

# The IBC at CSU

Colorado State University  
Institutional Biosafety Committee

Updated October 2021



# What are the training requirements?

- ▶ According to the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*
  - ▶ “The institution is responsible for ensuring that the PI has sufficient training” regarding laboratory safety and implementation of the NIH Guidelines.
  - ▶ “The PI is responsible for ensuring that laboratory staff are appropriately trained.”
- ▶ The CSU IBC has developed this online training course covering the implementation of the NIH Guidelines
- ▶ All PIs who work with biohazardous materials are required to complete this training; the training will be tracked in the IBC database.
  - ▶ All investigators working on an IBC project are strongly encouraged to complete this training.
- ▶ PIs at CSU are responsible for training their staff and tracking staff training. PIs will have access to download this PPT or may use their own training materials to train staff on the NIH Guidelines.

**This training does NOT fulfill the requirements for lab-specific training.**



# What are the training objectives of this course?

Understand the applicability of the NIH Guidelines for research involving recombinant or synthetic nucleic acid molecules

Understand the various types of experiments covered under the NIH Guideline, including the categories that apply to your research and level of review required

Understand the safety considerations for research involving recombinant or synthetic nucleic acid molecules (i.e., risk assessments and containment levels)

Understand the roles and responsibilities of everyone at the institution

Understand requirements for reporting incidents and accidents in the lab

Understand the CSU IBC review and approval processes and how that applies to various forms of research

Become familiar with DURC



# What are the “NIH Guidelines” and why does CSU follow them?

- ▶ The NIH Guidelines detail safety practices and containment procedures for constructing and handling\* recombinant and synthetic nucleic acid molecules (and the cells, organisms, and viruses containing such molecules), including the creation or use of genetically modified/edited organisms.
- ▶ All institutions that receive NIH funding for recombinant or synthetic nucleic acid molecules research must comply with the NIH Guidelines; *compliance with the NIH Guidelines is a mandatory term and condition of receiving NIH funding.*

Because CSU receives NIH funds for research, all work at CSU involving recombinant or synthetic nucleic acid molecules must comply with the requirements of the NIH Guidelines regardless of funding source (even if you do not have an NIH grant).

**\*Note: this applies to the USE of recombinant and synthetic nucleic acid molecules, even if someone else made it**



# “Guidelines” does not mean “optional”

Failure to comply with the NIH Guidelines could result in any of the following consequences:

- ▶ suspension, limitation, or termination of NIH funding for the noncompliant research project
- ▶ suspension, limitation, or termination of NIH funding for all recombinant research at CSU
- ▶ a requirement for prior NIH approval of any or all recombinant or synthetic nucleic acid molecule projects at CSU; in addition to local IBC approval



# What are Recombinant and Synthetic Nucleic Acid Molecules?

In the context of the NIH Guidelines, recombinant and synthetic nucleic acids molecules are defined as:

- ▶ molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell (i.e., recombinant nucleic acids),
- ▶ nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules (i.e., synthetic nucleic acids), or
- ▶ molecules that result from the replication of those described above.



# What Experiments are Covered by the NIH Guidelines?

Section III of the NIH Guidelines describes the covered experiments

- ▶ Six categories of experiments involving recombinant or synthetic nucleic acid molecules based on the risk and the level of review required (III-A, III-B, III-C, III-D, III-E, III-F)
- ▶ The term “*non-exempt*” refers to experiments that fall under sections III-A, III-B, III-C, III-D, or III-E of the Guidelines, all of which require some level of review
- ▶ Experiments that do not pose a risk to human health or the environment are “*exempt*” from the Guidelines (section III-F) and do not require review.

At CSU, all non-exempt experiments require IBC approval prior to initiation.



# Section III - Six Levels of Review

Increasing review and approval requirements, according to risk posed by experiments

Level of review	Example of recombinant DNA research	Relevant section of the <i>NIH Guidelines</i>
<b>IBC approval and NIH Director approval before initiation</b>	Experiments involving the deliberate transfer of antibiotic resistance into a pathogen, that would then compromise the use of that drug to treat the disease.	<u><b>III-A</b></u>
<b>IBC and NIH/OSP approval before initiation</b>	Experiments involving the cloning of toxin molecules lethal for vertebrates at an LD50 of less than 100 ng per kg body weight (e.g., such as the botulinum toxins, tetanus toxin, diphtheria toxin, and Shigella dysenteriae neurotoxin).	<u><b>III-B</b></u>
<b>IBC and IRB approval and NExTRAC Review (if applicable) before research participant enrollment</b>	Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA Derived from recombinant or synthetic nucleic acid molecules into a human research participant (i.e., human gene transfer)	<u><b>III-C</b></u>
<b>IBC approval before initiation</b>	Experiments that are typically be conducted at BSL2 or higher	<u><b>III-D*</b></u>
<b>IBC notice at initiation</b> <i>(IBC approval before initiation at CSU)</i>	Often a 'catch-all' category for experiments that can be conducted at BSL1	<u><b>III-E*</b></u>
<b>Exempt from the <i>NIH Guidelines</i> (IBC approval not required)</b>	Experiments that do not pose a risk to human health or the environment; most standard cloning	<u><b>III-F*</b></u>

**\*The majority of recombinant DNA research conducted at CSU falls under categories III-D, III-E, and III-F; more details/examples on subsequent slides**



# Section III-D Experiments

## Require IBC approval before starting

- ▶ III-D-1: Putting DNA/RNA into risk group 2, 3, or 4 organisms (i.e., using risk group 2, 3, or 4 organisms as host-vector systems)
- ▶ III-D-2: Cloning DNA/RNA from risk group 2, 3, or 4 organisms into nonpathogenic prokaryotic or lower eukaryotic host-vector systems
- ▶ III-D-3: Use of viral vectors (including replication deficient vectors), infectious DNA or RNA viruses, or defective DNA or RNA viruses in the presence of helper virus in tissue culture systems
- ▶ III-D-4\*: Experiments involving whole animals
- ▶ III-D-5\*: Experiments involving whole plants or algae that require BL2-P or higher containment
- ▶ III-D-6: Experiments involving large scale (>10 L) of culture organisms containing recombinant or synthetic nucleic acid molecules (refer to Appendix K for containment requirements)
- ▶ III-D-7: Experiments involving influenza viruses (influenza viruses generated by recombinant or synthetic methods such as generation by reverse genetics to produce re-assorted viruses or introduction of specific mutations)

\*More on animals and plants later

## Examples

Expressing genes from *M. tuberculosis* in any *E. coli* strain

Testing a live recombinant vaccine in mice

Using CRISPR-Cas9 to create transgenic mosquitos

Using a genetically modified pathogen purchased from ATCC

Putting any viral vector into a cell line or animal

Breeding transgenic zebrafish

Cloning GFP plasmid into *P. aeruginosa*

Injecting modified HeLa cells into rats



# Section III-E Experiments

## Require IBC approval before starting

- ▶ Somewhat of a catch-all category; includes experiments not included in III-A through III-D or III-F that can be conducted at BSL-1
- ▶ Involves RG1 organisms
  - ▶ III-E-1: The use of  $\leq 2/3$  eukaryotic viral genome in cell culture
  - ▶ III-E-2: Experiments involving whole plants or algae for which BSL1-P containment is appropriate
  - ▶ III-E-3: Generation of new transgenic strains of rodents that can be housed at BSL-1 containment

## Examples

Expressing human or RG1 genes in *E. coli* BL21

Creating AAV vectors

Using CRISPR-Cas9 to edit genes in wheat

Modifying Arabidopsis

Creating new transgenic mice requiring only BSL1



# A Note About Gene Editing...

IBC approval is required if your gene editing experiments involve *any* of the following:

- ▶ A viral vector
- ▶ Editing a pathogen's genome
- ▶ Editing an animal's genome
- ▶ Editing a plant's genome
- ▶ Putting gene edited materials into an animal
- ▶ Putting gene edited materials into a plant



# Exempt Experiments: Section III-F and Appendix C

## Exempt from the NIH Guidelines; do not require IBC approval

- ▶ Recombinant or synthetic nucleic acid molecules that
  - ▶ Are not contained in organisms, cells, or viruses and cannot penetrate cell membranes (e.g., encapsulated into synthetic or natural vehicles),
  - ▶ Can neither replicate nor generate nucleic acids that can replicate in any living cell,
  - ▶ Are not designed to integrate into DNA,
  - ▶ Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100ng/kg body weight,
  - ▶ Are from a single source as it exists in nature
  - ▶ Are from multiple sources known to exchange DNA
- ▶ Purchase, transfer, breeding of transgenic rodents
- ▶ Some uses of model systems, such as cell culture, E. coli K12 strains and yeast (see Appendix C for full description)

## Examples

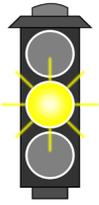
The purchase of transgenic mice that can be housed at BSL-1

Gene editing in cell lines by plasmid or ribonucleoprotein complex mediated CRISPR-Cas9

Amplification of DNA by PCR

Expressing human or RG1 genes in E. coli K12





# There are Several Exceptions to the Exemptions

**Any of the following exceptions may disqualify your work from category III-F, and would therefore require IBC approval**

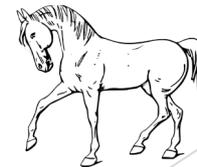
- ▶ If an experiment falls under Sections III-A, III-B, or III-C and also III-F, then the research is not exempt
- ▶ Using DNA from RG3 or 4 organisms or cells known to be infected with these agents
- ▶ Use of genes that encode molecules toxic to vertebrates
- ▶ Large scale experiments (>10 L of volume in a single culture vessel)
- ▶ Using an E. coli strain that is not derived from K12
  - ▶ E.g., E. coli BL21 is not exempt; either III-E or III-D would apply

**You should consult with the IBC if you are uncertain whether or not your research is exempt**





# Recombinant or Synthetic Nucleic Acid Molecules Research Involving Animals



# Section III-D-4: Experiments Involving Animals

- ▶ Experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals (including rodents, arthropods, etc.), including:
  - ▶ Genetically modified or attenuated bacteria, viruses, or cells which are put into an animal
  - ▶ Pre-clinical studies and data assessment for human gene transfer protocols
  - ▶ Veterinary clinical studies
    - ▶ These studies require additional approval from FDA-CVM or USDA
- ▶ A minimum containment of BSL2/ABSL2 is typically required
- ▶ **IBC and IACUC approval is required prior to initiation**



# Section III-D-4: Experiments Involving Animals (other than rodents)

- ▶ Experiments in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germline (i.e., transgenic animals)
- ▶ Applies to all transgenic animals, regardless of the technology used to create them, (including but not limited to, arthropods and zebrafish), and includes the following:
  - ▶ The generation of gene-edited, knock-out, or transgenic animals
  - ▶ The use of gene-edited, knock-out, or transgenic animals, regardless of where they were made
  - ▶ The purchase or transfer of gene-edited, knock-out, or transgenic animals
  - ▶ Any breeding of transgenic animals
- ▶ A minimum containment of BSL2/ABSL2 is typically required
- ▶ **IBC and IACUC approval is required prior to initiation**



# Section III-E-3: Experiments Involving Transgenic Rodents

- ▶ Experiments in which the rodent's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (i.e., transgenic), regardless of the technology used, and includes the following:
  - ▶ The generation of gene-edited, knock-out, or transgenic rodents
  - ▶ Breeding of transgenic or knock-out rodents to generate new strains
- ▶ Only applies to experiments that require BSL1/ABSL1 containment; experiments that require BSL2, BSL3, or BSL4 containment would fall under Section III-D-4
- ▶ **IBC and IACUC approval is required prior to initiation**



# Exempt Experiments Involving Transgenic Rodents

- ▶ Under Section III-F, and Appendix C-VII and C-VIII, certain uses of transgenic rodents are exempt from the NIH Guidelines
  - ▶ The purchase, transfer, or use of gene-edited, knock-out, or transgenic rodents, providing the experimental protocol does not involve the use of recombinant or synthetic nucleic acid molecules.
  - ▶ Breeding of transgenic or knock-out rodents for colony maintenance
  - ▶ Breeding of certain transgenic or knock-out rodents to generate new strains (see Appx C-VIII for details)
- ▶ Only applies to experiments that require BSL1/ABSL1 containment; experiments that require BSL2, BSL3, or BSL4 containment would fall under Section III-D-4
- ▶ **IACUC approval is required prior to initiation; no IBC approval required**



# Containment for Research Involving Animals

Containment, confinement, and decontamination practices for research involving whole animals are described in:

- ▶ Appendix G - Physical Containment
  - ▶ Applies to small laboratory animals such as, rodents, cats, dogs, arthropods, zebrafish, etc.
- ▶ Appendix M - Physical and Biological Containment Large Animals
  - ▶ Applies when research animals are of a size or have growth requirements that prevent the use of standard laboratory animal containment. Including but not limited to cattle, swine, sheep, goats, horses, and poultry.
  - ▶ When applicable, Appendix M supersedes Appendix G

The NIH Guidelines requires all liquid and solid waste containing recombinant or synthetic nucleic acid molecules from laboratories and animal rooms be appropriately decontaminated before disposal. This includes animal carcasses, bedding, and animal waste.



# Recombinant or Synthetic Nucleic Acid Molecules Research Involving Plants



# Sections III-D-5: Experiments Involving Plants

- ▶ Generation or use of transgenic plants (including algae) that involve noxious weeds, infectious agents, biological toxin, or pose some other type of threat
  - ▶ Genetically engineered by rDNA, synthetic biology or gene editing methods
  - ▶ Plants used together with microorganisms or insects that contain recombinant or synthetic nucleic acid molecules
  - ▶ Has a recognized potential for serious detrimental impact on managed or natural ecosystems
- ▶ Generally require BL2-P\* or greater containment
- ▶ Field studies require additional approval from the USDA
- ▶ **IBC approval is required prior to initiation**



# Section III-E-2: Experiments Involving Plants

- ▶ Generation or use of transgenic plants (including algae) that have *no* recognized potential to impact on managed or natural ecosystems
  - ▶ Genetically engineered by rDNA, synthetic biology or gene editing methods
  - ▶ Are not noxious weeds and will not hybridize with noxious weeds
  - ▶ Do not involve infectious agents
- ▶ Not covered in Section III-A, III-B, III-D, or III-F
- ▶ BL1-P\* containment is appropriate
- ▶ Field studies require additional approval from the USDA
- ▶ **IBC approval is required prior to initiation**



# Physical and Biological Containment for Plants - Appendix L

- ▶ Specifies physical and biological containment conditions and practices suitable to the greenhouse conduct of experiments involving recombinant or synthetic nucleic acid molecule-containing plants, plant-associated microorganisms, and small animals.
- ▶ Appendix L supersedes Appendix G (*Physical Containment*)
  - ▶ This applies when the research plants are of a size, number, or have growth requirements that prevent the use of standard laboratory containment. Including, but are not limited to, mosses, liverworts, macroscopic algae, and vascular plants including terrestrial crops, forest, and ornamental species.

The NIH Guidelines requires all liquid and solid waste containing recombinant or synthetic nucleic acid molecules from laboratories and greenhouses be appropriately decontaminated before disposal. This includes seeds, soil, and plants.



# Are there additional types of biohazards that require IBC approval at CSU?

In addition to non-exempt recombinant DNA/synthetic nucleic acid molecules, PIs must also obtain IBC approval prior to commencing research/teaching utilizing:

- ▶ Infectious agents requiring handling at BSL1-BSL3\* (applies to animal, human, and plant infectious agents)
  - ▶ \*CSU does not have a BSL4 facility
- ▶ Human and non-human primate blood and blood products, body fluids, tissues, and/or primary cells
- ▶ Biological toxins (including Botox)



# What are the Safety Considerations for Conducting Research with Recombinant or Synthetic Nucleic Acid Molecules?

Section II of the NIH Guidelines describes the process for conducting a *risk assessment* and determining *containment*

- ▶ **RISK ASSESSMENT** is a process used to identify the hazardous characteristics of a known infectious or potentially infectious agent or material, the activities that can result in a person's exposure to an agent, the likelihood that such exposure will cause a lab acquired infection (LAI), and the probable consequences of such an infection. The information identified by risk assessment provide a guide for the selection of appropriate **CONTAINMENT**.

The PI is responsible for conducting an initial risk assessment and proposing appropriate microbiological practices and containment for their research.



# Risk Assessment

## Steps for conducting a risk assessment

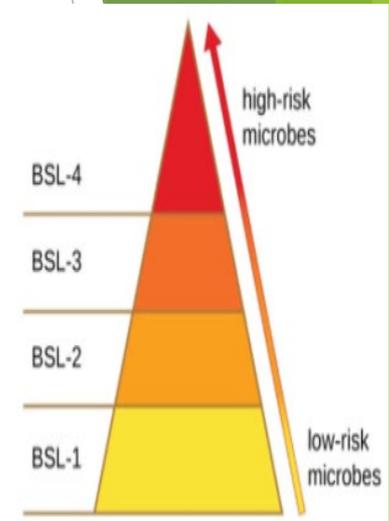
- ▶ Determine the risk group\* (RG) of the agent - Appendix B of the NIH Guidelines
- ▶ Evaluate agent factors
  - ▶ Virulence, pathogenicity, infectious dose, environmental stability, route of transmission, host range, impact of genetic modification, volumes handled, treatment/vaccine options, potential consequences of exposure
- ▶ What type of manipulations are planned?
  - ▶ Does the procedure generate aerosol?
  - ▶ Will sharps be used?
  - ▶ Will large volumes and/or concentrations be produced?
  - ▶ Will live animals or plants be utilized?

\*Described in detail in the BSL1/BSL2 Training Module



# Containment

- ▶ Physical Containment (physical barrier of protection)
  - ▶ Biosafety Level (BSL1-BSL4)\* - a variable comparative descriptor of the lab facility safeguards, safety equipment, and microbiological practices that serve to “contain” a microorganism, and to ensure the safe use of that organism, while it is being handled.
  - ▶ The recommended BSL is based on risk assessment and technical judgment and may change depending on how the agent is used.
  - ▶ Examples of physical containment
    - ▶ Personal Protective Equipment (PPE)
    - ▶ Biological Safety Cabinet



\*Described in detail in the BSL1/BSL2 Training Module, Appendix G, and the BMBL



# Containment

Biological Containment (natural/biological barriers of protection - Appendix I)

- ▶ When considering biological containment, the vector (plasmid, organelle, or virus) for the recombinant or synthetic nucleic acid molecule and the host (bacterial, plant, or animal cell) in which the vector is propagated in the laboratory should be considered together.
- ▶ Certain combinations of vector and host minimize the following types of "escape":
  - ▶ Survival of the vector in its host outside the laboratory
  - ▶ Transmission of the vector from the propagation host to other non-laboratory hosts.
- ▶ Examples of biological containment
  - ▶ A vector genetically designed to be replication defective outside of host
  - ▶ Separating Cas9 and guide RNAs so they are not encoded in the same organism
  - ▶ Working with genetically modified rice pathogens in a geographical location where rice cannot survive outside the lab.



# What are the Roles and Responsibilities Under the NIH Guidelines?

**Section IV details the roles and responsibilities for compliance with the NIH Guidelines**

- ▶ Institution (CSU)
- ▶ Institutional Biosafety Committee (IBC)
- ▶ Biological Safety Officer (BSO)
- ▶ Principal Investigator (PI)
- ▶ Researcher



# Institutional Responsibilities

- ▶ Establish and implement policies for the **safe conduct** of research subject to the NIH Guidelines
- ▶ Establish an Institutional Biosafety Committee (IBC)
- ▶ **Ensure compliance** with the NIH Guidelines by investigators
- ▶ Ensure appropriate **training** for IBC members and staff, PIs, and laboratory staff
- ▶ Determine the need for **medical surveillance** of personnel
- ▶ **Report** any significant accidents, incidents, or violations to the NIH Guidelines to NIH Office of Science Policy (OSP)



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# IBC Responsibilities

- ▶ Provide local review and oversight of research utilizing recombinant or synthetic nucleic acid molecules, and to ensure that such research is in compliance with the NIH Guidelines
  - ▶ Assess potential risk to human health and environment
  - ▶ Evaluate containment levels per NIH Guidelines
  - ▶ Determine adequacy of facilities, SOPs, PI and lab personnel training and expertise
- ▶ Ensure institutional and investigator compliance
- ▶ Periodically review use of rDNA or synthetic nucleic acid molecules for compliance
- ▶ Adopt emergency plans covering spills, contamination, other accidents



# IBC Responsibilities

At CSU, the IBC is also responsible for reviewing and approving research utilizing:

- ▶ Infectious agents requiring handling at BSL1-BSL3\* (applies to animal, human, and plant infectious agents)
  - ▶ \*CSU does not have a BSL4 facility
- ▶ Human and non-human primate blood and blood products, body fluids, tissues, and/or primary cells
- ▶ Biological toxins (including Botox)

All IBC reviews are conducted in accordance with the criteria outlined in the most current versions of the

- ▶ *NIH Guidelines*
- ▶ *Biosafety in Microbiological and Biomedical Laboratories (BMBL)*
- ▶ Select Agent regulations (42 CFR Part 73, 7 CFR Part 331, 9 CFR Part 121),
- ▶ Pertinent federal and state regulations, and university rules and procedures



# Biosafety Officer Responsibilities



- ▶ Provides technical advice to PIs and the IBC on research safety procedures, including
  - ▶ Assistance with risk assessments and containment procedures
  - ▶ Recommendations for personal protective equipment
  - ▶ Procedures for disposal of waste
  - ▶ Decontamination of laboratory and equipment
  - ▶ Accidents (emergency plans and response)
- ▶ Conduct periodic inspection of labs
- ▶ Report any problems, violations, research-related accidents or illnesses to the IBC and institution
- ▶ Develop emergency plans for handling accidental spills and personnel contamination
- ▶ Advice on lab security



# PI Responsibilities

- ▶ Understand and fully comply with the NIH Guidelines and institutional policies
- ▶ Get IBC approval before *initiating or modifying* research involving rDNA or synthetic nucleic acid molecule, or any other biohazardous materials under the IBC purview
  - ▶ Determine which sections of the NIH Guidelines your work falls under
  - ▶ Perform the initial risk assessment for the work
  - ▶ Be proficient in good microbiological techniques
  - ▶ Maintain accurate/up-to-date IBC documents
- ▶ Supervise laboratory staff
  - ▶ Adhere to all approval conditions required by the IBC
  - ▶ Correct work errors and conditions that may result in the release of biohazardous materials, including rDNA
  - ▶ Ensure the integrity of containment
  - ▶ Ensure proper PPE accessible for laboratory staff
- ▶ Notify lab animal/greenhouse staff prior to starting infectious or recombinant work within lab animal/greenhouse facilities



# PI Responsibilities

- ▶ **Immediately report** all research related illnesses, accidents, incidents, and violations of the NIH Guidelines to the BSO and IBC, and Greenhouse/Animal Facility Director (where applicable)
- ▶ Comply with permit and shipping requirements
  - ▶ See the CSU IBC Policy webpage (<https://vpr.colostate.edu/ricro/ibc/policies/>)
- ▶ Ensure laboratory staff
  - ▶ Understand risks associated with the work
  - ▶ Are provided lab-specific training
  - ▶ Understand and follow specified safety practices, PPE and containment procedures
  - ▶ Understand and follow procedures for dealing with accidents, incidents, and/or spills
  - ▶ Enroll in the Occupational Health Program

Even though these are the responsibilities outlined in the NIH Guidelines, it is the expectation that they be carried out for *all* research involving biohazardous materials.



# Researcher Responsibilities



All persons involved in biologically hazardous activity share biosafety responsibility, and must

- ▶ Follow all established safety procedures and institutional policies
- ▶ Be familiar with the NIH Guidelines and the responsibilities of their PI
- ▶ Complete all required biosafety and lab specific training prior to working with biological materials
- ▶ **Immediately report** all research related illnesses, accidents, incidents, and violations of the NIH Guidelines to the PI, BSO and IBC, and Greenhouse/Animal Facility Director (where applicable)
- ▶ Keep supervisor informed of
  - ▶ Changes to the research and/or unexpected outcomes that may change the risk assessment of the work
  - ▶ Any personal condition which could make the work more hazardous to themselves or others



# How Do I Obtain IBC Approval at CSU?

There are two IBC approval forms

## Agent Approval Request Form (AARF)

- ▶ Required for each infectious agent (genus species) a PI has in their possession (regardless of risk group or BSL); includes agents/collections in storage only
- ▶ Requests information specific to the agent (such as, risk group, pathogenicity, vaccinations, and inactivation of the agent)
- ▶ Only gives approval to possess the agent (a PARF is required to work with the agent)

## Project Approval Request Form (PARF)

- ▶ Required for each project that involves one or more of the biohazardous materials under the IBC purview
- ▶ Requests project specific information (i.e., who is doing what, where, and how?), including PPE
- ▶ Must be renewed/updated annually
- ▶ Each PARF is assigned a unique number which is required by Sponsored Programs in order to release funds

AARFs and PARRs are filled out and submitted through IBC Online Database:

<https://protocols.research.colostate.edu/rco/>



# How will I be notified of the IBC review outcome?

## ▶ Notification of IBC review outcome

- ▶ Following IBC review, the PI (and delegate) will receive an email from the IBC Coordinator with the subject line
  - ▶ IBC Review Notice: PI name - AARF name
  - ▶ IBC Review Notice: PI name - PARF title
- ▶ There are four possible outcomes (Approved as submitted; Modifications required; Tabled; Denied)

Note of caution: These emails are automatically generated from the database and they sometimes end up in junk mail. Be sure to check junk mail or set up a rule in your email account, so that these important notifications are not lost.

## ▶ Responding to IBC review outcome

- ▶ If the IBC requests modifications/additional information, the PI should reply directly to email notification with their responses; the IBC Coordinator will make edits to the form
- ▶ Once an application has been reviewed by the IBC, the PI is not able to edit the form directly



# When can I expect to receive my IBC approval?

- ▶ The IBC meets every 2<sup>nd</sup> Wednesday of the month
- ▶ Applications are due by NOON on the 1st Wednesday of each month; late applications will be reviewed the following month
- ▶ PARFs involving recombinant DNA and/or synthetic nucleic acids that fall under the NIH Guidelines must be reviewed by the full IBC at a convened meeting
- ▶ Certain low-risk applications that do NOT involve recombinant DNA and/or synthetic nucleic acids may be reviewed by designed review
- ▶ Average days to approval
  - ▶ Full IBC = 15 business days
  - ▶ Designated review = 13 business days



# Who is the IBC at CSU?

- ▶ A faculty-governed committee
- ▶ Constituted in accordance with the NIH Guidelines
- ▶ Made up of faculty, staff, and community members\*
  - ▶ \*NIH Guidelines requires at least two members which are not affiliated with the institution to represent the interest of the surrounding community with respect to health and protection of the environment
- ▶ Collectively have experience and expertise in the relevant research areas of review, including biological safety and physical containment
  - ▶ Multiple departments represented; for the full IBC roster, contact the IBC Coordinator
- ▶ Members are appointed by the Vice President for Research (VPR) for three-year terms and may be reappointed. The IBC reports to and is advisory to the VPR and recommends actions necessary to maintain and/or improve biosafety.
- ▶ IBC Coordinator
  - ▶ Liaison between investigators and the IBC
  - ▶ Assists researchers with the IBC review process
  - ▶ Notifies investigators of IBC review outcome
  - ▶ Ensures committee operations comply with federal and state regulations



# Are there special considerations for the IBC?

## DURC: Dual Use Research of Concern

- ▶ Because CSU receives federal funding for life sciences research, *all* CSU researchers must comply with the *2014 USG Policy for Institutional Oversight of DURC*
- ▶ Non-compliance could result in suspension, limitation, or termination of federal funding, or loss of future federal funding opportunities for all life sciences research at CSU
- ▶ The [CSU DURC Policy](#) provides more details on DURC oversight at CSU
- ▶ An Institutional Review Entity (IRE) has been established to review research at CSU with DURC potential
- ▶ *Anyone* who works with *any* of the 15 “DURC” agents (listed on next slide), must complete the DURC Training Module
- ▶ If you are the primary PI on a sub-award and any portion of the subrecipient’s proposed work involves the use of one or more of the 15 DURC agents, you need to contact the CSU IRE.
- ▶ Several tools and resources have been developed to assist investigators in assessing their work for DURC potential; these are available on the CSU/IBC website.

***Very few research activities at CSU qualify as DURC under the USG definition!***



# What are the DURC agents?

The following 15 high-consequence pathogens and toxins have been identified by the USG Policy as having the greatest DURC potential

- ▶ Avian influenza virus (highly pathogenic)
- ▶ Bacillus anthracis
- ▶ Botulinum neurotoxin (*in any quantity; including BoTox*)
- ▶ 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



# IBC Resources and Contacts



# How can the IBC, BSO, and IBC Coordinator help you?

- ▶ Ensure that you are working with infectious agents, human samples, rDNA or synthetic nucleic acid molecules, and biological toxins safely
- ▶ Meet all compliance requirements associated with NIH funding for research involving rDNA or synthetic nucleic acid molecule
- ▶ Meet all compliance requirements associated CSU
- ▶ Avoid preventable accidents and incidents that might cause harm or undermine public confidence in your research activities



# IBC Contacts

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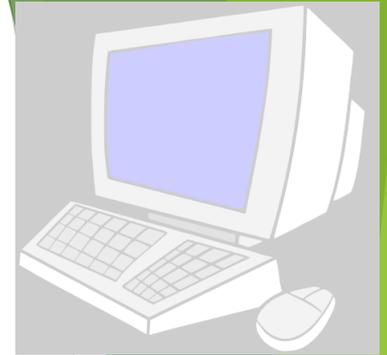
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# Web Resources



- ▶ **Download a copy of this training here:**  
<https://vpr.colostate.edu/ricro/ibc/ibc-training-and-tutorials/>
- ▶ **CSU IBC website** <https://vpr.colostate.edu/ricro/ibc/>
  - ▶ CSU IBC polices, tutorials, and FAQs
- ▶ **NIH Guidelines for Research Involving Recombinant DNA Molecules**  
[https://osp.od.nih.gov/wp-content/uploads/2019\\_NIH\\_Guidelines.htm](https://osp.od.nih.gov/wp-content/uploads/2019_NIH_Guidelines.htm)
- ▶ **Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th Edition**  
<https://www.cdc.gov/biosafety/publications/bmbl5/>
- ▶ **National Select Agent Registry** <http://www.selectagents.gov/>
  - ▶ **Select Agent and Toxins list**  
<https://www.selectagents.gov/selectagentsandtoxinslist.html>
- ▶ **Department of Health and Human Services (DHHS) general information on the USG Dual Use Research Policy**  
<https://www.phe.gov/s3/dualuse/Pages/default.aspx>
- ▶ **ABSA International (ABSA)**
  - ▶ **Risk group database:** <https://my.absa.org/tiki-index.php?page=Riskgroups>



# PI Verification of Training

- ▶ I acknowledge that I have read and understand the IBC training module.
- ▶ I didn't quite get it and would like to review the training one more time.

