Appalachian State University Research Protections and Institutional Biosafety Council Standard Operating Procedures		
SOP #1 **Revision #0**	**TITLE: New Protocol Review**	Date Effective: Revision Date:
Approved By: IBC Chair	Signature Jennifer P. Czach	Date 8/9/16
Approved By: RP Director	Signature Erin Shroyer Mundell	Date: 8/12/16

PURPOSE

To describe the policies and procedures for conducting initial reviews of Institutional Biosafety Council (IBC) protocols. Continuing reviews are discussed in SOP2, Continuing Review of Approved Protocols.

GENERAL DESCRIPTION

The process begins when a request for review of an IBC request for review or request for exemption ("Application") is received by the IBC Administrator ("Administrator").

The process ends with an approved IBC study request for review or request for exemption, or a disapproved/withdrawn request for review or request for exemption.

RESPONSIBILITY

Unless otherwise excepted by the provisions hereof, this procedure shall apply to all persons who perform research involving recombinant DNA molecules. It is applicable to activities that occur in University facilities as well as other locations whenever projects involve University funding, faculty scholarship or staff/student/agent effort as part of University activities. The provisions of this document shall be interpreted and applied in conformity with Federal, State, and UNC System Policies and Procedures.

Applicability

- All Appalachian employees or persons who perform research involving recombinant DNA molecules, as well as those whose job duties involve interactions with such persons in the course of their research.
- Any individual serving as an affiliate of Appalachian conducting any of these activities off campus on behalf of or under the instruction of the university.
- Source of funding (or lack of funding) does not negate the requirement.

PROCEDURES

1. Submission of request for review or request for exemption
2. Review process
3. Designated Reviewers (DR) process
4. Conducting reviews
5. Review results
6. Other council reviews
7. Approval dates
8. Memorandum of Understanding

SUBMISSION OF APPLICATION

The IBC will review recombinant DNA activities conducted at or sponsored by Appalachian State University for compliance with the NIH Guidelines as specified in Section III, Experiments Covered by the NIH Guidelines, and approve those research projects that are found to conform with the NIH Guidelines. IBC review will include: a. independent assessment of the containment levels required by the NIH Guidelines for the proposed research; b. assessment of the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research; c. implementing appropriate measures with the goal of ensuring compliance with all surveillance, data reporting, and adverse event reporting requirements set forth in the NIH Guidelines; and d. implementing appropriate measures with the goal of ensuring that the research does not involve human subjects in gene transfer trials as the IBC will not approve this research at this time.

For new protocols, the Principal Investigator (PI) or instructor must submit a new request for review or request for exemption.

For annual renewal of approved protocols, or for proposed changes to an active protocol, the PI must submit a completed request for annual renewal or protocol amendment review, respectively.

Activities involving recombinant DNA that are not exempt from the NIH Guidelines will be reviewed at a convened meeting of the IBC. Members with a personal or financial interest in the activity will be recused. In addition, members with expertise to review the proposed activities must be present for the IBC to approve activities. For example, a member with expertise in plant, plant pathogens or plant containment principals must be present to approve experiments described in Appendix P of the NIH Guidelines.

Current versions of these request for review or request for exemptions can be found on the Appalachian State University IBC website.

Completed and signed* request for review or request for exemptions must be submitted to IBC@appstate.edu as email attachments.
All supporting documentation (e.g. - grant request for review or request for exemptions, copies of approvals from collaborating IBCs) should accompany the request for review or request for exemption.

*The IBC accepts e-signatures on the request for review or request for exemptions.

Incomplete request for review or request for exemptions will be returned to the PI for completion. Missing supporting documentation will be required before approval can be issued.

Training Requirement
All personnel listed on the Application must complete the required training use of recombinant organisms. Training requirements for various levels are posted on the Appalachian State University IBC website.

REVIEW PROCESS

The Administrator notifies the Chair that a new request has been received and recommends level of review. The chair will approve or reassign the level of review. Level of review recommendations are shown in table below.

Type of protocol	Minimalist level of review possible
Exempt	Designated Reviewer
Registration	Designated Reviewer
Transgenic plant or animal	Full Council Review
Non-exempt BL1	Full Council Review
Non-exempt BL2	Full Council Review

DESIGNATED REVIEWERS (DR) PROCESS

No IBC member with a direct interest in the request for review or request for exemption may participate in a review except to provide information.

The chair recommends three Designated Reviewers (DRs) based on council availability, knowledge, and any perceived conflicts of interest. These members are emailed the application and associated files along with the review checklist. Once the members agree to be reviewers, they are emailed the information to review and comment. After 7 days, the DRs review the information; all comments and concerns are compiled by the administrator and responses will be requested from the PI. When they feel they have enough information and all of the information they have is acceptable, they recommend approval.

Once all DRs recommend approval, the Administrator will process the approval and send the PI the approved application and the approval letter. Any DR can recommend the protocol be reviewed by a full council at any time during the review process.

CONDUCTING FULL COUNCIL REVIEWS

Once the Chair has been notified, and the study has been added to the next meeting's agenda, the Administrator updates the PI with the status of the request for review or request for exemption. The PI may be invited to the meeting to discuss the proposed research.

1. The Council will provide comments at the convened meeting.
2. If the PI is using facilities not owned by Appalachian State, or the study has researchers from multiple institutions, a Memorandum of Understanding (MOU) may be used to designate responsibilities.

No IBC member with a direct interest in the request for review or request for exemption may participate in a review except to provide information. During full IBC Reviews, IBC members with any direct interest must recuse themselves prior to voting and cannot contribute to the quorum.

Applications are reviewed according to the requirements outlined in:

1. *The NIH Guidelines For Research Involving Recombinant Or Synthetic Nucleic Acid Molecules (NIH Guidelines)*
2. Sponsored programs agreement/requirements of sponsor.
3. Requirements from other University programs or policies (such as safety, IACUC, etc.).

Discussion is recorded in the minutes of IBC meetings.

A quorum must be present (after recused members) in order to vote for any action regarding a request for review or request for exemption. The Chair will open for a motion prior to council discussion. After discussion, a vote is taken. The IBC can vote to:

1. Approve/Exempt
2. Require changes or clarification for approval/exemption
3. Disapprove
4. Table/Defer for next convened meeting.

The vote is recorded in the meeting minutes.

IBC Voting Option Definitions:

1. Approve— The IBC finds that all review criteria have been addressed by the PI. The Administrator or Chair sends a letter to the PI with the approval date set from the date of the IBC meeting. Exempts do not have an expiration date.
2. Require changes or clarification for approval —The IBC requires changes in the submitted materials. The IBC then determines whether the response by the PI will be reviewed by the Chair or IBC. The approval date and period will be tied to approval of the updated materials.
3. Disapprove— The IBC determines that the review criteria are not sufficiently met to a degree that the request for review or request for exemption requires more than modifications.
4. Table/Defer—The IBC determines that additional expertise is needed to make a decision on the request for review or request for exemption, or that the request for review or request for exemption lacks sufficient information to render a decision.
5. If a quorum is not present for the review, there is no vote, and the review is discontinued until the next convened meeting.

REVIEW RESULTS

The Administrator prepares the result of the review and sends to the chair. The chair sends results to the PI.

a. The Administrator prepares the result of the review to the PI via written notification:

1. Approve: The Administrator prepares a letter of approval and sends to the Chair to sign, along with a copy of the approved request for review or request for exemption. The Chair returns the signed documents and the Administrator sends to the PI and files a copy.
2. Require changes or clarification for approval: The Administrator prepares a letter for the PI that is emailed to the Chair for review and forwarding. The Chair sends the email to the PI, copying the Administrator.
3. Disapprove: The Administrator prepares a letter for the Chair to sign. The Chair returns the signed letter, and the Administrator sends to the PI and files a copy.
4. Table/Defer: The Administrator notifies the PI via email. The study is moved to the agenda of the next convened meeting.

b. If the PI is required to make changes for approval, the IBC chair confirms the changes are appropriate and makes the determination to approve, send back to the PI for further changes, or add to the next IBC agenda for review.

OTHER COUNCIL REVIEWS

The IBC will work with sister councils, like the IACUC and IRB, as needed for any project that falls under the purview of multiple regulatory councils. In such cases, the applications should be submitted with the understanding that the IBC will not approve a protocol application (exempt or otherwise) without the sister council's recommendation that the portion of a protocol under their purview is ready for approval. The councils may require approval of the other councils before they approve the protocol.

APPROVAL DATES

The approval date is the day the Chair signs the approval letter. If the PI provides the requested modifications to secure approval, the approval date is the date Chair approves the modifications to secure approval and signs the approval letter.
Approvals are good for 364 calendar days.

MEMORANDUM OF UNDERSTANDING

The IBC Administrator and Chair may determine that an agreement should be in place to designate responsibilities with a collaborating institution that either:

1. Provides housing and or care for Appalachian-owned organisms in the proposed research,
2. Provides or shares research staff for the proposed research,
3. Shares funding with Appalachian for the research, or
4. Conducts research on live organisms that are not owned by Appalachian;
5. Reviews Appalachian research conducted in non-Appalachian facilities.

If the PI is using privately owned organisms temporarily for research, an MOU may not be required; a letter from the owner granting permission to use the organisms with an understanding of the proposed research procedures may suffice.

If an MOU is required, the Administrator contacts the collaborating institution to determine terms and conditions.

The Administrator obtains signatures on the agreed-upon document. The Institutional Official and IBC Chair serve as signatory officials for Appalachian State.

SUPPORTING PROCEDURES AND PROCESSES

Appalachian Policy #212, *Use of Recombinant DNA in Research and Teaching Laboratories*
SOP2, Continuing Review

RESOURCES

- Biosafety Guidance
- NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)
- CDC and HHS Select Agents and Toxins List
- The CDC Publication: Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition
- Guidelines for Biosafety Laboratory Competency