**IBC Standard Operating Procedures**

**A. Activities Covered by the NIH Guidelines**

Certain research and educational activities undertaken at the University of Wisconsin-Stevens Point require review by, and the approval of, the Institutional Biosafety Committee (IBC). The IBC is charged under the [**NIH Guidelines**](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) to review, approve, and oversee projects involving recombinant or synthetic nucleic acid (r/sNA) molecules.

**It is the responsibility of the principal investigator (PI) or instructor of record to discern whether the activities which they direct are subject to the NIH Guidelines; specifically Appendix B–Classification of Human Etiological Agents on the Basis of Hazard.**

The NIH Guidelines not only establish the requirement for an IBC but also allow the extension of those responsibilities. Oversight includes:

1. Recombinant and synthetic NA (and RNA) including purchase, creation, or use of transgenic plants and animals.
2. Biohazardous agents, including bloodborne pathogens (e.g. bacteria, viruses, fungi, protozoa, prions, see NIH guidelines Appendix B and OSHA list of biological agents) and biological materials carrying or suspected to carry these agents.
3. Human and non-human primate source material (e.g. blood, body secretions and tissues, primary and established cell lines).
4. Select agents and biologically derived toxins (including strain and amounts exempted from the Select Agent regulations).
5. Any material requiring a CDC import license or a USDA permit.

**If research and/or teaching activities involve any of the above you are required to submit a Biosafety Protocol Application (BPA) for IBC review** unless your research specifically falls under the following two categories:

1. The activities use only commercially available deregulated transgenic crops.
2. The activities involve only the *in vitro* use of nucleic acids (*i.e.*, PCR, synthetic double stranded RNA) and does not involve the cloning and propagation of recombinant DNA in cells. For clarification, nucleic acids that are not and cannot be replicated inside organisms, cells, or viruses are **not considered** recDNA. Commonly encountered examples of synthetic DNA not considered to be recDNA include polymerase chain reaction (PCR) products, synthetic oligonucleotides/primers, and complementary DNA (cDNA) obtained by reverse transcription of RNA.

**B. Classification of Activity—Risk Assessment/Biosafety Protocol Application**

1. **Risk Assessment—**If the PI/instructor uses materials as described in 1-5 above, they must perform an **initial risk assessment** based on the Risk Group (RG) of agents associated with the materials used (see Appendix B, Classification of Human Etiologic Agents on the Basis of Hazard-NIH Guidelines).

Agents are classified into four Risk Groups (RGs) according to their relative pathogenicity for healthy adult humans by the following NIH criteria:

Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans.

* If recDNA work is not being performed and the biological materials do not harbor RG2 or higher agents, a BPA is not required.
* If recDNA work is being performed using RG1 agents, a BPA is required. Proceed to #2 below (Exempt Research) to determine what type of BPA is required.

Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

* Working directly with (culturing, manipulating, etc.) RG2 agents requires a non-exempt BPA.
* If working with biological materials that may contain RG2 agents but with no intent to propagate or manipulate RG2 agents, see #4 below.

Risk Group 3 (RG3) agents are associated with serious or lethal human disease for which preventive or therapeutic interventions *may be* available. [Not allowed at UWSP facilities]

Risk Group 4 (RG4) agents are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are *not usually* available. [Not allowed at UWSP facilities]

2. **Exempt Research**—If the answer is “no” to **all** of the following questions, then your recDNA research is exempt. Once these questions are answered, proceed to #3 below. Does your activity involve:

* **a construct containing viral DNA that represents more than 2/3 of any eukaryotic viral genome?**
* **using risk group 2, 3, or 4 agents as host or vector?**
* **cloning DNA for risk group 2, 3, or 4 agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems?**
* **using infectious or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems?**
* **creation of transgenic animals or plants?**
* **using more than 10 liters of culture?**
* **cloning of toxin molecules with LD50 of less than 100 ng per kg of body weight?**
* **deliberate transfer of recombinant DNA, or DNA or RNA derived from rDNA into one or more human subjects?**
* **deliberate transfer of a drug resistant trait to microorganisms not known to acquire this trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture?**

3. **Non-Exempt Research**—An answer of “yes” to any of the questions in section 2 **or** identification of an agent as RG2 is non-exempt and requires a full BPA. If you answered “no” to all questions in section 2, you are required to submit an exempt (partial) BPA.

4. **Activities using living or dead animals that potentially carry RG2 or higher agents**

If your activity includes handling live or dead animals acquired from a source that cannot guarantee the animal is free from RG2 or higher microbes *and* there is no attempt to culture microbes from the animal, the protocol is exempt (a partial BPA is required).

Activities that attempt to culture microbes from tissues require non-exempt status (a full BPA is required) unless techniques are used to prevent the growth of RG2 or higher agents.

For exempt activities that use living or dead animals, include the following information in the Experimental Design section (Part 2B) of the BPA:

* A list of the types of animals expected to be used in the activity.
* A statement
	+ that no attempts to culture microbes will be made.

*or*

* + describing how techniques used to purify or culture microbes will prevent growth of any RG2 or higher agents present.
* Describe safety protocols used for handling the animals, including any PPE required and/or recommended for handling the animals.
* List lab spaces used for handling/housing the animals and for storage of any waste materials (used PPE, animal carcasses, etc.) generated from the activity.
* Describe protocols for disposal of animal carcass and/or other waste material and list the location of any equipment used for disposal or companies contracted for disposal.

**C. Applications Reviewed by the IBC**

1. **Submission of the BPA:** The BPA form is available from the UWSP IBC website. If your work is **exempt**, you must complete parts 1, 2, and 3-1 of the BPA. If your work is **non-exempt**, you must complete all applicable sections of the BPA.
2. **Initial Application Review by the IBC**: Initial review of applications will be conducted by the IBC chair, or another member of the IBC designated by the IBC chair. The initial review will determine what level of review (**full committee**, **designated member**, or **administrative**) is necessary for the protocol based on the activities and whether the NIH Guidelines apply. The PI will be contacted by IBC staff to clarify any questions from the initial reviewer. A primary reviewer(s) will be assigned by the chair. The reviewers will use the respective checklists from the IBC for consideration of the applications.
3. **IBC Coordination of Review with other Institutional Oversight Committees (IACUC or IRB):** Order of review is not prescribed in the NIH Guidelines. UWSP requests that research or teaching activities that require IBC review and additional institutional oversight (*i.e.* IACUC or IBC review) submit the applications simultaneously. Approval of the protocol by the IBC will be contingent upon approval by the additional oversight committee(s).
4. **Procedure for Full Committee Review**
5. Required for non-exempt protocols.
6. IBC administration confirms a meeting date when a quorum can be present, prepares the meeting agenda, and distributes the materials to the IBC two weeks prior to the meeting. The PI may be requested to be present to explain the proposed research and answer any questions. The primary reviewer will present their findings to the committee.
7. IBC members who have a conflict of interest with the presented protocol may be present to answer questions but will abstain from voting.
8. Members will be physically present, however, in rare circumstances teleconference or videoconference in real time may be utilized. If a protocol involving plants is on the agenda, the member with plant expertise will be present or submit their review comments in advance. If a protocol involving animals is on the agenda, the member with animal expertise will be present or submit their review comments in advance. The biosafety officer will be present or submit any review comments or concerns in advance.
9. Minutes of meetings are recorded and will include any dissenting views and resolution through vote. The minutes are shared with the committee following the meeting.

4. **Designated Member Review:** may be used for evaluation of exempt protocol applications or when changes to existing protocols are made. The IBC Chair or an IBC member delegated by the chair (i.e., primary reviewer) may verify that the changes have been made satisfactorily. If the IBC uses designated member review subsequent to full committee review, the approval date is the date that the designated IBC member(s) were satisfied with the revisions made.

5. **Administrative Review:** may be used to verify minor points of order or clarifications requested when determined through vote by the full IBC to be administrative in nature with no impact on biosafety. This review can be conducted by the IBC Administrator or IBC Chair. Examples of minor points of order/clarification include but are not limited to: typographical or grammatical errors, funding source information, linking IRB or IACUC protocols, contact information, addition of personnel and verification of training, or verification of biosafety cabinet certification, etc.). If the IBC uses Administrative Review subsequent to Full Committee Review, the approval date is the date that the full committee approved the study pending the minor points of order/clarification.

**D. IBC Actions**

Review by the IBC will result in one of the following:

1. Approval-work may begin subject to NIH requirements.
2. A request to modify the protocol to secure approval-the submitter will make the requested changes in consultation with the chair who will determine the subsequent level of review.
3. Deferment or tabling of the protocol-it will be on the agenda for the next meeting of the IBC.
4. Withhold approval.
5. The PI will be notified in writing by IBC Administration of the determination made by the IBC.

If approval is withheld, the IBC must provide the rationale in writing and give the PI an opportunity to respond or appeal the findings. The PI has the right to appeal the decision, within two weeks of notification from IBC that approval has been withheld. The appeal should be initiated by submitting a letter to the IBC Chair (biosafety@uwsp.edu) addressing relevant issues. The appeal will be discussed by the full committee. Any decision to reverse a non-approved protocol requires a vote by the full committee.

Protocols may be approved for a maximum period of 3 years. The PI will be informed in writing of the IBC’s review decision. The Department Chair or supervisor will be copied electronically on the correspondence.

The approval date is the date the Full Committee approves the changes. If the IBC uses administrative review subsequent to full committee review, the approval date is the date that the full committee approved the study pending the minor points of order/clarification.

Any member of the IBC may, at any time, request to see the revised protocol and/or call for Full Committee Review.

**E. Modifications to an Approved IBC Protocol**

1. If a PI would like to report a change in laboratory personnel (excluding changes in PI), a new Personnel Training Form must be completed and submitted.
2. If a PI would like to amend their active protocol, they must submit revised BPA to biosafety@uwsp.edu. The “Modification Form” box should be selected on the coversheet.
3. Depending on the type of modification requested, the modification may be reviewed through administrative review, designated member review, or full IBC review.
	* + - 1. Modifications allowable under administrative review must have no impact on biosafety. Administrative changes may include typographical or grammatical errors, funding source information, linking IRB or IACUC protocols, contact information, or verification of biosafety cabinet certification, etc.
	1. The IBC Chair, an IBC member delegated by the chair (designated reviewer) may review modifications to protocol that they determine are minor in nature. For example, a change in room where the work is conducted.
	2. Significant changes to protocols that may have an impact on biosafety, must be reviewed by the Full Committee.

3. The PI will be notified in writing by IBC Administration of the determination made by the IBC. Changes may not be implemented until a modification request has been approved by the IBC.

**F. IBC Protocol Renewal Process**

Principal Investigators will be notified approximately 60 and 30 days prior to their protocol expiration date. At this time, the PI must decide whether they wish to request an IBC renewal or to close the project. Principal Investigators who plan to renew their project must review and update their protocol and re-submit a BPA form selecting the 3-year renewal on the application prior to the protocol expiration date. The IBC will conduct a de novo review of the renewal BPA following the review procedures described in Part B. The PI will be notified in writing of the determination made by the IBC.

**G. IBC Closures**

If a PI wishes to close their protocol, they may submit a Protocol Closure Form to biosafety@uwsp.edu.