Institutional Biosafety Committee

Standard Operating Procedures (SOPs)

Version 1.0

IBC Approval Date: November 3, 2014

Effective Date: February 12, 2015

1731 East 120th Street
Los Angeles, CA 90059
Telephone: (323) 563-4966
FAX: (323) 563-4826
E-mail: Biosafety-IBC@cdrewu.edu
http://www.cdrewu.edu/IBC/Guidances

Table of Contents

1. Introduction

In accordance with the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (*NIH Guidelines*), the Charles R. Drew University of Medicine and Science (CDU) has established an Institutional Biosafety Committee (IBC) to have oversight of the use of recombinant or synthetic nucleic acid molecules and other biohazardous agents and materials. Usage includes receipt, storage, transfer and disposal of known or potential biohazardous materials.

The University President is the Institutional Official for the CDU IBC and have charged the IBC with the authority and responsibility to regulate the safe, ethical, and compliant use of biohazardous agents and materials by all individuals under the jurisdiction of CDU.

The primary concern of the IBC is the safety of the personnel, the public, and the environment when biohazardous agents or materials associated with risk are used for research or teaching.

The CDU IBC Standard Operating Procedures (SOPs) documents the policies and procedures of the Committee and administrative office to function effectively and efficiently. The IBC SOP is a working document that is to be used in conjunction with the Biosafety Manual and is reviewed at least once every 3 years in its entirety.

CDU does not have facilities for either Biosafety Level 3 (BSL-3)/Animal Biosafety Level 3 (ABSL-3) or BSL-4/ABSL-4 biological containment. Research requiring these containment levels are not currently allowed nor the use of select agents and toxins. Therefore, procedures involving the BSL-3 or BSL-4 facilites or the use of select agents and toxins are not described in the IBC SOP. In addition, CDU currently does not support human gene transfer experiments or research involving plants.

2. Scope of IBC Oversight

The scope of CDU IBC oversight includes any activities involving the use, receipt, storage, transfer or disposal of known or potential biohazardous agents or materials, including recombinant or synthetic nucleic acid molecules that may potentially pose a risk to humans, animals, public health and/or environment. The activities encompass research and teaching conducted by faculty, staff, students, and others under the jurisdiction of CDU. CDU IBC oversight includes activities conducted on CDU campus, facilities or property. Activities may be funded or not funded.

3. Institutional Biosafety Committee

3.1 Member Composition

3.1.1 The IBC is comprised of no fewer than five members and must collectively have the experience and expertise in recombinant or synthetic DNA technology and

biohazardous agents. The members collectively shall be capable of assessing the safety and identify any potential risk to public health, animal or environment.

3.1.2 Member Expertise and Advocates. The IBC will include individuals who collectively will (1) have expertise in recombinant or synthetic nucleic acid technology, biological safety, and physical containment, (2) have knowledge in institutional commitments and policies, applicable law, standards of professional conduct and practice, community attitudes, and the environment, and (3) have expertise in animal research and animal containment principles.

In addition, there will also be (1) at least one member representing the laboratory technical staff, (2) at least two members who are not affiliated with the institution and who represent the interest of the surrounding community with respect to health and protection of the environment, and (3) a Biosafety Officer.

3.2 Appointment to the Committee

3.2.1 All IBC members are appointed by the University President (or his/her designee), who serves as the Institutional Official for the IBC. The IBC Chair shall recommend candidates for membership to the University President upon suggestions from the current IBC members and other colleagues. The University President formally appoints IBC Chair, Vice Chair, and Biosafety Officer (BSO) after consultation from various sources.

3.2.2 Each term is for 3 years. IBC Chair and members can serve more than one term.

3.2.3 Unless otherwise designated, all members of the committee are voting members, which includes the Chair, Vice Chair, and BSO.

3.2.4 Vice Chair is expected to succeed the Chair upon vacancy. If the Vice Chair is unable to do so, the University President will appoint a new Chair.

3.3 Alternate Members

3.3.1 Some members are designated as alternate members. Alternate members are also appointed by the University President and can take part in the IBC meeting.

3.3.2 Alternate members can only vote when their designated voting members cannot attend the meeting in person or via teleconference. If the voting members are present and do not have a conflict of interest, the alternate members do not count towards the quorum and cannot vote, although they can participate in the discussion and can receive copies of the meeting material.

3.4 *Ad hoc* Consultants

3.4.1 To assist with the review, the IBC may request the services of a consultant, who will provide written review and may attend the convened meeting, but will not have voting privileges.

3.4.2 IBC shall retain a copy of the most current curriculum vitae or biosketch from the consultant and a conflict of interest disclosure for each of the registration reviewed by the consultant.

3.4.3 *Ad hoc* consultant shall be included in the annual report to the NIH/OBA.

3.5 *Ex officio*

3.5.1 The IBC may include *ex officio* members who can or cannot vote. Biosafety Officer (BSO) is an *ex-officio* who has voting rights. Director of Office of Research Integrity and Compliance (ORIC) is an *ex-officio* with no voting rights.

3.6 Honorarium

3.6.1 Honoraria are usually not available for the IBC members who are CDU faculty, staff, or students.

3.6.2 Unaffiliated community members may receive an honorarium for reviewing the IBC meeting material, attending the IBC meetings, and other committee activities.

3.7 IBC Member Education and Training

3.7.1 Initial and continuing training of all IBC members involves completion and passing the prescribed CITI online training for IBC members every three years.

3.7.2 Members also obtain continuing education from various avenues, such as during the convened IBC meetings, biosafety presentations through the Division of Research Operations, webinars, distribution of biosafety articles through e-mail, attendance at American Biological Safety Association (ABSA), Public Responsibility in Medicine and Research (PRIM&R), or other biosafety conferences. Continuing training also occurs during the meeting when substantive issues pertaining to the review are discussed or special presentations are given on current biosafety topics, regulations, or procedures.

3.7.3 IBC Chair, BSO, or ORIC Director gives orientation session to new IBC members about the *NIH Guidelines*, California Occupational Safety and Health

Administration (Cal/OSHA) Bloodborne Pathogens Standard, CDU Biosafety Manual, and CDU IBC SOP.

3.7.4 IBC members receive CDU Biosafety Manual, CDU IBC SOP, *NIH Guidelines*, Cal/OSHA Bloodbourne Pathogen Standard as reference manuals in DVD or hardcopy format or electronically.

3.8 Meeting Attendance

3.8.1 Members are required to attend the scheduled meetings, which are held on the second Tuesday of every month. Members who miss more than four regularly scheduled meetings may be removed from the IBC.

3.8.2 Members must inform the Chair and the ORIC Director in advance, if they are unable to attend.

3.8.3 Members are encouraged to attend by teleconference or arrange for their alternates to attend the meeting.

3.9 CDU E-mail

3.9.1 All IBC members whether affiliated or not affiliated with CDU must have CDU E-mail for receiving research protocols for review and communication from the Chair, BSO, or ORIC Director. The ORIC Director will arrange CDU E-mail for any unaffiliated members.

3.10 Confidentiality and Non-disclosure Agreement

3.10.1 All IBC members, alternates, *ad hoc* consultants, *ex-officios*, must sign the Confidentiality and Non-disclosure Agreement before they can attend the IBC meeting or review any IBC-related documents.

3.10.1 IBC documents are confidential and may also contain proprietary information. Individuals who are authorized to review these information must not dislose, discuss, or disseminate the information, except when fulfilling their responsibilities as an IBC member.

3.11 IBC Member Registration with NIH/Office of Biotechnology Activities (OBA)

3.11.1 The Director of ORIC is the contact person for CDU IBC and is responsible for registering IBC members with the National Institutes of Health (NIH) Office of Biotechnology Activities (OBA). The individual cannot be listed as IBC member nor be counted towards a meeting quorum until the registration has been submitted and approved by the NIH/OBA. IBC registration and annual reports

are submitted online through the NIH/OBA Institutional Biosafety Committee Registration Management System (IBC-RMS).

3.11.2 The Director maintains and updates curriculum vitae or biosketch of each committee member for Annual Reporting to the NIH/OBA.

3.11.3 The Director updates the IBC website for the current IBC roster.

3.12 IBC Member Evaluation

3.12.1 Each committee member will do an annual self-assessment.

3.12.2 The ORIC Director will compile and submit a report to the Chair, which includes the self-assessment, attendance, review assignments, training completion.

3.12.3 The Chair will present an overall assessment of the committee during the meeting. Open discussion will be solited toward quality improvement, including type of training and education requested from the members for the next year.

3.12.4 The Institutional Official (or designee) and ORIC Director will discuss self-assessment and program needs with the Chair.

4 Responsibilities

4.1 Institutional Biosafety Committee

4.1.1 To ensure that all research and teaching activities involving the use of biohazardous agents or materials, including recombinant or synthetic nucleic acid molecules are registered and that the review and approval is granted before applicable activities can be initiated.

4.1.2 To review and approve research and other activities involving the use and/or possession of biohazardous agents or materials (including recombinant or synthetic nucleic acid molecules) conducted at or sponsored by CDU for compliance with the federal regulations, state and local laws, CDU policies and procedures, including but not limited to, *NIH Guidelines*, Cal/OSHA regulations, and CDU Biosafety Manual.

4.1.3 To notify the Principal Investigator of the results of the IBC review and approval or disapproval of registration.

4.1.4 To lower containment levels for certain experiments as specified in Section III-D-2-a, 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.

4.1.5 To set containment levels as specified in Sections III-D-4-b, Experiments Involving Whole Animals.

4.1.6 To periodically review recombinant or synthetic nucleic acid molecule research conducted at CDU to ensure compliance with the *NIH Guidelines*, as well as research involving other biohazardous agents and materials for adherence to Cal/OSHA regulations under California Code of Regulation, Title 8, and other applicable California and Los Angeles County laws and regulations.

4.1.7 To adopt emergency plans covering accidental spills and personnel contamination resulting from activities involving recombinant or synthetic nucleic acid molecule research or other biohazardous agents and materials.

4.1.8 To review reports of any spills, accidents, and personnel contamination resulting from research involving recombinant or synthetic nucleic acid molecules and/or other biohazardous materials or agents.

4.1.9 To report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH/OBA within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator. Reports to NIH/OBA shall be sent to the following address:

Office of Biotechnology Activities
National Institutes of Health
6705 Rockledge Drive, Suite 750, MSC 7985
Bethesda, MA 20892-7985 (20817 for non-USPS mail)
Telephone: 301-496-9838
FAX: 301-496-9839

4.1.10 To immediately report any confirmed BSL-2 research-related illnesses, and any accidents, or significant problems with or violations of the *NIH Guidelines* to the appropriate institutional officials and NIH's Office of Biotechnology Activities.

4.1.11 To not authorize initiation of experiments, which are not explicitly covered by the *NIH Guidelines* until NIH establishes the containment requirement

4.1.12 To conduct program evaluation and compliance management review of essential elements of the program.

4.2 IBC Chair

4.2.1 To convene regular monthly or unscheduled emergency IBC meetings.

4.2.2 To approve the agenda for the convened IBC meetings.

4.2.3 To approve attendance of individuals other than IBC members or staff.

4.2.4 To convene the meeting, including calling the meeting to order, directing deliberations of the committee, requesting motions and seconds, taking votes, closing the meeting at the conclusion of business.

4.2.5 To sign the approved minutes.

4.2.6 To sign the correspondences to the Principal Investigators, including IBC meeting decisions and requirements for IBC registration and inventory involving the use of biologically hazardous agents and materials, including recombinant or synthetic nucleic acid molecules.

4.2.7 To review protocols that were accepted at the meeting that require minor modifications for final approval. The Chair may request other committee members to assist in the review of responses from the investigators.

4.2.8 To review protocols that do not require review at the full convened meetings. The Chair may assign committee member(s) of the IBC to review expeditable protocols. The Chair signs approval notice or correspondences to the investigator resulting from expedite review mechanism. Registration approved through the expedited mechanism are reported at the next convened IBC meeting.

4.2.9 To assign subcommittees composed of subset of IBC members to review issues, manuals, SOPs, as necessary.

4.2.10 To evaluate the committee members annually.

4.2.11 To interview and nominate potential IBC members and communicate the choice to the Institutional Official.

4.2.12 To provide education and consultation to the institution, IBC members and investigators.

4.2.13 To maintain up-to-date knowledge about recombinant DNA technology, California OSHA standards, biosafety, biosecurity, waste management, shipping requirements, institutional policies and procedures.

4.2.14 To attend local, regional, and national conferences, as well as training through webinars and other available education and training opportunities.

4.3 IBC Members

4.3.1 To request a full IBC review of any registration submission, amendment, or renewal at any time, even if the action to the registration does not normally warrant a full IBC review.

4.3.2 To independently review minor amendments to a previously approved IBC registration outside of the full committee as assigned by the IBC Chair.

4.3.3 To vote on each registration, amendment, renewal, incident reports presented before the full committee.

4.3.4 To assist Principal Investigators (PIs) if they have questions or require clarification regarding requested revisions to a protocol or amendment as necessary.

4.3.5 To be familiar with the *NIH Guidelines*, Cal/OSHA regulations under CCR Title 8, CDU Biosafety Manual, and BMBL recommendations.

4.3.6 To independently assess the containment level for each protocol.

4.4 Biosafety Officer (BSO)

4.4.1 Be a voting member of the IBC and review registrations and other applicable documents provided to the IBC.

4.4.2 To conduct periodic inspections to ensure that laboratory standards as determined by the IBC are rigorously followed.

4.4.3 To report to the IBC and the institution 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 PI.

4.4.4 To develop emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving recombinant or synthetic nucleic acid molecule or biohazardous agents or materials.

4.4.5 To provide advice on laboratory security.

4.4.6 To conduct biosafety risk assessments, training, and facility inspection to ensure that the University is in compliance with all applicable federal regulations and state and local laws for biosafety.

4.4.7 To oversee the review of BSL-1/ABSL-1 and BSL-2/ABSL-2 research projects and teaching laboratories on campus in conjunction with the IBC, and conducting all relevant inspections on these facilities.

4.4.8 To provide technical advice to PI and the IBC on research safety procedures.

4.4.9 To develop and implement a comprehensive biosafety program for CDU.

4.4.10 To provide and serve as a source for biosafety and biosecurity education and training.

4.4.11 To provide guidance for the design and management of containment facilities.

4.4.12 Other duties as assigned or necessary to ensure biosafety and biosecurity.

4.5 Administrative Staff

4.5.1 To process IBC registration, inventories, and incident reports from the investigators.

4.5.2 Distribute IBC documents to IBC Chair for expedited review or to the members for full Committee meeting.

4.5.3 Take minutes and distribute to IBC members for review.

4.5.4 Draft IBC correspondences to the investigators.

4.5.5 Prepare for IBC meeting, including distributing meeting materials to the reviewers, scheduling meeting dates and location, and providing snacks.

4.5.6 Process honoraria for non-affiliated IBC members.

4.5.7 Maintain census of the primary reviewer assignments, meeting attendance, current CV and training records.

5. Research Protocol Submission

The CDU IBC Project and Material Registration Form is used by the IBC to review and approve research involving recombinant or synthetic nucleic acid and/or biohazardous materials.

5.1 Initial Registration

5.1.1 The CDU IBC Project and Material Registration Form and Inventory must be submitted to the IBC for any new research involving the use of recombinant or synthetic nucleic acid molecule or biohazardous material.

5.1.2 IBC must approve the protocol prior to starting the research for any BSL-2 and recombinant DNA research covered by the *NIH Guidelines*, Section III-A to III-D.

5.1.3 As defined by the *NIH Guidelines*, BSL-1 recombinant DNA research under Section III-E requires IBC registration at the time research is initiated.

5.1.4 Research conducted in BSL-1 or BSL-2 with pathogenic organisms must be reported to the IBC using the IBC Registration Form and must be approved prior to the initiation of the research.

5.1.5 No research involving biological select agent organisms or toxins are allowed at CDU.

5.1.6 The IBC Protocol Registration Form includes a Biosafety Level evaluation and solicits information about the PI's facilities, engineering controls, containment equipment, and safety procedures. This information must be completed in full when submitting the registration.

5.1.9 The BSO will arrange an inspection of the lab when the research will be conducted in BSL-2 and using BSL-2 or BSL-3 practices whether engineering controls and containment facilities are appropriate for the designated Biosafety Level.

5.2 Annual Review

5.2.1 IBC Registration must be renewed annually using the Continuing Review Form and updated Inventory.

5.2.2 The IBC administrator will remind the PI to submit a continuing review approximately two months before the approval expires.

5.2.3 Lapses in continuing review will be reported to the Committee. The Committee may request a corrective and prentive action plan from the PI.

5.2.4 Investigators must submit a revised registration form when there will be a change in the personnel, research site, or to the approved protocol. PIs are not allowed to initiate the changes until the revised registration form has been approved by the IBC.

5.3 Five Year Re-Registration

5.3.1 PI must submit a new IBC Protocol Registration Form every 5 years.

5.3.2 The IBC administrator will remind the PI to submit a new IBC Protocol Registration Form approximately two month before the expiration date.

6. Institutional Biosafety Committee Review

6.1 Administrative Review

6.1.1 The IBC Registration Forms and Inventory will be reviewed by the IBC administrator to ensure that the PI has signed the form, all the appropriate forms have been completed, and the forms contain sufficient detail to determine which type of committee review is required (i.e. expedited review or full committee review). A complete initial registration form and inventory must be received and the PI must only use the latest forms from the IBC website.

6.1.2 If the protocol involves the regulatory approval from other institutional committees, such as IACUC, IRB, RSC, OHSC, COIC, the IBC administrator will confirm and attach an approval letter and approved IACUC, Radiation Safety, or IRB protocol. If not, the IBC administrator will inform the PI that IACUC, radiation safety, or IRB approval is also required.

6.1.3 The IBC administrator will ensure that all appropriate training has been satisfied by the research personnel through CITI online training or by other mechanisms. A certificate of training education must be on file for all research personnel involved in the project as appropriate.

6.2 Expedited Review (IBC Chair Review and Approval)

6.2.1 New Studies

6.2.1.1 *NIH Guidelines* do not allow expedited review for non-exempt recombinant DNA research. All non-exempt recombinant or synthetic

nucleic acid molecule research requires review and approval at the fully convened IBC meeting.

6.2.1.2 IBC Chair verifies which section(s) of the *NIH Guidelines* applies to the new registration.

6.2.1.3 Expedited review and approval by IBC Chair are reported to the IBC at the next regularly scheduled meeting of the committee. The committee accepts the expedited review.

6.2.2 Amendments

6.2.2.1 Amendments involving non-exempt recombinant DNA research can be approved by the IBC Chair, if the amendment does not change the safety, compliance, or risk assessment of the currently approved research. If the amendment changes the safety or risk, the convened IBC must review and approve the amendment.

6.2.2.2 Amendments indicating a minor change that has no impact on biosafety level or on the classification of approved recombinant DNA research are reviewed by the IBC Chair. They may request additional information from the PI with notification to the IBC Administrator.

6.2.2.3 Minor amendments such as addition of new staff, or the use of new rooms under BSL-1 or BSL-2 conditions, are approved by the IBC Chair.

6.2.2.4 IBC registrations or amendments involving **exempt** recombinant DNA research including exempt transgenic vertebrate and invertebrate animals are recorded by the IBC Administrator, then sent to the IBC Chair for review. Following satisfactory resolution of any issues raised by this review, the submission is considered to be "registered" and the Principal Investigator may proceed with the generation or manipulation of vertebrate animals, unless IACUC approval is required. The approved registration are reported to the IBC at the next regularly scheduled meeting of the committee.

6.2.2.5 The full committee is informed in scheduled meetings of all new registrations and amendments that have been approved by the IBC Chair.

6.3 Convened Committee Review

6.3.1 CDU IBC uses the primary reviewer system to review all registrations that require full Committee review. The IBC Administrator and IBC Chair will conduct preliminary review. Issues should be resolved or addressed by the PI before it is assigned to the reviewers. The IBC Chair assigns at least two primary reviewers for each protocol that are tabled for the meeting.

6.3.2 The primary reviewers have the responsibilities of presenting the research protocols during the meeting, raising any issues or concerns and making any recommendations. The committee determines if there are remaining issues or concerns that must be satisfactorily addressed by the PI prior to approval. At the end of the deliberation, the primary reviewer recommends one of the following motions:

- **Approved:** The research protocol satisfactorily addresses all issues and the registration is fully approved, no further modification by the PI is required.

- **Accept Pending Minor Modifications:** Minor issues remain that must be addressed by the PI prior to approval. The revised registration is reviewed by the Chair. The Chair may request additional IBC members to assist in the review of the PI's response. The Chair or any of the committee members are authorized to bring back any submission to a convened meeting to the IBC if he/she is not satisfied with the PI's response.

- **Deferred:** Significant issues remain requiring the full committee to review the PI response.

- **Disapproved:** The registration is not recommended for further consideration by the committee. **IBC must justify any registration that has been disapproved.** The PI has 30 days to submit a written appeal directly to the IBC Chair for consideration or to submit as a new study.

- **Tabled:** Loss of quorum, lack of expertise, or not enough information to review the protocol.

6.3.2 The PI will receive written communication and comments for any decisions made by the committee. The communications will be sent to the investigator via e-mail.

6.4 Annual Protocol Review

6.4.1 The Continuing Reviews are processed by the IBC Administrator.

6.4.2 Continuing Reviews that do not contain changes are reviewed and approved by the IBC Administrator.

6.4.3 Continuing Reviews that contain minor amendments that do not change the risk level or containment are reviewed and approved by the IBC Chair.

6.4.4 Continuing Reviews that describe changes that affect the risk assessment are reviewed and approved by the IBC at the convened meeting.

6.5 Delinquent PI Responses to IBC Review Letters

6.5.1 Failure to respond to IBC review letters (*e.g.*, IBC requests for additional information provided to the PI before or after an expedited review or convened IBC meeting) within 30 days may result in withdrawal of the original registration.

6.5.2 The PI needs to contact the IBC Administrator if the PI is unable to respond to the review letters on a timely basis and request for additional 30 day extension.

7. IBC Meetings

7.1 IBC Meetings

7.1.1 The IBC must meet at least quarterly in a year regardless of whether there is a protocol to be reviewed. The scheduled IBC meeting dates should be posted on the website.

7.1.2 The IBC Chair has the discretion to include additional unscheduled meetings or cancel a regularly scheduled meetings.

7.2 Meeting Material

7.2.1 CDU IBC will rely on a primary reviewer system for review. However, all members are expected to review the meeting material. Primary reviewers are expected to review in depth, so that they can lead the discussion and respond to any questions by the other committee members during the meeting.

7.2.2 Members will receive meeting material through their CDU e-mail approximately one week before the actual meeting date.

7.2.3 Meeting material may consists of but not limited to the following:

- Agenda
- Minutes from the last convened meeting
- List of registration approved by expedited review mechanisms
- List of exempt registration

- IBC Protocol and Material Registration
- Inventory
- Supporting documents from IRB, IACUC, OHSC, RSC, COIC
- Education material
- Current Topics

7.2.4 The primary reviewers must notify the Office of Research Integrity and Compliance (ORIC), if he/she has a conflict of interest in reviewing the IBC Registration and Inventory.

7.2.5 Primary reviewers are expected to send their comments to ORIC by e-mail, even if they are not able to attend in person or by teleconference.

7.3 Quorum and Attendance

7.3.1 Quorum consists of one-half the total number of committee members, plus one. The voting procedure involves a motion, a second of the motion, and a vote seeking a simple majority.

7.3.2 Alternate members attending a meeting are not counted towards the quorum, unless the committee member they represent is (1) absent in person or by teleconference or (2) has conflict of interest in the project being reviewed.

7.3.3 Committee members may participate and vote in a meeting by teleconference, provided they have access to the materials being discussed.

7.3.4 Members must inform the IBC Chair and IBC administrator at least 24 hours in advance if they cannot attend the meeting in person or request attendance by teleconference.

7.4 Public Meeting

7.4.1 The *NIH Guidelines* states that "When possible and consistent with the protection of privacy and proprietary interests, the institution is encouraged to open its IBC meetings to the public".

7.4.2 The dates of the scheduled IBC meetings are posted on the IBC website along with contact information at http://www.cdrewu.edu/IBC/MeetingCalendar.

7.5 Closed Meetings

7.5.1 The IBC Chair has the discretion to close all or part of the meeting to the public, such as discussion of proprietary or confidential information during the IBC meeting.

7.5.2 The minutes will document the section of the meeting that was closed to the public and the justification.

7.5.3 IBC members who represents the community and appointed by the University President are considered to be functioning for the university and are not considered as public. Similar to alternate members, community members can remain during the closed section of the meeting. Other visitors or guests may remain under the discretion of the IBC Chair.

7.6 Agenda

7.6.1 IBC Chair determines the meeting agenda with assistance from the administrative staff. Committee members may also request a topic to be included on the upcoming agenda.

7.6.2 Agenda items includes announcement from the Chair or staff, conflict of interest disclosures, reports from the BSO, new registrations, amendments, continuing review, incident reports, inspection reports, non-compliance, previous meeting minutes, education, and other discussions.

7.7 Minutes

7.7.1 The elements of the IBC meeting minutes per the NIH/OBA guidance will include the following:

- Meeting date, time, and location
- Attendance (voting, alternate, ex-officio, guests, public)
- Quorum
- Conflict of interest and recusal (name of member and time)
- Approval of minutes from prior meeting
- Closed and public sections of the meeting and the justification
- IBC actions on each registration and any modifications/clarifications for IBC approval
- Votes
- Discussion, minority dissent, controverted issues
- Meeting end time

7.7.2 Draft minutes of the prior IBC meeting are included in the next agenda packet for review by committee members. IBC members makes any comments or changes to the minutes and then a formal motion shall be made, seconded, and discussed, followed by a vote on approval of the minutes.

7.7.3 Approved IBC minutes, which reflects the committee's business, are available to the public upon request.

7.8 Redactions to IBC Minutes

7.8.1 Redactions to the IBC meeting minutes will comply with Freedom of Information Act (FOIA). Examples of information that may be redacted include trade secret information, other confidential commercial information, and specific information that may directly compromise institutional or national security if disclosed.

7.9 Proprietary Information

7.9.1 Proprietary information that is received by the IBC should be marked as such and is protected under the Confidential Research and Investment Information Act (CRIIA) as long as it meets all of the criteria for CRIIA. When proprietary information is to be discussed during an IBC meeting, the meeting will be closed to the public for that segment. The closing of the meeting will be reflected in the minutes. The minutes will clearly mark the relevant section to indicate that it includes a detailed discussion of proprietary information and should be maintained in confidentiality.

7.10 Conflicts of Interest

7.10.1 *NIH Guidelines* states, "No member of an Institutional Biosafety Committee may be involved (except to provide information requested by the Institutional Biosafety Committee) in the review or approval of a project in which he/she has been or expects to be engaged or has a direct financial interest."

7.10.2 Committee members are asked upon appointment whether they or their families have a significant financial interest in an entity that may be relevant to registrations assigned for review.

7.10.3 IBC members are expected to recuse themselves from the review and voting of projects in which they expect to be engaged or in which they have a direct financial interest. A committee member will not be assigned to review a registration if a conflict of interest has been identified. At each meeting committee members will be given an opportunity to identify any conflicts of interest pertaining to items on the agenda.

8. Annual Report to the Office of Biotechnology Activities (OBA)

8.1 ORIC Director or BSO (in the absence of the Director) will file an annual report with the NIH/OBA, which includes,

8.1.1 Updated roster of all members, including the Chair, contact person, Biosafety Officer, animal expert, plant expert (if applicable), human gene therapy expert (if applicable), or *ad hoc* consultant (if applicable) and

8.1.2 Biographical sketches of all IBC members, including community members

8.1.3 The due date of the next annual report are based on the most recent submission and acknowledgement from the NIH/OBA. The annual report is submitted through the Web-based IBC Registration Management System (IBC-RMS) at http://ibc-rms.od.nih.gov/Contents/IBC_HOME.aspx.

9. Record Keeping

9.1 IBC Filing System

9.1.1 The IBC mains a hard-copy file folder. These folders contain printouts of registrations, reviewer's comments, copies of approval letters, other correspondences, laboratory inspection reports, training completion, and e-mails related to investigator's IBC registration and inventory.

9.2 IBC Database

9.2.1 An excel spreadsheet is used to keep track of all the IBC submissions and approvals, as well as committee performance.

9.3 IBC Meeting Materials

9.3.1 The IBC maintains records of the IBC meetings in a meeting binder. The meeting binder contains the sign-in sheet, agenda, educational materials, registrations that were reviewed, and a copy of the approved minutes for that particular meeting.

9.4 Record Retention

9.4.1 The IBC will retain the records for at least 3 years after the completion of the research or project.

- IBC meeting minutes
- IBC registration material
- IBC member roster
- IBC procedures

9.4.2 The IBC will retain the initial NIH/OBA registration, annual reports, and new member registration until the IBC is no longer registered with the NIH/OBA.

10. Monitoring

10.1 Annual Review

10.1.1 The Annual Review process confirms the staff members who are working on the project, the location of the work, and reminds the PI to review the approved protocol and make any appropriate revisions by submitting an amendment.

10.2 Laboratory Inspections

10.2.1 Annually and at the request of the IBC, the BSO conducts BSL-2 and ABSL-2 inspections based upon the standards set forth in most current edition of the *BMBL,* the *NIH Guidelines for Research Involving Recombinant DNA Molecules.*

10.2.2 At each IBC meeting, the BSO will present a summary of each inspection that was conducted since the last meeting. These reports will include any inspections conducted for initial purposes, the annual scheduled inspections, or close out inspections.

10.2.3 If an inspection reveals major, unacceptable deficiencies in laboratory biosafety conditions or practices, the BSO will immediately contact the IBC Administrator, IBC Chair and ORIC Director to discuss appropriate action which may include an order of cessation of all laboratory work until biosafety conditions are met.

10.2.4 Any action of this matter by the BSO, IBC Chair, or ORIC Director will be reported at the next scheduled IBC meeting.

10.2.5 In case of major biosafety hazards or violation of *NIH Guidelines*, an *ad hoc* IBC meeting will be called as quickly as possible, to discuss corrective and prentive action plans and confirming or amending any actions taken by the BSO, IBC Chair, or ORIC Director. Any initial or final report that will be sent to NIH/OBA will be reviewed at the convened IBC meeting.

10.3 Training

10.3.1 All individuals involved in the use of recombinant DNA and/or biohazardous materials must complete the Collaborative IRB Training Initiative (CITI) online course for Biosafety/Biosecurity.

10.3.2 Additional biosafety training is provided by the BSO and ORIC Director on a regular basis throughout the year, as requested by the investigator, IBC, or ORIC, as part of the corrective action and preventive action (CAPA) plan or after change in the policy or procedure. These training will focus on institutional policies and procedures, including but not limited to incident response, biosafety, biosecurity, and good microbiological practices.

10.3.3 Initial and continuing BSL-2/ABSL-2 and Viral Vector training is required for all personnel working with Risk Group 2 infectious agents and genetically modified human cell lines.

11. Other IBC Policies

11.1 Conflict of Interest

11.1.1 No member of the IBC may be involved in the IBC's deliberation, review or approval of a submission in which he or she, or his/her spouse or domestic partner, is listed as an investigator, otherwise expects to be engaged, or has a financial interest, except to provide information requested by the IBC (including information requested during a convened IBC meeting). IBC members are obligated to report their conflict of interest to the IBC Chair prior to discussion of the protocol in question, and to leave the meeting room during discussion and voting on that protocol, unless requested by the IBC Chair to remain to answer questions or provide additional information.

11.2 Antibiotic Sensitivity

11.2.1 Research involving organisms with known human biosafety concerns (Risk Group 2 and above) which may be partially or fully resistant to clinical treatment in humans, animals or plants by such agents as antibiotics, antivirals and antifungals, must be described in detail, providing human safety health risks, available treatments, proposed containment measures and, if appropriate, specialized testing procedures.

11.3 Spills and Accidents Involving Biohazards or Recombinant or Synthetic Nucleic Acid Molecules

11.3.1 Any spill involving a biohazardous agent or recombinant DNA material must be reported to the BSO, IBC Chair, and ORIC Director.

11.3.2 Exposures

11.3.2.1 All exposures (inhalation, inoculation, ingestion or skin contact) involving biohazardous material or recombinant DNA must be immediately reported to the BSO, IBC Chair, and ORIC Director.

11.3.3 NIH Reporting Requirements

11.3.3.1 Significant problems with or any violations of the *NIH Guidelines* including all accidents and exposures involving recombinant DNA, must be reported to the BSO, IBC Chair, and ORIC Director as soon as possible, within the specified deadlines for NIH's Office of Biotechnology Activities reporting. ORIC Director will prepare a report and will notify NIH and appropriate institutional officials. In the absence of ORIC Director, BSO will prepare and send the report.

11.3.3.2 The BSO reports to the IBC any injury or exposure involving biohazardous material, genetically modified materials or organisms manipulated in BSL-2. Also reported are any injuries or exposures in BSL-1 involving research described on an approved IBC protocol, or that should be covered by an IBC protocol which is in review or for which submission has been or will be requested.

12. Non-compliance with the *NIH Guidelines* or Other Regulations

The IBC investigates all concerns brought to its attention. Reports of suspected non-compliance with *NIH Guidelines*, Cal/OSHA standards, or any other regulatory agency concerns can be made to the BSO, IBC Chair and members, or ORIC Director. Reports should indicate, times, dates, place and procedures of concern.

12.1 Initial Evaluations and Actions

12.1.1 Whoever receives an allegation of non-compliance or other concern will immediately notify the IBC Chair, BSO, and ORIC Director. Incident Report should be filed using the appropriate form.

12.1.2 The BSO and ORIC Director will conduct the initial review and submit a report to the IBC Chair, or to the Vice Chair if the Chair is not available, or if the Chair is involved with the protocol to which the concern is related.

12.1.3 If appropriate to the particular concern, or if the Chair and Vice Chair are both not available, other IBC members will be notified and charged with acting on behalf of the Chair in implementing this procedure.

12.2 Investigation

12.2.1 A subcommittee appointed by the Chair should conduct the investigation of the circumstances underlying the concern and report findings to the IBC. It is important to avoid actual or perceived conflicts of interest in this process and to protect the identity of the complainant. The IBC should charge the subcommittee to gather information and should impose a deadline for reporting to the IBC. The time allowed will depend on the initial determination of whether immediate action may be required.

12.2.2 The nature and sources of the information required will vary depending on the circumstances, but may involve:

- Interviewing complainants (if known), any persons against whom allegations were directed, and pertinent program officials;
- Observing the environment; and
- Reviewing any pertinent records, (e.g. protocol and other documents).

12.2.3 The subcommittee should provide a report to the IBC that summarizes:

- the concern(s) as reported to the IBC,
- the results of interviews,
- the condition of the environment,
- the results of records and other document reviews,
- any supporting documentation such as correspondence, reports, and animal records,
- conclusions regarding adherence to applicable regulations, state and local laws, institutional policies and procedures; and
- recommended corrective and preventive actions and deadlines, if appropriate.

12.2.4 IBC consideration of the concern and determination of corrective and preventive actions:

- The report of the subcommittee investigation should be provided to all IBC members,
- The IBC should convened to accept the recommendations of the investigating subcommittee.

12.2.5 Based upon the report of investigation the IBC will determine required actions, if any.

12.2.6 IBC determinations may include, but are not limited to:

- investigation did not reveal an issue of non-compliance,
- investigation revealed non-compliance,
- related aspects of the program require further review; and
- other related institutional programs may require review.

12.3 For any noncompliance, the IBC must prescribe corrective and preventive action plan along with appropriate deadlines and reporting requirements. Such plan should also include root cause analysis and monitoring plan. The IBC must also determine whether the noncompliance meets the criteria "serious or continuing noncompliance" or "serious deviation" so as to require reporting to NIH as discussed below.

12.3.1 Notification in Writing

- IBC Chair will communicate, in writing, the results of the IBC evaluation of a reported concern to the person(s) responsible for the situation reported, the Institutional Official, and the person reporting the concern if they wish to be notified of the outcome. The communication will contain a summary of the concern, the findings of the investigation, determinations of the IBC, and the recommended corrective actions/sanctions. The letter will also inform the person(s) responsible for the situation reported of his/her option to appeal the decision by writing the IBC Chair, within 10 days of receipt of the letter detailing the basis of the appeal and requesting a meeting with the IBC.

12.3.2 Examples of IBC actions that may be appropriate in response to situations that constitute non-compliance are:

- terminate approval of the respective research study,
- suspend approval of the respective research study pending completion and acceptance by the IBC of an independent inspection of the study and/or the submission, by the principal investigator, of a written plan for the correction and/or prevention of the problem,
- Confiscate the biohazardous material
- institute an IBC-mandated corrective and preventive action plan and independent inspection of the study; and
- take such other actions as necessary

12.3.3 The IBC is obligated to report, through the Institutional Official or his/her designee, any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to NIH's Office of

Biotechnology Activities within thirty days; unless the institution determines that a report has already been filed by the Principal Investigator or BSO.

13. Appeals

13.1 Disputes regarding interpretation of this policy or decisions made by the IBC are referred to the Institutional Official for adjudication.

14. Review and Approval of CDU IBC Standard Operating Procedures (SOP)

14.1 Material changes to any part of the SOP and any associated forms will be reviewed and approved by the Committee at a fully convened meeting. Final approval for any part of the SOP shall be done by the Institutional Official, before the revisions can be enacted. Editorial or administrative revision that does not alter the content of the policy or procedures can be made by the administrative staff in consultation with the Chair. The Chair will make a report of such changes at the next convened meeting.

15. References

1. Recombinant DNA – NIH *Guidelines* for Research Involving Recombinant DNA Molecules (NIH *Guidelines*).
2. Biological Agents – Bisoafety in Microbiological and Biomedical Laboratories (BMBL)
3. California OSHA, Title 8
4. CDU Biosafety Manual
5. Indiana University, Purdue University Indianapolis, Institutional Biosafety Committee (IBC) Policy and Procedure Manual (version 2/14/2011)