University of Arkansas
Biological Safety Committee

Procedures for Review and Approval of Protocols and Protocol Modifications

The University of Arkansas *Biological Safety Manual* applies to all University of Arkansas and Division of Agriculture activities, funded and unfunded, performed on the campus and at the farms, extension stations, and other off-campus facilities, and to activities performed by University personnel at other, non-University facilities. Both teaching and research activities are covered, as well as field operations. Personnel covered by the program include graduate and undergraduate students, part- and full-time faculty and staff, and visitors. The manual specifies controls and handling practices required for microbiological agents, (bacterial, viral, and fungal, as well as certain multi-cellular parasites), biological toxins, recombinant DNA molecules (r-DNA), human or non-human primate blood or tissues, and animal cell cultures.

The following types of research must be reviewed and approved at a properly convened meeting of the Biological Safety Committee ("Committee"), i.e., a meeting where a majority of the voting members, including at least one Community Member, are in attendance.

1. Protocols involving recombinant DNA (r-DNA) research in accordance with National Institutes of Health (NIH) guidelines;
2. Protocols involving Risk Group (RG) 3 or Biosafety Level (BSL) 3 agents (Appendix I of the *Biological Safety Manual*);
3. Protocols involving RG-2 or BSL-2 agents (Appendix I of the *Biological Safety Manual*) propagated in production quantities or used in procedures in which the agent is likely to become aerosolized;
4. Protocols involving biological toxins, human or non-human primate blood, tissues or cell lines derived thereof.

Investigators are referred to the UA *Biological Safety Manual* and the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (2011, and as amended from time to time) for specific guidelines and requirements.

NEW PROTOCOL REVIEWS

New protocols must be submitted to the Compliance Coordinator at least one week prior to the next scheduled meeting. Investigators *may not* start their project until they have received a written Protocol Approval Notice from the Chair. The only exceptions to this are those projects for which simultaneous notification is required, in accordance with NIH *Guidelines For Research Involving Recombinant DNA Molecules*, Section III-E. Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation (http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc7261573).

Review and discussion of a protocol by the Committee will result in one of four outcomes:

a. *Disapproval*. This outcome is usually the result of the PI submitting a protocol which contains information or procedures which the Committee feels that it cannot approve. A Protocol Disapproval Notice will be sent to the Principal Investigator (PI) informing him/her of the outcome of the review. The notice will contain the reasons for disapproval and suggestions that may result in approval if the PI wishes to submit a new protocol. If the PI wishes to revise the proposed project, a new protocol is required and a new protocol number will be assigned.

b. *Revise and Resubmit.* In this case, the committee concluded from initial reading that the protocol provided insufficient information to the committee to fully deliberate and make a final determination, or the protocol, as submitted, remains unclear in major areas. The committee is requesting a revision of the proposal in order to document compliance with regulations and policies. An Action Notice will be sent to the PI asking the PI to revise and resubmit the protocol.

This notice will list the protocol deficiencies which must be addressed. Depending on the degree of revision required and the seriousness of the issues, the PI will be advised that the revised protocol will be reviewed at the next scheduled meeting. The revised protocol must be sent to the Compliance Coordinator. The Compliance Coordinator will distribute the revised protocol to the entire Committee.

c. *Conditional Approval Contingent upon Information/Clarification.* The Committee determined that the information provided in the protocol is sufficient to allow evaluation, but the protocol requires additional information or clarification. The PI will be notified via email of minor changes or stipulations required. The PI must submit a revised protocol with the suggested changes/ information to the Compliance Coordinator. Once the response is received from the PI, the Chair and BSO will review response. If the Chair and BSO determine that the response is complete and satisfactory, the Chair will notify the Compliance Coordinator who will include it in the protocol file and issue a Protocol Approval Notice. Either the Chair or the BSO can refer the protocol to the full Committee for review at the next scheduled meeting of the Committee. In any case, the project cannot be initiated prior to receipt of the signed Protocol Approval Notice.

d. *Approved* – Voting members present at the meeting voted by majority assent to approve as written or, again with majority assent, with specific conditions imposed by the Biosafety Committee. The Coordinator will email a Protocol Approval Notice to the investigator.

PROTOCOL MODIFICATION REVIEW

Modifications to protocols previously approved by the Committee will be reviewed by one of two methods. All modifications should be submitted to the Compliance Coordinator via email.

1. Minor modifications such as adding additional vectors or organisms of the same BSL will be forwarded to the Chair and BSO for joint approval.
2. For all other modifications, the Compliance Coordinator will place the Protocol Modification Request on the agenda for the next meeting. Such requests will be reviewed and approved in accordance with the procedures for review of a new protocol as indicated above.

All documents and subsequent correspondence will be placed in a protocol file and maintained in the Compliance Coordinator's office.