Tips for Successful Completion of your IBC Protocol Form

This document is intended to serve as a guide and help you navigate the questions in the IBC Protocol Form that require more details or specific details. Tips are not given for each item. If you have any questions while completing this form, please contact the Office of Biosafety (OBS) by calling 706-542-2697 or emailing ibc@uga.edu.

Front Page- The signatures of the PI and Department Head will be required before the protocol can be approved. If the signatures cannot be obtained prior to submission, this page can be provided during the review process.

Key Personnel-

List all personnel involved in this protocol, including the PI. For each person, provide:

- Highest degree obtained
- Experimental duties
- Brief description of relevant laboratory experience (including years of training)

See the example below. If additional information is needed to clarify roles or training, you can add it in a separate appendix (Word document).

Example:
Name: Dr. Jane Doe
Highest Degree: Ph.D.
Experimental Duties: Preparation of diphtheria toxin dilution, animal injections, sample collection.
Relevant Laboratory Experience: 10 years of experience in microbiology research, including 5 years working with bacterial toxins.

Additional information on specific training requirements for personnel:

- A *Proficiency in Standard and Special Microbiological Practices* form must be filled-out for each person working in the laboratory, whether they are listed on this protocol or not. This is a one-time request for each person**. This form should only be filled out and submitted by the PI or lab manager once lab personnel have demonstrated proficiency in daily work practices in the laboratory**. This form will need to be submitted for any personnel who join the lab later.
- PIs performing recombinant DNA work must complete the NIH Guidelines training before you can receive your IBC approval. The NIH requires PIs that conduct research involving rDNA to receive training on the NIH Guidelines. This training can be found on UGA's PEP.
    - Log in and go to Browse Training.
    - In the search box, search for "UGA NIH Guidelines for Recombinant or Synthetic Nucleic Acid Molecules" and select the title.
    - Next, select Launch and the PowerPoint will download in a new window. Read through the slides – there is no test.
    - Once complete, close the PowerPoint, go to Transcripts and mark Completed. Print out or download the certificate for your records. This training only needs to be completed once, regardless of the number of active protocols involving rDNA you may have.
- Personnel using human materials or NHP materials in the lab and/or animal room are required to take UGA's Right to Know: Bloodborne Pathogens Training at least once per year. This training can be found on UGA's PEP.
- **Working with NHPs or NHP materials requires further special training.** In addition to completion of the Proficiency for Standard and Special Microbiological Practices form and UGA Right to Know: Bloodborne Pathogen Training, lab personnel must complete the following:
    - Enrollment in the Research-Occupational Health and Safety Program
    - Documented Agent-Specific B virus training
    - BSL-2 Curriculum online training module (available on UGA's PEP)
    - Hands-on BSC training is strongly recommended
- Transportation of infected animals and biohazard material on public roads must comply with DOT regulations for transporting dangerous goods. Personnel involved in such transportation must be trained, tested, certified, and retain a record (electronic or paper) of the training. Please contact the Office of Biosafety to schedule this training.

Please note that when required, these training courses are a component of the approval process and failure to respond to these requirements will delay the approval process.

Non-Technical Synopsis-

This section provides a clear and concise overview of the project for a general audience.

- What are we trying to achieve? Explain the overall goal in simple terms.
- What will we be working with? Describe the organisms and materials involved.
- What do we expect to learn? Outline the anticipated outcomes.
- Why is this research important? Highlight the potential benefits for humans, animals, agriculture, etc.

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Biosafety

Tips for Successful Completion of your IBC Protocol Form

Examples:

Overall Goal:

- Understand how a specific disease works (e.g., how malaria invades red blood cells)
- Develop a new vaccine or treatment for a particular illness (e.g., creating a vaccine to prevent mosquito-borne diseases)
- Improve crop yields or resistance to pests (e.g., studying the effects of bacteria on plant growth)

Organisms and Materials:

- Bacteria, viruses, insects (e.g., studying mosquitoes that transmit diseases)
- Animal models (e.g., using mice to understand how a disease affects the body)
- Plant cells, tissues, or whole plants (e.g., researching how to improve crop resistance to drought)

Expected Outcomes:

- Identify new targets for drugs or vaccines
- Develop new methods for disease diagnosis or treatment
- Gain a deeper understanding of how organisms interact with each other or their environment

By following this format and using clear, non-technical language, you can create a compelling synopsis that effectively communicates the importance of your research to a general audience.

Technical Synopsis

This section provides a detailed description of the experiments, with a focus on biohazardous material use and handling. A step-by-step breakdown of the procedures will aid the Committee's review process.

Project Locations:

- Specify where each procedure will be conducted (e.g., lab, animal facility, insectary).
- If samples are transported between laboratory locations, provide method(s) of transportation for biological materials (infectious agents, infected animals, infected carcasses, biological waste, recombinant material, etc.)
    - Please note that transportation of biohazard material on public roads must comply with DOT regulations for transporting dangerous goods. Personnel involved in such transportation must be trained, tested, certified, and retain (electronic or paper) a record of the training. UGA policy mandates the use of state or university owned vehicles.

Biosafety Levels: If multiple containment levels are involved (e.g., BSL-1, BSL-2, BSL-3, ABSL-1, ABSL-2), clearly indicate which parts of the project will be performed at each level.

Experimental Procedures:

- Describe all in vitro (cell culture) and/or in vivo (animal studies) procedures.
- Specify the maximum volumes and titers of cultures grown at any given time.
- Identify any procedures that may create a splash or aerosol hazard and outline the corresponding risk mitigation strategies.

Biohazardous Materials:

- Provide detailed information on the use and handling of all biohazardous materials, including:
    - Type of agent (e.g., bacteria, virus)
    - Strain/serotype
    - Risk group classification

By incorporating these elements and maintaining a clear, step-by-step approach, you can create a comprehensive technical synopsis that effectively communicates the project's methodology and biosafety considerations.

Part A, Questions #1-4- Complete this section for use of transgenic animals and/or transgenic insects (such as fruit flies, mosquitoes, etc.).

Part B, Question #5- As the PI, you will need to identify the sections of the NIH Guidelines that apply to this work. Below is a guide you can refer to in order to help you determine applicable guidelines (please note that this guide is not comprehensive, and the PI is responsible for providing the appropriate guidelines for their work). Most of the recombinant work at UGA falls into categories III-D, III-E, and III-F of the NIH Guidelines.

Please note that the NIH Guidelines were updated in April 2024. They can be accessed at the NIH's Office of Science Policy website , or by this direct link.

Experiments	Section
Experiments involving the deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally *	III-A
Experiments involving the cloning of toxin molecules with LD50 of <100 nanograms per kilogram body weight *	III-B
Experiments involving the deliberate transfer of recombinant or synthetic nucleic acid molecules into human research participants *	III-C
Experiments using Risk Groups 2, 3, 4, or Restricted Agents as Host-Vector Systems	III-D-1
Experiments in which DNA form Risk Groups 2, 3, 4, or Restricted Agents is cloned into nonpathogenic E. coli or lower eukaryotic host-vector systems	III-D-2

UNIVERSITY OF GEORGIA
Office of Research
Biosafety

Tips for Successful Completion of your IBC Protocol Form

Experiments involving the use of infectious DNA or RNA viruses or defective DNA or RNA presence of helper virus in tissue culture systems	III-D-3
Experiments involving whole animals (including transgenic animals)	III-D-4
Experiments involving whole plants (including transgenic plants)	III-D-5 and/or III-E-2
Experiments involving more than 10 liters of culture	III-D-6
Experiments involving influenza viruses	III-D-7
Experiments involving gene drive modified organisms	III-D-8
Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds the genome of any eukaryotic virus	III-E-1
Experiments involving the generation of transgenic rodents	III-E-3
Exempt experiments**	III-F

** These experiments require NIH approval prior to initiation (in addition to IBC approval).*

*** Experiments considered to be exempt under the NIH Guidelines still require submission of an IBC protocol for review. See the NIH Guidelines for examples of exempt experiments.*

Part B, Question #7- Provide some detail on the specific genes being cloned. If certain genes have not yet been identified or selected, please indicate that a list of genes to be cloned will be provided to the IBC as they are identified. See the example below.

Example:
For transformation of plant pathogens, the inserted DNA sequences contain 20-nt DNA fragments from Phytophthora palmivora or Phytophthora capsici, Cas9 coding region derived from Streptococcus pyogenes, promoter and terminators from Phytophthora sojae and Bremia lactucae, and NPTII gene from Escherichia coli. For transformation of plants, the inserted DNA sequences contain 20-nt DNA fragments from Cucurbita pepo, Cas9 coding region derived from Streptococcus pyogenes, promoter and terminators from Arabidopsis thaliana and Cauliflower mosaic virus, and NPTII gene from Escherichia coli. The lists of genes to be knocked out from the pathogens or plants will be submitted as an addendum once candidate gene lists are available.

Part B, Question #8- If you are using *E. coli* or a similar organism for plasmid expression, make sure to add that here and please specify strain(s). Other types of recipients include plants, animals, cell culture (including human or non-human primate cell lines), etc.

Part B, Question #9- List vectors/plasmids to be used- please list the function of each vector system. Vector/plasmid maps should also be provided with your submission (in a common file format such as PDF, JPG, DOCX, etc.). Please do not provide links for vector maps.

Example:
pET30a vector will be used for E. coil (DH5-alpha) replication, and insertion deletion mutagenesis in S. pneumoniae. Vector provides KanR2 gene for kanamycin resistance and allows genetic disruption of inserted gene fragments.

Part B, Question #11- If a USDA-APHIS permit is required for this work, please indicate so here and provide the permit number. A copy of the permit should also be provided with your submission. If no USDA-APHIS permit is needed for this work, please type "N/A" in the permit number box. (This also applies for question #17.)

Part C, Question #13- If a CDC permit is required for this work, please provide the permit number. A copy of the permit should also be provided with your submission. If no CDC permit is needed for this work, please type "N/A" in the permit number box.

Part C, Question #14- To ensure that the Committee can perform a risk assessment of your work, the following characteristics should be provided for each infectious agent that will be used in this project:

- Pathogenicity: Can the agent cause disease, and if so, in what species? Identify whether there are any particularly vulnerable populations (e.g., immunocompromised individuals, pregnant women, etc.). If there are any vulnerable populations, identify any specific precautions they will take to mitigate exposure risk in the lab.

- Virulence factor: What are the symptoms and severity of the disease caused by the agent?

- Stability of agent in the environment: Is the agent difficult to neutralize with autoclaving or certain disinfectants? Does it have characteristics that may make it more able to persist in the lab or environment (such as the ability to form spores)?

- Mode of transmission in laboratory/animal workers: What types of procedures in the lab/animal room could result in potential exposure? (e.g., pipetting, animal bite, etc.) Please be very specific to the procedures in this project.

  Please see some examples of procedures in the lab and animal room that generate aerosol:

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Tips for Successful Completion of your IBC Protocol Form

Examples of aerosol- or splash-generating procedures:

- Pipetting
- Centrifuging steps (including loading & unloading containers)
- Opening "pop-top" or "flip top" style tubes
- Pouring liquids
- Vacuum aspiration
- Flaming loops or slides
- Using equipment designed to agitate materials such as shakers, sonicators, vortexers, grinders, blenders, and stomachers
- Filling a syringe, pulling a needle from a rubber stopper/septum
- Removing stoppers/septa from containers
- Harvesting infected material from animals, eggs, and other virology procedures
- Performing necropsies
- Changing animal caging/bedding

Part D, Question #18- Select any biosafety levels that will be used in your lab and any other research facilities like animal facilities or greenhouses.

The guide below can be used to help determine which categories of biosafety levels you may need to use in your work.

For work with recombinant DNA and/or transgenic organisms:	Select a biosafety level in this section if your project includes:
rDNA Biosafety Level (BL1, BL2, BL3)	Recombinant/synthetic nucleic acid molecule research or production
rDNA Animal Biosafety Level (BL1-N, BL2-N, BL3-N)	Whole animals who have had their genome altered by stable introduction of recombinant/synthetic nucleic acid molecules, or DNA derived therefrom, into the germ-line *and/*or experiments involving recombinant/synthetic nucleic acid molecule-modified microorganisms tested on whole animals *
rDNA Plant Biosafety Level (BL1-P, BL2-P, BL3-P)	Research involving recombinant/synthetic nucleic acid molecules in plants or associated with plants **
rDNA Large Scale Biosafety Level (BL1-LS, BL-2-LS, BL3-LS)	Recombinant/synthetic nucleic acid molecule research or production involving more than 10 Liters of culture

* BL1-N, BL2-N, and BL3-N apply to animals covered by Appendix M of the NIH Guidelines (including but not limited to cattle, swine, sheep, goats, horses, and poultry).

** BL1-P, BL2-P, and BL3-P apply for recombinant work in plants covered by Appendix L of the NIH Guidelines and are only applicable for work in greenhouses.

For work with human pathogens or toxins:	Select a biosafety level in this section if your project includes:
Biosafety Level (BSL-1, BSL-2, BSL-3)	Research with infectious or potentially infectious material that can affect humans
Animal Biosafety Level (ABSL-1, ABSL-2, ABSL-3)	Animal research with infectious or potentially infectious material that can affect humans

For work with animal-only or plant-only pathogens or toxins:	Select a biosafety level in this section if your project includes:
Biosafety Level (BSL-1, BSL-2, BSL-3)	Research with infectious or potentially infectious material that can affect animals or plants
Animal Biosafety Level (ABSL-1, ABSL-2, ABSL-3)	Animal research with infectious or potentially infectious material that can affect animals or plants

The guide below can be used to help determine the appropriate biosafety level needed within each category. Please note that this is a general guide, and biosafety level must ultimately be determined by a comprehensive risk assessment.

Biosafety Level 1	Appropriate for work with defined and characterized strains of viable biological agents not known to consistently cause disease in healthy adult humans. Agents handled at BSL-1 present minimal potential hazard to laboratorians and the environment.
Biosafety Level 2	Appropriate for work with biological agents that are associated with human, animal, or plant diseases of typically mild to moderate severity. Agents handled at BSL-2 present moderate potential hazard to laboratorians and the environment; treatments are often available. **All human materials (cells, blood, etc.) require BSL-2 containment.**
Biosafety Level 3	Appropriate for work with biological agents that may cause serious and potentially lethal infection. Agents handled at BSL-3 present serious potential hazard to laboratorians and the environment; treatments may or may not be available or effective.

Part D, Question #19- Provide the decontamination method you will use for each type of biological waste generated (e.g., solid waste, liquid waste, carcasses, seeds, plants, soil), as well as any laboratory equipment and/or surfaces.

- For decontamination by autoclave: Include the autoclave cycle's exposure time, temperature, and pressure. Indicate the final disposition of any autoclaved waste (e.g., autoclaved bags are placed in a black trash bag and transported to building's dumpster).

UNIVERSITY OF GEORGIA
Office of Research
Biosafety

Tips for Successful Completion of your IBC Protocol Form

- For chemical treatment: Include the disinfectant, its final concentration, and contact time. Indicate the final disposition of any chemically treated waste (e.g., after exposure, bleach-treated waste is poured down lab sink).
- For surfaces and equipment: Include the disinfectant, its concentration, and contact time. Include how frequently disinfectant solution is prepared. If any physical methods of removal are used with this (such as wiping with paper towel), indicate this. Please note that this is referring to routine disinfection of surfaces in the lab, not for biological spill cleanup procedures.

- If working with animals: Include a row for carcasses and indicate the disposal method.
- If working with plants: Include a row for seeds, plants, and soil as applicable. Include the decontamination and final disposal method. If a greenhouse space is used, add a row for greenhouse surfaces.

Note on bleach usage: The concentration of sodium hypochlorite in bleach may vary by manufacturer.
The minimum sodium hypochlorite concentration that should be used is 5.25%.
When using bleach to decontaminate liquids, bleach should be added to the solution until the final concentration of bleach is 10% by volume.
The solution of bleach **must** be freshly prepared.

See below for an example of a properly completed question #19.

- **Solid Waste**: Autoclaved at 121°C (15 psi) for a minimum sterilization time of 30 minutes. Autoclaved waste bags are securely placed in black bag and taken to building dumpster.
- **Liquid Waste**: Clorox bleach (5.25% sodium hypochlorite) is added to solution until final concentration of bleach is 10%; left for at least 20 minutes exposure time before flushing down sink.
- **Surfaces and Equipment**: Surfaces and equipment are sprayed with 70% EtOH (prepared fresh weekly); ethanol is left for 2 to 3 minutes and is then wiped down with paper towels.
- **Animal Facility Waste**: Per URAR facility requirements.
- **Animal Carcasses**: Incinerated.
- **Soil and Plant Material**: Heat-sterilized by raising the temperature of 2 cubic yards of material to 320°F (160°C) for 4 hours, using a commercially built soil sterilizer.

Part E, Question #20- Select any PPE that will be required in the laboratory (not animal facilities, as this is addressed in question #26).

- If "Face shield/goggles/safety glasses" is checked, be sure to specify which of these is required in the provided text box.
  - Please note that the use of certain chemicals, such as bleach, requires eye protection.
- If "Mouse/nose/respiratory" is checked, be sure to specify which of these is required in the provided text box.
  - Please note that surgical masks can be used for splash and direct contact protection.
  - Please note that if N95s (or other tight-fitting respirators) are required for your work, personnel are required to enroll in the Research Respiratory Protection Program (R-RPP) through the Research Occupational Health and Safety Program (R-OHSP), which will include spirometry testing and annual fit testing.

Part E, Question #21- When completing the special precautions for laboratory safety, be sure to address the following:

- If the lab has an incident response & reporting plan in place
- How biological waste is prepared for transport and transported to the autoclave
- If the lab has a protocol for safe handling and disposal of sharps and whether a sharps reduction plan is in place
- If a strict hand-washing policy is in place
- If lab personnel are enrolled in the Research Occupational Health Program (R-OHSP)
- If tight-fitting respirators such as N95s are required, whether lab personnel have enrolled in the Research Respiratory Protection Program (part of the R-OHSP)
- If agent-specific training has been provided to personnel (documentation of this training completion is required)
- If any other project-specific trainings are required for this research (e.g., NHP Zoonosis training)
- If human or NHP materials are used: if UGA Right to Know: Bloodborne Pathogens Training has been completed, and if Hepatitis B vaccination series has been offered to personnel
- If lentiviral vectors are used: if a lentiviral post-exposure and reporting plan is in place and signed by all personnel

Please see the following information that may be helpful in answering #21:

Sharps reduction plan: Each laboratory should have a sharps reduction policy as the first step in reducing the risk of needlesticks and sharps injuries. Identify all sharps that are being used as part of any procedures and determine whether or not an alternative is available to perform the procedure without using a device sharp enough to puncture skin. An example of sharps reduction could be using a blunt tip needle instead of a regular needle to disperse clumped cells.

Hand-washing policy: *At minimum*, personnel should wash their hands after working with hazardous materials in the lab and before leaving the lab. Personnel should wash their hands vigorously with soap and water for at least 30 seconds.

Incident response: Personnel should be trained in proper first aid procedures as well as spill clean-up procedures. If medical attention is needed following an incident, paid employees must seek medical attention at Piedmont

Tips for Successful Completion of your IBC Protocol Form

Occupational Medicine; unpaid employees must seek medical attention at University Health Center. In an emergency situation, personnel should report to the nearest emergency room. Contact OBS if assistance is needed in developing incident response plans. An incident response flow chart can be found here.

Incident reporting: All incidents with biohazardous materials must be reported to OBS in a timely manner. The incident reporting process is initiated when an employee reports an incident to their supervisor. The employee's supervisor must contact OBS to report the biohazardous incident/accident as soon as reasonably possible. PIs of high-containment and Select Agent labs will report immediately to the BSO/RO if there is any incident resulting in the potential release of an agent outside of primary containment (and as established in their written plan). An incident reporting flow chart can be found here.

Research Occupational Health Program: All personnel working with animals and/or those who work in BSL-2 containment are required to enroll in the R-OHSP. At this time personnel may decline enrollment, but if they choose this they must submit this declination to the R-OHSP. More information and directions for enrollment can be found on here.

Transportation of waste: All solid biological waste bags must be closed for transportation. Waste must be transported to the autoclave in a leak-proof container on a cart. When you arrive at the autoclave, re-open the autoclave bags between 2-3 inches to allow for adequate steam penetration. Tape a chemical test indicator strip on the outside of at least one bag being autoclaved in a run. An autoclave logbook is required; used chemical test indicator strips must be kept in the logbook.

Part F, Question #22- Include all laboratory spaces, animal facilities, greenhouses, and field locations as applicable.

Part F, Question #23-
List all biological safety equipment to be used with this research, including:

- Biosafety cabinets (BSCs)
- Autoclaves
- O-ring sealed centrifuge rotors

For BSCs only, include the most recent certification date (or pending certification, if this is scheduled but not yet complete). Do not include certification dates for any other equipment.

Part G- Complete this section for animal use only. Work with insects does not need to be included in this section.