**Committee Standard Operating Procedures for IBC**

The Institutional Biosafety Committee (IBC) review process at UW Oshkosh aims to ensure the appropriate and safe use of biological materials used for teaching and research projects. This manual describes the committee operating procedures for IBC application submission and review process for new, renewal, and amended protocols. Questions may be directed to IBC Administration at biosafety@uwosh.edu or by calling (920) 424-3215.

**A. IBC Application Submission Process**

1. Any faculty or staff member that would like to begin a new teaching or research project utilizing biological materials must complete an [**IBC Application Form**](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/) found on the IBC forms page. The PI must submit one signed, hard copy of the application to Office of Sponsored Programs and Faculty Development, Dempsey 214, and an electronic application to biosafety@uwosh.edu for electronic distribution and storage
2. All applicable sections of the IBC Application must be completed by the PI. Biological materials that will be subject to review by the IBC include:
* Bacteria, viruses, viral vectors, fungi, prions
* Human/Non-human primate cell lines, tissues, or blood products
* Animal cell lines, tissues, or blood products
* Plants (exotic or grown in association with pathogenic or recombinant microbes/animals)
* Biological toxins
* Recombinant DNA (rDNA) or Synthetic Nucleic Acids
* Administration of biological materials to live animals (vertebrate or invertebrate)
1. The IBC will use the following regulations, state statutes, guidelines, and institutional polices when conducting their review:
	1. [*NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines),*](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) *April 2016 Edition*
	2. [*Biosafety in Microbiological and Biomedical Laboratories, 5th Edition (BMBL)*](http://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf)
	3. [Occupational Safety and Health Administration (OSHA) Blood borne Pathogens Standard, 29 CFR 1910.1030](https://www.osha.gov/pls/oshaweb/owadisp.show_document?p_id=10051&p_table=STANDARDS)
	4. [ANSI Laboratory Safety Standards](https://webstore.ansi.org/laboratory_safety/Default.aspx)
	5. [DNR Regulations](http://dnr.wi.gov/topic/waste/)
	6. [University of Wisconsin Oshkosh Biological Safety Program Manual](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/)
	7. IBC Standards and Policies
	8. Institutional Policies
2. The [**IBC Application Companion Help Guide**](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/) may be used as a guide for faculty and staff preparing their applications.
3. For research or teaching experiments involving recombinant or synthetic nucleic acid molecules, the PI will cite all applicable categories of research as defined in the NIH Guidelines (**see Appendix A: Research Involving Recombinant or Synthetic Nucleic Acid Molecules**).
4. Training requirements for faculty, staff, and students based on project type (research vs. teaching) can be found on the [IBC Training](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-training/) page.

**B. Review of New and Renewal IBC Applications**

1. **Initial Review of IBC Applications**: Initial review of IBC Applications will be conducted by the IBC Chair, Biological Safety Officer (BSO), or another member of the IBC designated by the IBC Chair. The initial review will determine what level of review is necessary for the protocol based on the activities and whether the NIH Guidelines apply. The PI will be contacted to clarify any questions from the initial reviewer.
2. **Applications involving** **research or teaching experiments involving recombinant or synthetic nucleic acid molecules:**
	1. Exempt projects, as defined in the [**NIH Guidelines**](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) Section III-F, shall be designated for review by the IBC Chair, Biological Safety Officer, or a member of the IBC as determined by the IBC Chair; the designated reviewer may make a determination to approve, approve with contingencies, or move to have the project reviewed by the full IBC. The IBC will be notified of these projects at the next properly convened IBC meeting and any IBC member may request that the project be reviewed by the full IBC.
	2. Non-exempt projects, as defined by the *NIH Guidelines* Section III-E, shall be designated for review by the IBC Chair, Biological Safety Officer, or a member of the IBC as determined by the IBC Chair. The designated reviewer may make a determination to allow the initiation of the project. The IBC will be notified of these projects at the next properly convened IBC meeting, and the IBC will make a determination if the project is approved, approved with contingencies, or tabled pending further IBC review.
	3. Non-exempt projects, as defined by the *NIH Guidelines* Sections III-A through III-D, shall be reviewed by the full IBC at a properly convened IBC meeting. The IBC Chair will assign a primary, secondary, or any other appropriate reviewer to review the project and present the project to the IBC. The IBC will determine if the project is approved, approved with contingencies, or tabled pending further IBC review.
	4. NIH Office of Science Policy can help with determinations of exempt vs. non-exempt if the IBC is uncertain.
	5. IBC meetings will be scheduled ad hoc. IBC Protocol applications will be stored in a shared folder accessible to IBC Members.
	6. The PI will be notified in writing of the determination made by the IBC.
3. **Applications involving research or teaching activities involving non-recombinant work with biological materials reviewed by IBC:**
	1. IBC oversight of biological materials extends beyond experiments involving recombinant and synthetic nucleic acids (see list in Section A.1.). The IBC will review the following non-recombinant work:

 i. Projects involving non-recombinant [Risk Group 2](https://my.absa.org/Riskgroups) or greater organisms

 ii. Projects with toxins

* 1. This work will be reviewed using a Designated Member method.
	2. The IBC Chair, BSO, and/or a member of the IBC designated by the chair will conduct a review of the IBC Application materials.
	3. The reviewer(s) may:
		+ - 1. approve the protocol as submitted
				2. request modifications to secure approval, or
				3. request full IBC review at a convened meeting.
	4. The PI will be notified in writing of the determination made by the IBC.
	5. Protocols involving non-recombinant work are approved through the designated member method and are reported to the IBC at the next convened meeting. These protocols are accessible to all IBC members in a shared folder.
1. **IBC Coordination of Review with other Institutional Oversight Committees (IACUC or IRB):**
	1. Order of review is not prescribed in the NIH Guidelines. UW Oshkosh requests that research or teaching activities that require IBC review and additional institutional oversight (i.e. IACUC or IBC review) submit the application simultaneously. Approval of the protocol will be contingent on approval from the additional oversight committee.
2. **Procedure for Full Committee Review**
3. IBC Administration confirms a meeting date when a quorum can be present, prepares the meeting agenda and distributes the materials to the IBC one week prior to the meeting.
4. The PI’s presence may be requested at the convened meeting to explain the proposed research and answer any questions the IBC may have. However, the PI must leave the room while the IBC discusses and votes on the protocol.
	* 1. Any IBC members who have a conflict of interest with the presented protocol may be present to answer questions posed by the committee but will excuse themselves from the room prior to discussion and formal vote.
5. Meetings are typically conducted in person, however, in rare circumstances teleconference or videoconference in live time may be used for a convened meeting.
6. Protocols for Full Committee Review can only be approved at a convened meeting of a quorum of the IBC, with the approval vote of a majority (>50%) of the members present, and with a formal vote.
	* 1. An established quorum includes a minimum of one non-affiliated member. 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 to achieve quorum or submit their review comments in advance. The biosafety officer will be present or submit any review comments or concerns in advance.
7. 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.
8. Required Modifications Subsequent to Full Committee Review: If the IBC requires modifications to secure approval of a protocol at a convened meeting, such modifications are reviewed as follows:
	* 1. Changes determined by the convened IBC to be significant and impact biosafety will be sent back through Full Committee Review following all applicable procedures as delineated above in section B.5.
			1. The approval date is the date the Full Committee approves the changes.
		2. Designated Member Review if the IBC agrees at the meeting that the requested changes can be reviewed in this manner. The IBC Chair, biological safety officer, or an IBC member delegated by the chair (i.e., (primary reviewer) may verify that the changes have been made satisfactorily.
			1. 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.
		3. Administrative Review may be used to verify minor points of order/clarification requested when determined through vote by the convened IBC to be administrative in nature with no impact on biosafety. This review can be conducted by IBC Administration Staff or IBC Chair.
			1. Example of minor points of order/clarification: 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.).
			2. 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.
			3. Any member of the IBC may, at any time, request to see the revised protocol and/or call for Full Committee Review.
			4. **Modifications to Approved IBC Protocols**
9. If a PI would like to amend their active protocol, they must submit a [**Modification Request Form**](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/) along with their revised IBC Application Form to biosafety@uwosh.edu. The IBC Application Form amendment box should be selected on the coversheet.
10. Depending on the type of modification requested, the modification may be reviewed through Administrative Review, Designated Member Review, or Convened IBC Review.
	* + - 1. Modifications allowable under administrative review must have no impact on biosafety. Administrative changes may include Personnel changes and verification of training (not including a change in PI), typographical or grammatical errors, updated funding source information, linking IRB or IACUC protocols, contact information, or verification of biosafety cabinet certification, etc.
	1. The IBC Chair, biological safety officer, or 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 could be reviewed through Designated Member Review.
	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.

* + - 1. **Categories of IBC Actions**

As a result of the review of a new protocol, renewal, or modified protocol, an IBC may take one of several different actions depending on their findings:

1. Approval
2. Require modifications to secure approval
3. Defer or table protocol
4. Withhold approval
5. If approval is withheld, the IBC must provide reasons for their decision 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 to withhold approval. The appeal should be initiated by submitting a letter to the IBC Chair (biosafety@uwosh.edu) addressing relevant issues. The appeal will be discussed by the full committee. Any decision to reverse a disapproved study requires a vote of presiding quorum of the IBC.

The PI will be informed in writing of the IBC’s review decision. IBC protocols will have an approval period of 3 years.

* + - 1. **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 if necessary and re-submit their IBC Application 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 IBC Application following the review procedures described in Part B. The PI will be notified in writing of the determination made by the IBC.

* + - 1. **IBC Closures**

If a PI wishes to close their protocol, they may submit an [IBC Closure Form](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/) to biosafety@uwosh.edu.

* + - 1. **Periodic Lab Assessments**

The IBC will conduct an initial lab safety assessment prior to initiation of a new project and approximately 18 months thereafter. The lab assessments will be conducted by the Biological Safety Officer and will focus on safe work practices. A copy of the [Lab Assessment Checklist](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/) is located on the IBC website and will be made available to PIs in advance. A comprehensive biological/chemical lab safety visit may be conducted if the Chemical Hygiene Officer or another member from EHS is available to attend.

##### **Appendix A: Research Involving Recombinant or Synthetic Nucleic Acid Molecules**

**Exempt Research**

Exempt status activities, as defined in the [**NIH Guidelines**](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) Section III-F (page 23) shall be determined by the IBC Chair or a member of the IBC designated by the chair.  The following experiments involving recombinant or synthetic nucleic acids are considered exempt from the NIH Guidelines:

* III-F-1:  Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase.
* III-F-2:  Those that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.
* III-F-3:  Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.
* III-F-4:  rDNA molecules consisting entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses where propagated only in that the host (or a closely related strain of the same species) or transferred to another host by know physiological means.
* III-F-5:  rDNA molecules consisting entirely of DNA from a eukaryotic host (including mitochondria, chloroplasts, or plasmids but excluding viruses) when propagated only in that host or a closely related strain of the same species.
* III-F-6:  rDNA molecules consisting entirely of DNA segments from different species that exchange DNA by known physiological processes and are described in Appendix A.
* III-F-7:  Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA
* III-F-8:  Experiments not posing significant risk to health or the environment, as determined by the NIH Director, and are described in [***Appendix C*** of the NIH Guidelines](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948398):
	+ ***Appendix C***Reference:
	C-I: Recombinant or Synthetic Nucleic Acid Molecules in Tissue Culture
	C-II: E. coli K-12 Host-Vector Systems
	C-III: Saccharomyces Host-Vector Systems
	C-IV: Kluyveromyces Host-Vector Systems
	C-V: Bacillus subtilis or Bacillus licheniformis Host-Vector Systems
	C-VI: Extrachromosomal Elements of Gram Positive Organisms (see list in C-VI)
	C-VII: The Purchase or Transfer of Transgenic Rodents
	C-VIII: Generation of BL1 Transgenic Rodents via Breeding

If activities involving recombinant or synthetic nucleic acid molecules are determined to be Exempt by the IBC Chair (or their designee),  the PI will be notified of the determination in writing.  All research using rDNA and/or synthetic nucleic acids must be registered with the Institutional Biosafety Committee even if it is deemed Exempt from NIH Guidelines.

**Non-Exempt Research**

Projects that are considered Non-Exempt from the [NIH Guidelines](http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines) are generally those that fall under NIH Guidelines Sections III-A through III-E.  All protocols that fall under these categories must be reviewed and acted on at a convened meeting of the committee.  Research activities that are non-exempt include:

* III-A-1: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire that trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture.
* III-B-1:  Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.
* III-B-2:  Experiments that have been Approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines and determined by NIH/OBA.
* III-C-1:  Experiments involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants.
* III-D-1: Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems.
* III-D-2:  Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems.
* III-D-3:  Experiments involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems.
* III-D-4:  Stable introduction of rDNA into an animal genome or testing of rDNA-modified microorganisms in whole animals.
* III-D-5:  Experiments to genetically engineer plants by rDNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing rDNA.
* III-D-6:  Experiments involving more than 10 Liters of Culture (in a single vessel)
* III-D-7:  Experiments involving Influenza Viruses
* III-E:  Experiments not included in Sections III-A, III-B, III-C, III-D, III-F and their subsections
* III-E-1:  Formation of rDNA molecules containing no more than two-thirds of the genome of any eukaryotic virus
* III-E-2:  Experiments with genetically modified plants
* III-E-3:  Experiments involving the generation of transgenic rodents