UCI Environmental Health & Safety

Institutional Biosafety Committee (IBC) Program

Responsible Administrator: Biosafety Officer
Revised: December 2023

Summary: This section outlines the policy and procedures related to the Institutional Biosafety Committee Program that is administered through the Environmental Health & Safety (EHS) Department.

1. Program Description

The Institutional Biosafety Committee (IBC) is a committee created under mandate from the National Institutes of Health (NIH). The IBC is responsible for enforcing policies and guidelines related to university-related use of all potentially hazardous biological agents including but not limited to infectious agents, human and non-human primate materials (including established cell lines and stem cells), CDC/USDA select agents and toxins, recombinant or synthetic nucleic acid, clinical trials involving human gene therapy, genetically modified animals and whole plants and animals or animal specimens known to be reservoirs/vectors of zoonotic diseases. It is the policy of the University to provide a safe and healthy work environment. All persons involved in these activities at UCI must abide by the regulatory and policy requirements pertaining to the acquisition and use of these materials for research, teaching, or testing (hereto referred to as activities) as outlined in the:

- NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules (NIH Guidelines)
- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- Federal Select Agent Program administered by CDC and USDA
- Public Health Security and Bioterrorism Preparedness and Response Act
- California OSHA bloodborne pathogens and aerosol transmissible disease standards
- Applicable federal, state, and local laws
- The contents of this policy
- All other policies of the University of California, Irvine

2. Scope

This policy applies to all UCI faculty, staff, hosted visitors, students, participating guests, and volunteers working at locations where EHS has management control of specific biohazards. UCI School of Medicine research locations are covered by this policy. UCIMC clinical locations are under UCIMC EHS requirements.

Mission

The charge of the Institutional Biosafety Committee (IBC) is to assure the safe acquisition, use, and disposal of all biological agents at the University of California, Irvine (UCI). It is the responsibility of the Committee to establish appropriate health and safety policies in accordance with federal regulations and guidelines that cover biological safety and to evaluate research being conducted at UCI for biological safety considerations.

Purpose and Scope

UCI acknowledges its responsibility to provide a program for the handling, storage, and disposal of biological agents; to provide emergency response to incidents involving biological agents; and to educate the UCI community about the safe use of biological agents in research, teaching, and public service activities. The IBC reports to the Vice Chancellor for Research on matters related to the use of biological agents in research, teaching, and public service activities at UCI. Specific tasks include:

1. Ensuring UCI compliance with:
    - NIH Guidelines
    - All other federal, state, and local regulations
    - Procedures and principles relating to the prevention and/or control of infectious diseases.
    - The procurement, storage, use, and disposal of biological agents used in UCI research, and teaching facilities.
2. Certifying investigators, their laboratories, and/or their practices for work at appropriate biological safety levels.
3. Overseeing the development and maintenance of written biohazard safety/ infectious disease control plans that minimize exposures for all affected personnel using proper engineering controls and work practices; to make the plan available to the institutional community; and to recommend updates to the plan, as necessary. Additionally, overseeing the development and implementation of educational programs related to infectious diseases and biohazard safety.
4. Investigation and reporting for laboratory acquired infections, potential exposures, and laboratory accidents/injures.
5. Identifying tasks that carry the risk for transmission of the infectious agents and the occupational groups involved.
6. Environmental Health & Safety (EHS) implements IBC-approved programs.

3. Definitions

Animal Biosafety Levels (ABSL): ABSL's establish the defining characteristics of the work environment and required containment levels.

- ABSL-1: Animal Biosafety Level 1 (ABSL-1) is suitable for work involving well-characterized agents that are not known to cause disease in healthy adult humans, and that are of minimal potential hazard to laboratory personnel and the environment.
- ABSL-2: Animal Biosafety Level 2 involves practices for work with those agents associated with human disease. It addresses hazards from ingestion as well as from percutaneous and mucous membrane exposure.
- ABSL-3: Animal Biosafety Level 3 involves practices suitable for work with animals infected with indigenous or exotic agents that present the potential of aerosol transmission and of causing serious

or potentially lethal disease.
- ABSL-4: Animal Biosafety Level 4 involves practices suitable for addressing dangerous or exotic agents that pose high risk of life-threatening disease, aerosol transmission, or related agents with unknown risk of transmission. UCI does not have facilities or agents designated ABSL-4

Animal Husbandry: The production and care of animals.

Adverse Events:

An adverse event involving a biohazard is:
Any event (i.e., laboratory accident) that involves contamination of personnel and/or the environment with a biohazard that has the potential to cause illness or one that may cause significant concern to the general public.

An adverse event involving gene transfer is:
Any event involving risk to the subject or others, that is both unexpected and associated with 1) the use of the gene transfer product (i.e. there is reasonable possibility that the event may have been caused by use of the product); or 2) any finding from tests in laboratory animals that suggests a risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity.

Non-compliance is:
Failure of the principal investigator during the conduct of the research to: (1) supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed; (2) investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures; (3) correct work errors and conditions that may result in the release of biohazardous materials; and (4) ensure the integrity of the physical containment [e.g., biosafety cabinets] and the biological containment [e.g., purity and genotypic and phenotypic characteristics]; or 5) any violation of the NIH Guidelines that results in personal injury.

Animals or animal specimens known to be reservoirs/vectors of zoonotic diseases: All animals procured from certified commercial vendor with a health certificate clearance are exempt and will not require submission of an IBC application. Work with non-human primates and specimen obtained from non-human primates must receive IBC approval before initiation of work. Research with other animals not covered by the above will require IBC approval under IBC's discretion.

Biological Toxin: A colloidal proteinaceous poisonous substance that is a specific product of the metabolic activities of a living organism and is usually very unstable, notably toxic when introduced into the tissue, and typically capable of inducing antibody formation.

Biohazards: Biohazards are defined as biological agents and materials which are potentially hazardous to humans, animals, and other forms of life. They include known pathogens and infectious agents including bacteria and their plasmids and phages, viruses, fungi, and parasites; cell lines, animal remains, and laboratory animals including insects which might harbor such infectious agents; and primate body fluids. Also included are potentially biohazardous organisms used in procedures such as recombinant DNA and genetic manipulations. Biohazards are classified according to risk levels requiring appropriate containment.

Biohazardous Material: Biological agents and materials which are potentially hazardous to humans, animals, and other forms of life. They include (but are not limited to): bacteria and their plasmids and phages, viruses, fungi, mycoplasmas, parasites, prions, cell lines, human or animal fluids, tissues, remains, and laboratory animals (including insects) which may harbor such infectious agents.

Biosafety Level (BSL): A description of the degree of physical containment being employed to confine infectious organisms to reduce the potential for exposure of laboratory workers, persons outside of the laboratory, and the environment. These are designated BSL-1 (the least restrictive) to BSL-4 (the most

restrictive).

Containment Levels

- **Biosafety Level (BSL-1):** This containment level is suitable for work involving agents that do not cause disease in healthy adult humans. A standard wet laboratory with cleanable surfaces, sink for handwashing, and standard laboratory safety equipment. All laboratory waste contaminated with BSL-1 agents must be rendered inactive prior to disposal.
- **Biosafety Level (BSL-2):** This level of containment is suitable for work involving agents that can cause disease in healthy adult humans. The agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are reliable. A standard wet laboratory with sink for handwashing, standard laboratory safety equipment, negative airflow (preferred) and a BSC cabinet for aerosol producing procedures. All laboratory waste contaminated with BSL-2 agents must be collected as biohazardous waste or inactivated prior to disposition.
- **Biosafety Level 3 (BSL-3):** Applicable to work with done with indigenous or exotic agents which may cause serious disease. Agents with a primary route of exposure by the inhalation route as well as agents of public health concern may be BSL-3. Laboratory personnel have specific training in handling pathogenic and potentially lethal agents and are supervised by competent scientists who are experienced in working with these agents. Specially designed and validated facilities are required at BSL-3.

Biological Safety Officer (BSO): An individual appointed by an institution to oversee management of biosafety risks. The NIH Guidelines require that a BSO be appointed when the institution is engaged in large-scale research or production activities, or in research requiring containment at BSL-3 or BSL-4. The duties of the BSO are described in Section IV-B-3 of the NIH Guidelines.

Bloodborne Pathogens: Pathogenic microorganisms which present in human blood and can cause disease in humans. These pathogens include but are not limited to HBV, HCV, and HIV.

Categories of Potentially Infectious Materials:

- Human, animal, and plant pathogens (bacteria, parasites, fungi, viruses);
- All human blood, blood products, tissues, Other Potentially Infectious Materials (OPIM)
- Cultured cells and potentially infectious agents these cells may contain;
- Clinical specimens; and
- Animals and animal tissues that are known to be infected or obtained from an area known to be a reservoir of an infectious agent.

Class I Biosafety Cabinet: An enclosure with an inward airflow through the front opening. Provides protection for the worker and the laboratory environment but not to product being utilized in the cabinet.

Class II Biosafety Cabinet: An enclosure with an inward airflow through the front opening. Provides protection to the worker, the environment, and the product being utilized in the cabinet.

Containment: Used to describe safe methods for managing infectious agents in the laboratory environment where they are being handled and maintained. The purpose of containment is to reduce or eliminate exposure of laboratory workers, other persons, and the outside environment to potentially hazardous agents.

Dual Use Research: A general term that covers any research or technology that has a bona fide research purpose or use; but in the wrong hands, could be misused or used for military purposes.

Dual use research in biology encompasses biological research with legitimate scientific purpose that may be misused to pose a threat to public health and/or national security. Examples of dual use research include genetic manipulations of organisms that can result in:

- New pathogens;
- Increased pathogenicity;
- Resistance to an antibiotic used to control disease in humans, animals, or crops;
- Altered host range of a pathogen;
- Increased transmissibility of an infectious agent; and/or
- The ability to escape diagnosis/detection.

Dual use research could also encompass studies that yield information about how to increase the lethality of a toxin; manipulations of threat agents that might impair vaccine effectiveness; and ways to enable the weaponization of a biological agent.

The National Science Advisory Board for Biosecurity (NSABB) is the federal agency charged with providing advice, guidance, and leadership regarding biosecurity oversight of dual-use research. As policies and advice become available from NSABB, the IBC and ORC will develop appropriate policies, procedures, and guidance to respond to these requirements.

Environmental Health & Safety (EHS): EHS provides the following through the assignment and designation of qualified individuals, including the BSO:

- Performance of periodic inspections to ensure that laboratory standards are rigorously followed.
- Administration of the IBC to plan, develop, and conduct training on biological safety practices and procedures relating to r/sNA, infectious agents, and potentially hazardous biological materials.
- Report to the IBC any significant problems, violations of the NIH Guidelines, and any significant research-related accidents or illnesses of which the BSO becomes aware, unless the BSO determines that a report has already been filed by the Lead Researcher.
- Develop and implement emergency plans for handling spills and personnel contamination, and investigating laboratory accidents involving r/sNA, infectious agents, and potentially hazardous biological materials.
- Provide advice on laboratory security (access control procedures).
- Implement decisions of the IBC.
- Review the project facility construction/remodeling plans and specifications and inspect the site for compliance.
- Provide technical advice to investigators and the IBC on research safety Procedures; to include the selection, installation, maintenance, and use of laboratory equipment which provides or aids in containment of biological materials.

Host: Organism in which the r/sNA replicates.

Infectious Biological Agents: Infectious biological agents or biologically derived infectious materials present a risk or potential risk to the health of humans or animals, either directly through infection or indirectly through damage to the environment. Infectious agents have the ability to replicate and give rise to the potential for large populations in nature when small numbers are released from controlled situations.

Institutional Biosafety Committee (IBC): An institutional committee created under the NIH Guidelines to review research involving recombinant DNA. The UCI IBC also review other forms of research that entail biohazardous risks as part of their institutionally assigned responsibilities.

Lead Researcher (LR): The person with primary responsibility for meeting all ethical, scientific, and regulatory requirements for conduct of a UCI study protocol, whether or not acting as the Principal Investigator (PI) for the award that funds said study.
Lead Researchers are eligible to submit applications to the IBC for biological materials in research. A LR should not be confused with a PI.

- **Lead Researcher Eligibility**: Individuals who meet the criteria for PI by virtue of their University appointment status may also serve as LR on a research protocol. Individuals who do not meet the criteria for a PI may serve as a LR if they obtain a Faculty Sponsor for the activity.
- **The Faculty Sponsor:** The Faculty Sponsor must be eligible to be a PI. Refer to the Office of Research Administration (ORA) Website under, "Who is eligible."

For exceptions, please consult the ORA website https://research.uci.edu/sponsored-projects/pi-eligibility-project-leadership/ Individuals who do not meet the UCI appointment criteria for a LR may serve in that capacity with the addition of a Faculty Sponsor for project responsibility.

National Institutes of Health (NIH): One of the world's foremost medical research institutions and the preeminent federal funder of medical research in the U.S. The NIH, comprised of 27 separate Institutes and Centers, is one of eight health agencies within the Public Health Service, which is an agency within the U.S. Department of Health and Human Services. The goal of NIH research is to acquire new knowledge to help prevent, detect, diagnose, and treat disease and disability. The NIH mission is to uncover new knowledge that will lead to better health for everyone.

Negative Airflow: Directional airflow from areas exterior to a laboratory into the laboratory.

Primary Containment: Methods to protect the internal laboratory environment.

Principal Investigator (PI): The scientist or scholar responsible for the conduct of research or other activity, described in a proposal for an award. The Principal Investigator is responsible for all programmatic and administrative aspects of a project or program. The scientist or scholar with primary responsibility for the scientific, technical, and administrative conduct of a funded research project.

Recombinant or Synthetic Nucleic Acids (r/sNA): molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or molecules that result from the replication of those described above.

Risk Group: A description of the degree of risk a biological compound poses according to its relative pathogenicity for healthy adult humans.

1. **Risk Group (RG1)** - This risk group contains agents that are not associated with disease in healthy adult humans.
2. **Risk Group (RG2)** - This risk group contains agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.
3. **Risk Group (RG3)** - This risk group contains agents that are associated with human disease which can cause serious illness or death. Interventions are not often available.

Secondary Containment: Methods to protect the environment external to the laboratory.

Select agent: Biologics and toxins listed by HHS or USDA, including: HHS non-overlap select agents and toxins; high consequence livestock pathogens and toxins/select agents (overlap agents); USDA high consequence livestock pathogens and toxins (non-overlap agents and toxins); and listed plant pathogens. **Reference for list: 42 CFR 73, interim final rule;** www.cdc.gov/od/sap.

Sharps: Any object that can penetrate the skin, e.g., needle, scalpel, knife, etc.

Vector: Carrier used to introduce r/sNA into the host system and that facilitates replication in the host.

4. Responsibilities

The Institution

1. The responsibility for compliance with applicable regulations concerning r/sNA (with or without infectious agents) used in research rests with the Vice Chancellor for Research as the Institutional Official. The Vice Chancellor for Research shall be assisted in the discharge of this responsibility by the IBC.

2. The responsibility for compliance with applicable regulations concerning the use of biological materials, infectious agents, hazardous materials/hazardous waste management, radiation safety, environmental regulatory affairs, and other general institutional safety requirements rests with the Vice Chancellor for Administrative and Business Services. The Vice Chancellor for Administrative and Business Services is supported by EHS and the BSO.

3. When the institution participates in or sponsors r/sNA research involving human subjects, the institution must ensure that (a) the IBC has adequate expertise and training (using ad hoc consultants as deemed necessary) and (b) all aspects of applicable sections of the NIH Guidelines regarding experiments involving deliberate "gene transfer" derived from r/sNA into one or more human subjects have been appropriately addressed by the Lead Researcher prior to protocol submission to NIH Office of Biotechnology Activities (OBA).

Chairperson, Institutional Biosafety Committee

1. Ensure that the Institutional Biosafety Committee is properly constituted and fulfills its requirements under the appropriate regulations, rules, etc.
2. Ensure that all members of the Institutional Biosafety Committee are adequately trained in appropriate containment practices, secondary containment procedures, and accidental spill containment procedures to fulfill their responsibilities as members of the Institutional Biosafety Committee. Per NIH guidelines: **Section IV-B-1-h.** Ensure appropriate training for the Institutional Biosafety Committee Chair and members, Biological Safety Officer and other containment experts (when applicable), Principal Investigators, and laboratory staff regarding laboratory safety and implementation of the NIH Guidelines. **The Institutional Biosafety Committee Chair** is responsible for ensuring that Institutional Biosafety Committee members are appropriately trained. The Principal Investigator is responsible for ensuring that laboratory staff are appropriately trained. The institution is responsible for ensuring that the Principal Investigator has sufficient training; however, this responsibility may be delegated to the Institutional Biosafety Committee.
3. Call and preside over meetings of the Institutional Biosafety Committee.
4. Review and ensure compliance of all authorized researchers utilizing biohazardous materials.
5. Coordinate the review process of researchers seeking use of biohazardous material through research programs at the University.

Institutional Biosafety Committee

1. Advise the Vice Chancellor for Research, Deans, and Department Chairs on matters related to biohazards and biosafety within their respective areas of responsibility.
2. Develop, recommend, and implement policies and procedures for biological risk assessment and biological risk reduction throughout the University.
3. Oversee all research and teaching activities involving biohazardous agents including review and approval prior to initiation, annual reviews and updates, reviews of laboratory safety equipment and procedures, and certification of compliance with all applicable rules and regulations governing the

use of biohazardous materials. Approve those research projects that are found to conform with the NIH Guidelines, OSHA, and the CDC including **(a)** an independent assessment of the containment levels required by the NIH Guidelines for the proposed research; and **(b)** assessment, if applicable, of the facilities, procedures, practices, and training and expertise of personnel involved in the proposed use of infectious biological agents.

4. Ensure that all principal investigators are sufficiently trained in appropriate containment practices, secondary containment procedures, accidental spill containment, and their responsibilities as principal investigators as they pertain to laboratory safety.
5. Advise and provide technical expertise, whenever possible, to the Biosafety Officer on matters regarding biosafety.
6. Conduct investigation of serious violations or problems and to make recommendations to the Vice Chancellor for Research for the resolution of continued non-compliance or serious infractions.

Biosafety Officer (BSO)

The institution will appoint a Biosafety Officer (BSO) if it engages in large-scale research or production activities involving viable organisms containing r/sNA molecules, biological agents in RG-3 or 4, or Select Agents. The institution must appoint a BSO if it engages in r/sNA research at BSL-3 or 4. The BSO will be a member of the IBC. Additional responsibilities are as follows:

1. Investigate laboratory accidents and report problems, violations, and injuries or illnesses associated with biohazardous research activities, to the Institutional Biosafety Committee.
2. Conduct periodic inspections of laboratories to ensure compliance with established procedures.
3. Provide advice and assistance to the Institutional Biosafety Committee and Principal Investigators concerning containment procedures and practices, laboratory security, recommended laboratory containment equipment, rules, regulations, and other matters as may be necessary.
4. Provide oversight and assurance that laboratory safety containment equipment is functioning properly.
5. Serve as a member of the Institutional Biosafety Committee.

IBC Administrator

The IBC Administrator is responsible for overall compliance and administrative oversight of UCI's Biosafety Program. The IBC Administrator works in cooperation with the IBC, the Biosafety Officer, and if necessary, other UCI departments to coordinate the campus-wide Biosafety program including:

1. Risk-based laboratory inspections
2. Accident investigations
3. Record keeping
4. Assessment of University facilities to determine suitability for use in potentially hazardous biomedical research operations.
5. Advising professional and technical staff regarding Biosafety practices, procedures, and regulatory requirements.

Environmental Health and Safety

1. Provides industrial hygiene and safety support for all laboratory operations.
2. Transports and disposes of all infectious waste in compliance with all applicable federal, state, and local ordinances.
3. Assists, as necessary, in the emergency response, cleanup, and decontamination of biological spills and accidents.
4. Administers the campus Occupational Health program.

5. Program Components

The IBC is comprised of at least, but not limited to, five members with collective experience and expertise in r/sNA technology and the capability to assess the safety of r/sNA research and identify any potential risk to public health or the environment.

IBC Committee Membership

The Institutional Biosafety Committee meets monthly. At least half of the voting membership is necessary to establish a quorum to conduct business. Committee members are selected from a pool of faculty and community members with expertise in the properties and safe use of human and non-human primate materials, infectious agents, carcinogens, select agents, recombinant DNA, and human gene transfer trials.

The Institutional Biosafety Committee shall consist of at least five voting members appointed by the Vice Chancellor for Research. Members shall serve for a term of three years, which may be renewed by the Vice Chancellor for Research. The Chair of the committee shall be designated by the Vice Chancellor for Research and selected from among the faculty members representatives on the Committee.

The membership of the IBC includes:

1. Two members who are not affiliated with the institution (apart from their membership on the IBC) and who represent the interests of the surrounding community with respect to health and protection of the environment such as officials of state or local public health or environmental protection agencies, members of other local government bodies, or persons active in medical, occupational health, or environmental concerns in the community
2. A member representing the laboratory technical staff of the University.
3. A member with expertise in r/sNA technology, biological safety, and physical containment
4. Biological Safety Officer
5. An individual with expertise in plant, plant pathogen, or plant pest containment principles when experiments involve plants and require prior IBC approval.
6. A scientist with expertise in animal containment principles when experiments involve animals and require prior IBC approval.

When the institution participates in or sponsors r/sNA research involving human subjects, the IBC will have adequate expertise and training or will appoint ad hoc consultants, as necessary, to ensure that the Committee has the professional competence necessary to review such research.

The IBC is responsible for reviewing all protocols that involve the use of biohazardous materials. Two weeks prior to a scheduled meeting, the IBC member will be asked to confirm (via e-mail) his/her attendance to ensure a quorum of members will attend the meeting and to determine the pool of reviewers available to review protocols.

Meeting packets are sent to IBC members one week prior to an IBC meeting. Packets will include the meeting agenda, all applications designated for full committee review received by the meeting deadline, minutes from the previous meeting and any other information for discussion. **Members are expected to review and to be prepared to discuss all materials included in the packet at the time of the** meeting.

Each Application that will undergo full committee review will be assigned a primary and secondary reviewer. The responsibilities of the primary and secondary reviewer are as follows:

- If requested by the committee, the primary reviewer might contact the Principal Investigator (PI) to discuss the questions and concerns of the committee members. NOTE: The PI will be required to respond in writing and/or submit a revised protocol if additional information is required to secure approval. It is possible additional comments and questions may be raised during the committee discussion.

- The primary reviewer presents the protocol at the committee meeting. The secondary reviewer presents any additional concerns not raised by the primary reviewer.
- Written comments from both the primary and secondary reviewers should be submitted to the IBC administrator.
- Both reviewers conclude the presentation of the protocol with one of the following recommendations:
    - Approval
    - Tabled Administratively
    - Tabled for Designated Review by Subcommittee
    - Resubmission
    - Disapproval

Protocols Tabled for Designated Review by Subcommittee

When protocols are tabled for subcommittee review and approval, the PI will be required to address the IBC's concerns in writing. When a response is received, the IBC Administrative Office will perform a preliminary administrative review to assure all the information requested is included in the response. T he response is then sent to the primary and secondary reviewer (and any other member who is a part of the subcommittee) and each member of the subcommittee must indicate his/her approval of the protocol via e-mail. Once all required votes are received by e-mail, the IBC Administrator will proceed with the approval process.

Experiments at BSL-1 Level of Containment or Exempt Protocols

All work involving recombinant DNA that is subject to the current NIH Guidelines must be reviewed and approved by the Institutional Biosafety Committee before such work can begin. If the application requires a BSL-1 level of containment, the application may be exempt. However, such exemptions can only be determined by the IBC. Contact ibc@uci.edu with a description of the BSL-1 work proposed.

IBC Administrator Preliminary Review and IBC Exemption Determination:

Upon receipt of application, the IBC Administrator will assess the proposal for completeness of information and provide a preliminary assessment based on NIH, CDC, and USDA requirements. If the Activities are eligible for an exemption from IBC review, the exemption will be issued at that time. If the activities require review, then the application and preliminary review will be forwarded to full committee review.

The IBC member will evaluate the project's protocol, equipment, work space, and other pertinent information for safety. The PI will be advised concerning the acceptability of the proposal and any modifications, additions, etc. required.

Criteria for IBC Approval

The IBC will determine if the research proposal conforms to the institution's NIH Assurance and meets the following Criteria:

- The hazards and risks associated with the project or activity are appropriately minimized by safe procedures.
- The risk to personnel, students, or visitors is reasonable in relation to the threats and hazards associated with use of the materials.
- The risk to the community's health and environment is reasonable.
- The facilities are adequate to minimize the risks of using the materials.
- Preventative medical measures are taken to minimize risks associated with breaches in safety procedures. This includes any required occupational health consultations.
- Appropriate IACUC, IRB, hSCRO, RAD approvals are in place.

Notification of IBC Decisions

All communications regarding committee actions will be sent to the PI by the IBC Administrative Office in writing within 3 working days following the full IBC meeting.

Approvals by subcommittee will be acknowledged at the next convened full IBC meeting and will be appended to the minutes.

Notifications must be signed by the IBC Chair before they become effective.

Revised Applications

IBC revisions will be requested in the online IBC Biological Use Authorization (BUA) Management System, RSS. Changes are made by the PI or Designee and returned to the IBC for final approval.

Medical Surveillance

The committee will also determine the need for Medical Surveillance based on the discussion of the risk assessment presented via the submitted protocol. All personnel working with BSL-3 agents will be required to complete medical surveillance. The need for other personnel working with infectious agents to complete medical surveillance and the recommendation for prophylaxis will be determined by the committee.

Further details for medical surveillance can be found in the document titled “Medical Surveillance for Personnel Working with Infectious Agents” which is attached as Attachment A.

Administration of the Biosafety Program and Technical Support of the IBC

EHS will provide management and administrative support to the IBC. Staffing of the IBC and the Biosafety program will be proportional to the volume of activity and levels of risk associated with r/sNA and Biological Agent Activities at UCI. As part of its general staffing duties, EHS will prepare and maintain records of IBC activities for at least 3 years and records related to protocols and user authorization for at least 9 years after the completion/termination of the research per UC Records Retention Schedule. EHS will keep IBC records of the following items:

- Copies of all IBC Applications and supporting materials that are reviewed;
- Minutes of the IBC meetings with sufficient detail to show attendance, actions taken at the meeting, and votes on actions, the basis for requiring changes in research, and a summary of the IBC discussion of controversial issues and their resolution;
- Copies of lab safety reviews, surveys, and security protocols
- A list of IBC members and their qualifications for serving on the board
- Written IBC policies and procedures
- Statement of significant new findings on the safety of biological activities at UCI
- Standard Operating Procedures approved by the IBC.
- Biosafety training materials, dates, and names of all persons who have completed required training.

Records

The IBC, through Environmental Health and Safety, will maintain for a period of at least nine years; minutes of IBC meetings including records of attendance, activities of the committee, and committee deliberations. Environmental Health and Safety will also maintain all records of applications, proposals, and proposed significant changes in activities involving recombinant DNA or other biological materials. All records shall be accessible for inspection and copying by authorized institutional officials.

Policy on Public Access to Meetings and Request for Meeting Minutes

Meetings Document Management

1. Agenda
   EHS sets the IBC meeting agendas in cooperation with the IBC Chair. The agenda must include a review of the previous meeting's summary, a summary of activities reviewed or exempted since the last meeting, and administrative updates.

2. Meeting Minutes
   A meeting summary will be written and provided to all IBC members after the completion of each IBC meeting. The summary will include date, attendance, absentee members, motions, and a synopsis of meeting activities and discussions. The summary is for official documentation purposes only and not intended for general distribution or public access.

3. Public Request for and Redaction of IBC Minutes
   The Biological Safety Officer (BSO), IBC Administrator, and/or IBC Chair may receive requests for meeting minutes. All requests must be made in writing and sent via standard mail or email. The requestor must include their name, address, phone number, email address and affiliation. A nominal fee may be charged to cover the cost of processing the request. The BSO and the IBC Chair may redact information from the minutes. The request along with the preliminary redactions is sent to General Counsel for review. General Counsel may also assist with any appropriate redactions. General Counsel will process and redact appropriate information and inform the BSO when the copies of the minutes may be released to the requestor.

   Information that compromises the safety and security of UC Irvine personnel, research and/or intellectual property, the institution or the nation will be redacted.
   Examples include but are not limited to:

   - trade secret information;
   - other confidential or proprietary commercial information;
   - personal information about IBC members (home telephone numbers, home address);
   - locations of laboratories, animal facilities and offices;
   - location of biohazardous materials;
   - personal information about the PI and research personnel;
   - select agent information;
   - specific details regarding animal experimentation;
   - specific information whose disclosure would compromise institutional or national security.

Attendance

Members of the IBC are responsible for attending all convened meetings and staying until business has been completed, whenever possible. When attendance is not possible, IBC members must notify the IBC Administrator at **ibc@uci.edu** as soon as possible.

A member who will be unable to attend a meeting but not contact the IBC Administrator prior to the mailing out of packets, will be expected to review any protocols they are assigned. It is this member's responsibility to contact the other reviewer with their comments so that the other reviewer can present both reviewers' comments and recommendations to the IBC.

Attendance of Non-Members

IBC meetings are considered open and, as such, members of the UC Irvine community and the public at large may request to attend an IBC meeting. Those who wish to attend an IBC meeting must notify the IBC Administrator in advance at (949) 824-6200 or **ibc@uci.edu** regarding the desire to attend. While no one will be denied access to a meeting, the IBC Administrator must be made aware of additional attendees in order to schedule a room of appropriate size. Last minute requests may not be honored if

the meeting room cannot accommodate additional attendees.

Confidentiality

Members of the IBC are responsible for maintaining all committee proceedings and documents in strict confidence. Such information may not be used for any purpose other than IBC review and may not be disclosed to anyone outside of the IBC unless permission is granted in writing by the Vice Chancellor for Research.

Conflict of Interest Disclosure

It is the expectation of the University that committee members will voluntarily recuse themselves from situations that create, or appear to create, a conflict of interest. Members of the IBC are responsible to disclose to the IBC Chair or IBC Administrator any conflict of interest that may arise in the review of research or compliance matters for the IBC. In a meeting of the full committee, recused members must leave the room during discussions and voting. A similar expectation for disqualification exists for members on subcommittees.

1. Members who are primary investigators, faculty sponsors, or other investigators in the project under review, or whose spouse or child is a project investigator or faculty sponsor, must recuse themselves from committee action.
2. Members who have a significant financial or management interest as defined by federal policy in the extramural sponsor or provider of the drug, device, or test product, or whose spouse or dependent child has same, must recuse themselves from committee action.
3. Members who believe existing circumstances may directly affect their objectivity may request that they be recused from committee action.

Regulatory Compliance

Members of the IBC are responsible for keeping abreast of and being in accordance with all applicable federal regulations and policies, state law, and UC and UCI policies as provided by the IBC Administrator that pertain to r/sNA.

References on Public Access

- NIH Guidelines for Research Involving Recombinant DNA Molecules Section IV-B-2- a-(7)
- May 14, 2004 Memo from OBA/NIH
- February 23, 2007 Memo from OBA/NIH

Institutional Biosafety Committee Basics of Protocol Review

The primary responsibility of the IBC is to review and assess the following:

- Research involving recombinant or synthetic nucleic acid technology;
- Research involving Select Agents identified by the CDC and USDA as posing a severe threat to public health and safety to animal and plant health or animal or plant products.
- Any other research involving biohazardous materials.

The Office of Biotechnology Activities at NIH delegates responsibility to the Institutional Biosafety Committee for evaluating the potential hazards of the work (risk assessment), assigning appropriate physical containment and safety practices, and evaluating the relevant experience and training of the research staff to perform the work.

When reviewing protocols and applications, the IBC should consider:

- Begin by reviewing Section II (Safety Considerations) of the NIH Guidelines for risk assessment and biological containment level. **NIH Guidelines**

- Any strain that is known to be more hazardous than the parent (wild-type) strain should be considered for handling at a higher containment level than the parent strain.
- Certain attenuating strains or strains that have been demonstrated to have irreversibly lost known virulence factors may qualify for a reduction of the containment level compared to the Risk Group assigned to the parent strain.

At times, risk assessment of infectious agents and recombinant agents should be completed prior to beginning work with that agent. Below are some guidelines:

- Virulence – Review the Risk Group Classifications in the NIH Guidelines.
- Pathogenicity – Consider the wild-type agent itself and how genetically engineering the agent affects its disease-causing potential.
- Infectivity – Consider the host range, availability of vaccine or treatment, and the possibility of reverse mutations and recombination.
- Route of Spread and Communicability – Consider how the agent is transmitted.
- Operations (e.g., creation of aerosols) – Consider whether operations in the lab will affect the virulence, pathogenicity, infectivity, route of spread, and communicability of the agent.
- Quantity – Consider the amount of virus to be manipulated and its concentration.
- Gene product (e.g., toxicity or physiologic activity) – Consider what is being inserted into the agent and whether it affects virulence, pathogenicity, infectivity, route of spread, and communicability. Biosafety levels consist of combinations of laboratory practices and techniques, safety equipment, and laboratory facilities appropriate for the operations performed and are based on the potential hazards presented by the agents used and by the laboratory functions and activities.

Circumstances requiring an increase in the level of containment:

- When animals are used as a host, recombinant agents could result in infection of other animals.
- Operations that create increased infectivity (e.g., inoculation, aerosolization)
- Viral chimeras

Use of Primary and Established Cell Lines:

- Primary human or non-human primate cell lines should be considered potentially infectious and handled using BSL-2 containment practices.
- Established human or non-human primate cell lines (e.g., purchased from (ATCC should be considered potentially infectious and handled using BSL- 2 containment practices, unless the vendor providing the cell line certifies that the cell line is pathogen-free.

Application Process

Environmental Health and Safety is responsible for coordinating the review process for applications to possess and use r/sNA and other potentially infectious agents at UC. Visit the IBC website at: https://www.ehs.uci.edu/research-safety/biosafety/ibc/index.php

The application must be completed and electronically signed by the Principal Investigator before the IBC can begin to review the study. The application for protocol submittal is online using RSS: https://ehs.ucop.edu. Other documents and SOPs may be required to complete the submission to the IBC.

Proposals must be received two weeks in advance of a proposal deadline to permit time for Committee review. Approval to use biohazardous materials and recombinant DNA must be obtained prior to initiation of any research project using these materials. Upon receipt of a proposal, the IBC Administrator will prepare an official record file and forward the documents to the Chairperson of the Institutional Biosafety Committee for final signature.

Protocol Components

There are several important components of the protocols. In addition to the information below, refer to the **UCI Biological Safety Manual** for general biosafety information.

Regulatory Compliance

- Recombinant or Synthetic Nucleic Acid activities - The NIH Guidelines for Research Involving r/sNA governs all r/sNA activities including those exempt by the guidelines.
- Educational Activities and Non-r/sNA research involving microorganisms and exempt r/sNA – Activities involving these agents are not federally regulated but it is the position of the IBC that the procedures and containment levels outlined in the CDC publication Biosafety in Microbiological and Biomedical Laboratories will govern such activities.
- Biological Toxins - These agents are not governed by NIH or CDC regulations or guidelines. Although Material Safety Data Sheets (MSDS) are available for most of these agents, specific exposure levels, to our knowledge, have not been established. EHS will work with the PI to interpret the MSDS and to establish work and disposal procedures which will protect the users of the materials and the environment outside the laboratory.
- Exposures to Bloodborne Pathogens, Blood, and Other Potentially Infectious Materials (OPIM) - OSHA's standard for bloodborne pathogens will govern any activity involving human blood or OPIM. Compliance with this standard is administered by EHS. Information on UCI's Bloodborne Pathogens
- Disposal of Infectious Materials - Governed by the Environmental Protection Agency and administered by EHS.

Laboratory Safety Training

All laboratory personnel must be informed of the hazards associated with the work and proper safety precautions. Such training is a continuing process that begins before a person starts laboratory work and requires regular supervision and emphasis. Each person **identified** on the protocol is required to complete safety training. Laboratory Fundamentals and Hazardous Waste training are required in addition to lab and agent specific training. Bloodborne pathogens training, when necessary, is required annually. Based on the nature of the work performed in the study, specialized training such as Select Agents and Viral Vectors may be required.

Risk Assessment

The Committee will evaluate the potential risk of exposure based on the use of the infectious agent(s) proposed in the protocol. Approval of a protocol will be contingent upon the Principal Investigator's follow through of the Committee's recommendations for Medical Surveillance. As part of the Medical Surveillance program, the Principal Investigator and each person listed on the protocol must complete the Risk Assessment form. The risk assessment will include requirements for engineering controls, personal protective equipment, health assessment, prophylactic immunizations, titers, and serum surveillance recommendations. Based on the completed Risk Assessment, the BSO along with the Licensed Health Care Provider will determine the appropriate health assessment.

Specimen Transport

Human specimens and diagnostic samples are frequently transported between locations on the campus or from the campus to off-campus locations. A properly labeled (biosafety sticker indicating agent identity) leak-proof transport carrier should be used during transport. Examples of acceptable containers include a Playmate cooler or a Nalgene Bio Transport Carrier. If materials are being transported outside the United States, you will need to contact the Export Control Administrator at 949-824-0445 to determine if the shipment is allowed and if a permit is required.

Packaging and Shipment of Biological Materials

The importation or shipment of biological materials is governed by various agencies including but not limited to the Centers for Disease Control and US Department of Agriculture. Contact biosafety@uci.edu for more information. Use of Animals

The requirements governing the use of animals with biohazardous agents are similar to, but not identical to, the requirements for the use of the same agent in laboratory situations. The PI, in conjunction with the Institutional Animal Care and Use Committee (IACUC), is responsible for determining the appropriate Animal Biosafety Level (ABSL) for the specific agent being utilized.

6. Reporting Requirements

In accordance with Section IV-B-7-c-(3) of the NIH Guidelines, all changes to a protocol that occur subsequent to IBC approval must be promptly reported to the IBC. Any revised documents must be submitted to the IBC for review and approval prior to initiation of these changes. Amendments are submitted online in RSS.

Review Process for Research Involving Animals or Human Subjects

Reviews by the Institutional Animal Care and Use Committee (IACUC) and the Institutional Review Board (IRB)/ Human Stem Cell Research Oversight Committee (hSCRO) can take place either before or concurrently with IBC review. However, the IACUC or IRB/hSCRO cannot grant final approval until IBC approval has been granted. Data concerning the IBC protocols are shared with the Office of Research database on a regular basis. Upon request, the IBC Administrator will provide the IACUC or IRB/hSCRO Administrator with a copy of the IBC approval letter.

The IBC will notify the IACUC or IRB/hSCRO if they note any concerns. In addition, the IACUC or IRB/hSCRO can invite an IBC member to the meeting where the continuing report is reviewed if they have concerns about the protocol.

7. References

- NIH Guidelines
- Office of Biotechnology Activities Recombinant DNA and Gene Transfer
- CDC and NIH Biosafety in Microbiological and Biomedical Laboratories (BMBL)
- American Biological Safety Association Risk Group Classification for Infectious Agents
- Select Agents Toxins List
- Recombinant DNA and Gene Transfer Frequently Asked Questions