Institutional Biosafety Committee

Policy and Procedures Guidebook

I. Background

Louisiana State Health Sciences Center – New Orleans (LSUHSC-NO) uses recombinant DNA (rDNA) molecules in scientific research and receives NIH funding. Therefore, LSUHSC.NO must comply with the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* for all of its research activities independent of support for the project. The *NIH Guidelines* require the university to establish an Institutional Biosafety Committee (IBC) whose responsibilities need not be restricted to recombinant DNA (rDNA). The scope of LSUHSC's IBC includes the review of all research activities for biological safety.

As described in this Guidebook, LSUHSC-NO will make available requests for IBC meeting minutes under the FOIA. As allowed by regulation, certain proprietary, confidential or personal information or other information that could compromise safety may be redacted.

The IBC reports to the Director, Office of Research Services, who manages the IBC process and acts as the contact person for the IBC. The Executive Director, Office of Research Services, reports to the Vice-Chancellor for Academic Affairs.

II. Mission Statement

The IBC reviews, approves and oversees research using rDNA to ensure compliance with *NIH Guidelines*. However, the LSUHSC-NO IBC has an expanded scope of oversight to review all research conducted at LSUHSC-NO for biological safety issues.

As such, LSUHSC-NO's IBC acts as the framework for risk management associated with research-related, bio-safety issues. The committee works in concert with the LSUHSC-NO Office of Environmental Health and Safety and the Office of Research Services. The objectives of this risk management program are threefold:

1) To assure that the Institution is in compliance with all state and federal regulatory agency bio-safety requirements including the *NIH Guidelines*;
2) To review projects for use of "Select Agents" under the Select Agents Program of DHHS and USDA and/or "Dual use items" under export control regulations of the Department of Commerce, items on the U.S. Munitions list of the Dept. of Defense ITAR regulations, and DURC (dual use research of concern) under NIH guidelines; and

3) To protect individuals and research animals from potential dangers in the use of or exposure to such things as pathogens, organs or tissues of biological origin, genetic therapy products, transgenic genes, bacteria, viruses, parasites, prions and chemicals and toxins that may affect health.

The program is also used to verify and track required bio-safety training as mandated by the state Office of Risk Management.

All research projects must be registered with the Office of Research Services via the IRB, IACUC and or IBC. The IBC reviews Research Registration Forms and IBC applications to determine whether all bio-safety concerns are resolved or managed, or that the project is exempt from further IBC oversight. Except where explicitly exempted by the IRB, all projects requiring IRB and IACUC oversight must obtain IBC review and approval before commencing.

IBC provides the experience and expertise in research involving these materials and the capability to assess the safety of research protocols to protect personnel and the environment. The policies and procedures of the LSUHSC-NO IBC are described in this guidebook. This guidebook and forms related to the IBC process are available on the IBC website *https://www.lsuhsc.edu/administration/academic/ors/ibc.aspx*.

III. IBC Membership

The Vice-Chancellor for Academic Affairs appoints a minimum of seven IBC members and designates the Committee Chairperson. IBC members will be appointed for three years, with automatic renewal terms until the member resigns or the membership is terminated. The sole exception is the Biosafety Officer, who is a permanent member of the IBC. Members will be selected to ensure they collectively have experience and expertise in rDNA technology and pathogenic agents. They have to have the capability to assess research safety and to identify any potential risk to public health and the environment. Membership must satisfy the first five categories listed below and have sufficient number of individuals who satisfy the remaining categories. In the absence of membership expertise in the research presented, the Chairperson may invite a consultant who is experienced in the field to assist in the review; the consultant, however, will not have voting privileges.

1) The IBC Chairperson.

2) The Biological Safety Officer (BSO) (Vice-chairperson: in the absence of Chairperson or when Chairperson has a conflict of interest, the BSO has the authority vested in Chairperson).

3) Director, Office of Research Services (*ex officio* and IBC contact person).

4) At least two members not affiliated with the LSUHSC (apart from their membership on the IBC) who represent the interests of the surrounding community with respect to health and protection of the environment.

5) At least one individual with expertise in animal containment principles.

6) If rDNA research involving plants is proposed, at least one individual with expertise in plants, plant pathogen, or plant pest containment principles.

7) If rDNA research involving human subjects is proposed, at least one individual who has adequate experience and training in the field of human gene transfer.

8) Additional members will be selected to ensure the competency necessary to review and approve work involving rDNA or other pathogenic agents.

IV. Institutional Biosafety Committee Responsibilities

1) Review and approve all IBC applications. Establish procedures that the IBC will follow in its initial and continuing review and approval of applications, proposals, and activities.

2) Convene at an IBC meeting for full committee review of any project that
   - meets specific criteria of the NIH *Guidelines*, Select Agents or DURC
   - requires BSL-3 containment
   - provides core laboratory services
   - is required by any federal or state regulatory agency

   All other projects will be reviewed by the Chairperson and or the BSO outside of a convened meeting.

3) Set containment levels.

4) Approve emergency plans for accidental spills, personnel contamination, and other related emergencies with an emphasis on preventing occupational infections or environmental contamination.

5) Assess the facilities, procedures, practices, and expertise of personnel performing research involving work with rDNA or other potentially infectious materials. The IBC may suspend or deny approval to conduct research involving these materials when the assessed criteria are deemed inadequate.

6) In conjunction with the Office of Environmental Health and Safety (OEH&S), conduct investigations of any significant problems or violations and any significant research-related accidents or illnesses related to biological safety issues. Following each investigation, the IBC will communicate their recommendations for resolving the situation to the Vice-Chancellor for Academic Affairs through the Director, Office of Research Services; and the Principal Investigator's (PI) Department Chairperson and Dean. The IBC can refuse, suspend, or cancel authorization to use biohazardous materials in the event of continued non-compliance or serious infractions with biosafety policies and procedures.

7) For recombinant DNA research that comes under the purview of the NIH *Guidelines*, determine that such projects conform with the NIH Guidelines and verify if additional approval is required by the NIH Director or NIH Office of Science Policy (OSP) prior to giving the project permission to initiate.

a. Experiments that requires review and/or approval by the NIH OSP, requires LSUHSC IBC approval prior to initiation.
    i. Deliberate transfer of a drug resistance trait to microorganisms that are not know to acquire the trait naturally which could compromise the ability to control or treat the disease in humans, veterinary medicine or agriculture.
    ii. Deliberate formation of recombinant DNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight (e.g., microbial toxins such as botulinum toxins, tetanus toxin, diphtheria toxin, and *Shigella dysenteriae* neurotoxin).

b. Human Gene Transfer (HGT) protocols that require other regulatory authorization(s) do not require NIH review and approval. In addition to federal agency approval (e.g., Food and Drug Administration (FDA)), IBC approval from the clinical study site is also required. While the clinical study site IBC has primary oversight for monitoring and reporting, LSUHSC IRB and IBC will provide oversight and conduct annual reviews.
    i. When conducted under a FDA regulated individual patient expanded access Individual New Drug (IND) or protocol, including for emergency use, NIH Guidelines states that the deliberate transfer of recombinant or synthetic nucleic acids into one human is not research subject to the NIH Guidelines and thus does not need to be submitted to an IBC. However, LSUHSC IBC review and approval is required and will be conducted under expedited review to ensure required institutional oversight as directed by the NIH.

V. IBC Chairperson Responsibilities

Specific responsibilities of the Chairperson include:

1) Manage IBC email account and submissions for research.
2) Schedule meetings, prepare agendas, and record minutes during IBC meetings.
3) Notify PIs of the results of IBC review and approval.
4) Make an initial determination of projects that can be reviewed for approval upon receipt or must receive full committee review and if NIH review and approval will be required.
5) Review all projects for biological safety concerns and communicate these concerns to investigators. The Chairperson may require changes in project procedures to assure biological safety of the project. No project can be initiated without IBC approval.
6) The Chairperson may suspend a project at any time if an emergent biological safety issue presents itself.

7) Maintain accurate and complete IBC records (e.g. applications, minutes, agendas)

8) Direct and prioritize IBC activities and facilitate each IBC meeting.

9) For applications that must be considered by the full committee, assignment of primary reviewers will be done based on an area of expertise.

10) For full committee review (FCR) studies, comparison of the methods section of any related federal grant to the IBC application will be performed to determine congruency.

11) Define meeting frequency to ensure that the applications are reviewed in a timely manner.

12) Ensure compliance with membership and procedure requirements in IBC Charter.

13) Ensure that all committee members are adequately trained to perform their duties.

14) Report any significant problems with or violations of the *NIH Guidelines* and any significant research-related accidents or illnesses to the appropriate institutional official(s) and NIH/OSP within 30 days, unless the IBC determines that a report has already been filed by the Principal Investigator.

15) Submit annual report to NIH/OSP (e.g. roster and biographical sketches)

16) Investigate any complaints involving the use of rDNA or other biohazardous materials, assess and take appropriate actions for resolution to ensure compliance with all institutional policies and governmental regulations.

17) Perform other functions as required to promote compliance with *NIH Guidelines* and general biological safety of projects.

VI. Biological Safety Officer (BSO) Responsibilities

The Biological Safety Officer (BSO) is responsible for the daily management of the biosafety program. Specific responsibilities related to the IBC include:

1) Conduct regular inspections to ensure laboratory standards are strictly followed, and in compliance with LSUHSC policies and biosafety regulations and guidelines.

2) Investigate laboratory accidents and report to the IBC Chairperson any significant problems or violations, and any significant research-related injuries or illnesses associated with biological agents. Following each investigation, the research personnel involved will be notified of the recommended corrective actions.

3) Develop and implement emergency plans for handling accidental spills and personnel contamination resulting from work with biohazardous materials.

4) Provide technical advice on laboratory security, research safety procedures, biosafety administrative controls, facility design, and compliance requirements.

5) Maintain the general laboratory biosafety training module.

6) Assist with providing general oversight of IBC operations to promote compliance.

7) Perform duties of the Chairperson in absence of the Chairperson, when Chairperson has a conflict of interest, or when designated by the Chairperson to act on behalf of the Chairperson.

VII. IBC Member Responsibilities

All IBC members are responsible for actively supporting IBC activities and responsibilities as described in this document. Specific responsibilities include:

1) Provide knowledge and expertise to the broad scope of biosafety issues, with primary responsibility for providing guidance in acknowledged areas of expertise.

2) Attend and participate at IBC meetings. All members are encouraged to attend every meeting. The Vice-Chancellor for Academic Affairs will be informed of any member who attends less than 50% of IBC meetings over a one-year period for reconsideration of their appointment to the IBC.

3) Perform a comprehensive and timely review of application forms, and follow all application review and approval procedures as defined in this document.

4) Complete all compliance training required for researchers. Review and have a working knowledge of the *NIH Guidelines for Research Involving rDNA Molecules*. Members will be expected to participate in any IBC training offered by this institution and is encouraged to participate in IBC training offered by other sources, e.g., regional or national meetings.

VIII. Principal Investigator Responsibilities

PIs must submit an IBC application for all applicable research projects they wish to conduct as an employee of LSUHSC-NO and receive approval from the IBC Chairperson prior to initiation of the project.

1) Prior to protocol submission to IBC, the PI will:

   a) Make an initial determination of the required levels of physical and biological containment (BSL) and risk group assessment (RA) in accordance with the *NIH Guidelines*;

   b) Select appropriate microbiological practices and laboratory techniques to be used for the research;

   c) Submit the IBC application and all required supporting documents (e.g., SOPS, vector maps, federal grant for congruency check) IBC for review and approval;

   d) Never initiate or modify research involving biohazardous materials which requires IBC approval prior to initiation until that research or the proposed modification has been approved by the IBC and has met all other requirements of the *NIH Guidelines*;

e) As required in the IBC application for rDNA research, identify the appropriate *NIH Guidelines* category under which the project will be conducted and provide adequate information for the committee to make its own determination.

f) Ensure that appropriate procedures are followed;

g) Have and maintain current biological and chemical inventories per *EHS-300.03 Biological Materials Inventory and Control Policy* and *EHS- 200.07 Chemical Inventory and Control Policy*;

h) Validate that all laboratory personnel have completed applicable training: Bloodborne Pathogen Training (annual for high risk groups, every five years for low risk group), Laboratory Safety Training (every two years) and IBC Training (every 5 years) via the Knowledge Delivery System;

i) Submit IRB or IACUC applications as required.

2) Prior to initiating research, the PI will:

a) Obtain all applicable approvals from the LSUHSC-NO IBC, IRE, IACUC, IRB and EH&S, NIH SOP or NIH Director.

b) Make available to all laboratory staff the protocols that describe the potential biohazards and the precautions to be taken;

c) In addition to completion of compliance training listed in Section VIII.1.h., provide initial training to study team members and laboratory staff in good microbiological techniques, the practices and techniques required to ensure safety, and the procedures for dealing with accidents. Provide training for all activities that are specific to the project. A training template is provided at the Environmental Health and Safety website (http://www.is.lsuhsc.edu/safety/default.aspx) which can serve to document training in writing and to determine when annual training must be repeated;

d) Inform the laboratory staff of the reasons and provisions for any precautionary medical practices advised or requested (e.g., vaccinations or serum collection);

e) Comply with *EHS 300.04 Bloodborne Pathogens Exposure Control Plan*; this is required for personnel who will have physical contact with humans or animals and/or who will physically handle biological materials, biohazardous agents or rDNA molecules and are conceivably at risk from research procedures involving the use of these biological materials;

f) Maintain a *Laboratory-Specific Biosafety Manual* in accordance with the LSUHSC standard template (for BSL2 and BSL3 laboratories).

3) During the Conduct of the Research, the PI will:

a) Supervise the safety performance of the laboratory staff to ensure that the required safety practices and techniques are employed;

b) Correct work errors and conditions that may result in the release of recombinant DNA materials;

c) Ensure the integrity of the physical containment (e.g., biological safety cabinets) and the biological containment (e.g., purity and genotypic and phenotypic characteristics). This includes ensuring that any biological safety cabinet used to conduct the research has received an updated annual certification by a LSUHSC approved vendor;

d) Investigate and report any significant problems pertaining to the operation and implementation of containment practices and procedures in writing to the IBC (EHS-400.06 Incident/Accident Reporting and Investigation Policy);

e) Report any significant problems, violations of the *NIH Guidelines*, or any significant research-related accidents and illnesses to the IBC;

f) Adhere to IBC-approved emergency plans for handling accidental spills and personnel contamination (*EHS-300.2 Biological and rDNA Spill Response Procedures*);

g) Comply with shipping requirements for rDNA molecules and other biological materials in accordance with *EHS-300.05 Shipping Biological Materials Policy and Manual*;

h) Submit an amendment prior to making any changes to the research as described in the original protocol.

i) Unless given exempt status under these policies, submit an *IBC Annual Update Form* each year the project is active. If continuing the project beyond the fifth annual, submit a new application.

IX. Conduct of Business

1) The IBC will meet every month as necessary throughout the calendar year to ensure the timely review of research applications, provide training for IBC members, or address IBC business.

2) Committee quorum consists of a numerical majority of IBC members. Each IBC meeting also requires sufficient members to ensure the collective experience and expertise to assess the safety and identify any potential risk involved with the research under review.

3) Formal business will only be conducted when a quorum of the IBC is present at a convened meeting. The IBC approves protocol applications by a majority vote of the membership during the session.

4) The full committee will review studies categorized under Sections IIIA-D of the NIH Guide before initiation of the study.

5) Studies categorized under Section III-E of the NIH Guide will be reviewed at a meeting of the full committee subsequent to initiation of the study and after submission of the IBC application and initial review for biological safety concerns.

6) Information among IBC, IACUC, and IRB is shared to ensure all research requiring IBC review and approval are being captured.

7) No member of the IBC will be involved (except to provide information requested by the IBC) in the review or approval of a project in which he/she has been, or expects to be, engaged or has a conflict of interest.

X. Meeting Minutes

1) Meeting minutes reflect the date and place of the meeting, whether minutes of the prior meeting were approved, individuals in attendance, whether and why the meeting was open or closed, a list each protocol reviewed (including the IBC number, PI name, protocol title, description of materials involved, approved biosafety level, and applicable section of *NIH Guidelines*), all significant motions including their disposition, and the time of meeting adjournment.

2) Meeting minutes should offer sufficient detail of the IBC's rationale for particular decisions by documenting any significant discussions of the following matters:

   - Conducting an assessment of the containment levels required by the *NIH Guidelines* when reviewing proposed research
   - Assessing the facilities, procedures, practices, and training and expertise of personnel involved in recombinant DNA research
   - Periodically reviewing recombinant DNA research to ensure compliance with the *NIH Guidelines*
   - Agent characteristics (e.g. virulence, pathogenicity, environment stability)
   - Types of manipulations planned
   - Source(s) of the inserted DNA sequences (e.g., species)
   - Nature of the inserted DNA sequences (e.g., structural gene, oncogene)
   - Host(s) and vector(s) to be used
   - Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced
   - Containment conditions to be implemented
   - Applicable section of the *NIH Guidelines* (e.g., Section III-D-1)

3) Meeting minutes will reflect the final voting decision of the IBC for each protocol application form.

4) Meeting minutes will be kept in the IBC Office. A copy of the minutes will be sent out to the Director of Office of Research Services, and the Vice- Chancellor for Academic Affairs.

5) Due to the proprietary nature of much of the information discussed at IBC meetings, the meetings are not open to the public. However, minutes of the meeting will be available in the event of a request under the FOIA. The IBC may redact from the minutes proprietary,

confidential or private information or information that might compromise the safety, but will do so judiciously and consistently for all requested documents. Some examples of information that may be redacted include: trade secret information and other confidential commercial information, home telephone numbers and home addresses of IBC members, and specific information whose disclosure might directly compromise personal or institutional safety or national security.

XI. Protocol Submittal Form Review & Approval Procedures

The principal Investigator must submit one of three IBC application forms (listed below) for applicable research activity. The PI is required to complete all sections that apply in the application based on the nature of the experiments and type of exposure to biological materials that will occur during the experiments. All IBC forms must be submitted electronically to the IBC Chairperson at IBCoffice@lsuhsc.edu. The applications and amendments also require submission of an original PI signature page to the IBC Office. Annual review forms do not require PI signature but must be submitted electronically by email from the PI or he/she must be copied on the email when someone submits the IBC form on behalf of the PI.

- Research Registration Form is used only to register a project that does not require institutional oversight by the IRB, IACUC or IBC. In most instances, research personnel do not conduct any laboratory work or collect, process, test, store or ship any research materials whether biological, pathological, diagnostic specimens, radiological, vertebrate or invertebrate animals, recombinant or synthetic molecules.

- IBC Clinical Studies Application is used for the collection and processing of human samples for standard clinical testing (e.g., blood metabolite levels, urine pregnancy test), storage and shipping of blood, bodily fluids, or tissue samples performed by any LSUHSC research study personnel including PI for a specific research project.

- IBC Application and Amendment Form is used for all research projects that cannot use the Registration Form, IBC-Clinical Studies Application or meets a specific criteria for IBC exemption listed in the *IRB Section II.D Table for IBC Requirements*.

1) The Principal Investigator should submit the application form in a timely manner to allow for adequate review and determination by the IBC. For projects likely to require Full Committee Review (FCR) prior to initiation of the project, the Principal Investigator is encouraged to submit the application well in advance to allow scheduling of an IBC meeting so that a determination can be made that meets the expected time requirements of the investigator.

2) The IBC Chairperson will review each application to determine if additional information, further clarification, or suggested protocol revisions are needed. The PI must provide a response and/or revised protocol and resubmit the application to the IBC Chairperson.

3) The IBC Chairperson will assess and approve claims for exemption from IBC oversight, e.g., chart reviews or surveys where no human conduct will occur. If exempt from IBC oversight, PI need only to notify the IBC of project closure.

4) The IBC Chairperson will assess if the application meets the requirements for Full Committee Review (FCR) or Expedited Review. If FCR is not required, the IBC Chairperson shall conduct a final review of the application in conjunction with the OEH&S to make a determination on the project safety and give approval to initiate the study.

5) FCR is required for the following applications.

   - Core laboratory/facility
   - Projects that use a Risk Group agent greater than RG2
   - Projects conducted at a Biosafety Level of 3 or higher rating
   - Use of rDNA or transgenic animals subject to the NIH Guidelines. The IBC application is a mechanism used for the registration of experiments falling under Section III-D of the NIH Guidelines. All rDNA projects subject to the Guidelines, (i.e., III-A, B, C, D, or E) must have FCR. Some rDNA projects may be "Exempt" from the Guidelines as defined in section III-F (and as expanded in Appendix C) of the Guidelines. These projects are still subject to IBC oversight and may be processed by Expedited Review Mechanism and will also require annual re-approval.

6) If FCR is required, the Chairperson will place the protocol on the agenda of the next scheduled IBC meeting. The IBC Chairperson will distribute a copy of all application forms to be reviewed to all committee members at least seven calendar days prior to the convened meeting The Chairperson will select one or two primary reviewers based upon their experience and expertise as it pertains to the application under review. The primary reviewer (s) will receive a copy of any related grant proposal for a determination of congruence between the IBC application and grant project. The primary reviewer(s) assigned to each application will facilitate the discussion due to their relevant area of expertise. After committee discussion is completed, the committee will vote on the determination of the application

7) After review, each application will be categorized as Approved, Modifications Required to Secure Approval (MRSA), Defer for Information, Approval Withheld, or Review Terminated. The PI will receive a notice of his/her application's status via email within one week of the review date. The categories are defined as follows.

   - Approved: The IBC approved the application.
   - Modifications Required to Secure Approval (MRSA): The IBC approved the application contingent on receipt of minor modifications and/or additional information within 21 calendar days of notice. Requested modifications or clarifications received within 21 days may be given final approval by the IBC Chairperson without subsequent review at a convened IBC meeting.
   - Defer for Information: The PI must respond with protocol modifications and/or

additional information within 21 calendar days of notice. Requested modifications or clarifications received within 21 days must be reviewed for approval by a quorum vote of IBC members.

- Approval Withheld: The protocol application is denied because the IBC has determined the work may pose a significant safety risk, the risks outweigh the benefits, or other reasons the IBC cannot justify granting approval.
- Review Terminated: The protocol application is administratively terminated when the PI does not respond to all IBC requests within 21 calendar days of notification. Therefore, a new application form is required to be submitted by the PI and a new unique IBC protocol number will be assigned.

8) When applicable, projects requiring additional review and approval by the NIH/OSP for Sections III-A, B, or C project categories, the Chairperson shall forward the IBC approved application to the appropriate NIH agencies. In these cases, the PI will be notified that the project cannot commence until NIH/OSP has approved the application. Refer to NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules* at *http://osp.od.nih.gov/biotechnology/nih-guidelines/*.

9) When applicable, IRB or IACUC approval will be contingent upon IBC approval. Refer to IACUC policies and procedures and application forms at *http://www.lsuhsc.edu/no/administration/rs/IACUC_Forms.htm*. Specific IRB projects are exempted from filing an IBC application; refer to IRB policies and procedures and forms at *http://www.lsuhsc.edu/no/administration/rs/irb/default.htm*).

10) All protocol application forms are approved for a period of one year from the date of approval with subsequent annual reviews for up to five years or until the PI notifies the IBC Office that the project is completed.

11) The Principal Investigator is required to submit an Amendment, Change in Personnel Form or an Annual Update Form prior to introducing new experiments, materials or new personnel to the project. All training must be completed by the new personnel prior to participation in the project.

12) The PI must not modify research involving rDNA or biohazardous materials until the proposed modification has been approved by the IBC. The Biosafety Officer and IBC Chairperson will determine if the change is minor and can be administratively approved, or if the change is more significant and requires review and approval by voting at a convened IBC meeting.

13) A new IBC application is required at the end of five years following the initial IBC approval of the previous application.

14) Additional review by the Institutional Review Entity will be required for use of "Select Agents" or "DURC" items used in research. Refer to IRE Policy and Procedures at *http://www.lsuhsc.edu/administration/academic/ors/docs/DURC%20Policy%202015.pdf*.