# Institutional Biosafety Committee Application for Teaching Laboratories Permit

Teaching laboratory activities involving any of the agents listed below must be approved by the Prairie View A&M University Institutional Biosafety Committee (IBC) prior to initiation:

* Infectious agents and potential pathogens of humans, animals or plants;
* Materials potentially containing human pathogens (including biotoxins, human blood, tissue, organs, and cell lines;
* Materials potentially containing non-human primate blood, tissue, and cell lines;
* Recombinant DNA (and RNA) including creation or use of transgenic plants and animals;
* Select agents and toxins (see [http://www.selectagents.gov)](http://www.selectagents.gov/) including strains and amounts exempted from the select agent regulations;
* Field collection or sampling (e.g. animal products, plants, insects, microorganisms, water, wastewater, soil and rock depositions); and
* Any material requiring a CDC import license or a USDA permit.

**This *Application for Teaching Laboratories Permit* form is intended for Biosafety Level 1 (BL1) agent use only. If you are planning to work with BL2 agents, please complete the research-centered IBC protocol form.**

The course faculty/instructor is responsible for completing all appropriate parts of this permit form and for notifying the IBC before information submitted in this permit form changes such as personnel, laboratory location, procedures, and funding.

*Application for Teaching Laboratory Permits* are currently approved for the duration of three (3) years with annual renewals and laboratory inspections required.

**Important Notes:**

* **Only typed forms will be accepted**. For your convenience, the permit form is available electronically.
* Only the most current forms will be accepted and reviewed; therefore, we ask that you access our website for most current forms.
* The application must be completed, signed by all appropriate personnel, and submitted to the **IBC** at **Wilhelmina Delco Building Room 156** through the Office of Research Compliance, **prior** to initiation of teaching laboratory activities.
* At the time of submission, you are asked to also submit all grant proposals pertaining to your teaching activities (if applicable).
* Failure to provide all information requested, including requested signatures, will lead to a delay in processing your request.
* Failure to secure IBC approval before the start of class may delay laboratory assignments. **Please allow sufficient time for processing of your application.**

If further instructions are necessary, please contact the IBC at Researchcompliance@pvamu.edu or call (936) 261-1553.

# Institutional Biosafety Committee Application for Teaching Laboratories Permit

**Instructions:**

1. Provide a complete *Application for Teaching Laboratories Permit* form for each course (one permit for all sections is adequate if all sections are conducting the same activities).
2. Provide a copy of the course syllabus with a laboratory activities outlined.
3. Provide a copy of the Laboratory Teaching Manual/Procedures with a detailed description of the activities that the students will do in the lab.
4. Provide a copy of the laboratory contract/ informed consent containing:
	1. Laboratory rules, and
	2. List of agents used in the laboratory.
5. Review and attach the Biosafety Level 1 (BL1) Standard Operating Procedures (SOP)for the Teaching Lab, which includes biosafety procedures and practices that will be followed by the student(s) and instructor(s) in the lab.
6. Provide a copy of all applicable grant proposals using teaching labs or related biohazard activities (e.g. exhibition, contests, soil analysis, water analysis, etc…).
7. Provide a TrainTraq transcript for all personnel (i.e. Instructor, Teaching Assistant, Lab Technician) for the following courses:
* BioSafety Training – RMS, 2111399,
* Laboratory Safety 2111393, and
* Fire and Life Safety Training – RMS, 2111398.
1. Provide a CITI training transcript for all personnel for the CITI Basic Biosafety Training.

# Institutional Biosafety Committee Application for Teaching Laboratories Permit

1. **Instructor Information**

 Last Name:       First Name:

 Department:       College:

 Campus Mail Stop:

 Office location: Building number       Room number

Phone:

 Office Laboratory Emergency/after hours

Email:       (Please provide official University email)

Summary of Teaching Activities (please include Instructors experience):

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# Instructor Assurance

1. I affirm that the information contained in this application is accurate and complete.
2. I affirm that all individuals (including students) handling the materials described in this application are technically competent and will be properly trained in the handling and disposal of these materials.
3. I will include a statement in the syllabus informing those concerned that the experiments are in compliance with University and IBC requirements.
4. I acknowledge that IBC approval granted by this application is non-transferable to any other PVAMU instructor.
5. I agree to comply with all Prairie View A&M University IBC requirements regarding research involving biohazardous and / or recombinant materials.
6. I agree not to initiate any BL1 laboratory teaching activities unless I have received IBC approval.
7. I agree to notify the IBC immediately of incidents involving biohazardous and / or recombinant agents.
8. I acknowledge my responsibility for the conduct of this teaching activity in accordance with Section IV- B-7 of the *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines)*.
9. I have the knowledge and training required to safely handle the materials described.
10. Entry doors to the laboratory will be closed and locked when the laboratory is unattended.
11. I agree to add visitors or collaborators who will have potential exposure to biohazards to this IBC Teaching Laboratory Permit by an amendment and confirm that they are enrolled in the Occupational Health and Safety Program at PVAMU before allowing them to enter the lab.
12. I will provide casual visitors who will not be conducting teaching activities and who will not be exposed to biohazards with the appropriate personal protective equipment required for entrance to the lab.
13. I agree to provide all personnel and students working in the laboratory notification, information and training on the hazards, laboratory security and emergency policies and procedures associated with working in this BL1 laboratory. **I agree to inform all personnel and students working in the laboratory that potentially all microorganisms can be pathogens under certain conditions. When necessary, work procedures and protocols are in place to prevent aerosols and exposure to microorganisms. All personnel and students are provided training in sterile technique, the use of automatic pipettes and the proper disposal of biohazardous materials.**
14. **All personnel and students are advised that if they are in an immunocompromised/ immunosuppressed condition, that they are at risk for infection from the general environment and susceptible to infections that would normally not be a problem for an immunocompetent individual. All personnel and students are further advised that working in a laboratory that conducts experiments using live microorganisms could increase their risk of infection and be hazardous to their health. All personnel and students are advised that if they are in an immunocompromised/ immunosuppressed condition, that they should self-identify to their healthcare provider for appropriate counseling and guidance.**

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Signature of Teaching Faculty or Instructor Date Typed/Printed Name

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Signature of Teaching Faculty or Instructor Supervisor Date Typed/Printed Name

# Funding Information

* 1. **Funding Source** (Please check all that apply)

[ ]  No Funding [ ]  NIH [ ]  NSF [ ]  DOD [ ]  USDA

[ ]  Other:

## Routing Agency

[ ]  PVAMU [ ]  Other:

## Grant Proposal

Please include a copy of all grants associated with this IBC Teaching Laboratory Permit. The submission should include all sections of the grant that contain information pertaining to the teaching activities.

Grant Awardee (if different from this permit application):

Grant Title(s):

# Teaching Laboratory

## Course Information:

## [ ]  New Permit [ ]  Permit Renewal [ ]  Amendment to Permit

## Course Prefix and Course Number:

## Course Title:

## Course description:

## Semester the course to be taught:

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| --- | --- | --- | --- | --- |
| Fall | Spring | Summer I | Summer II | Other (specify): |
| [ ]  Single Lab | [ ]  Single Lab | [ ]  Single Lab | [ ]  Single Lab | [ ]  Single Lab |
| Section | Section | Section | Section | Section |
| [ ]  Multiple Lab | [ ]  Multiple Lab | [ ]  Multiple Lab | [ ]  Multiple Lab | [ ]  Multiple Lab |
| Sections | Sections | Sections | Sections | Sections |

6. Locations of teaching activities:

|  |  |  |  |
| --- | --- | --- | --- |
| Building Number\*: | Room: | Room capacity: | Room Purpose |
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\*Building Numbers: **668** – M.T. Harrington Science, **724** – Austin Greaux Chemical Engineering,

**745** – Jesse H. & Mary Gibbs Jones (aka: CARC or AGRL), **790** – Elmer E. O’Banion Science (aka: NSB or NSCI), **793** – New Electrical Engineering (aka: NENR), **849** – Agriculture and Business, and **707** – E. Kika De La Garza (aka: IGRC)

## Document Practices

 [ ]  I will require a student laboratory safety/informed consent agreement for all students enrolled in the course. (Agreement must inform students about the biosafety procedures and practices, safety precautions and the hazardous nature of the agents used in the course.)

 [ ]  I will make a binder with laboratory documents available in the lab.

 [ ]  Approved *Application for Teaching Laboratories Permit*

 [ ]  BL1 SOPs for this Teaching Lab

 [ ]  Laboratory Teaching Manual/Procedures

 [ ]  Safety Data Sheets (SDS)

 [ ]  The *PVAMU Biosafety Manual*.

[ ]  *Biosafety in Microbiological and Biomedical Laboratories (*[*BMBL*](https://www.cdc.gov/labs/pdf/CDC-BiosafetyMicrobiologicalBiomedicalLaboratories-2009-P.PDF)*), 5th Edition*

 [ ]  I will post emergency procedures and updated contact information in the laboratory.

 [ ]  I will post proper signage on the laboratory entrance and exit doors (i.e. entry and exit biohazard signs).

 [ ]  I will document and report all injuries and spills to Risk Management & Safety and the IBC, and follow university policy.

## Agents Chart

Please provide all of the information for each of the biological agents, toxins, or recombinant DNA being used in the teaching laboratory activities in the chart below:

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| --- | --- | --- | --- | --- | --- | --- |
| Name ofBiological Material1 | Type ofBiological Material 2 | OriginalSource 3 | Strain (ifapplicable) | Risk Group(RG)4 | BiosafetyLevel (BSL)4 | Where willthe agent be handled and/or stored? |
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1. If it is a biological agent, list the genus and species. If it is a biological toxin, list the genus and species the toxin was derived from. If it is rDNA list the gene(s) and the vector(s).
2. B=bacteria, V=virus, F= fungus, P= protozoan parasite, rDNA= recombinant DNA, T= toxin, P= prion, O= other (please provide additional information if other is selected)
3. Specify the type and name of the source- including vendor, or if it came from a collection or hospital. Please be specific.
4. Refer to the *PVAMU Biosafety Manual, BMBL*, and *NIH Guidelines* to find risk groups and biosafety level information.

Risk group classifications are primarily used in the research environment as part of a comprehensive biosafety risk assessment. Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans. Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

**D. Biohazard Component**

* 1. Biohazard Component

[ ]  **YES**  [ ]  **NO** Does this teaching laboratory use procedures that involve recombinant or synthetic nucleic acid molecules? (Refer to Appendix A)

[ ]  **YES**  [ ]  **NO** Does this teaching laboratory involve the use of **potentially infectious agents** (human, plant or animal pathogens, including bacterial, viral, fungal, or protozoan agents; or viral vectors)?

[ ]  **YES**  [ ]  **NO** Does this teaching laboratory involve the use of **human or non-human primate tissue or fluids (including blood, saliva, excreta or primary, continuous or transformed mammalian cell lines)**?

[ ]  **YES**  [ ]  **NO** Does this teaching laboratory involve the use of **biotoxins**?

* 1. Are there any potential risks of adverse effects to the following that may result from exposure to the agent(s) or recombinant DNA being used in this laboratory?

Humans? [ ]  Yes [ ] No

Animals? [ ]  Yes [ ] No

Plants? [ ]  Yes [ ] No

Other environmental (please describe):

If you answered yes to any of the questions in #1 or #2 above, please contact the Office of Research Compliance at researchcompliance@pvamu.edu, or 936.261.1588, as soon as possible.

* Instructors must inform students that it is their responsibility to consult with their primary care physician if they are immunocompromised before working with agents in this class

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1. **Recombinant DNA (rDNA) Tables**

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| Host organism for vector: genus, species, strain (e.g., *E.coli* K-12; Arabidopsis, *S. cerevisiae, etc.*) | Risk Group of Host: e.g., RG1, RG2 | Vector to be used in the host cell (e.g. pCAL-kc; *E. Coli* expression vector from Stratagene; pBR 322 derivatives; pcDNA 3.1 | Source(s) and identity of DNA insert (e.g. Gene/UTR/enhancer; biological source (genus, species, strain) | Risk Group of Source DNA:(e.g., RG1, RG2) | Purpose (e.g., protein expression, cloning, propagation) If known to be harmful, include in the purpose | NIH Guidelines Category |
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Risk group classifications are primarily used in the research environment as part of a comprehensive biosafety risk assessment. Risk Group 1 (RG1) agents are not associated with disease in healthy adult humans. Risk Group 2 (RG2) agents are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available.

See Appendix A or the NIH Guidelines Category for assistance choosing the appropriate category.

* + 1. Read the standard practices and physical containment procedures as defined for your BSL level in [**Appendix G**](http://oba.od.nih.gov/oba/rac/Guidelines/APPENDIX_G.htm) of the [***NIH Guidelines***](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm)(Physical Containment). Do you agree to abide by these guidelines with respect to standard procedures and physical containment?

 [ ]  Yes [ ]  No [ ]  N/A

* + 1. Do any of the agents being used express antibiotic resistance, or, if rDNA, does the rDNA containing vectors express antibiotic resistance?

 [ ]  No [ ]  Yes

 If yes, indicate the agent(s) and the specific antibiotic resistance that each possess.

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**F. General Questions**

1. Will you culture an organism?

 [ ]  No [ ]  Yes

 If yes, will you generate 10 liters or more of the culture at a time?

 [ ]  No [ ]  Yes

If yes, explain the culture procedure(s), types of equipment being used for culturing the large quantity, special procedures in place for handling large quantities, and where the culture will be performed.

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1. Field Collection or Sampling:

Laboratory activities involving the field collection or sampling of certain plants, animal products, microbes, soil, water and wastewater requires submission of an *Application for Teaching Laboratories Permit* and approval by the IBC prior to initiation of work activities.

Field collection or sampling of:

|  |  |
| --- | --- |
| **Sample** | **Location of Collection** |
| Plant |       |
| Animal Products |       |
| Microbes |       |
| Soil |       |
| Water |       |
| Wastewater |       |
| Other: |       |

1. Will you be using any of the following in your laboratory (check all that apply):

[ ]  None

[ ]  Homogenization [ ]  Centrifugation [ ]  Sonication

[ ]  Dissection [ ]  Pipetting [ ]  Shaking

[ ]  Blending/Mixing [ ]  Other (specify):

Explain the special procedures and personnel protective equipment that will be put in place to minimize the risk for contamination from aerosols and/ or splashes from using the above equipment/ procedures.

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1. What personnel protective equipment will you require in the teaching laboratory (check all that apply)?

[ ]  Disposable Gloves [ ]  Safety Goggles/Glasses [ ]  Lab Coat [ ]  Face Shield

[ ]  Head Covers [ ]  Shoe Covers [ ]  N 95 Respirator

[ ]  Other (specify):

1. What safety equipment will be available in the laboratory during the teaching sessions (check all that apply)?

[ ]  Chemical fume hood (for chemical use only) [ ]  Biological Safety Cabinet

[ ]  Centrifuge with Safety Cups/ Sealed Rotor Heads

[ ]  Automatic Pipettes [ ]  Safety Blender

[ ]  Other (specify):

1. Which of the following controls will you employ in the laboratory (check all that apply)?

[ ]  Biosafety training for personnel [ ]  Biohazard signage (BSL-1 or greater are required)

[ ]  Controlled/ restricted access [ ]  Incident reporting for spills and exposures

[ ]  Sharps containers and precautions

[ ]  Prohibiting all eating/ drinking in lab [ ]  Hand washing practices training and monitoring

[ ]  Other (specify):

1. What type of laboratory safety controls does this teaching laboratory employ (check all that apply)?

[ ]  Hand-washing sink [ ]  Eyewash station [ ]  No carpets/ rugs

[ ]  Lab chairs covered in non-porous material [ ]  Chemical/ heat resistant bench tops

[ ]  Safety Shower [ ]  Lab not in public access areas

 [ ]  Other (specify):

1. What types of disinfectants will be employed (check all that apply)?

[ ]  10% bleach solution (1:10 dilution bleach: water)

[ ]  70% isopropyl alcohol or 70% ethanol

[ ]  Other (specify):

1. How will biohazardous waste be de-contaminated and disposed of after use in the lab?

[ ]  Autoclave (specify time, temperature, and PSI):

[ ]  Chemical inactivation (specify):

[ ]  Other (specify):

1. Autoclave location:
	1. [ ]  The autoclave is departmentally operated.

Contact name:      Phone No:

Building Location: Building No.:      /Room No.:

 b. [ ]  The autoclave is individually operated (supervised by Principal Investigator)

Building Location: Building No.:       Room No.:

1. The IBC requires that the treatment of each load of Biohazardous waste be documented on an autoclave waste treatment record. The record should contain the date of treatment, the amount of waste treated, the method/conditions of treatment, and the printed name and initials of the person performing the treatment. If provided for, charts or printout strips should be kept with the record as documentation. Additionally, documentation of the date and results of all verification tests using biological indicators is required.

[ ]  I give assurance that the method indicated above will be used.

1. If a biotoxin is being used, please explain how the toxin(s) will be inactivated and disposed of after use.

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1. Are any of these agents transported or transferred outside of the room in which they are stored?

[ ]  No [ ]  Yes

If you answered yes, what location(s) will you be transporting/ transferring the agent(s)/ toxin(s)/ rDNA to, and from what location(s)?

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How will these agents be contained in secondary containment for transportation to minimize risk of contamination?

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Contact the Office of Research Compliance at (936) 261-1553 or by email at **Researchcompliance@pvamu.edu**for more information on disposal of hazardous materials.

# Risk Assessment

**Yes No**

[ ]  [ ]  Will any experimental procedures result in acquisition of new characteristics such as enhanced virulence, infectivity, or change in host range?

[ ]  [ ]  Will any of the agents be transported outside of the laboratory?

[ ]  [ ]  Will more than 1 liter of agent be generated at any one time?

[ ]  [ ]  Will any of the agents be administrated to animals? If yes please describe the activity in detail (e.g. animal species, how is the agent given, how long will the animal be followed.)

[ ]  [ ]  Does this teaching activity involve the environmental release of genetically engineered material?

[ ]  [ ]  Does this teaching activity involve the environmental release of pathogenic or potentially pathogenic material (other than recombinant agents)?

[ ]  [ ]  Will human tissue or cells be transplanted into animals?

[ ]  [ ]  Will animal tissue or cells be transplanted into a different species of animal?

[ ]  [ ]  Do any of the agents you intend to work with require pre-project serum samples, immunization, medical monitoring, and/or health surveillance?

[ ]  [ ]  Will the deliberate aerosolization of any agent occur?

**If you answered “Yes” to any of the above questions, please explain in the space provided on the following page.**

**Risk Assessment Explanation**

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# Personnel

All personnel must be identified on the application. The IBC must be notified of any change in personnel who will be directly involved in laboratory teaching, training, and/or supervision. List the information of ALL personnel. *The personnel list must be completed by the instructor when working in teaching laboratories that are BSL1 and above containment.*

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| **Action Type Add - A Delete - D Modify -M** | **First Name** | **Last Name** | **Phone Number** | **Employee Email Address** |
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# Training

**All** personnel are required to take biosafety training prior to release of IBC approval. Each person must provide the most recent date of training completion. **REMINDER: All TrainTraq training must be repeated annually. If you need information about training completion dates or have questions, please contact the Office of Research Compliance.**

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| PERSONNEL | [BioSafety](http://research.umbc.edu/2041-2/)[Training](http://research.umbc.edu/2041-2/) – RMS 2111399***Enter the date below*** | Laboratory Safety 2111393***Enter the date below*** | Fire and LifeSafety Training – RMS2111398***Enter the date below*** | [CITI](http://research.umbc.edu/2041-2/) Basic Biosafety Training***Enter the date below*** |
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**Appendix A: NIH Guidelines Category**

**NIH Category:**

**Classification of activities involving recombinant and synthetic nucleic acid molecules.** Use the classification guide to refer to the relevant section of the *NIH Guidelines*. The questions in the left column categorize the experiments into six levels of review specified in the *NIH Guidelines.* Access the complete details from the NIH Office of Science Policy, online at <https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf>.

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| **CATEGORY OF EXPERIMENTS (A-F)** | **Yes** | **No** | **LEVEL OF REVIEW IN THE NIH GUIDELINES** |
| **A** Does the experiment involve the transfer of a drug resistant trait to microorganisms that are not known acquire the trait naturally, if this acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture? |  [ ]  |  [ ]  | Section III-A: Major ActionsExperiments require IBC and NIH/RAC review, and NIH Director approval before initiation.See the NIH Guidelines and FAQs at http://osp.od.nih.gov/office-biotechnology-activities/biosafety/nih-guidelines |
| **B**Does the experiment involve cloning genes for toxin molecules with an LD50 of less than 100 ng/kg body weight?ORHas the experiment been approved previously as a Major Action under Section III-A-1-a of the NIH Guidelines? |  [ ]  |  [ ]  | Section III-BExperiments require IBC approval and NIH review for containment determinations before initiation.Principal Investigator must submit relevant information to NIH/OBA and PVAMU IBC.See NIH Guidelines Section IV-B-7-b-(3). |
| **C**Does the experiment involve the transfer of recombinant or synthetic nucleic acid molecules into human research participants? |  [ ]  |  [ ]  | Section III-C: Human Gene TransferExperiments require NIH/RAC review and IBC and IRB approval before research participant enrollment.See Appendix M of the NIH Guidelines |
| **D**Does the experiment involve:∙ Using Risk Group (RG) 2 - 4, or restricted agents as host-vector systems? ….......................… …….Section III-D-1∙ Cloning DNA from RG 2, RG 3, RG 4, or restricted agents into nonpathogenic prokaryotic or lower eukaryotic host-vector systems ............... …………………Section III-D-2∙ Using infectious viruses OR defective DNA or RNA viruses in the presence of helper virus in tissue culture systems? ................................................................... Section III-D-3∙ Whole animals: e.g., creating stable germ-linealterations of an animal’s genome............ Section III-D-4∙ Testing viable recombinant-modifiedmicroorganisms on whole animals?.......... Section III-D-4∙ Whole plants (e.g., nucleic acid-modified plantsor plant-associated organisms with recognizedpotential for detrimental impacts on ecosystems)? .................................................................. Section III-D-5∙ More than 10 liters of culture? ………. .Section III-D-6∙ Influenza viruses generated by recombinant orsynthetic methods? ................................... Section III-D-7 |  [ ]  |  [ ]  |

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| **Section III-D: Experiments require IBC approval before initiation**Submit an IBC application, signed by the PI and containing: (i) the source of DNA;(ii) the nature of the inserted DNA sequences; (iii) the host and vector to be used; (iv) if an attempt will be made to obtain expression of a foreign gene, and if so, indicate the protein that will be produced; and (v) the containment conditions. Refer to the *NIH Guidelines* for details of Risk Group classifications and containment: ∙ Appendix B, *Classification of Human Etiologic Agents on the Basis of Hazard* ∙ Appendix E, *Certified Host-Vector Systems* ∙ Appendix G, Physical Containment∙ Appendix I, Biological Containment∙ Appendix K, Large Scale Uses of Organisms∙ Appendix P, Research Involving Plants∙ Appendix Q, Research Involving Animals |

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| **E**Does the experiment involve:∙ the formation of recombinant or synthetic nucleic acid molecules containing no more than two-thirds of the genome of any eukaryotic virus, propagated and maintained in cells in tissue culture using BL1 containment and demonstrated lack of helper virus?∙ whole plants, or modified organisms associatedwith plants, where plant biosafety level 1 (BL1-P) or BL2-P containment is appropriate?∙ the generation of BL1 transgenic rodents?∙ experiments not included in III-A through III-Dor III-F, where BL-1 containment is appropriate? |  [ ]  |  [ ]  | **Section III-E: IBC approval at initiation**Submit an IBC application, signed by the PI. For many experiments in this category, all components are derived from non-pathogenic prokaryotes and non-pathogenic lower eukaryotes.The experiments can be initiated under a provisional approval until the IBC review is completed (see the NIH Guidelines Section IV-A, Policy). |
| **F**Is the experiment exempt from the NIHGuidelines? Refer to the full text of the NIH Guidelines and FAQs at https://osp.od.nih.gov/wp-content/uploads/NIH\_Guidelines.pdf |  [ ]  |  [ ]  | **Section III-F Exempt Experiments**Although Section III-F experiments are exempt from the NIH Guidelines, other federal and state standards of biosafety may still apply. The final determination of whether a project meets the definition of exempt status rests with the IBC. |
| Note: If an experiment falls into Section III-F and into either Sections III-D or III-E as well, the experiment is considered exempt from the NIH Guidelines.Section III-F Exempt Experiments• Section III-F-1. Synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell, and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.• Section III-F-2. Recombinant or synthetic nucleic acid molecules that are not in organisms, cells, or viruses and that have not been modified or manipulated (e.g., encapsulated into synthetic or natural vehicles) to render them capable of penetrating cellular membranes.• Section III-F-3. Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature.• Section III-F-4. Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or a closely related strain of the same species), or when transferred to another host by well-established physiological means.• Section III-F-5. Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species).• Section III-F-6. Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent. A list of such exchangers will be prepared and periodically revised by the NIH Director with advice of the RAC after appropriate notice and opportunity for public comment (see Section IV-C-1-b-(1)-(c), Major Actions). See Appendices A-I through A-VI, Exemptions under Section III-F-6--Sublists of Natural Exchangers, for a list of natural exchangers that are exempt from the NIH Guidelines.• Section III-F-7. Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA.• Section III-F-8. Those that do not present a significant risk to health or the environment (see Section IV-C-1- b-(1)-(c), Major Actions), as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public comment. See Appendix C, Exemptions under Section III-F-8 for other classes of experiments which are exempt from the NIH Guidelines (also note that exceptions apply):o Recombinant or synthetic nucleic acid molecules containing less than one-half of anyeukaryotic viral genome viral genome, that are propagated and maintained in cells in tissuecultureo Escherichia coli K-12 Host-Vector Systemso Saccharomyces Host-Vector Systemso Kluyveromyces Host-Vector Systemso Bacillus subtilis or Bacillus licheniformis Host-Vector Systemso Extrachromosomal Elements of Gram Positive Organismso The purchase or transfer of transgenic rodents for experiments that require BL1 containmento The breeding of transgenic rodents to create a new strain that can be housed at BL1containment. |