Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #6 **Revision # 1**	**TITLE: Full IRB Review of Research**	Date Effective: 8/8/2012 Revision Date: 9/3/2014
Approved By: IRB Chair	Signature	Date: 9/3/2014
Approved By: Interim Vice Provost for Research	Signature	Date: 9/8/2014

PURPOSE

To describe the procedures for conducting full review by the Institutional Review Board (IRB).

GENERAL DESCRIPTION

The IRB conducts initial reviews, modifications and addendum reviews, and continuing reviews for non-exempt research at convened meetings unless the research is eligible for exempt or expedited review.

RESPONSIBILITY

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

PROCEDURES

1. The IRB Administrator, or designee, makes a preliminary determination that an initial protocol review, continuing protocol review, or a proposed modification to an approved protocol is not eligible for expedited review based on an assessment of the level of risk; the DHHS review categories and FDA requirements; and sponsor requirements. The IRB Administrator informs the IRB Chair that a full review by the IRB is required. Expedited reviewers and PIs may also request full review by the IRB. The IRB Chair makes a final determination that full review is required.
2. RP staff invites the PI or co-Investigator to attend part of the IRB meeting to answer questions regarding the study.
3. The IRB Administrator screens the review request to determine whether additional expertise is needed to conduct the review. If additional expertise is required, the IRB Chair appoints an ad hoc or cultural consultant with appropriate expertise in the discipline, population, or location. RP staff confirms that consultants do not have a conflict of interest and send consultants the same study information as IRB members.
4. The IRB Chair, or designee, appoints a primary reviewer and in some cases, a secondary reviewer, based on the IRB member's educational background and expertise. RP staff confirms that reviewers do not have a conflict of interest and can serve.
5. The IRB Administrator reviews the study to determine any sponsor requirements, applicable regulations (e.g., U.S. Department of Education requirements, HIPAA,

Subparts B, C, or D of the Common Rule), and institutional review requirements that must be considered in the review. The IRB Administrator places the appropriate criteria for IRB approval as specified in 45 CFR 46.111, 21 CFR 56.111, and 38 CFR 16.111, and any additional sponsor or institutional requirements in the agenda for the meeting. The IRB Administrator will identify any procedures that meet the practice of medicine under NC state law in order to ensure that licensed medical professional(s) are responsible for all medical procedures in compliance with NC law.

6. Approximately 1 week prior to the Board meeting, an agenda for the meeting and all study materials (i.e., application, consent form, data collection instruments, grant/contract if any, recruitment materials, letters for off-site research) are made available electronically to all Board members and the Institutional Official.
7. Appointed reviewer(s) are responsible for:
    a. Comparing the detailed grant application or contract with the IRB application and identifying any discrepancies between the detailed protocol and the application materials;
    b. Conducting an in-depth review based on the criteria for approval; and
    c. Contacting Principal Investigator(s) (PI), or asking the IRB administrator to contact a PI, with questions related to the criteria of approval to clarify any unresolved issues.
8. All IRB members review the application, informed consent/assent process, any HIPAA forms, additional materials (proposed data instruments, recruitment notices, etc.) in advance of the meeting in enough depth to be familiar with the protocol, prepared to discuss the protocol at the meeting, and prepared to determine whether the research meets the IRB criteria for approval.
9. Ad hoc or cultural consultants provide comments or recommendations in writing to the IRB prior to the meeting or attend the convened meeting to participate in the review. RP staff maintains records of their written comments or reports in the study file. In cases where the consultant participates in the meeting, the minutes of the meeting document the information provided by the consultant.
10. When the IRB reviews research that involves human subjects vulnerable to coercion or undue influence, RP staff ensures that adequate representation or consultation is present for discussions of research involving vulnerable human subjects.
11. A majority of the voting IRB members (or their designated alternates), including at least one member whose primary concerns are in nonscientific areas, must attend the meeting to establish a quorum to conduct a convened meeting (e.g., IRB Members = 11; majority = 6). Ad hoc and cultural consultants, and members who are recused for a conflict of interest, do not count toward quorum. If a quorum is lost during the meeting, the IRB does not take further protocol actions that require a vote unless quorum is restored.

a. A member or consultant with a conflict of interest must leave the room during the IRB review and IRB vote on any study.
b. Members can attend the meeting by being present at the meeting, or communicating via telephone or video conference simultaneously with the meeting.
c. When the IRB reviews FDA regulated research, there must be one member present who is a licensed physician.
d. All IRB members attending the meeting have the opportunity to discuss each protocol during the convened meeting and participate in the determination of whether the research meets the regulatory criteria for approval.

12. The IRB Chair, or any designated voting member, chairs the convened meeting.
13. To the extent possible, the proceedings of the convened meeting are confidential. Individuals, such as students or other representatives, may attend as observers if the IRB Chair or IRB Administrator grants permission to attend and obtains a statement of confidentiality. Observers do not receive a copy of review materials.
14. Full Review:
    a. The IRB reviews any questions about a protocol with the PI or co-investigator present unless the PI waives the opportunity.
    b. After the PI leaves the meeting, the appointed reviewers, and ad hoc consultants if appointed, present the protocol and summarize issues applicable to the criteria for approval in an organized format.
    c. Following the appointed reviewers presentation, the IRB Chair invites the full committee to discuss issues associated with the criteria for approval. This discussion includes determining the risk level of the research; any determinations to waive elements of informed consent; and whether the research requires an Investigational New Drug Application or Investigation Device Exemption to the Food and Drug Administration. The IRB discusses any controverted issues and their resolution prior to voting.
15. Review Outcome(s): To approve a review outcome, a simple majority of the meeting quorum must vote for that outcome. An IRB member makes a motion, another member seconds the motion, and then the convened IRB votes for, against, or abstains from one of the following actions:
    a. Approved: The Board finds that the a) the research meets the criteria for approval, b) the study's informed consent process and documentation meets the requirements as specified in 45 CFR 46.116 and 21 CFR 50.25 unless the IRB waives the requirements in accord with federal regulations, and c) adequate procedures to protect vulnerable subjects (prisoners, children, pregnant women,

seriously ill patients, and mentally incapacitated adults) and any applicable regulatory criteria (Subpart B, C, or D) are met.

i. The Board assigns the approval period at intervals appropriate to the degree of risk and history of compliance of the PI but not more than one year. The IRB may set a shorter approval period for high risk protocols or protocols with high risk/low potential benefit ratios. The date the Board approves the study is the date the approval period starts.

ii. When a protocol receives IRB approval, RP staff will confirm that all applicable institutional approvals and any required letters/training are in place prior to issuing the IRB approval letter. If applicable approvals/letters/training are not in place, RP staff request the appropriate information from the investigator.

iii. To issue IRB approval, RP staff process the approval by 1) sending an email notice of approval, with the approval period dates and investigator's responsibilities, to the PI and any research personnel designated to receive IRB correspondence, and 2) sending an email with the approved study documents to the PI and any research personnel designated to receive IRB correspondence. A hard copy of the letter of approval follows within 2 weeks.

b. Minor Stipulations to Approval: The IRB approves the protocol pending minor stipulations to approval. Minor stipulations do not include substantive issues that interfere with the ability of the Board to find that the criteria for approval have been met.

i. The member chairing the meeting appoints a member to approve the revisions if the minor stipulations are satisfied.

ii. RP staff sends the PI a letter describing the minor stipulations requested by the IRB copying the IRB member who chaired the meeting. When RP staff receives the PIs revisions, RP staff sends the revisions to the appointed reviewer and IRB Chair for review. The appointed reviewer can request additional information or approve.

iii. If approved, the approval procedures are followed. The date of IRB approval starts from the meeting date of the convened IRB when the IRB initially reviewed the protocol.

iv. If the PI does not respond with revisions or concerns within 45 days of notification, RP staff send the PI an email noting that the study will be withdrawn in 7 days unless a response with revisions or concerns is received.

c. Deferral: The IRB withholds approval pending major revisions, additional information, and/or other rationale to protect human subjects. The IRB may appoint one or more members to discuss the reasons for deferring approval (i.e., tabling) with the PI.
    i. RP staff notifies the PI via email of the reasons for deferral with a description of any revisions and clarifications requested by the Board and copies the IRB member who chaired the meeting. When RP staff receives the PIs revisions, the review is placed on the agenda for the next IRB meeting.
    ii. If the PI does not respond with revisions or concerns within 45 days of notification, RP staff send the PI an email noting that the study will be withdrawn in 7 days unless a response with revisions or concerns is received.

d. Disapproved: The IRB disapproves a study when the risks of the procedures outweigh any potential benefit to be gained; or if the proposed research does not meet the federal criteria for IRB approval.
    i. RP staff sends the PI a letter describing the reasons for disapproving the protocol copying the IRB member who chaired the meeting.

16. Minutes of convened meetings: Minutes of meetings are sufficiently detailed to show attendance at the meeting; actions taken by the IRB; the vote on these actions including the number voting for, against, and abstaining; the basis for requiring changes in or disapproving research; and a written summary of the discussion of controverted issues and their resolution.
    a. Meeting minutes are sufficiently detailed to determine how the IRB arrived at its decisions.
    b. Minutes may not contain information provided in protocols the IRB has previously approved. This process assumes that if IRB members do not discuss a particular issue, the IRB deems the issue acceptable.
    c. Approved minutes are shared with the Institutional Official.
17. Investigator's Right of Appeal: If the PI has concerns regarding the IRB decision, he/she may submit them to the IRB via a written document that includes a justification for changing the IRB decision. In accordance with federal regulations, no research involving human subjects may be conducted under Appalachian State University's auspices without the prior and continuing approval of the Board. Any investigator who disagrees with a decision of the Board may request a hearing before the duly-convened IRB to appeal its decision. Relevant arguments and/or witnesses may be presented on behalf of the investigator. The investigator may also request that the Authorized Institutional Official be informed of the appeal. However, final decision rests with the Board.

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)