West Virginia University
Institutional Biosafety Committee Charter

I. Purpose and Appointment

West Virginia University (WVU) conducts research involving recombinant DNA (rDNA) and receives funding from the National Institutes of Health (NIH) for at least part of this research. According to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (*NIH Guidelines*), an institution receiving NIH funds for rDNA research must comply with the *NIH Guidelines* for all rDNA research. The *NIH Guidelines* also state that any institution conducting rDNA research which is covered by the *NIH Guidelines* must establish an Institutional Biosafety Committee (IBC) which will be responsible for review of that research. WVU has installed a Biosafety Officer (BSO) to facilitate meetings and to coordinate biosafety activities for the entire university. The BSO also has the responsibility for conducting periodic inspections of laboratories that use covered materials to ensure compliance with all regulations, the *NIH Guidelines* and WVU policies. The IBC reports to the Vice President for Research.

II. Scope of Review

At WVU the IBC is *charged* with review of work being conducted on all campuses involving rDNA as well as work involving infectious agents.

Recombinant DNA

Definition: Molecules which are constructed outside living cells by joining natural or synthetic DNA segments to DNA molecules that can replicate in a living cell, and the molecules that result from the replication of those cells.

Section III of the *NIH Guidelines* covers the different types of rDNA research and the levels of review required for each, ranging from exempt to full review by the NIH depending on the safety risk posed.

Pathogens

A pathogen or infectious agent is any agent associated with disease in humans, animals, or plants. This includes blood borne pathogens in human samples and cell lines. There are four Risk Groups (RGs) discussed in the *NIH Guidelines* which generally correlate with the biosafety levels described in the CDC publication "*Biosafety in Microbiological and Biomedical Laboratories* (BMBL)".

III. The Committee

The NIH priorities of transparency and community partnership are upheld by the WVU IBC. WVU and the IBC are committed to research that is safe for the community as well as those doing the research.

The committee is composed of ten to fifteen members with expertise in rDNA and/or biosafety. The committee will be comprised of the following required members: the IBC chair, the biosafety officer, two non-affiliated members, an animal expert, and a plant expert. Additional members will ideally include lab personnel, PI's, and experts in safety and occupational medicine. The Vice President of Research, with advice from the biosafety officer and IBC chair, will appoint members and select the chair of the committee. The expected term of service is three years, with the option to renew. Meetings will generally be held monthly but may be more or less frequent depending on business needs. A quorum requires at least 50% of voting members.

The meeting must be conducted by the chair, vice chair or BSO. If the type of work being reviewed requires the advice of a particular expert then this person must be present or in rare instances, if they are unable to come in person, they may participate by teleconference. All members will have appropriate training to be able to effectively review projects. This training will be conducted by the BSO on an annual basis.

Anyone interested in attending an IBC meeting should contact the biosafety officer (304)293-7157 or visit the EHS Biosafety website for details on the next meeting. The IBC will accommodate requests when possible in accordance with privacy and proprietary concerns. Meeting minutes will be taken at each meeting and kept on file.
Meeting minutes may be obtained by placing a request with the biosafety officer or IBC chair and allowing at least two weeks for processing and, if necessary, redaction of documents. Information that may be redacted includes but is not limited to: proprietary information such as trade secrets or other intellectual property, personal information such as home phone numbers or addresses, or information that could compromise institutional or national security.

IV. Responsibilities

The IBC responsibilities are derived from the *NIH Guidelines*:

- Review research that involves recombinant DNA, pathogens or other biohazards, including a full risk assessment, selection of proper containment and assignment of any special provisions. The IBC may lower or raise containment within what is allowed by the *NIH Guidelines* based on the risk assessment.
- Notify PIs of the results of the review.
- Periodically review approved research.
- Adopt emergency plans for spills or exposures.
- Ensure that WVU biosafety policy is in compliance with the *NIH Guidelines* for rDNA.
- Submit an annual report containing the IBC roster to NIH/OBA.
- Report any significant problems with or violations of the *NIH Guidelines* or any significant accidents or illnesses to the institutional official and the OBA according to the requirements of the *NIH Guidelines*. Significant violations or incidents may include items such as:
    - Breach of containment for rDNA such as escaped animals or microorganisms, or a spill outside of containment (ie: BSC) that cannot be easily and quickly cleaned up by one person. Any spill in a BSL3 facility, which is outside of containment, should be reported.
    - Any worker exposure of rDNA to mucus membranes, open skin, or inhalation of aerosols and any potential exposure at BSL3.
    - Any illness likely caused by rDNA exposure.
    - Workers or PIs that willfully violate protocols or conduct work without prior IBC approval.

Note: PIs, workers, and other staff must report any of the above items to the Biosafety Officer.

V. The Review Process:

Anyone working with agents covered in the scope of review by the IBC must have their research reviewed by the IBC *whether the research is funded by NIH or not.* This document applies to all research areas on all WVU campuses.

To initiate a review by the committee you must submit:

- The IBC registration form.

- Standard Operating Procedure (SOP) for any process that involves rDNA or a pathogen.

Note: the IBC form may require other documents to be submitted, depending on other hazards that may be involved in the work or as deemed necessary.

The documents must be sent to the biosafety officer via email. The submission email should be come from the primary PI. It is fine for someone else associated with the lab to submit the forms for the primary PI, however, the primary PI must be copied on the email. A primary PI is the PI who is ultimately responsible for the lab space and thus ultimately responsible for safety. Proposals must be received at least 2 weeks prior to a meeting to be on the agenda for that meeting. Meeting dates are available on the EHS website on the IBC page.

Each proposal to be reviewed will be sent in advance to all committee members for preliminary review. The committee will review the material at a regularly scheduled meeting and will conduct a risk assessment based on the documents submitted. The committee will determine the proper containment and any other procedures that are deemed necessary for safety. The PI for the lab or representatives sent by the PI may be invited to the meeting to answer questions by the committee but may not be present during discussion. If anyone on the committee, due to a conflict of interest may not be able to provide an unbiased opinion, they must be excused from the discussion of that particular proposal. If someone must be excused from discussion on a protocol, the minimum attendance and expertise must still be maintained using members, visitors or ad hoc consultants.

The committee will then decide whether to approve the research. Approval requires a two thirds vote but every effort should be made to gain unanimous approval. If more information is needed or if there are serious problems with the proposal, the committee will notify the applicant as to what is needed and take it up again at the next scheduled meeting. If there are only some small changes needed, the committee may approve the proposal contingent on these items being corrected. When the items are corrected, only a signature from the BSO is required for full approval. If approved, a letter of approval will be sent to the submitter.

Approvals are effective for 3 years. Protocols may be re-approved only by full committee review when they expire or at the discretion of the committee. The IBC may revoke an approval if it is determined that the research is not in compliance with
NIH Guidelines. To renew a protocol, a complete IBC form must be submitted along with supporting documents; similar to a new submission.

Periodic Reviews

Each approved project will be reviewed annually. The BSO will contact the PI to inquire if there are any changes to the research. The PI must update the IBC form to reflect any changes. The BSO will review any changes to determine if there is anything significant enough to require an amendment. This initial review will check not only for changes to the protocol but also changes in regulations, law or university policy that may necessitate changes to the protocol.

Amendments

If significant changes are made during the course of ongoing approved research, then the proposal must be amended. The PI should make the amendment when the change occurs and not wait until the annual review. A substantial change would include: a change in research class or biosafety level; a new pathogen; a major modification of a unique, non-commercial expression vector; any change in an expression vector resulting in increased levels of transgene expression; large changes in the nature of an inserted gene (i.e.: oncogene, virulence, origin or

If research involving human gene transfer is submitted, the committee will ensure that: no participant will be enrolled before all requirements of the *NIH Guidelines* (including appendix M) are completed including:

- The detailed protocol and consent form are submitted to the IBC for the review and these documents clearly indicate how to report incidents that may arise.
- The committee has adequate expertise and training to review the project (using ad hoc consultants as needed).
- All necessary external reviews and/or approvals have been obtained whether from the NIH/RAC, FDA or others.
- The research has been approved by the WVU IBC and IRB.

VI. Inspections

Laboratory facilities and other areas where research under *NIH guidelines* is conducted will be inspected annually by the BSO or other IBC members to ensure that work is being done at the proper containment level and in compliance with NIH guidelines. Facilities used for research that does not fall under *NIH guidelines* will be inspected before IBC approval is given for a new protocol or a protocol renewal. Inspections may be more frequent depending on the risk level.