify the training of all new members of research team
   b. Confirm that the request is complete
   c. Confirm other regulations are not applicable to the review (i.e., FDA)
4. If a MOD request is incomplete, RP staff notifies the PI (any research personnel designated to receive correspondence on the IRB application) via email or by returning the request through the IRBIS system. If the request remains incomplete after 45 days, RP staff notifies the PI that the request will be withdrawn if the MOD request is not completed within 7 days.
5. If the MOD request includes a new unanticipated problem/adverse event, RP staff separate the problem/adverse event report and process the report using standard procedures.
6. An IRB administrator screens complete MOD requests to determine the level of review based on any potential change in risk to participants. 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.
7. The modification is reviewed in accordance with the established review procedures.
8. An IRB administrator screens complete MOD requests to determine the level of review: exempt, 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.
   a. MOD requests for a study voted more than minimal risk which include only incidental changes (other than personnel), and do not affect the procedures in a significant manner or increase participant risk, may be approved without full board review under the following condition: A decision to approve the changes must be made by the IRB Chair, the IRB Administrator, and one voting member of the IRB unanimously agreeing. The IRB would be provided a summary of the decision at the next convened meeting.

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 #2 Requesting IRB Review
SOP #5 Expedited Review of Research
SOP #6 Full IRB Review of Research
SOP #8 Unanticipated Problems Involving Risks to Subjects or Others, Adverse Events, and Other Problems
SOP #9 Conducting Exempt and Limited Reviews

REFERENCES

45 CFR Part 46.109, 21 CFR 56.108(a)(1)&(2), 21 CFR 56.109(f), 21 CFR 56.110, 21 CFR 56.111, 21 CFR 56.115(a)(3)&(7)