The University of Chicago
Institutional Biosafety Committee (IBC)
& Select Agent (SA)-IBC

Policy & Procedure Manual

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The University of Chicago has two Institutional Biosafety Committees (IBCs). The Select Agent IBC is responsible for the review and approval of all research at the University of Chicago involving the use of Select Agents and for all research involving biohazardous materials, including recombinant agents, conducted at the Howard Taylor Ricketts Laboratory, whether involving Select Agents or not. The other IBC is responsible for any other research conducted with biohazardous agents, as defined below. Unless otherwise noted, the term "IBC" in this manual refers to the two University of Chicago Institutional Biosafety Committees. Policies or procedures that are unique to one of the two IBC's are clearly indicated.

Charge of the Committee

The IBC is charged with the responsibility for review, approval and surveillance of all research at the University of Chicago involving the use of biohazards. Biohazards are defined as recombinant/synthetic DNA (r/sDNA), agents infectious to humans, animals or plants, other genetically altered organisms and agents, and certain biological toxins (determination made based upon the LD_{50} of the toxin in question).

Additionally:

- Cells/blood/tissues/organs harvested directly from humans only require IBC approval if they are used in the following manner:
    - As a recipient or source for r/s DNA experiments?
    - As a recipient/host for or source of a pathogenic and/or genetically modified microorganism?
    - As a recipient of biological toxins *in vitro?*

Regardless of its source of financial support, all research with biohazards must be approved by the IBC and conform to IBC policies and procedures.

Both IBCs have regularly scheduled monthly meetings. Additional special meetings are called as necessary. These meetings are not open to anyone other than members of the IBC, staff of the IBC Office and Office of Biosafety or individuals who have received permission from the IBC Chair.

The University of Chicago lacks facilities requiring BSL4 or ABSL4 containment. Therefore, research requiring such containment cannot be performed at the University of Chicago. Investigators wishing to perform research requiring BL3 or ABSL3 containment should consult with the University of Chicago Office of Biological Safety prior to grant preparation or IBC protocol submission.

Exempt from IBC Submission Requirements:

- The use of human cell lines, primary human tumor cells or transformed cells does not require submission of an IBC protocol when the cells have not been modified with methods using recombinant or synthetic DNA.
- Teaching activities involving biohazardous agents, as defined above, do not require an IBC protocol or IBC approval. However, teaching activities involving biohazardous

agents require that all students be appropriately trained and thus, such teaching activities should be coordinated through the Office of Research Safety.
- Work with microbial agents that are not known to cause diseases in healthy adults, animals or plants are exempt from IBC review when the microbial agents have not been modified by recombinant or synthetic DNA methods. The IBC Chair and the BSO are responsible for confirming this exception.

Responsibilities

IBC

The IBC is responsible for:

- reviewing research conducted at the University of Chicago involving biohazardous agents or recombinant/synthetic nucleic acids for compliance with the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)* and the policies of the University of Chicago IBC,
- notifying the Principal Investigator of the results of the IBC's review and approval,
- lowering containment levels for certain experiments as specified in Section III-D-2-a (Experiments in which DNA from Risk Group 2, Risk Group 3, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems),
- setting containment levels as specified in Section III-D, including Sections III-D-4-b (Experiments Involving Whole Animals, and III-D-5, Experiments Involving Whole Plants),
- periodically reviewing recombinant/synthetic DNA research conducted at the institution to ensure compliance with the *NIH Guidelines*,
- reporting any significant problems with or violation of the NIH *Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official and NIH Program for Biosecurity and Biosafety Policy (NIH PBBP) within 30 days, unless the IBC determines that a report has already been filed by the PI,
- The IBC may not authorize initiation of experiments that are not explicitly covered by the NIH *Guidelines* until NIH establishes the containment requirement.

Principal Investigator

In accordance with University Research Administration Policy on Principal Investigator Eligibility, only those individuals who are eligible to serve as principal investigators on proposals for external funding may serve as the principal investigator (PI) for an IBC protocol. Individuals wishing to serve as PI who lack the necessary appointment should contact the University Research Administration and/or their departmental Chairperson.

On behalf of the institution, the Principal Investigator is responsible for full compliance with the *NIH Guidelines* in the conduct of recombinant/synthetic nucleic acid research and for adherence to the policies and procedures of the University of Chicago IBC. While having said that, the PI should take particular note of the following responsibilities:

- The PI should make the initial determination of the required levels of physical and biological containment in accordance with the *NIH Guidelines* and the most recent edition of *Biosafety in Microbiological and Biomedical Laboratories* (BMBL).
- The PI should make the initial determination as to whether their proposed research involves *Dual Use Research of Concern (DURC*-contact the Office of Research Safety with questions concerning DURC).
- The PI should select the appropriate microbiological practices and laboratory techniques to be used for the research and provide sufficient details for IBC to conduct proper risk assessment.
- The PI should ensure that the staff listed on the protocol have sufficient knowledge, are sufficiently trained, and have demonstrated the appropriate competence to safely perform the responsibilities for which they have been assigned.
- The PI ensures that the protocol participants fully understand the steps necessary following any spills or potential exposures with the agents described in the protocol.
- The PI should report any significant research-related accidents and illnesses to the IBC within 30 days.

PI Responsibilities for Human Gene Transfer Research

For human gene transfer research, the following unique responsibilities of the Principal Investigator should be noted:

- The PI responsible for this research must ensure that all aspects of Appendix M of the *NIH Guidelines* have been appropriately addressed.
- For a clinical trial site that is added after the NIH Recombinant DNA Advisory Committee (RAC) review process, the PI must ensure that no research participant is enrolled until the following documentation has been sent to the NIH Office of Biotechnology Activities (OBA):
  - IBC approval
  - IRB approval
  - IRB-informed consent document
  - Curriculum vitae of the PI
  - NIH grant number(s) if applicable
- The PI must prepare a written report of any serous adverse event that is both unexpected and associated with the use of the gene transfer product (i.e., there is a reasonable possibility that the event may have been caused by the use of the product) and any finding from tests in laboratory animals that suggests a significant risk for human research participants including reports of mutagenicity, teratogenicity, or carcinogenicity. The report must be clearly labeled as a "Safety Report" and must be submitted to the NIH Office of Biotechnology Activities and to the University of Chicago IBC that approved the protocol within the timeframes set forth in Appendix M-I-C-4-b of the *NIH Guidelines*.

Biological Safety Officer

The responsibilities of the Biological Safety Officer (BSO) and/or a BSO designee include, but are not limited to:

- Serving as a voting Member of Institutional Biosafety Committee
- Serving as the Vice Chair of Select Agent Institutional Biosafety Committee
- Conducting announced and unannounced laboratory inspections to ensure that appropriate laboratory standards as determined by the IBC are rigorously followed,
- Reporting 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,
- Developing emergency plans for handling accidental spills and personnel contamination and investigating laboratory accidents involving r/s nucleic acids or biohazardous agent research,
- Providing advice on laboratory security and Dual Use Research of Concern, providing technical advice to PI's and the IBC on research safety procedures.
- Serving as the Responsible Official for the University's Select Agent Program
- Developing, deploying & overseeing a comprehensive Biosafety program for the University of Chicago,
- Together with the IBC, overseeing review of BSL2-enhanced, BSL3 and BSL3-enhanced research projects on campus and conduct all relevant inspections for these facilities.
- Conducting biosafety risk assessments and training to ensure the Hyde Park campus and H. T. Ricketts Laboratory are in compliance with all applicable federal biosafety laws and regulations.
- Collaborating with investigators and staff in all matters related to biosafety.
- Providing expertise for the design and management of containment facilities
- Serving the University as a resource and leader in all aspects of education and training in biosafety.

Protocol/Amendment Submission & Review Process

Submission Process

IBC protocol submissions, whether they are new IBC protocol submissions, amendments to revise existing submissions or resubmissions of approved protocols must be submitted to the IBC Office through AURA-IBC by the Principal Investigator (PI). For information on who is eligible for PI status, please refer to the IBC Policy on PI Eligibility found in this document. Once IBC protocols are approved by the IBC they are approved for a period of three years. Research utilizing biohazardous agents or r/s nucleic acids may not be initiated prior to the approval of the IBC. Changes to approved protocols (e.g., room changes, new procedures or agents) must be reviewed and approved by the IBC prior to initiation of the protocol. Amendments to simply add new staff members are approved automatically in AURA-IBC if the individual(s) being added has completed the IBC-mandated training required for the protocol. Information on the training courses that are offered and when they are required is found in the IBC Training Policy found later in this document.

Resubmission

Principal Investigators who plan to continue conducting the research described in a current approved IBC protocol are required to resubmit that protocol so that it can be reviewed and approved by the IBC prior to the three year expiration. These resubmissions are reviewed in the same manner as new protocol submissions. PI's are sent reminders of the need to resubmit at least four months prior to expiration and reminded monthly to do so until the resubmission is received by the IBC office.

Expiration of protocols

All IBC protocols are only approved for three years. If a protocol resubmission has not been submitted by the PI or if one has been resubmitted and is not approved by the IBC prior to the three year expiration date, that protocol is automatically expired. No research described in this protocol may be conducted until the resubmission is approved by the IBC. Expiration of the IBC protocol may require termination of any related IACUC and IRB protocols, and notification of other agencies (OLAW and granting agencies).

Review Process

After receipt by the IBC Office, the protocol submissions must then receive one or more levels of review prior to the protocol being approved and the research proceeding. Upon receipt, all protocol submissions are reviewed by an IBC Administrator. Subsequently, submissions may then be reviewed by the Biosafety Officer or designee, a member of the IBC and then by the full committee at one of the convened meetings. The Principal Investigator should expect questions throughout the review process. The submission will not be sent to the next review level until the PI has satisfactorily answered the previous review questions.

Most submissions (new, resubmitted protocols and amendments), but not all, must go to a convened meeting for review and approval. The following table lists the review stages that submissions must undergo based on their type or the biohazardous agent that is involved.

Agent or Submission Type	Administrative Review	Expedited Review*	IBC Member Preliminary Review	Full Committee Review
Human cell lines, primary human tumor cells or transformed cells (purchased/obtained with no further manipulation of DNA)	Does not require review and approval by IBC			
Transgenic Animal production requiring BL1 containment only	X	X		
Amendments just adding new staff or rooms (except for BL3)	X			
Amendments describing minor changes with no impact on Risk	X	X		

Group or Biosafety Level				
All other submissions	X		X	X

* Expedited review, described below, may determine that review by a convened meeting of the IBC is required.

Administrative Review

Upon receipt, the IBC protocols are reviewed by the IBC Administrator to ensure they contain sufficient detail and determine which type of committee review is required (i.e., Administrative Review Only, Expedited Chair/BSO review or Full Committee Review).

If the IBC submission involves the use of animals, the IBC Administrator confirms if there is an associated approved Institutional Animal Care and Use (IACUC) protocol with a description of biohazardous agent use that is consistent with what is described in the IBC submission. If not, the PI is informed that IACUC approval is also required. If the IBC submission involves the administration of biohazardous or recombinant agents/molecules to humans or the acquisition of tissues directly from humans, the IBC Administrator will confirm with the Institutional Review Board (IRB) if there is an associated approved IRB protocol. If not, the PI is informed that IRB approval is also required. Failure to attain required IACUC or IRB approval may delay approval of the IBC protocol submission.

Amendments requesting the use of new rooms under BL2 conditions must first be approved by the Biosafety Office (Biosafety Officer or Assistant Biosafety Officer) prior to final IBC Administrator approval.

Expedited Review (Chair/BSO Review/Approval)

Amendment submissions indicating a minor change that has no impact on risk or biosafety level are reviewed by the Chair and the Biological Safety Officer (or BSO designee). Upon their review, these reviewers may request additional information or clarification of the PI, approve the submission with no modifications, or send it to full committee review if they have determined that such review is warranted.

IBC protocols or amendments solely involving transgenic animal generation requiring BL1 containment are initially reviewed by the IBC Chair or Biological Safety Officer (or BSO designee). 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 of the animals, unless IACUC approval is also required. These Chair/BSO approved submissions are presented to the IBC at the next regularly scheduled convened meeting of the committee for final approval.

The full committee is informed quarterly of all submissions that have been approved by the IBC Administrators, the IBC Chair and the Biological Safety Officer (or BSO designee).

Full Committee Review

Following IBC Administrative review, if Full Committee Review is required, the IBC submission is reviewed by at least one member of the IBC. Protocols involving human gene

therapy are typically reviewed by two IBC members, with one of the members being a physician. Any questions or concerns raised during IBC member preliminary review must be satisfactorily addressed prior to placing the submission on the agenda of the next convened meeting of the IBC.

At the conclusion of the committee review, the committee has the following decision options:

- **Approved or Approved with Comment:** The protocol submission satisfactorily addresses all issues and the submission is fully approved with no modification by the PI required.
- **Approved with Stipulations:** The protocol submission is approved, but the approval is limited pending satisfactory resolution to specific issues (e.g., Animal work may not begin until IACUC has approved the corresponding animal protocol).
- **Pending-Conditions:** Minor issues remain that must be addressed by the Principal Investigator prior to approval. The revised protocol submission is reviewed by the Chair who may have follow-up questions, may request the response to be evaluated by another member of the Committee or require full Committee Review if the response is not sufficient.
- **Deferred:** Significant issues remain requiring the full committee to review the PI response.
- **Rejected:** The protocol submission is not approved and has been withdrawn from further consideration by the committee.
- **Suspended:** The approval of the IBC protocol is temporarily suspended. None of the activity that is described in the IBC protocol involving IBC-regulated materials may be performed during the period in which the protocol is suspended. The IBC may suspend a protocol during instances of serious or continuing non-compliance with IBC or institutional policies and guidelines or with the *NIH Guidelines.* The activity of protocol suspension can only be executed in a convened meeting of the IBC. However, in circumstances utilizing an immediate threat to health and safety, the IBC empowers the Biosafety Officer to immediately suspend the hazardous activity.
- **Terminated:** The IBC protocol is no longer approved and will not be reconsidered for approval by the IBC Committee. All activities described in the protocol utilizing IBC-regulated materials must cease upon receipt of the notice of termination. The IBC will not reconsider re-approving the IBC protocol and it may not be re-submitted by the PI for IBC review. The IBC may terminate a protocol during instances of serious or continuing non-compliance with IBC or institutional policies, guidelines or with NIH *Guidelines*. The activity of protocol termination can only be executed in a convened meeting of the IBC.

Delinquent PI responses to IBC Review Letters

Failure to respond to submission review letters (e.g., administrative, preliminary or full committee) within 30 days will result in a Final Notice letter from the IBC Administrator. If the PI fails to respond to the Final Notice in 30 days, this will result in withdrawal of the original submission. The PI needs to contact the IBC office if the PI is unable to respond to the review letters on a timely basis.

Monitoring Proceedings

Lab Inspections

i) EHS – General: All buildings and laboratories comprising the University of Chicago are inspected on an annual basis to identify and locate infractions of fire or industrial safety concerns.

ii) Office of Research Safety/Biosafety Office – Protocol Specific Inspection
At the request of the IBC or SA-IBC, members of the Office of Biological Safety conduct BL2, BL2-N, BL3 and BL3-N inspections based upon the standards set forth in the most recent edition of the BMBL, the *NIH Guidelines,* and Select Agent regulations (when applicable). In addition, BL3 and BL3-N inspections are conducted semi-annually.

Relationships

IACUC

IBC protocol submissions that involve the use of live vertebrate animals (i.e., administration of biohazardous agents or generation of transgenic/knock-out or knock-in animals) require IACUC review and approval before they can be approved by the IBC. IBC submissions that involve the use of animals may receive 'Approved with Stipulation' status if there is non-animal bench work described in the IBC submission that can begin without the immediate need for live animal work. Such a stipulation requires IACUC approval prior to work with the live animals and is controlled by the Animal Resources Center not allowing the animals on the referenced IACUC protocol to enter the biosafety facility.

IRB

IBC protocol submissions that involve the administration of biohazardous agents or r/s nucleic acids to humans, requires IRB approval prior to initiation. Protocols involving the transfer of r/s nucleic acids to human research participants require review and approval by the IBC. The review process of these protocols is coordinated with the IRB review of the same protocol such that no IRB approval to initiate a human gene transfer trial is granted in the absence of approval by the IBC. Also, cells/blood/tissues/organs harvested directly from humans only require IBC approval if they are used in the following manner:

- As a recipient or source for r/s nucleic acid experiments?
- As a recipient/host for or source of a pathogenic and/or genetically modified microorganism?
- As a recipient of biological toxins *in vitro?*

IBC Administrators confirm approval with the IRB staff for all IBC submissions that indicate IRB approval is required. Only after IRB approval is confirmed is IBC approval granted for these submissions.

Grants

Upon receipt of funding proposals, the Grant & Contract Administrators (Office of Research Services) review to determine if an IBC protocol is indicated or seems warranted. If the need for an IBC protocol is confirmed, the Grants Administrator verifies whether a corresponding IBC has been approved.

Greenhouse

The IBC is responsible for reviewing protocols involving r/sDNA-containing plants and plant-associated microorganisms. Once the protocol is approved, a copy of the protocol and approval letter will be forwarded to the Greenhouse Manager. If a PI contacts the Greenhouse to coordinate DNA-related research without the required IBC approval, the Greenhouse Manager will require the PI to submit a protocol to the IBC. In order to keep the Greenhouse files current, copies of protocol renewals and terminations letters will be forwarded to the Greenhouse Manager.

Cores

The IBC is responsible for reviewing protocols involving biohazardous material and/or r/sDNA-containing organisms, tissues or microorganisms. The IBC is currently establishing processes designed to route requests for services received by Core Facilities through the IBC to ensure that the service requested is described on an approved IBC protocol. Once the protocol is approved, a copy of the protocol and approval letter will be forwarded to the Core Laboratory manager. If a PI contacts the Core Laboratory to coordinate DNA-related research without the required IBC approval, the Core Laboratory Manager will require the PI to submit a protocol to the IBC. In order to keep the Core Laboratory files current, copies of protocol renewals and terminations letters will be forwarded to the Core Laboratory Manager. The Biosafety Office is also currently working with these Core Laboratories to establish appropriate standard operating procedures to insure that all steps to minimize potential exposures of Core Laboratory staff to biohazardous materials are taken.

Environmental Health and Safety (EHS)

Environmental Health and Safety is responsible for the development and coordination of the University's safety and environmental compliance programs including radiation safety. These programs include, but are not limited to, the following:

- Industrial hygiene;
- Fire safety;
- Inspections: All buildings and laboratories comprising the University of Chicago are inspected on an annual basis to identify and locate infractions of fire industrial or general safety concerns.
- Training;
- Plan review;
- Environmental issues;
- Ergonomics; and
- Regulatory compliance.

Specific IBC Policies

IBC Training Policy

Approved by IBC 1/4/2013

It is the policy of the University of Chicago Institutional Biosafety Committee (IBC) that all investigators, technicians and students involved with research activities described on a given IBC Protocol be appropriately trained to mitigate research-associated risks as well as to ensure compliance with applicable local, State and Federal regulations and guidelines. This training will include IBC-mandated training elements, developed and provided by the Office of Biological Safety (OBS) as well as lab-specific training, provided by the Principal Investigator (PI) for each of his/her IBC research protocols.

As part of the UC IBC risk management process, it is the responsibility of the PI to assess research-associated risks; this risk assessment process is facilitated and documented through completion of the UC AURA-IBC system. The PI must also ensure that all lab personnel named as staff member on the IBC protocol are sufficiently trained to safely work with the biohazardous materials and that each staff member is aware of what to do in the event of spills or exposures to potentially infectious materials. Accordingly the PI is responsible for the following:

- Ensure that each staff member is aware of the specific risks associated with the work to be conducted, as described in each IBC protocol.
- Ensure that each staff member has been trained and has demonstrated that they can safely perform the procedures as described in that protocol.
- Ensuring that each staff member listed on the PI's IBC protocols have completed the training required by the IBC as outlined in this Policy.
- Ensuring that each staff member has completed any additional training identified by the IBC during its risk assessment of the research project.

OBS staff is available to assist the PIs in the training of their staff.

Rationale for the Training Policy:

Laboratory safety begins with a comprehensive assessment of risks posed by research reagents and associated lab activities as well as an assessment of compliance issues associated with research conducted within that lab. An important component of this risk assessment process is the identification of laboratory safety issues that can only be mitigated through appropriate training. The responsibility to perform this assessment is a shared responsibility, beginning with the principal investigator and augmented by the risk assessment performed by the IBC during the protocol review process. This process is concluded with implementation within the lab of the risk mitigation requirements (including required training) and recommendations articulated by the IBC as part of the IBC Protocol approval process.

It is obvious that educating UC student, investigator scientists, and research staff about the risks associated with their research activities, as well as how to mitigate these risks, is a responsibility and an ethical obligation. However, training activities are also required by Federal and State laws and Guidelines [e.g. OSHA Laboratory Standard (29CFR1910.1450), OSHA Bloodborne Pathogens Standard (29CFR1910.1030), CDC Select Agent Regulation (42CFR73.10(c)), CDC *Biosafety in Microbiological and Biomedical Laboratories*-5th edition, *NIH Guidelines* (IV-B-1-h), DOT Shipping Infectious Substances (49CFR172.704(a),49CFR173.134, 49CFR173.199(e)]. **Failure to comply with these training requirements places the UC at risk for the imposition of monetary fines, the potential loss of research funding and even criminal penalty**.

A comprehensive laboratory safety training program involves specialized training elements (Biosafety Courses offered by the OBS) as well as lab or project-specific training elements provided by each PI. The final determination of which of the available Biosafety Courses (listed below) is/are required for staff associated with a given protocol is made by the IBC during their review of the IBC Protocol submission. The training programs currently offered by the OBS and when they are required are described below.

COURSES AVAILABLE from CHALK and from the OFFICE OF BIOLOGICAL SAFETY

rDNA/BL1 Course: This training module is required for all personnel listed on an IBC protocol that describes work managed at BL1 utilizing recombinant or synthetic nucleic acids (as defined in the *NIH Guidelines*). Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

rDNA/BL2 Course: This training module is required for all personnel listed on an IBC protocol that describes work managed at BL2 with or without the usage of recombinant or synthetic nucleic acids. This includes work with transactive or infectious proteins and biological toxins regulated by the IBC. If a protocol includes both BL2 and BL1 work, the rDNA/BL2 Course will satisfy both requirements. Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

Viral Vectors Course: This training module is required for all personnel listed on an IBC protocol that describes work utilizing viral vectors (both replication competent and incompetent) regardless of the biosafety level used to manage them. Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

Biological Toxins Course: This training module is required for all personnel listed on an IBC protocol that describes work with any of the toxins regulated by the IBC. Each individual shall complete this course every five (5) years unless a significant change in legal or institutional policy or safety guidelines dictates a shorter time interval.

Review of the Human Gene Transfer Trial NIH Review Process and the other resources available for Human Gene Therapy research: This material, found on the IBC website (http://researchadmin.uchicago.edu/ibc/), must be reviewed by all personnel listed on an IBC protocol describing the use of human subjects for a gene transfer study.

OSHA Blood Borne Pathogen Training: This training is required for all personnel listed on an IBC protocol that describes work with human cells, blood or tissues. Each individual shall complete this course annually as stated in the Occupational Safety and Health Administration (OSHA) Bloodborne Pathogens Standard (29 CFR 1910.1030).

DOT/IATA Shipping of Infectious Substances: This training is required when shipping infectious substances categorized as Class 6.2 dangerous goods by the Department of Transportation (DOT) and the International Air Transport Association (IATA). Anyone shipping Category A, Category B or Exempt samples will be required to receive this training module (http://www.phmsa.dot.gov/staticfiles/PHMSA/DownloadableFiles/Files/Transporting_Infectious_Substances_brochure.pdf). The PI may choose to designate only a subset of individuals listed on the IBC protocol to fulfill this role for the entire laboratory. These individuals must be trained and certified to package and ship infectious substances and will be the only ones allowed to perform this role for the laboratory. Each individual responsible for shipping infectious substances shall complete this course every two (2) years as required by the IATA Dangerous Goods Regulations.

Providing Meeting Minutes to the Public

Approved by IBC and SA-IBC 6/6/2014

Background:

Section IV-B-2-a-(7) of the *NIH Guidelines* states: "*Upon request, the institution shall make available to the public all Institutional Biosafety Committee meeting minutes and any documents submitted to or received from funding agencies which the latter are required to make available to the public.*"

Policy

Upon written request, The University of Chicago will provide copies of minutes from meetings of its Institutional Biosafety Committee (IBC), following their approval at a convened meeting of the IBC. Any production of IBC minutes for dissemination to the public will be redacted. Information to be redacted includes locations (laboratories, animal facilities and offices), proprietary or commercial information, and specific information whose disclosure would directly compromise personal, institutional or national security.

PI Eligibility

The University of Chicago IBC follows URA Policy on PI Eligibility with regards to defining who is eligible to serve as Principal Investigator on an IBC protocol. Essentially, full time, salaried academics with the titles of Professor, Associate Professor, Assistant Professor, Instructor, Senior Scientist, Senior Research Associate, Research Scientist, or Research Associate with parenthetical rank of Assistant Professor, Associate Professor, or Professor are eligible to serve as PI. For further details on eligibility or for information on procedures requesting PI status for an IBC protocol for those individuals lacking any of the above titles, please refer to URA Policy on PI Eligibility.

Mobile Isolation Chambers

Mobile Isolation Chambers (MICs) provide product protection equivalent to a Class II Biosafety Cabinet with personal and environmental protection greater than a Class II BSC, but slightly less than a Class III. Training on the use of such cabinets and decontamination of the units is provided by the manufacturer. The certification schedule of the units depends on the manufacturer. The use of MICs is approved for the preparation of biological vectors after approval by University Safety. Amendments adding just the use of MICs can be approved by the IBC administrative staff.

Viral Replication Competency Testing

The IBC requires replication-defection viral vectors to be tested on a regular basis to confirm the absence of replication competent viruses (RCVs). Viral preparations for direct injection into animals or for transduction of cells subsequently injected into animals must be tested for the presence of RCV prior to use. Any producer cell lines or transduced cells placed in a laboratory repository must be tested for RCV. If viral vectors are being purchased from a commercial company, the IBC will accept from the company documentation verifying the material is replication incompetent and the absence of RCVs. For details on testing methods and suggested frequency of testing, please consult the IBC Testing Requirements for Viral Vectors Guidelines on the IBC website.

Transportation of Animals Following Administration of Biohazardous Agent

Transportation of animals following the administration of biohazardous agents must be described in the IBC protocol form and approved by the IACUC and the IBC. The description in the IBC protocol should include the route and the method of transport. This transportation information must be consistent to what has been approved by the IACUC. If patient care areas are involved in this transport, the review and approval of Infection Control is also required.

Antibiotic Sensitivity

For BL2 and above bacterial agents, the antibiotic susceptibility must be indicated and referenced or testing for sensitivity may need to be performed.

Review of Clinical Trial Safety Reports

During the conduction of human gene therapy, Principal Investigators must submit a written report to the NIH Program for Biosecurity and Biosafety Policy (NIH PBBP) with the occurrence of any serious adverse event that is both unexpected and associated with the use of the gene transfer product (i.e., there is a reasonable possibility that the event may have been caused by the use of the product). The University of Chicago IBC must be copied on any such serious adverse event that is reported to the NIH Program for Biosecurity and Biosafety Policy (NIH PBBP) for human subjects under study at the University of Chicago.