Institutional Biosafety Committee Policy and Procedures Guidebook

I. Background

Louisiana State Health Sciences Center – New Orleans (LSUHSC-NO) uses recombinant and/or synthetic nucleic acids (r/sNAr/sNAs) molecules in scientific research and receives federal funding. Therefore, LSUHSC.NO must comply with the NIH *Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*[1] for all of its research activities independent of support for the project. The NIH *Guidelines*[1] require the university to establish an Institutional Biosafety Committee (IBC) whose responsibilities need not be restricted to r/sNAr/sNAs. The scope of LSUHSC's IBC includes the review of all research activities for biological safety.
Failure to comply with the NIH *Guidelines*[1] may result in suspension, limitation, or termination of NIH funds for any and all recombinant or synthetic nucleic acid research at LSUHSC,
As described in this Guidebook, LSUHSC-NO will make available requests for IBC meeting minutes under the Freedom of Information Act (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 Executive 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 r/sNAr/sNA to ensure compliance with NIH *Guidelines*[1]. However, the LSUHSC-NO IBC has an expanded scope of oversight to review all research conducted at LSUHSC-NO for human, biological and environmental safety issues.

As such, LSUHSC-NO's IBC acts as the framework for risk management associated with research-related, biosafety 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 agencies biosafety requirements including the NIH *Guidelines*[1];
2) To review projects that use "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*[1]; and

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

The program is also used to verify and track required biosafety 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 submitted via the current electronic Kuali platform[3] to determine whether all biosafety 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. Other information and forms related to the IBC submission and review process are available on the IBC website[2].

III. IBC Membership

Based on federal regulations, the Institutional Biosafety Committee (IBC) must comprise no fewer than five members so selected that they collectively have experience and expertise in recombinant or synthetic nucleic acid (r/sNA) molecule technology and the capability to assess the safety of recombinant or synthetic nucleic acid molecule research and to identify any potential risk to public health or the environment.

For the LSUHSC-NO IBC, the Vice-Chancellor for Academic Affairs appoints a minimum of seven IBC Members of the types listed below and designates the Committee Chairperson and Vice Chairperson. The Biosafety Officer, the individual with animal expertise, and community members are permanent members of the IBC and are appointed to an indefinite term. All other members will be appointed for a 3-year term in their specific role with the option of one additional 3-year term in that role upon mutual agreement between the IBC member, the Committee and Vice-Chancellor for Academic Affairs. All such members may serve more than six years on the IBC if their role changes, for instance from a regular member to Vice-Chairperson. When the term limit for the Committee Chairperson occurs, either at the three-year renewal or at six-year term limit, the Vice-Chairperson will assume the role of the Committee Chairperson, which will then require a new Vice-Chairperson to be named and approved by the Vice-Chancellor for Academic Affairs.

Alternative Members may be established for instances where IBC members are unable to attend meetings. In addition, Alternative Members are established with the intent to replace IBC Members

once a three-year term is not renewed or the six-year maximum term limit for the IBC Member occurs. IBC Members and Alternative Members must ensure they collectively have experience and expertise in r/sNA technology and pathogenic agents. They must 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 (voting member)
2) The Vice-Chairperson (voting member)
3) The Biological Safety Officer (BSO) (voting member)
4) Director, Office of Research Services (*ex officio* and IBC contact person). (non-voting member)
5) 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, commonly referred to as "laypersons". (voting members)
6) At least one individual with expertise in animal containment principles (i.e. LSUHSC-NO DOAC veterinarian(s)). (voting member(s))
7) If r/sNA research involving plants is proposed, at least one individual with expertise in plants, plant pathogen, or plant pest containment principles. (non-voting member(s))
8) If r/sNA research involving human subjects is proposed, at least one individual who has adequate experience and training in the field of human gene transfer has to be present. (non-voting member(s))
9) Additional members will be selected to ensure the competency necessary to review and approve work involving r/sNA or other pathogenic agents (voting members)
10) EH&S personnel (non-voting member(s))
11) IBC/IACUC Research Coordinators or Compliance Analysts (non-voting member(s))

IV. Committee Responsibilities

1) Convene at an IBC meeting for Full Committee Review of any project that:
   - meets specific criteria of the NIH *Guidelines*[1], 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 Vice Chair outside of a convened meeting.

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

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 r/sNA or other potentially hazardous 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 Department of Environmental Health and Safety (EH&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 r/sNA research that comes under the purview of the NIH *Guidelines*[1], determine that such projects conform with the NIH *Guidelines*[1] 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 or synthetic NAs encoding 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*[1] states that the deliberate transfer of recombinant or synthetic nucleic acids into one human is not research subject to the NIH *Guidelines*[1] 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.

8) IBC members with a conflict of interest in a particular application being reviewed shall be recused during the IBC's deliberations. However, they may be asked to provide clarifying information to the IBC.

V. IBC Chairperson Responsibilities

Specific responsibilities of the Chairperson, with support from the IBC Office staff, 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 within 7 calendar days whether projects can be reviewed for approval upon receipt, must receive Full Committee Review and/or require NIH review and approval. After 7 calendar days, the IBC protocol will be passed to the Vice-chairperson for further determination.
5) Review, in conjunction with a convened IBC, when necessary, 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) 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, assign primary reviewers based on area of expertise.
10) For Full Committee Review (FCR) studies, perform comparison of the methods section of

any related federal grant to the IBC application to determine congruency.

11) Define meeting frequency to ensure that the applications are reviewed in a timely manner as outlined on the IBC website for tentative FCR meeting dates.

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*[1] 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 r/sNA 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*[1] and general biological safety of projects.

VI. Vice-Chairperson Responsibilities

1) The Vice-Chairperson is authorized to conduct official IBC business in the following instances:
   a) as requested by the Chair for a planned absence, or as needed in an unplanned absence
   b) in the event the Chair has a conflict of interest with materials under review
   c) in the event that the Chair is unreachable, unresponsive or incapacitated

2) When serving as Chair, the Vice Chair will assume all duties, rights, and responsibilities of the Chair, as described in Section V, including making an initial determination of project disposition (Section V(4)) if the determination has not been made by the Chairperson within 7 calendar days.
   a) The Vice-Chairperson will then have an additional 7 calendar days to make a determination on the IBC protocol.
   b) Once 7 calendar days have passed and both the Chairperson and Vice-Chairperson fail to make a determination due to negligence, then the Director of the ORS will appoint another IBC member with scientific background to expeditiously review the protocol and make a determination.

VII. Biological Safety Officer (BSO) Responsibilities

The Biological Safety Officer (BSO) is responsible to advice the research personnel and the IBC about the most appropriate safety practices to ensure the safe management of biohazards. The BSO shall have voting privileges. 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.

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) Performing the required risk assessment of research laboratories to determine appropriate biosafety containment and personal protective equipment (PPE) for handling and dispose biohazards.

VIII. IBC Members Responsibilities

All IBC Members and Alternative 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 and Alternates 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*[1]. Members and Alternates will be expected to participate in any IBC training offered by this institution and are encouraged to participate in IBC training offered by other sources, e.g., regional or national meetings.

IX. 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*[1];

   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 require 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*[1];

   e) As required in the IBC application for r/sNA research, identify the appropriate NIH *Guidelines*[1] 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 courses: Bloodborne Pathogen Training (annual for high risk groups, every five years for low risk group), Laboratory Safety Training (every three years) and IBC Compliance (once), Shipping Biological Materials (once, if applicable)via the Knowledge Delivery System;

   i) Ensure that all study personnel have completed their annual Conflict of Interest (COI) in Research Disclosure via the Kuali COI Module.

   j) 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 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 r/sNA 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 r/sNA 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 and with EH&S (EHS-400.06 Incident/Accident Reporting and Investigation Policy);

e) Report any significant problems, violations of the *NIH Guidelines*[1], or any significant research-related accidents and illnesses to the IBC using the Kuali submission platform "Incident Reporting"[4];

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

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

h) Submit an amendment using the Kuali submission platform[3] prior to making any changes to the research as described in the original protocol.

i) Unless given exempt status under these policies, submit an annual renewal via the Kuali submission platform[3] each year the project is active. If continuing the project

beyond the fifth annual, submit a new application no later than 15 days before the continuing review date.

X. 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. A schedule of meetings and submission deadlines to have an IBC protocol reviewed at each meeting may be found on the IBC website[2].

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) Alternative members may take the place of IBC members absent from the meeting with the intent to establish a quorum. Alternative members will be able to vote on reviews of protocols just as a IBC member would.

4) 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.

5) The full committee will review studies categorized under Sections IIIA-D of the NIH *Guidelines*[1] before initiation of the study.

6) Studies categorized under Section III-E of the NIH *Guidelines*[1] 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.

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

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.

XI. Meeting Minutes

The LSU Health New Orleans IBC is responsible for oversight of all research involving biohazardous materials, including r/sNA. According to the NIH memo *Implementation Update: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*, starting June 1, 2025, the NIH expects that approved meeting minutes from all IBC meetings occurring on, or after this date will be posted publicly on an institutional website. It is NIH's expectation that minutes will be posted immediately after approval and once all appropriate and allowable redactions have been made. Please note that the provisions of this memo only apply to meetings taking place on, or after June 1, 2025. Minutes from meetings before that date do not need to be posted but still must be provided to members of the public upon

request.

The NIH Guidelines do not specify the required level of detail for IBC meeting minutes; however, they should reflect IBC oversight as outlined in Section IV-B-2-b of the NIH Guidelines. 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*[1], and any incident reporting submitted to the IBC in writing, to EH&S and using Kuali), all significant motions including their disposition, and the time of meeting adjournment.

1) Meeting minutes should offer sufficient detail of the IBC's rationale for decisions by documenting any significant discussions of the following matters:
    a) Conducting an assessment of the containment levels required by the NIH *Guidelines*[1] when reviewing proposed research
    b) Assessing the facilities, procedures, practices, and training and expertise of personnel involved in r/sNA research
    c) Periodically reviewing r/sNA research to ensure compliance with the *NIH Guidelines*[1]
    d) Agent characteristics (e.g. virulence, pathogenicity, environment stability)
    e) Types of manipulations planned
    f) Source(s) of the r/sNA sequences (e.g., species)
    g) Nature of the r/sNA sequences (e.g., structural gene, oncogene)
    h) Host(s) and vector(s) to be used
    i) Whether an attempt will be made to obtain expression of a foreign gene, and if so, the protein that will be produced
    j) Containment conditions to be implemented
    k) Applicable section of the NIH *Guidelines*[1] (e.g., Section III-D-1)

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

3) Meeting minutes will be uploaded in the agenda for the next meeting in Kuali for review and approval. Hard copies may also be kept in the IBC Office. Approved meeting minutes from all IBC meetings occurring on, or after June 1, 2025 will be posted publicly on our institutional website[6].

4) Redaction of Meeting Minutes:

    To ensure that proprietary and sensitive information is protected while maintaining compliance with the NIH Guidelines, redaction will be performed consistently by the IBC prior to public release of minutes.

    Redacted information may include, but is not limited to:
    - Private information of IBC members (e.g., home addresses, phone numbers)
    - Names of guests attending IBC meetings
    - Proprietary, confidential, or trade secret information

- Locations of laboratories, animal facilities, and storage of biohazardous materials
- Personal or identifying information about Principal Investigators (PIs)
- Specific dates or procedural details of animal experiments
- Sponsor-provided proprietary information, such as data from gene transfer studies or pending patent materials
- Other information that could directly compromise institutional or national security

Information that will not be redacted includes:

- Names of IBC members (except where private contact information is involved)
- Names of guests or public attendees, if relevant to FOIA requests
- Statements of recusal from discussion or voting due to conflicts of interest
- Basic risk assessment details and biosafety containment justifications required under the NIH Guidelines

Resources:

- Implementation Update: Promoting Maximal Transparency Under the NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules https://grants.nih.gov/grants/guide/notice-files/NOT-OD-25-082.html

XII. Protocol Submission, Review, Approval, and Expiration Procedures

The principal Investigator (PI) must submit an IBC application for review and approval for all applicable research activity. The PI or a PI approved designee 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. The PI is ultimately responsible for reviewing an IBC protocol and is the only individual able to submit an IBC protocol for review. All initial and post-approval IBC applications must be submitted through the Kuali submission system[3].

A guide to assist researchers with creating and submitting protocols in the Kuali platform is found on the "Resources" page of the IBC website[5].

1) The Principal Investigator should submit the application via the Kuali platform in a timely manner to allow for adequate review and determination by the IBC. Meeting dates and submission deadlines to be considered at these meetings can be found on the IBC website[6]. 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, or his/her designee, 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 Office.

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.

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 EH&S officers to make a determination on the project safety and give approval to initiate the study.

5) FCR is required for the following applications.

    a) Core laboratory/facility
    b) Projects that use a Risk Group agent greater than RG2
    c) Projects conducted at a Biosafety Level of 3 or higher rating
    d) Use of r/sNA or transgenic animals subject to the *NIH Guidelines*[1]. The IBC application is a mechanism used for the registration of experiments falling under Section III-D of the *NIH Guidelines*[1]. All r/sNA projects subject to the *NIH Guidelines*[1], (i.e., III-A, B, C, D, or E) must have FCR. Some r/sNA projects may be "Exempt" from the Guidelines as defined in section III-F (and as expanded in Appendix C) of the *NIH Guidelines*[1]. 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, with support from the IBC Office staff, will place the protocol on the agenda of the next scheduled IBC meeting and distribute a copy of all application forms via the Kuali platform 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 the 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 the Kuali submission system within one week of the review date. The categories are defined as follows.

    a) **Approved:** The IBC approved the application.

    b) **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.

    c) **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.

d) **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.

e) **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.

PI's are notified of the status of their review(s) via comments left in the Kuali system after the submission is returned back to the researcher.

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*[1].

9) When applicable, IRB or IACUC approval will be contingent upon IBC approval. Please refer to IACUC Policies and Procedures Guidebook[7]. Specific IRB projects are exempted from filing an IBC application[8].

10) All protocol applications submitted via the Kuali platform are approved for a period of one year from the date of approval with subsequent annual renewals for up to five years or unless the PI requests closure of the study[9] before the 5-year period expires. Notification of expiration of protocol approval is generated by Kuali system at least one calendar month before the protocol is set to require an annual renewal or expire after the 5-year period after initial approval.

11) **Protocol Amendments**

a. Any modification to an approved protocol must be submitted to the Institutional Biosafety Committee (IBC) for review and approval **prior** to implementation. The Principal Investigator (PI), or personnel with Full Access, is responsible for submitting an amendment through the Kuali system before introducing new experiments, materials, procedures, or personnel. All required training must be completed by newly added personnel prior to participation in the project. Additional guidance on amendments is available on the IBC website under *"Submissions to the IBC."*[10]

When a proposed amendment does not clearly fall within the categories described below, the IBC Chairperson, in consultation with the Research Compliance Analyst, shall determine the appropriate review category.

The IBC classifies amendments to approved protocols as **minor** or **major**. All amendments undergo an initial administrative review by the IBC Office.

During the Administrative Review, the IBC Office verifies that the amendment submission is complete and administratively compliant. This review includes, but is not limited to,

confirmation of the following:

- The amendment form is complete and accurately reflects the proposed changes
- All required supporting documentation has been provided
- All personnel listed on the protocol have completed required biosafety and institutional training appropriate to their role and scope of work
- Conflict of Interest (COI) disclosures are current and compliant for the Principal Investigator and all listed personnel, as applicable
- The proposed changes are consistent with institutional policies and applicable regulatory requirements
- The amendment has been appropriately categorized as a minor or major amendment or referred to the IBC Chairperson for determination when categorization is unclear.

i. **Minor Amendments** are those that do not involve a significant change and may be reviewed administratively by the Research Compliance Analyst without review by the full committee or via Designated Member Review (DMR), as described below. The Analyst or DMR may require modifications to secure approval and may consult with the IBC Chairperson as needed prior to making a determination.

    1. **Examples of Minor Amendments** include, but are not limited to:

        a. Adding or removing research personnel (excluding the PI)

        b. Adding or removing laboratory room numbers

        c. Adding or removing a project funding source

        d. Adding or removing cell lines of a previously approved organism

        e. Adding or removing strains of a previously approved transgenic animal

        f. Adding or removing vector constructs for a previously approved viral vector

        g. Changes that do not meet the criteria for a major amendment

ii. **Major Amendments** are defined as amendments involving a **significant change** to the approved protocol and require Full Committee Review (FCR).

    1. **Examples of Major Amendments** include, but are not limited to:

        a. Adding a new animal species

b. Adding or changing a transgene

c. Adding or changing infectious agents

d. Changes to applicable sections of the NIH Guidelines

e. Changes in containment level

f. Changes that do not meet the criteria for a minor amendment

iii. The Designated Member Review (DMR) process may be used for amendments involving significant changes that **do not** meet the criteria for Full Committee Review.

iv. Designated Member Review (DMR) may be utilized for amendments involving significant changes, except for those requiring Full Committee Review. The DMR process is conducted as follows:

1. The amendment, original approved protocol, and any supporting documentation are distributed to all IBC members to allow the opportunity to request Full Committee Review.

2. Members have two (2) business days from notification to request Full Committee Review **or to submit any comments or concerns** regarding the amendment to the IBC Analyst. If any member requests FCR, the amendment will be placed on the agenda for the next convened IBC meeting.

3. If Full Committee Review is not requested, the IBC Chairperson, or a qualified member designated by the Chairperson, has the authority to approve the amendment, require modifications to secure approval, or refer the amendment for Full Committee Review. Withholding approval is not an allowable outcome of DMR.

12) The PI must not modify research involving r/sNA 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 and needs to be submitted via the Kuali system. More information can be found on the IBC website under "Submissions to the IBC"[11].

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[12].

15) PIs are encouraged to submit annual renewal applications for approved protocols well before the continuing review date. If an annual renewal is not submitted within 45 days after the continuing review date, protocols will be **administratively closed**. During the 45 day grace period, the PI and the personnel listed on the protocol will receive, at minimum, 4 notifications

via email generated by the Kuali system, Kuali. If a renewal application has not been submitted by the end of the 45 day grace period, the protocol will be irreversibly closed administratively. Notification of administrative closure will be provided to the PI, the PI's Department Head and if applicable, the PI's business manager. After administrative closure of the protocol, the work covered by the previous IBC approval is no longer considered in compliance with LSUHSC IBC policies and a new IBC protocol must be resubmitted via the Kuali Kuali system to continue the research project. In the 5th year of an approved study, the protocol will expire on the Expiration Date. There are no further options for renewal. A new protocol must be submitted to continue the research.

REFERENCES

1. https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf
2. https://www.lsuhsc.edu/administration/academic/ors/ibc/
3. https://www.lsuhsc.edu/administration/academic/ors/ibc/submission_amendment.aspx
4. https://www.lsuhsc.edu/administration/academic/ors/ibc/comp_noncompliance.aspx
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