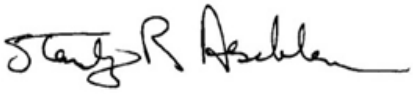
Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #3 **Revision #**	**TITLE: Continuing Review of Research**	Date Effective: 8/8/2012 Revision Date:
Approved By: RP Director	Signature 	Date: 8/15/2012
Approved By: IRB Chair	Signature 	Date: 8/15/2012

PURPOSE

To describe the procedures for conducting continuing review of human subject research.

GENERAL DESCRIPTION

Principal Investigators are responsible for requesting continuing IRB review of human subject research 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.

RESPONSIBILITY

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

PROCEDURES

Continuing IRB Review (CR) requests

1. Research Protection (RP) staff maintain an IRB website with instructions for requesting CR of human subject research. RP staff sends reminders of the expiration of IRB approval approximately 90 days, 60 days, and 30 days prior to expiration.
2. The Principal Investigator (PI) must request CR in advance of IRB expiration when the research:
    a. continues to enroll new subjects and/or interactions/interventions with enrolled subjects are ongoing, or
    b. is active for long-term follow-up (even when the research is permanently closed to enrollment and all subjects have completed all research-related interventions), or
    c. includes access to private identifiable information.
3. A complete CR request includes:
    a. an application requesting continuing IRB review which includes, when applicable, the number of subjects enrolled and withdrawn from the study;

summary of unanticipated problems/adverse events involving risks to the subject or others; complaints about the research; and any new, significant findings or recent literature that have implications for subject participation described;

b. revised sponsor protocol for externally funded research, if applicable;
c. data safety monitoring reports, if applicable; and
d. a copy of the informed consent document, if applicable.

4. Upon receipt of a review request, RP staff:
    a. enter the request in an IRB management system,
    b. acknowledge receipt of the request through an email to all research personnel designated to receive correspondence on the IRB application,
    c. confirm whether research personnel have completed any IRB mandated training, and
    d. confirm that the request is complete.
5. 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 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 in 7 days unless a complete request is submitted.
6. If the continuing review request includes a modification request or a new unanticipated problem/adverse event, RP staff separate the modification request or unanticipated problem/adverse event report and process these requests using standard procedures.
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 subject 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 subjects to continue participating in the research activities, RP Staff or the IRB Chairperson will contact the PI through an email or letter to communicate that subjects may continue in the study while the continuing review process is completed.
3. A PI can request continuing review for an expired study if the CR request can be reviewed and approved within 90 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

IRB SOPs

REFERENCES

45 CFR Part 46.103(b)(4)(i), 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), 45 CFR 46.103(b)(4), 45 CFR 46.108(b), 45 CFR 46.109(e), 45 CFR 46.110, 45 CFR 46.111, 45 CFR 46.115(a)(3)&(7), 45 CFR 46.103(a), 21 CFR 56.103(a), and 38 CFR 16.103(a)