



Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #4 Rev. 3	Modifications and Addendums	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 the procedures for conducting reviews of modifications and addendums (MOD requests) for approved human subject research projects.

II. AUTHORITY

In accordance with federal regulations, each IRB shall establish and follow written procedures for ensuring prompt reporting to the IRB of proposed changes in research and for ensuring that changes to the research procedures are not implemented prior to IRB approval, except when necessary to eliminate apparent immediate hazards to the subject. Federal regulations establish the authority of an IRB to use the expedited review procedure to review minor changes to previously approved research during the period for which approval is authorized.

III. RESPONSIBILITY

1. Research personnel are responsible for requesting IRB review of proposed changes to approved human subject research and for promptly informing the IRB of any changes implemented to eliminate apparent immediate hazards to subjects. Research procedures currently approved by the IRB may be conducted while the IRB reviews a modification (MOD) request.
2. RP staff is responsible for receiving the MOD request in the electronic research administration (eRA) system, verifying that the request is complete and personnel are properly trained, contacting the study team with requests for additional information or revisions, determining the level of review (if RP staff cannot determine the level of review, the IRB Chair is responsible for this determination), issuing administrative approval for certain MOD requests, approving modifications to exempt research, and coordinating the review process for MOD requests that require IRB review.

IV. PROCEDURES

1. Research personnel must submit a MOD request for proposed changes to an approved research protocol, associated documents, and/or informed consent process prior to implementing changes, except when necessary to eliminate apparent immediate hazards to subjects. In cases where changes are made to eliminate apparent immediate hazards to subject(s), the PI must inform the IRB Chairperson or Director of RP as soon as possible.

- a. Modifications consisting only of minor personnel changes (*not* a change in PI, overseeing MD, or other significant role) and/or changes to contact information on study documents can be processed by RP staff by administrative review. All new personnel must complete applicable required training before they can be approved to conduct human subjects research procedures.
2. A complete MOD request includes:
 - a. A Request for Modification submission in the eRA system 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, which should replace the previous versions of the documents in the application, and
 - c. data safety monitoring reports, if applicable.
3. Upon receipt of a MOD request, RP staff:
 - a. Verify the training of all new members of research team
 - b. Confirm that the request is complete.
4. If a MOD request is incomplete, RP staff notifies the PI via email or by returning the request through the eRA system. If the request remains incomplete after 45 days, RP staff may notify the PI that the request will be withdrawn if the MOD request is not completed within 7 days.
5. RP staff screens complete MOD requests to determine the level of review. If RP staff 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 using expedited review procedures.
6. The MOD request is reviewed in accordance with the established review procedures.

V. 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.

VI. 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

VII. REFERENCES

45 CFR 46

21 CFR 56