The IBC

The Third "I" of Research Compliance

Northwestern

ACCR Board Monthly Lunch Series January 15, 2021

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Learning Objectives



The Three I's (IACUC, IBC, IRB)



The IBC

- Institutional Biosafety Committee
- Required by the NIH Guidelines
- Establish and implement policies that provide for the safe conduct of recombinant or synthetic nucleic acid molecule research and that ensure compliance with the *NIH Guidelines*
- Responsibilities need not be restricted to recombinant or synthetic nucleic acid molecule research

Northwestern | RESEARCH SAFETY

The mission of the Research Safety office is to help faculty, staff, students, and visitors create safe workplaces, work safely, and achieve compliance.



IBC Makeup and Training



IBC Binder, one on one with BSO

Recruiting – huge overhaul in 2018

Safety/IACUC/IRB



4 safety staff membersPI/lab staff traininginvolved in review processPI inspection history



3 Veterinarians review IACUC and IBC protocols for congruency



ABSO sits on the IRB and IBC

The IBC is Responsible For...

- Reviewing recombinant or synthetic nucleic acid molecule research conducted at or sponsored by the institution for compliance and approving compliant projects.
- > Notifying the Principal Investigator of IBC determination.
- Lowering containment levels for certain experiments involving host-vector systems.
- Setting containment levels for experiments involving whole animals, and whole plants.
- > Periodically reviewing research to ensure compliance with the NIH Guidelines.
- Adopting emergency plans covering accidental spills and personnel contamination.
- Reporting any problems with or violations of the NIH Guidelines and any research-related accidents or illnesses to the NIH OSP.
- Performing such other functions as may be delegated to the Institutional Biosafety Committee.

Purview of the IBC



All recombinant DNA laboratory research that is conducted at Northwestern University



Research utilizing regulated select agents and toxins



Protocols utilizing specific human and zoonotic pathogens in the laboratory and in facilities that house vertebrate animals



Review biosecurity for the protection of microbial agents from loss, theft, diversion, or intentional misuse



Recommend policy in the relevant areas to the Vice President.



Human gene transfer research

Northwestern

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Human gene transfer research

Northwestern

What is recombinant DNA (rDNA)?

- molecules that join nucleic acid molecules and can replicate in a living cell
- nucleic acid molecules that are chemically or synthesized or amplified, or
- molecules that result from the replication of those described in (i) or (ii) above.



The NIH Guidelines

Specify the **biosafety practices** and **containment principles** for constructing and handling:

- Recombinant nucleic acid molecules,
- > Synthetic nucleic acid molecules,
- Cells, organisms, and viruses containing such molecules.

As a condition for NIH funding such research conducted at or sponsored by the institution, **<u>irrespective of the source</u>** <u>of funding</u>, shall comply with the *NIH Guidelines*.

Sections III-A, III-B, and III-C

- Experiments that Require NIH Director Approval and Institutional Biosafety Committee Approval Before Initiation.
 - The <u>deliberate</u> transfer of a <u>drug resistance trait</u> to microorganisms that are not known to acquire the trait naturally.
- Experiments That Require NIH OSP and Institutional Biosafety Committee Approval Before Initiation
 - Deliberate formation of toxin molecules lethal for vertebrates at an LD₅₀ of less than 100 nanograms per kilogram body weight.
- Experiments Involving Human Gene Transfer that Require Institutional Biosafety Committee Approval Prior to Initiation
 - Deliberate transfer of recombinant or synthetic nucleic acid molecules, into one or more human research participants

Section III-D

Experiments that Require Institutional Biosafety Committee Approval Before Initiation

- Risk Group 2, 3, 4, or Restricted Agents as Host-Vector Systems
- DNA From Risk Group 2, 3, 4, or Restricted Agents is Cloned into Host-Vector Systems
- Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses
- Whole Animals
- > Whole Plants
- More than 10 Liters of Culture
- Influenza Viruses

Section III-E

- Experiments that Require Institutional Biosafety Committee Notice Simultaneous with Initiation.
 - Formation of rDNA Containing No More than Two-Thirds of any Eukaryotic Virus
 - Whole Plants
 - Transgenic Rodents

Section III-F

Exempt Experiments

- PCR primers, probes and products
- Mitochondrial DNA
- Bacterial plasmids
- Cloning
- Purchase/transfer/breeding of transgenic rodents

DURC

Dual Use Research of Concern

- Life sciences research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences
- Preserving the benefits of life sciences research while minimizing the risk of misuse

What is DURC?

Agents and Toxins

- Avian influenza virus (highly pathogenic)
- Bacillus anthracis
- Botulinum
- Burkholderia mallei
- Burkholderia pseudomallei
- Ebola virus
- Foot-and-mouth disease virus
- Francisella tularensis
- Marburg virus
- Reconstructed 1918 Influenza virus
- Rinderpest virus
- Toxin-producing strains of Clostridium botulinum
- Variola major virus
- Variola minor virus
- > Yersinia pestis

Categories of Experiments

- Enhances the harmful consequences of the agent or toxin
- Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
- Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
- Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
- Alters the host range or tropism of the agent or toxin
- Enhances the susceptibility of a host population to the agent or toxin
- Generates or reconstitutes an eradicated or extinct agent or toxin listed to the left

DURC Review



- Subcommittee of IBC members
- Strictly adhere to the agents and experiments outlined in USG DURC Policy
- No DURC research at Northwestern

Registering Laboratory Research

Each Principal Investigator (PI) must complete his/her safety profile in Lumen. In order to be added to Lumen, new PIs must send an email to me at ahall@northwestern.edu with following information:

- Principal Investigator's full name
- Principal Investigator's netid
- Facility Name
- Department
- Main Lab building and room number
- Main Lab phone number
- Will the PI/Facility use biological materials and/or genetically modified animals (Y/N)
- Will the PI/Facility use radioactive materials (Y/N)

Registering HGT Research

We contract to two different companies for review of our human gene transfer studies. We don't have any preference to one over the other. You can go with whichever company works best for your needs.





Protocol Review

- Electronic system LUMEN (BioRAFT)
- PI submits, RS pre-review, IBC
 - IBC members review and add comments online via LUMEN
- Ability for PI to upload supplemental documents to bio registration
 - > SOPs, experiment protocols, transport protocols
- Review 10 registrations per month
- Designated reviewers
 - ➤ 5 6 reviewers per protocol

Meetings

- Meet the fourth Wednesday of every month
- In person and videoconference
 - In person is in Evanston and Chicago
- Open to the public
 - Schedule posted on IBC website
- Serve lunch for people who attend in person
- Primary reviewer provides protocol summary and makes recommendation to committee
- Discussion and voting

Incident Reporting

- All incidents reported to research safety
- RS reviews incident reports for rDNA
- BSO gives PI NIH incident report
- IBC reviews incident at next convened meeting
- Any follow up from NIH OSP discussed at convened meeting.



Resources

- Biological Safety Program information
- Biosafety Manual and Viral Vector Toolbox are both available on the Research Safety website.
- ABSA <u>COVID-19</u> Toolbox
- rDNA and Biosafety <u>training</u> through RS.

Research Safety and COVID

- Pandemic Plan for restarting research
- Pandemic training
- Welcome back kit

PPE and Supplies Available in the Research Safety Offices

- Masks NO N95s
- Posters
- Hand sanitizer
- Disinfectant

Procurement PPE/Supplies

- Welcome kit (bag with hand sanitizer and two re-usable masks)
- Re-usable cloth mask
- Personal size hand sanitizer (4 ounces)
- Disposable three-ply surgical masks
- Office hand sanitizer pump bottle (16 ounces)
- Vinyl gloves (to be used for occasional cleaning of office work spaces, not for continuously wearing in labs)
- Disinfectant wipes
- See through masks for hearing impaired
- <u>https://www.northwestern.edu/procurement/purchasing/purchasing-strategic-sourcing/ppe-supply-ordering.html</u>

Research Safety Contact Information

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Questions?