Research Café

Preparing IBC Applications: From Project Design to Compliance

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LSU Health NEW ORLEANS

Learning Objectives

1. **Determine when IBC approval is required for a research project**
2. Identify critical elements to complete a protocol submission
3. Applying institutional and federal biosafety requirements in project planning to avoid delays

IBC @ LSU
Risk Management Objectives

1. To protect individuals, research animals, facilities, and the community from the potential dangers of biohazardous materials
2. To assure that LSUHSC-NO is in compliance with all biosafety requirements mandated by state and federal regulatory agencies
3. To review research involving:
    1. The use of **Biological Select Agents** and **Toxins** which have the potential to pose a severe threat to public, animal or plant health or to animal or plant products
    2. To review research involving the use of **Dual Use Research of Concern (DURC)** agents that, while used for legitimate research, could be directly misapplied to pose a severe threat to public, animal health, safety, or agriculture.

Activities That Typically Require IBC Approval

- Recombinant or synthetic nucleic acids
- Viral vectors (Lenti/retrovirus, adenovirus, herpesvirus)
- Genetically modified organisms (microbes, cells, animals)
- Human or primate material (OPIM):
  - Cell lines
  - Blood, tissues, bodily fluids
- Pathogens (BSL-1, BSL-2, BSL-3, BSL-4 agents)
- Gene editing (CRISPR/Cas systems)

Activities That Typically Require IBC Approval

- Human Gene Transfer (HGT) protocols in addition to LSUHSC-IBC, NIH, FDA and clinical site approvals are required
- Attenuated or replication-deficient organisms
- Exosomes & Conditioned media (case dependent)

Activities That Do Not Require IBC Approval

- Synthetic nucleic acids
  - non-replicative
  - cannot integrate into mammalian DNA
  - do not produce toxins/oncoproteins
  - cannot infect cells
  - purely chemically synthesized
- Overall, those experiments that do not present a significant risk to health or the environment

  However, even for these activities, it is crucial to consult the

  IBC office all this activities **require IBC registration**

Purview of the IBC

- The **IBC** must evaluate research experiments regarding potential environmental risk to the laboratory workers and the immediate environment
  - Containment level and practices according to the **NIH Guidelines**
  - Adequacy of facilities
  - Applicable SOPs
  - Investigator/laboratory staff training
  - Institutional and investigator compliance (e.g. incident reporting)

Conclusions

- IBC approval is **risk-based**, not funding-based
- Recombinant DNA, viral vectors, genetically modified organisms, and human or animal biological materials **almost always** trigger IBC review
- ***When uncertainty exists, early consultation prevents noncompliance and delays***

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Main IBC Core Application Questions

1. What biological materials are used?
2. What are the risks?
3. How are those risks mitigated?

Main Core Elements of the IBC Application

- Project Narrative (language understood by a layman)
- Project Description (scientific language)
- Biological agents and materials
- Experimental procedures
- **NIH Guidelines**
- Containment level (BSL-1/2/3/4, ABSL-1/2/3)
- Risk group (RG-1/2/3/4)
- Waste disposal
- Spill and exposure response
- **Personnel training (including the PI)**

Main Core Elements of the IBC Amendments

Minor Amendments → *Adding/removing*:

- research personnel other than PI
- laboratory room numbers
- project funding source
- cell lines of a previously approved organism
- strains of a previously approved transgenic animals
- vector constructs for a previously approved viral vector

Main Core Elements of the IBC Amendments

Major Amendments

- Adding new animal species
- Adding/changing transgenes
- Adding/changing infectious agents
- Change in sections of the **NIH Guidelines**
- Change in containment level

Main Core Elements of the IBC Renewals

- Confirmation of Active Work Scope
- Current Inventory of Biological Materials
- Verification of Biosafety Level and Containment
- Personnel and Training Updates
- Alignment With Other Oversight Protocols
- Adding new animal species
- Adding/changing transgenes
- Adding/changing infectious agents

LSUHSC Framework Biosafety Requirements

- IBC approval before work begins
- Protocol amendments required for: new biological agents, procedures*, personnel**, summer students
- Integrated oversight among IBC, IRB, IBC and EH&S
- Annual continuing review (every year)
- Renewals (every five years)

Training Requirements for Personnel

- LSUHSC-NO, under the purview of the **Office of Compliance** Programs and the **Office of Research Services**, requires specific training for individuals involved in research
- The Office of Research is responsible for confirming compliance with the training and disclosure requirements for all HSC investigators including those listed in the initial application and those added after study approval through an amendment request

Training Requirements for Personnel

Training Course/Disclosure	Frequency	Training Provider	Who must complete this training?
Conflict of Interest in Research Disclosure	Every year	Kuali Research	All personnel on an IBC-approved protocol
Laboratory Safety Training	Every year	CATS	All personnel on an IBC-approved protocol working in a laboratory setting
Bloodborne Pathogen	Every year or Every 5 years*	CATS	All personnel on an IBC-approved protocol
IBC Compliance	Once	CATS	All personnel on an IBC-approved protocol
Shipping Biological Materials	Every 2 years	CATS	All personnel on an IBC-approved protocol that are responsible for shipping/delivering biologicals, chemicals, pathogens, etc.
Radiation Safety	Once	EH&S	All personnel on an IBC-approved protocol that involve research utilizing radioactive substances.
Laser Safety	Once	EH&S	All personnel on an IBC-approved protocol that involve research utilizing Class 3B or 4 lasers.

***** *Every year for high-risk research (i.e. working in lab and/or with animals). Every 5 years for low-risk research (i.e. not in lab or working with animals).*

IBC Major Red Flags

1. Biological agents not clearly described (strain, source, modifications)
2. Mismatch between procedures and assigned biosafety level
3. Inconsistencies with IRB or IACUC protocols
4. Personnel listed without required biosafety training
5. Research initiated prior to IBC approval
6. Incomplete or missing SOPs for higher-risk agents
7. Containment and PPE not aligned with the risk-agent
8. Animal room numbers or lab locations missing or incorrect
9. Amendments submitted without updating all affected sections
10. EH&S & BSO concerns not addressed before submission

Viral Vector Red Flags

1. Replication competence not explicitly addressed
2. Integration risk not acknowledged (lentivirus/retrovirus)
3. Incomplete description of vector backbone or transgene
4. Missing spill response for high-titer stocks
5. Improper waste decontamination plans

Plasmids & rDNA Red Flags

1. Assuming PCR-only plasmids are exempt
2. No confirmation that plasmids cannot generate infectious agents
3. Host strain and antibiotic resistance markers omitted
4. Storage and disposal plans missing

Animal Work Red Flags

1. Route of administration not aligned with containment level
2. IACUC protocol inconsistent
3. Animal housing location not specified
4. Carcasses and bedding disposal unclear

Conclusions

- Successful IBC submissions clearly describe agents, procedures, and containment
- Reviewers should focus on risk pathways and mitigation, not scientific merit
- Incomplete descriptions-not high risk-are the most common reason for protocol holds
- The risk must be clearly explained.

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Federal Framework Biosafety Requirements

- **NIH Guidelines** for research involving r/s nucleic acid molecules
- **CDC/NIH** biosafety in microbiological and biomedical laboratories
- **Select** and **dual agent** regulations (when applicable)

NIH Guidelines

- **IBCs** were established under the **NIH Guidelines** to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules.
- **The purpose of the NIH Guidelines is to specify the biosafety practices and containment principles for constructing and handling:**
  - Recombinant nucleic acid molecules.
  - Synthetic nucleic acid molecules, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules.
  - Cells, organisms, and viruses containing such molecules.


NIH GUIDELINES FOR RESEARCH INVOLVING RECOMBINANT OR SYNTHETIC NUCLEIC ACID MOLECULES (NIH GUIDELINES)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
National Institutes of Health

Visit the NIH OSP Web site at:
https://osp.od.nih.gov

NIH OFFICE OF SCIENCE POLICY CONTACT INFORMATION:

Office of Science Policy, National Institutes of Health, 6705 Rockledge Drive, Suite 630, MSC 7985, Bethesda, MD 20892-7985 (20817 for non-USPS mail), (301) 496-9838; (301) 496-9839 (fax).

For inquiries, information requests, and report submissions: NIHGuidelines@od.nih.gov

These *NIH Guidelines* shall supersede all earlier versions until further notice.

Experiments Covered by the NIH Guidelines

LSU Health NEW ORLEANS
INSTITUTIONAL BIOSAFETY COMMITTEE

LSUHSC-NO IBC
DOC ID: IBC-100
VER: 2.1_10.7.22

NIH Guidelines – Covered Experiments

Instructions:

A. *Enter the Kuali protocol number for the application.*

PROTOCOL NUMBER:

B. *Identify the appropriate NIH Guidelines Section(s) for the covered experiments:*

1. *Select the type of experiment being reported: Ctrl + Click on one of the Table titles in section C; you will be directed to the corresponding table;*
2. *In the table, check the appropriate checkbox(es) corresponding to the experiment being conducted;*
3. *Return to the top of this document and repeat Steps B1-3, or scroll through the tables, to identify all applicable NIH Guidelines Sections.*

C. *Experiment Type Tables:*

- **Table1: Experiments involving non-viral host-vector systems**
- **Table 2: Experiments involving the use of viruses in tissue culture systems**
- **Table 3: Experiments using whole animals**
- **Table 4: Other experiments involving recombinant or synthetic nucleic acids (r/sNA)**
- **Table 5: Experiments requiring federal review & approval**

Level of Review	Relevant Section (s)
IBC approval, Recombinant DNA Advisory Committee (RAC) review, and NIH Director approval before initiation	III-A
NIH/OBA and IBC approval before initiation	III-B
IBC/IRB approval and RAC review before research participant enrollment	III-C
IBC approval before initiation	**III-D**
IBC notification before simultaneous with initiation	**III-E**
Exempt from the NIH Guidelines	**III-F**

- **IIIA**
  - The deliberate transfer of a drug resistance trait to microorganisms
  - Plants modified by rDNA
  - Vaccine studies
  - Treatment of patients with new drugs
  - Experiments involving human gene transfer
- **IIIB**
  - Cloning of toxin molecules
  - Experiments using risk group 2, risk group 3, risk group 4 and rDNA
  - Restricted agents cloned into nonpathogenic prokaryotic or eukaryotic host-vectors
- **IIIC**
  - Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into human research participants derived from r/sNA molecules
  - Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems

- **IIID**
  - Experiments using risk group 2, risk group 3, risk group 4, or restricted agents as host-vector systems
  - Experiments involving whole animals, whole plants and influenza virus
- **IIIE**
  - Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than Two-Thirds of the genome of any eukaryotic virus
  - Experiments involving transgenic rodents
  - Can be approved outside of Full Committee Review (BSL1)
- **IIIF**
  - Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes
  - Those that do not present a significant risk to health or the environment
  - The purchase or transfer of rodents for experiments that require BL1 containment
  - Further manipulations of these animals with rDNA are not necessarily exempt from the NIH Guidelines
  - Exceptions to these rules can apply

When a Full Committee Review (FCR) is required

- The use of r/sNA or transgenic animals subjected to the NIH Guidelines (Sections III-A,B,C,D or E (case dependent).
- Projects that use a Risk Group agent greater than RG2
- Projects conducted at a Biosafety Level of 3 or higher rating
- Core laboratory/facility

Integrated Oversight

- **Institutional Biosafety Committee**
  - Biological Risk
- Office of Environmental Health and Safety (EH&S)
  - Facilities and Safety
- Institutional Animal Care and Use Committee (IACUC)
  - Animal Welfare
- Human Research Protection Program & Institutional Review (Board IRB)
  - Human Research

IBC Principal Investigator Responsibilities

The **Principal Investigator** is responsible for full compliance with the NIH Guidelines in the conduct of research, ensuring that reporting requirements are fulfilled. The PI is accountable for any reporting lapses

- **Prior Submission and Initiating Research**
  - BSL, RG, techniques, SOPs, vector maps, identify NIG-Guidelines, chemical and biological inventory (Safety Stratus), CATS training / personnel training, biosafety manual, protocol dealing with accidents, lab personnel access to protocols.
- **During the Conduct of Research**
  - Safety performance, assess work errors, ensure integrity of physical containment, report of significant operational problems, report violations of the NIH Guidelines, shipment requirements, inventory registrations, submission of amendments, **emergency plans in case of accidents**.

How to Avoid Reviewer Delays

- Be specific about experimental changes
- Confirm training and COI status
- Ensure consistency across protocols
- Clearly describe all biological agents
- Match BSL/ABSL to the work described
- Address aerosol and exposure risks
- Include EH&S considerations
- Respond fully to reviewer comments
- Attach all required SOPs and vector maps

LSU IBC Responsibilities

Review timelines

- Minor Amendment: 1-2 business days
- Major Amendment: 3-10 calendar days
- Protocol not requiring FCR: 3-10 calendar days
- Full Committee Review: Up to 4 weeks

Important Notes

- Timelines begin after submission is complete and all required documents are provided
- Requests for additional information or revisions may extend review time
- Research activities may **not begin** until IBC approval is granted

Incident Reporting

- **Federal regulations** and **LSUHSC policies** require timely reporting of any significant problems, violations or any significant research-related accidents and illnesses, from research or teaching activities that involve potentially hazardous biological agents subject to IBC purview. Including lentivirus, adenovirus, AVV, toxins, viruses, bacteria, fungus, dual and select agents
  - Spills, direct exposure to materials, and aerosols
  - Injury with a needle
  - Illness from an infectious agents
  - Breach of containment in the research lab or when working with animals
  - Nonadherence to the **NIH guidelines**

Incident Reporting

- **EH&S Office:**
  - Email: safety@lsuhsc.edu
  - Phone: 504-568-6585
  - Website: here
- **IBC Office:**
  - Email: IBCOffice@lsuhsc.edu
  - Phone: 504-568-4372
- **IACUC Office:**
  - Email: IACUCOffice@lsuhsc.edu
  - Phone: 504-680-9350
- **Division of Animal Care:**
  - Website: https://intranet.lsuhsc.edu/animalcare/
- **Office of Compliance Programs**
  - Email: nocompliance@lsuhsc.edu.
  - LSUHSC-NO Hot Line: 855-561-4099
  - Website: How to Report Non-Compliance

Resources

Helpful Links

- LSUHSC-NO IBC Website
- IBC Policies and Procedures Guidebook
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)
- IRE DURC Policies and Procedures Guidebook
- Federal Select Agent Program
- Select Agents and Toxins List
- Excluded Strains of Select Agents and Toxins
- EH&S Select Agents Policy

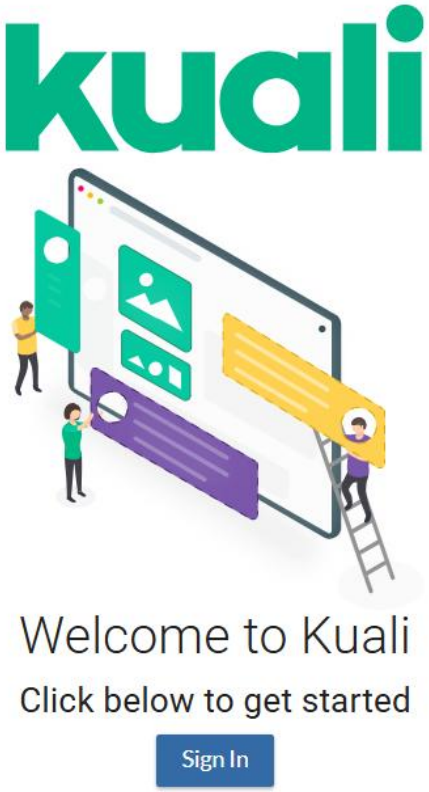
Conclusions

- Federal and institutional requirements must be integrated at the project design stage
- Tools like Kuali reward early planning and penalize last-minute submission
- Clear, detailed protocols reduce reviewer follow-up
- ***IBC it is not a joke. It is a critical component of research compliance that operates alongside the IRB and IACUC to ensure comprehensive ethical and physical safety.***

Kuali

Kuali: An Online Platform for IBC Protocol Submissions

- All new research applications for IBC review are submitted through the Kuali Research (KR) electronic submission platform: https://lsuhsc.kuali.co/
- If you are not a registered user in Kuali, you can create a user profile by following the instructions in the Kuali Quick guide ***Accessing Kuali Research***.
- Instructions for preparing and submitting initial and post-approval applications is available in the Kuali Quick guide *Creating & Submitting IBC Protocols in Kuali* that can be downloaded from the **Resources** page.



Questions?

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