

Appalachian State University Research Protections and Institutional Biosafety Council Standard Operating Procedures		
SOP #2 Revision #0	TITLE: Continuing Review of Approved Protocols	Date Effective: Revision Date:
Approved By: IBC Chair	Signature <i>Jennifer P. Ceale</i>	Date: <i>8/9/16</i>
Approved By: RP Director	Signature <i>John S. Mendenhall</i>	Date: <i>8/12/16</i>

PURPOSE

To describe the policies and procedures for conducting reviews of annual reviews of/changes to approved IBC protocols.

GENERAL DESCRIPTION

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

The process ends when an approved IBC study application, a fully executed Memorandum of Understanding, or a disapproved/withdrawn application.

This SOP applies only to changes to or renewals of already-approved IBC protocols.

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.

PROCEDURES

1. Annual review/ review
2. Amendments
3. Administrative review
4. Chair, Designated Reviewer or convened council review

ANNUAL REVIEW / DE NOVO REVIEW

The IBC can approve activities with biohazardous agents and/or recombinant DNA for a period of one year or less. After activities with biohazardous agents and/or recombinant DNA have been approved by the IBC, it is the investigator's responsibility to report to the Council any proposed changes in the research as well as unanticipated problems that arise involving risk.

1. IBC protocols that are approved but not exempt require annual renewals.
 - a. Once every 12 months from date of initial approval, the IBC must conduct a review of approved protocols to ensure that documented protocols have not changed or deviated.
2. The IBC Administrator ("Administrator") notifies PIs of pending annual review or expiration dates via emails approximately 2 months, 1 month, and 1 week before and again on the due date. The PI submits a completed form to IBC@appstate.edu. The Administrator notifies the Chair that a new request has been received.

Appalachian State University and Institutional Biosafety Council Standard Operating Procedures		
SOP #2 Revision #0	TITLE: Continuing Review of Approved Protocols	Page: 2 of 3

AMENDMENTS

1. Proposed change in approved protocol.

The nature of the change will determine if the review can be administrative, Chair Review or convened council review. The PI should request review of changes before the change is implemented.

Amendments that list significant changes require the submission of a replacement protocol. "Significant Changes" include, but are not limited to, changes:

- In the objectives of a study;
- Increase in Biosafety level;
- Resulting in greater risk to the personnel or general public;
- In the species receiving rDNA, gene used or in vector;
- In Principal Investigator;
- In changes to procedures used in protocol.

2. The Administrator advises the Chair whether the submission warrants Administrative, Chair Reviewer, Designated Reviewers or convened council review. If the IBC needs to review in a convened council, the request will be added to the agenda of the next scheduled convened meeting. A summary of review types and examples can be found below in a section labeled as such.

ADMINISTRATIVE REVIEW

Amendments that may require only Administrative Review include the following:

- Only personnel changes *other than* the PI role
- Funding change
- Closure of study

Administrative reviews do not require notification to the Chair or Council but can be processed internally by the Administrator. The protocol number, PI and change made may be listed on the next full council meeting agenda.

CHAIR REVIEW

Amendments requiring Chair review are processed internally by the chair and administration. Changes that were approved by Chair review will be shared with the IBC at the next convened meeting. Examples include:

- Change in host, vector, or strain that does not alter the BSL level
- Non-significant changes that do not affect level of review required or biosafety level

The Chair will review the documents, require modifications or approve as needed. The chair cannot approve changes on a protocol they are listed as personnel, or PI on. The protocol number, PI and change made will be listed on the next full council meeting agenda.

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

Appalachian State University and Institutional Biosafety Council Standard Operating Procedures		
SOP #2 Revision #0	TITLE: Continuing Review of Approved Protocols	Page: 3 of 3

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 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.

FULL IBC REVIEW

Amendments that may require Full IBC Review include the following:

- The protocol discusses a novel technique to the protocol or other changes the chair feels the IBC needs to discuss further
- The change contains new BSL2 material or procedures
- The change contains organismal containment aspects not discussed by the IBC in the past
- The change requires a lab visit

The reviews are conducted in accordance with SOP1, Protocol Review.

SUMMARY OF REVIEW TYPES AND EXAMPLES

Administrative	Chair	Designated Reviewers	IBC Convened Meeting
Minor change	Non-significant change	Non-biosafety change	Significant change
Personnel, funding, or closure	Change is host, vector or strain that does not change the biosafety level	All other changes that are not significant enough for a convened meeting review or a convened meeting has not been requested	A novel technique, new BSL2 material or procedures, organismal containment aspects not discussed by the IBC in the past, requires a lab visit, or other changes the chair feels the IBC needs to discuss further

SUPPORTING PROCEDURES AND PROCESSES

Appalachian Policy #212, *Use of Recombinant DNA in Research and Teaching Laboratories*
SOP1, Protocol Review

REFERENCES

- [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](#)