

Charge

The Institutional Biosafety Committee (IBC), also referred to in this document as *the Committee*, 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). The VC-RED may delegate authority for membership to the Assistant Vice Chancellor of the ORI. Members of the Committee include the campus Biosafety Officer (BSO) and other Environmental Health and Safety (EH&S) specialists who 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 the Executive Director of Environmental Health & Safety regarding campus biosafety issues and policy. Coordination with EH&S through the Committee supports the operation of the UCR Biosafety Program in collaboration with responsibility, guidance, and oversight to students, faculty and staff. The Biosafety Program assures the health and safety of all personnel working with biohazardous materials and infectious agents.

Committee members are appointed to reflect the diversity of the research on campus. Committee members ensure the understanding and support of novel and cutting-edge research methodology while engaging the UCR research community in biosafety concerns and a broad culture of safety.

All use of biohazardous materials in research and teaching must be reviewed and approved by the Committee, or by the IBC Chair operating within guidelines established and upheld by the IBC. 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/synthetic nucleic acids molecules 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 higher) such as viruses, bacteria, or fungi that can cause disease in humans or cause significant environmental or agricultural impacts.

- Select agents and select toxins, regardless of quantity, as defined by the CDC's Division of Select Agents and Toxins (DSAT) regulations
- Infectious proteins (prions) and cellular penetrating peptides
- Human and non-human primate materials (including established cell lines), as covered by the Cal/OSHA Bloodborne Pathogens Standard
- Materials that may be sources of Aerosol Transmissible Disease (ATD)
- At its discretion or IACUC request, the IBC may also review protocols involving animals or animal specimens known to be reservoirs and/or vectors of zoonotic diseases
- Dual Use Research of Concern (DURC) research

Materials not within the IBC purview by regulation that UCR may add to IBC oversight based on risk assessment include:

- 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

Biological organisms or material not known to infect or cause disease in other organisms, not known to vector diseases, not harboring any recombinant/synthetic nucleic acids, and are without potential environmental impact do not require oversight by the IBC.

Membership

The IBC consists of at least five individuals: two community members who are not affiliated with UCR, an appropriate recombinant or synthetic nucleic acid expert, plant and animal experts, and the Biosafety Officer. Members with additional expertise will be added and outside individuals consulted depending on the research focus and items under review. 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

Member Responsibilities

Biosafety Officer (BSO) or 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, and delegating review of BSL-1 applications and exempt determinations.

IBC Members

IBC members shall serve a term of 3 years, which may be renewed. Members must attend a minimum of two thirds of annual meetings or they may be asked to step down from the

Committee. Members must inform the ORI of any meeting absences in advance, if feasible, so that arrangements can be made to ensure meeting quorum.

Members are responsible for reviewing and presenting BUA's at the IBC meeting for which they are assigned, notifying the ORI when a review cannot be completed, and maintaining the confidentiality of the Committee discussions and decisions. Members are expected to review all the BUA's on the agenda and may be occasionally asked to serve on subcommittees.

IBC members shall be recused from the 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 membership may include alternate members to provide guidance or expertise regarding biohazardous materials. These alternate members will adhere to the same guidelines that apply to regular members. At IBC meetings, they may assist in providing quorum by standing in for members who are unable to attend. However, alternate members are considered separate from the IBC's regular membership, which determines quorum requirements.

IBC Chair

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

IBC Vice Chair

The Vice Chair serves as the Chair of the IBC in the absence of the Chair and has the same authority and duties as the Chair.

Principal Investigators (PIs)

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

- Determine the relevant section of the *NIH Guidelines* and submit a BUA to the IBC for review and approval.
- Maintain a copy of the approved BUA in the lab and ensure that all laboratory staff have reviewed the BUA.
- Provide instructions or training materials to laboratory staff to ensure safety and deal with potential accidents.
- Supervise laboratory staff to ensure that the required safety practices and techniques are employed and all requirements of the BUA are addressed.

- Address and correct laboratory accidents and conditions that may result in the release of recombinant or synthetic nucleic acid materials.
- Adhere to the IBC-approved emergency plans for handling accidental spills and personnel contamination.
- Submit BUA amendments to the IBC addressing any new materials, or substantially new work with previously approved materials.
- Report any significant problems pertaining to the operation, implementation, containment practices and procedures, violations of the *NIH Guidelines*, or any significant research-related accidents and/or illnesses to the ORI and the IBC.

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

IBC Administrator

The IBC administrator is responsible for documenting the IBC decisions and following the 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 the IBC decisions are communicated to the PIs in a timely and efficient manner.

Training & Education

Each member will be required to complete the UCR IBC member training module via the UCR [Learning website](#). The IBC training will define the IBC's roles, responsibilities and requirements. Completion and proof of training will be required within two months of the initial participation on the Committee. EH&S and ORI will provide continuous training opportunities for the IBC members on an as-needed basis. The UCR biosafety manual is available via the [UCR EH&S website](#).

Meeting Procedures

The IBC typically meets once per month – usually the 4th Thursday of the month. At least fifty percent of the voting membership is necessary to establish a meeting quorum, and a quorum must be maintained for each vote to occur. In order for each vote to be approved, it must receive the approval of the majority of the voting members.

All meetings are open to members of the public or the 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.

BUA Review and Approval Process

All research activities subject to IBC oversight, regardless of the review level, are required to be submitted in a Biological Use Authorization (BUA) application and subjected to a pre-review by the BSO prior to beginning any work. The pre-review includes a lab inspection, completion of relevant training and a complete review of the BUA and any supplemental documents (e.g., lab

specific standard operating procedures, manuals, etc.). Once a BUA is submitted, the PI will be contacted by the BSO to initiate the pre-review process.

In order for a protocol submission (new, renewal or amendment) to be placed on the agenda for an IBC meeting, the PI must submit a BUA application by the first Thursday of the month of the scheduled meeting (approximately three weeks before the meeting) and have adequately addressed any issues raised during the pre-review. If any major issues or key documents are still pending, the BUA may not be reviewed at a convened meeting. PIs are encouraged to submit renewal BUA applications at least two meetings before the BUA expiration date to allow sufficient time for the pre-review and to address any issues. Each BUA will be assigned a primary and a secondary reviewer based on expertise.

BUA applications for research at **Biosafety Level One (BSL-1)** that fall under Section III-F of the *NIH Guidelines* are considered exempt. Exempt research requires IBC registration for verification by the BSO as other federal and state standards of biosafety may still apply. Review and approval by the IBC is not required. However, PIs should consult with the BSO regarding any changes to the research as the changes may exclude the project from exemption.

BUA applications for research at **Biosafety Level One (BSL-1)** that do not fall under section III-F of the *NIH Guidelines* will be presented for discussion at an 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. The IBC may single out a particular BSL-1 application for discussion and action to be taken (approve, table, etc.) or the Committee may vote for a single action to be taken for all BSL-1 applications *en masse*.

BUA applications for research at **Biosafety Level Two (BSL-2)** will be reviewed individually and presented for discussion at an IBC meeting. After each BUA review, the IBC will vote on the action to be taken regarding that BUA.

BUA applications for research at **Biosafety Level Three (BSL-3)** will be reviewed by an IBC subcommittee and a summary will be sent to the High Containment Laboratory Oversight Group (HCLOG). If appropriate, the project will undergo review by IACUC and/or DURC review as well. After being reviewed by the IBC subcommittee (plus IACUC and DURC, if appropriate), the BUA will be presented for discussion at an IBC meeting and the IBC will vote on the action to be taken regarding that BUA.

Investigators proposing research at **Plant Biosafety Level Three (BSL-3P)** will require review and approval by the California Citrus Research Foundation (CCRF) prior to proceeding with a BUA application. Researchers should contact the Citrus Containment Director to initiate the CCRF application process. Upon CCRF approval, a BUA application can be submitted and reviewed following the BSL-3 process described above.

Some of the most common IBC voting outcomes are:

Approved
Recommend approval following satisfactory modifications
Subcommittee review and recommendations
Tabled
Not Approved
Exempt

BSL-1 and BSL-2 BUA approvals are valid for three years. BSL-3 BUA approvals are valid for one year.

Responding to Public Comments and Records Requests

The IBC shall refer to or coordinate with the UCR and the 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 the 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 (OBA). 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 the IBC minutes

The NIH Office of Biotechnology Activities has issued two documents pertaining to the minutes ([IBC Meetings and Minutes FAQs](#)) and the Nov 21, 2014 [Memo](#)).

When processing such requests, the IBC shall comply with the *NIH Guidelines* and pertinent supplementary guidance. In reviewing all requests for the 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 may 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 or 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 pathogens standard, select agent program, and non-recombinant/synthetic nucleic acid molecules 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 UCR 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 the NIH within 30 calendar days. Incidents occurring under BSL-2 or BSL-3 conditions that result in an overt exposure to organisms containing recombinant or synthetic nucleic acid molecules must be reported to the IBC immediately as per federal regulations. Incidents occurring under BSL-3 conditions resulting in a potential exposure must be reported to IBC immediately as per federal regulations.

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

Violations, such as a 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.

Additional reporting to federal agencies may be required if the research is federally supported. If reporting is required, the ORI will generate and send the report to the federal agency.

Appendices

1. [UCR Reporting and Duties, May 2017](#)
2. [UCR BSL-3 Approval Process, November 2019](#)

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/bmb15/>
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, January 2017 [cited 2018]. Available from: <https://www.cdph.ca.gov/Programs/CEH/DRSEM/CDPH%20Document%20Library/EMB/MedicalWaste/MedicalWasteManagementAct.pdf>
4. National Institutes of Health (NIH) guidelines for research involving recombinant or synthetic nucleic acid molecules. 2016 April; [cited 2016]. Available from: https://osp.od.nih.gov/wp-content/uploads/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: <https://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
8. Aerosol Transmissible Disease:
<https://www.cdph.ca.gov/Programs/CCDPPH/DEODC/OHB/CDPH%20Document%20Library/ATD-Guidance.pdf>
9. A Practical Guide to Containment: Plant Biosafety in Research Greenhouses.” Dann Adair and Ruth Irwin. 2008.
10. USDA Website: <https://www.usda.gov/>
11. APHIS Website: <https://www.aphis.usda.gov/aphis/home>