UCR | Office of Research Integrity

IBC Charter

UCR | Environmental Health & Safety

Charge

The Institutional Biosafety Committee (IBC) functions as the UCR review body responsible for approval and oversight of activities involving the use, storage and handling of biohazardous materials (defined below), in accordance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* (NIH Guidelines), *Medical Waste Management Act*, and the *CDC Biosafety in Microbiological and Biomedical Laboratories* (BMBL) document. The IBC may choose to implement additional guidelines based on risk assessments.

IBC members are appointed by the UCR Vice Chancellor for Research and Economic Development (VC-RED), and the office of the VC-RED provides administrative support for the Committee through the Office of Research Integrity (ORI). Members of the Committee include the Director of Environmental Health & Safety (EH&S) and the campus Biosafety Officer (BSO). The BSO and other EH&S specialists perform laboratory inspections and other activities in association with the IBC - both reporting to and acting as directed by the Committee. The Committee may provide recommendations to the VC-RED regarding issues of non-compliance and request additional training requirements for faculty researchers found to be non-compliant.

The Committee advises both the VC-RED and Director of EH&S regarding campus biosafety issues and policy. Coordination with EH&S through the Committee supports the operation of the UCR Biosafety Program which is a responsibility of EH&S and provides guidance and oversight to students and staff to assure the health and safety of all personnel working with biohazardous materials.

The Committee will strive to engage the UCR research community with the IBC and aim for fresh and diverse perspectives in membership.

All use of biohazardous materials in research and teaching must be reviewed and approved or disapproved by the Committee, or by the IBC Chair operating within guidelines established by the Committee. The IBC is responsible for formulating, implementing and enforcing policies and procedures involving biohazardous materials, such that applicable norms and regulations for biohazardous materials and/or recombinant DNA are met or exceeded.

Biohazardous Materials Overseen by the IBC:

- Recombinant/synthetic nucleic acid molecules and genetically-modified organisms, as covered by the NIH Guidelines
- Potentially infectious organisms (typically Risk Group 2 or greater organisms) such as viruses, bacteria, fungi, or prions that can cause disease in humans or cause significant environmental or agricultural impact
- Select agents and select toxins, as covered by the CDC DSAT regulations

- Human and nonhuman primate materials (including established cell lines), as covered by the Cal/OSHA Bloodborne Pathogen Standard
- At its discretion or IACUC request, the IBC may also review protocols involving animals or animal specimens known to be reservoirs/vectors of zoonotic diseases
- Dual Use Research of Concern

Biological organisms or material not known to infect or cause disease in other organisms, are not known to vector diseases, and are without potential environmental impact, do not require review or approval by the IBC.

ALL research activities regardless of review level is subject to a pre-review by EH&S prior to beginning work. The pre-review includes a lab inspection, completion of relevant training and review of the BUA and any supplemental documents (e.g., lab specific standard operating procedures).

Meeting Procedures and Membership:

The IBC meets at least once per month – usually every 4th Thursday of the month. Fifty percent of the voting membership is necessary to establish a meeting quorum. The membership will consist of at least five individuals: two community members who are not affiliated with UCR, an appropriate recombinant or synthetic NA expert, a plant and animal expert, and the Biosafety Officer. Members with additional expertise will be added, or will be consulted, depending on research focus. All voting members will be registered with the NIH pursuant to the NIH Guidelines. Information provided in the registration will include:

1. Name, Department and Professional Title
2. Business Contact Information
3. Curriculum Vitae or Resume
4. Role of Committee Member, as applicable

In order for a new protocol submission to be placed on the agenda for an IBC meeting, the PI must submit a Biological Use Authorization (BUA) application at least 3 weeks before the scheduled meeting and have adequately addressed any issues raised during the pre-review. If any major issues or key documents are still pending, the BUA will not be reviewed at a convened meeting. PIs are encouraged to submit renewal BUAs at least two meetings before the BUA expiration date to allow sufficient time for the pre-review and to address any issues. Each BUA (BSL2 & BSL3) will be assigned a primary and a secondary reviewer based on expertise.

Work involving BSL1 containment may be approved *en masse* at a convened IBC meeting pending a positive delegated review. A delegated review is done by an EH&S individual and may involve other members of the IBC if needed.
Exempt work involving recombinant or synthetic nucleic acid molecules under Section III-F of the NIH Guidelines requires IBC registration for verification by the BSO as other federal

and state standards of biosafety may still apply to the research. Review and approval by the IBC is not required.
Work that does not require IBC review may include: non-recombinant plant pathogens, non-primate mammalian cell lines, and RG-1 materials not covered under NIH Guidelines.

All meetings are open to members of the public or UCR staff and researchers provided there is adequate notice to accommodate attendance. The committee may go '*in camera*' for protection of private, sensitive or proprietary information.

Some of the most common IBC voting outcomes are:

Approved
Approved following satisfactory modifications
Subcommittee review
Tabled / Not Approved
Exempt

Responsibilities:

BSO delegate
The BSO will be responsible for reviewing the BUA, conducting laboratory inspections, advising the IBC on which section of NIH Guidelines apply, conducting risk assessments, delegated review of BSL1 applications, and exempt determinations.

IBC Members
IBC members must attend a minimum of two thirds of annual meetings or they will be asked to step down from the Committee. The members shall serve a term of 3 years, which may be renewed.
Members are responsible for reviewing and presenting at the IBC meeting BUAs for which they are assigned, notifying ORI when a review cannot be completed, and maintaining the confidentiality of Committee discussions and decisions.

IBC members shall be recused from discussion, except to provide information requested by the IBC, and voting on any protocol for which there may be connection or personal interest beyond their capacity as IBC members. This includes any project with which IBC members may be engaged or have a direct financial interest.

IBC Chair

The Chair calls the meeting to order, requests motions and seconds, closes the meeting once it has concluded its business, and otherwise has the same rights, privileges and responsibilities as all other members. The Chair may also assign a subcommittee to review an issue prior to committee meeting or request the subcommittee to review the responses of PIs after the meeting.

PIs/UCR Faculty member

Principal Investigators (PIs) are ultimately responsible for ensuring that all lab workers are trained regarding the hazards of infectious materials and r/sNA work and safe practices to be followed. PIs should select the appropriate microbiological practices and lab techniques to be used for research. PIs must also:

- Provide instruction or training materials to lab staff to ensure safety and deal with potential accidents.
- Supervise lab staff to ensure that the required safety practices and techniques are employed.
- Correct work errors and conditions that may result in the release of recombinant or synthetic nucleic acid materials.
- Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination.
- Determine the relevant section of NIH guidelines and submit a BUA to IBC for review and approval.
- Maintain a copy of the approved BUA in the lab and ensure all lab staff have reviewed the BUA.
- Submit BUA amendments to the IBC to address any new materials, or substantially new work with previously approved materials.
- Report any significant problems pertaining to the operation and implementation or containment practices and procedures, violations of the NIH Guidelines, or any significant research-related accidents and illnesses to the ORI and IBC.

For PIs who are new to UCR or those who are proposing novel or unique biosafety issues, the IBC encourages attendance at meetings to present their research and answer questions.

IBC Administrator

IBC administrator is responsible for documenting IBC decisions and following NIH standards for taking minutes. The administrator is responsible for preparing the meeting materials and coordinating with the BSO delegate before the start of a meeting. She or he must ensure that IBC decisions are communicated to PIs in a timely manner.

Training & Education

Each member will be required to complete the IBC training module via the UCR Learning website. IBC training will define IBC's roles, responsibilities and requirements. Completion and proof of training will be required within two months of initial participation on the IBC.

EH&S and ORI will provide continuous training opportunities for IBC members on an as-needed basis. The biosafety manual is available via UCR EH&S website.

Responding to Public Comments and Records Requests

The IBC shall refer to or coordinate with the UCR and University of California Office of the President (UCOP) legal counsel for any public comments that are made on the IBC's actions/ activities or public requests for IBC minutes or documents. The NIH Guidelines require that IBC minutes and documents be made available to the public upon request (Section IV-B-2-a-7). The IBC will be notified of all such comments and requests. For public comments, the comments and the IBC's response will be sent to the NIH Office of Biotechnology Activities. Principal Investigators identified in the minutes will be notified that a public request has been made and will be offered copies of the redacted minutes. All such requests will be handled expeditiously.

Redaction of IBC minutes:
The NIH Office of Biotechnology Activities has issued two documents pertaining to minutes (IBC Meetings and Minutes FAQs/April 2013) and the Nov 21, 2014 Memo). When processing such requests, IBC shall comply with the NIH Guidelines and pertinent supplementary guidance. In reviewing all requests for IBC minutes or other documents, the University reserves the right to redact information from IBC minutes or other IBC documents that will be made available to the public due to privacy, security or proprietary concerns. In order to ensure redaction is performed consistently, the following procedure is adopted.

Information that will not be redacted includes:
- Committee roster and biographical sketches of members
- Names of principal investigators
- Vectors, inserts, hosts, animal species employed
- Details of any significant problems with, or violations of, the NIH Guidelines
- Any significant recombinant DNA-related accidents and illnesses

Information that will be redacted includes, but is not limited to:
- Private information (names of research staff other than Principal Investigators, addresses, telephone numbers, e-mail addresses)
- Proprietary information, information that could affect the conduct or outcome of research or ability to patent or copyright the research, trade secrets, and proprietary information received from sponsors of clinical gene transfer studies
- Location of biohazardous agents/toxins or research animals, and any information that might compromise University, local, or national security.
- The IBC is also kept abreast of activities that are non-recombinant DNA-related and not subject to the public access provisions of the NIH Guidelines. This includes training initiatives, conference reports, facilities and engineering, risk and exposure assessments, medical surveillance program and regulatory compliance

such as the Cal/OSHA blood-borne pathogen standard, select agent program, and non-recombinant DNA-related accident reports. Such information will also be redacted.

Incident Reporting Requirements and Non-Compliance

Incidents that may result in exposure to infectious materials must be immediately evaluated and treated according to procedures described in the biosafety manual. Significant illnesses and accidents occurring during the conduct of research with recombinant or synthetic nucleic acid molecules, as well as violations of the NIH Guidelines, such as failure to obtain IBC approval or failure to follow IBC approval conditions, must be reported to NIH within 30 calendar days. Incidents occurring under BSL2 or BSL3 conditions that result in an overt exposure to organisms containing recombinant or synthetic nucleic acid molecules must be reported to NIH and IBC immediately.

Principal Investigators must report reportable incidents to the ORI and IBC immediately, and the IBC will generate and send the report to NIH within the required timeline.

Violations, such as lapse in IBC approval, failure to obtain IBC approval, or performing work not covered in an approved BUA will require the PI to stop the work subject to IBC oversight. EH&S and ORI will notify the PI, departmental heads (chair and/or dean) and the VC-RED that the work does not have IBC approval and cannot be conducted until approval is obtained. For PIs who fail to submit a renewal BUA in a timely manner, they will be notified to cease the work prior to the BUA expiration date and EH&S and ORI will coordinate with the PI on the corrective actions required to obtain IBC approval.

<u>Materials not within the IBC purview by regulation, that UCR may add to IBC oversight:</u>

Plant infectious agents or other infectious agents with potential environmental impact
Exotic arthropods
Exotic microorganisms
BSL-1 microorganisms
Biological material requiring an APHIS, CDFA, EPA or other governmental permit

References:

1. *CDC/NIH Biosafety in Microbiological and Biomedical Laboratories* (BMBL) 5th Edition, 2009 Dec; [cited 2016]. Available from: http://www.cdc.gov/biosafety/publications/bmbl5/
2. California Occupational Safety and Health Administration Bloodborne Pathogen Standard California Code of Regulation, Title 8 §5193 https://www.dir.ca.gov/title8/5193.html
3. Medical Waste Management Act, September 2015, September 2015 [cited 2016]. Available from: https://www.cdph.ca.gov/certlic/medicalwaste/Documents/MedicalWaste/2013/MWMAfinal2015.pdf
4. *National Institutes of Health (NIH) guidelines for research involving recombinant or synthetic nucleic acid molecules*. 2016 April; [cited 2016]. Available from: http://osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines.pdf
5. Federal Select Agent Program - Code of Federal Regulations. 7 CFR Part 331; 9 CFR Part 121; 42 CFR part 73. Available from: http://www.selectagents.gov/regulations.html
6. Animals and Animal Products: Federal Select Agent Program Code of Federal Regulations Title 9, Chapter I, Subchapter E, Part 121
7. Public Health: Federal Select Agent Program Code of Federal Regulations Title 42, Chapter I, Subchapter F, Part 73