University of Maine Institutional Biosafety Committee (IBC)

Protocol Form

Last updated: 9/4/24

**Before submitting a protocol form for approval, PIs must have a current** [**IBC Registration (Word)**](https://umaine.edu/research-compliance/resource/ibc-registration-form/) **on file.**

Protocol approval is required prior to any non-exempt rDNA work and/or any non-exempt work that is BSL2 or higher, per the [National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (PDF)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf), University of Maine Institutional Biosafety Program, and related Federal, State and University policies. **Technical information relating to this protocol is considered confidential.**

This protocol document is meant to provide sufficiently detailed information regarding each Biohazardous/Recombinant DNA research project so that it may be adequately reviewed by the University of Maine Institutional Biosafety Committee (IBC).

**Please refer to the** [**UMaine IBC website**](https://umaine.edu/research-compliance/biosafety/) **for more information, and** [**contact us**](https://umaine.edu/research-compliance/biosafety/#contact) **with any questions.**

**Form Guidance:**

* **You must use Microsoft Word to fill in the form.** All UMaine affiliated students, faculty, and staff can access Microsoft Office software (including Word) for free via [UMaine IT](https://umaine.edu/it/microsoft-office365/).
	+ Checkboxes – Click the empty checkbox once and an ‘x’ will appear to check off the box. Clicking once on the box again to remove the ‘x’.
	+ Text entry – Some questions will have a text entry box, appearing with grayed out text saying, “click here to enter text.” Click on that grayed out text, and you will be able to type as you would in any Word document. The text box will automatically expand as you type.
	+ Tables– Some questions have tables to fill in. Simply click on each empty cell of the table to type within it. The rows will automatically expand as you type.
		- If you need to add an additional row to a table, right click on the bottom row of the table, hover over “Insert” and click “Insert Rows Below.”
* One form should be used for each protocol. Thus, one PI may have multiple separate forms. The protocol form is for each individual project, not for the PI.
* You do not necessarily need to complete every section of the form. However, please complete ALL sections UNLESS it is specified that you should skip section(s) based on your responses and be sure to provide any required supporting documentation.
* **Protocol type guidance:**
	+ All protocols from *before 2019* should select “New IBC Protocol”
	+ All protocols from *2019 or later*:
		- New protocol: select “New IBC Protocol”
		- Amendment to a previously approved protocol from within the last 3 years: select “Amendment to IBC Protocol”
		- Protocol older than 3 years: select “Renewal to IBC Protocol”
* **Amendments to existing protocols**: Use Word to *edit your previously approved protocol form* (make sure you are using the final approved copy). Use a different color font or highlight (or track changes), edit all applicable sections of the previously approved protocol. In addition to editing the applicable sections of the form, also be sure to indicate it is an amendment in [Section 1.A](#_Registration_Type), and give a summary of the changes in [Section 1.E](#_Amendment_Type).
* **To submit the form, email the completed form and any necessary supporting documents to the Office of Research Compliance at** **umric@maine.edu** **with “IBC Protocol” in the subject line of the email.**

# Administrative Data

## Protocol Type

[ ]  New IBC Protocol

[ ]  Amendment to IBC Protocol #: Click or tap here to enter text.
*Existing protocol numbers can be found on the previously approved protocol form.*

[ ]  Renewal to IBC Protocol #: Click or tap here to enter text.

## Principal Investigator

|  |  |
| --- | --- |
| **PI Name:** Click or tap here to enter text. | **Email Address:**Click or tap here to enter text. |
| **Department:**Click or tap here to enter text. | **Phone #:**Click or tap here to enter text. |

**Co-PI** (if applicable; if N/A, leave blank)

|  |  |
| --- | --- |
| **Co-PI Name:** Click or tap here to enter text. | **Email Address:**Click or tap here to enter text. |
| **Department:**Click or tap here to enter text. | **Phone #:**Click or tap here to enter text. |

## Project Information

|  |
| --- |
| **Project Title for IBC Protocol:** Click or tap here to enter text. |
| **Granting Agency Proposal Title:** Click or tap here to enter text. |
| **Does the project have external funding?** [ ]  Yes [ ]  Pending [ ]  No *If YES then indicate Granting Agency/ORA Project # below.* |
| **Granting Agency:** Click or tap here to enter text. | **ORA Project #:** Click or tap here to enter text. |

## Summary of Biomaterials

**This project uses:** (check all that apply)

|  |  |
| --- | --- |
| [ ]  Biologically Derived Toxins[ ]  Prions and Related Biomolecules[ ]  Recombinant Activity/Synthetic Nucleic Acid[ ]  Microorganisms[ ]  Infectious Materials[ ]  Cell Lines/Tissues[ ]  Invertebrate Animals[ ]  Vertebrate Animals☐ Gene Drive Modified Organisms (GDMOs) | [ ]  Plants/Plant Parts/Algae[ ]  Large-scale (>10 L) production[ ]  Environmental Samples (soil, water)[ ]  Diagnostic/Clinical Samples (blood, urine, etc.)[ ]  Human Origin Material ([contact IRB](https://umaine.edu/research-compliance/human-subjects/))[ ]  Engineered Nanomaterials[ ]  Select Agents[ ]  DURC Concerns or Other |

## Amendment Type

COMPLETE the relevant portion of this section ONLY if protocol form is an AMENDMENT to an existing protocol. See Form Guidance on cover sheet for instructions on submitting an amendment.

SKIP this section if it is a new or renewed protocol. Proceed to [Section II](#_Project_Classification).

### Major Amendments

All major changes require a full committee review.

|  |
| --- |
| [ ]  Change in scope of research [ ]  Additional research projects/procedures [ ]  Change of Principal InvestigatorReason for Major Change(s):Click or tap here to enter text. |

### Minor Changes

Dependent upon the type of changes, full IBC review may not be required.

|  |  |
| --- | --- |
| [ ]  Additional Title [ ]  Add/Change Lab Location: Update [*Section VI.A*](#_Designated_Work_Areas)[ ]  Add or Delete Personnel: Update [*Section VI.C*](#_Personnel_Training.) | Update [*Section III*](#_Description_of_Biological) for the following:[ ]  Animal Strains [ ]  Animal Material [ ]  Human Material [ ]  Plant Material [ ]  Cell Lines[ ]  Genetic Constructs[ ]  Others (describe below) |
| Description of Minor Change(s):Click or tap here to enter text. |

# Project Classification

## Brief Project Description

Briefly (3-5 sentences) describe the purpose of the project using non-scientific language (in terms for the average citizen). This project description, title, and PI name will be in the publicly available IBC minutes.

|  |
| --- |
| Click or tap here to enter text. |

## Exempt Experiments

| **Item #** | **Does this project include any of the following recombinant or synthetic nucleic acid molecules? (Please check all boxes that apply)** | [**NIH Guidelines (PDF)**](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) **Reference** |
| --- | --- | --- |
| II.B.1 |[ ]  Those 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.
 | III-F-1 |
| II.B.2 |[ ]  Those 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. | III-F-2 |
| II.B.3 |[ ]  Those that consist solely of the exact recombinant or synthetic nucleic acid sequence from a single source that exists contemporaneously in nature. | III-F-3 |
| II.B.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. | III-F-4 |
| II.B.5 |[ ]  Those that consist entirely of nucleic acids from a eukaryotic host including itschloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species). | III-F-5 |
| II.B.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. | III-F-6;IVC-1-b-(1)-(c);Appendix A |
| II.B.7 |[ ]  Those genomic DNA molecules that have acquired a transposable element, provided the transposable element does not contain any recombinant and/or synthetic DNA. | III-F-7 |
| II.B.8 |[ ]  Those that do not present a significant risk to health or the environment as determined by the NIH Director following appropriate notice and opportunity for public comment. | III-F-8;IVC-1-b-(1)-(c);Appendix C |

## Non-Exempt Experiments

| **Item #** | **Does this project … (Please check all boxes that apply)** | [**NIH Guidelines (PDF)**](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) **Reference** |
| --- | --- | --- |
| II.C.1 |[ ]  Include deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally? | III-A |
| II.C.1.a |  | If YES for C.1 (above), could such a transfer compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture?[ ]  Yes [ ]  No |  |
| II.C.2 |[ ]  Include cloning toxin molecules with an LD50 of less than 100 nanograms per kilogram body weight? | III-B |
| II.C.3 |[ ]  Include experiments involving the deliberate transfer of recombinant DNA, synthetic nucleic acids, or DNA or RNA derived from recombinant DNA, into one or more human research participants? | III-C |
| II.C.4 |[ ]  Include experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Select Agents as host-vector systems? | III-D-1 |
| II.C.5 |[ ]  Include experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Select Agents is cloned into nonpathogenic prokaryotic or lower eukaryotic host-vector systems? | III-D-2 |
| II.C.6 |[ ]  Include experiments involving the use of replication-competent recombinant DNA or RNA viruses or defective DNA or RNA viruses in the presence of helper systems in tissue culture systems? | III-D-3 |
| II.C.7 |[ ]  Include experiments with recombinant influenza virus? | N/A |
| II.C.8 |[ ]  Include experiments involving whole animals in which the animal’s genome has been altered by introduction of DNA into the germ line (i.e., transgenic animals)? | III-D-4, III-E-3 |
| II.C.8.a |  | If YES for C.8 (above), does the animal contain a transgene encoding more than 50% of the genome of an exogenous eukaryotic virus?[ ]  Yes [ ]  No |  |
| II.C.8.b |  | If YES for C.8 (above), is the transgene under the control of a gamma-retroviral promoter?[ ]  Yes [ ]  No |  |
| II.C.9 |[ ]  Include experiments involving viable rDNA-modified microorganisms tested on animals? | III-D-4, III-E-3 |
| II.C.10 |[ ]  Include experiments involving genetically engineered whole plants? | III-D-5, III-E-2 |
| II.C.11 |[ ]  Include experiments involving more than 10 liters of culture? | III-D-6 |
| II.C.12 |[ ]  Include experiments involving gene drive modified organisms? | III-D-8 |
| II.C.13 |[ ]  Include experiments involving the formation of recombinant DNA molecules containing no more than two-thirds of the genome of any eukaryotic virus and propagated in tissue culture? | III-E-1 |
| II.C.14 |[ ]  Uses Select Agents (defined by HHS/CDC/USDA Select Agent Program) | N/A |
| II.C.15 |[ ]  Require biosafety level 3 containment (BSL3)? | N/A |
| II.C.16 |[ ]  Dual Use Research of Concern Agents or Toxins? | N/A |
| II.C.17 |[ ]  Requires Federal or State import permit?  | N/A |
| II.C.18 |[ ]  Uses unmodified Genomic Material only (e.g., DNA or RNA for sequence or expression analysis)? | N/A |

## NIH Classification

| **Item #** | **Please check all boxes that apply:**  | [**NIH Guidelines (PDF)**](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) **Reference** |
| --- | --- | --- |
| II.D.1 |[ ]  Use of animal cells/cell lines or tissues (e.g., tissue culture research) | II-A-3, Appendix C-1 |
| II.D.2 |[ ]  Use of human cells/cell lines or tissues (e.g., Human blood, 293 cell lines, CSF) | II-A-3 |
| II.D.3 |[ ]  Transfer of Drug Resistance trait to microorganisms | III-A-1-a |
| II.D.4 |[ ]  Use or cloning of toxin molecule genes | III-B-1 |
| II.D..5 |[ ]  Use of or the cloning of genes from, or into a Risk Group 2, 3, 4 or restricted agent | III-D-1, 2 |
| II.D.6 |[ ]  Use of virus or viral particles | III-D-3, III-E-1 |
| II.D.7 |[ ]  Propagating culture volumes exceeding 10 liters | III-D-6 |
| II.D.8 |[ ]  Use of gene drive modified organisms | III-D-8 |
| II.D.9 |[ ]  Creation or use of c-DNA/genomic libraries | III-E, III-F |
| II.D.10 |[ ]  Cloning and vector construction in bacteria and yeasts | III-E, III-F |
| II.D.11 |[ ]  Use of rDNA molecules for detection purposes (e.g., probes) | III-F |
| II.D.12 |[ ]  Expression of rDNA products in cultured cells | III-E, III-F |
| II.D.13 |[ ]  Administration of rDNA product into humans (e.g., Gene Transfer Protocol) | III-C-1 |
| II.D.14 |[ ]  Administration of rDNA material into animals (e.g., transformed cells, vectors) | III-D-4 |
| II.D.15 |[ ]  Experiments involving transgenic rodents | III-E-3 |
| II.D.16 |[ ]  Experiments involving whole transgenic plants | III-D-5 |
| II.D.17 |[ ]  This is an EXEMPT project, per Section II.B. | III-F |
| II.D.18 |[ ]  Select Agent or Toxins | N/A  |

# Description of Biological Materials

## Nanomaterials

The CDC defines a technology as engineered nanotechnology only if it involves all the following:

* Research and technology development involving structures with at least one dimension in the range of 1 to 100 nanometers (nm), frequently with atomic/molecular precision
* Creating and using structures, devices, and systems that have unique properties and functions because of their nanometer-scale dimensions
* The ability to control or manipulate on the atomic scale
* [NIEHS Nanomaterials](http://www.niehs.nih.gov/health/topics/agents/sya-nano/)
* [OSHA Nanotechnology](https://www.osha.gov/nanotechnology)
* [CDC Nanotechnology Guidance & Publications](https://www.cdc.gov/niosh/nano/guidance/)

### Does this project use engineered nanomaterials?

[ ]  Yes – COMPLETE this section.

[ ]  No – SKIP this section. Proceed to [Section III.B](#_Biotoxins).

IF YES, please describe the nanomaterials and how they will be used.

|  |
| --- |
| Click or tap here to enter text. |

## Biotoxins

### Does the project require possession, use, or transfer of any of the following?

[ ]  ANY biotoxins

[ ]  Acute biological toxins (mammalian LD50 <100 μg/kg body weight)

[ ]  Toxins that fall under the Federal Select Agent Guidelines, and/or the organisms, both natural and recombinant, which produce these toxins (see [Select Agents and Toxins List](https://www.selectagents.gov/SelectAgentsandToxinsList.html))

IF YES to ANY of the above:

* COMPLETE this section, AND
* ATTACH relevant Standard Operating Procedures, AND
* ATTACH a biotoxin-specific plan for storage, handling, waste disposal/neutralization

If NO to ALL of the above, SKIP this section. Proceed to [Section III.C](#_Recombinant_and_Synthetic).

| **Name of Biotoxin**(Please include ALL biotoxins involved in the project) | **Current Inventory** | **Source of Toxin**(Commercially acquired or produced in lab) | **Will experiments involve cloning a biological toxin gene?** | **Will toxin be used in animals (dosing)?** |
| --- | --- | --- | --- | --- |
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|  |  |  |  |  |
|  |  |  |  |  |

## Recombinant and Synthetic Nucleic Acids

**Does this work involve Recombinant/Synthetic Nucleic Acid Molecule Activity?** (Refer to the [NIH guidelines [PDF]](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf))

[ ]  Yes - COMPLETE this section.

[ ]  No - SKIP this section. Proceed to [Section III.D.](#_Microorganisms)

### Source of Nucleic Acid Sequence

| **Name** (Gene/siRNA Name, e.g., GFP green fluorescent protein) | **Source** (species, strain, cell line, cultivar, Vendor/Supplier) | **Function of the genetic element** |
| --- | --- | --- |
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### Nature of the Modified DNA

Describe the functional and structural elements of the recombinant DNA, including the regulatory and/or coding regions, percentage of the entire genome, promoter, synthetic antisense sequence, etc. Will this element be expressed? What is your risk assessment of the sequence (tumor suppressor, oncogene, etc.)?

|  |
| --- |
| Click or tap here to enter text. |

### Vectors

List the cloning and delivery vector(s) used, including selectable marker(s), reporter genes(s), oncogenes, promoters, packaging cell line, assay system for detection, quantification, and/or host range of packaged viral vector. Vector packaged in competent cells (E.coli), other host microbes must have an import permit. Detail the Risk Attenuation Phenotype (e.g., replication defective, helper systems, disarmed, K-12 derived, potential for reversion, etc.). **Reference any literature from commercially available vectors.**

| **Name**(include the genus species if derived from plasmid/virus) | **Type**(plasmid, phage, virus, etc.) | **Source**(Vendor/Supplier) | **Generation**(1st , 2nd, 3rd, 4th, etc..) | **Risk Attenuation Phenotype** |
| --- | --- | --- | --- | --- |
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### Recipient Organism

Specify the type of organism, species, strain, cell line, or cultivar receiving the nucleic acid.

|  |
| --- |
| Click or tap here to enter text. |

### Will you express a toxin or oncogene?

[ ]  Yes [ ]  No

If YES, please specify.

|  |
| --- |
| Click or tap here to enter text. |

### Will the vector host range be altered?

[ ]  Yes [ ]  No

If YES, please describe.

|  |
| --- |
| Click or tap here to enter text. |

### Will the project use infectious DNA/RNA viruses, defective DNA/RNA viruses, or phages in the presence of helper systems (e.g. helper viruses, packaging cell lines, transient transfection systems, or replicon systems) in a tissue culture system?

[ ]  Yes [ ]  No

If YES, provide details on the pathogenicity, host range or generation system.

|  |
| --- |
| Click or tap here to enter text. |

### Will the project use a gene drive system or have the possibility to generate a gene drive?

[ ]  Yes [ ]  No

If YES, provide details on the system, which genes are modified, whether it will alter pathogencity or transmissibility, and please attach a risk assessment for the research.

|  |
| --- |
| Click or tap here to enter text. |

## Microorganisms, Cell Lines, and Tissues

**Does this protocol use any microorganisms AND/OR cell lines AND/OR tissues?**

[ ]  Yes - COMPLETE this section.

[ ]  No - SKIP this section. Proceed to [Section III.E.](#_Animals)

### Microorganisms

Identify and describe microorganisms to be employed by this protocol. If none, please indicate N/A or leave blank.

| **Microorganism Name (genus, species, strain name)** | **Source** | **Human Pathogen** | **Animal Pathogen** | **Plant Pathogen** | **Produce Toxin** | **In Vivo Use** | **Receive rDNA material** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |[ ] [ ] [ ] [ ] [ ] [ ]
|  |  |[ ] [ ] [ ] [ ] [ ] [ ]
|  |  |[ ] [ ] [ ] [ ] [ ] [ ]

### Cell Lines and Tissues

Identify and describe cells and tissues to be employed by this protocol. If none, please indicate N/A or leave blank.

| **Cell Lines/Tissue Name** | **Source** | **Technical Name (e.g., NIH3T3)** | **Passage (Primary/ Established/ Immortalized)** | **In Vivo Use** | **Receive rDNA construct** | **Receive microorganism** | **Chemically altered** |
| --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |[ ] [ ] [ ] [ ]
|  |  |  |  |[ ] [ ] [ ] [ ]
|  |  |  |  |  |  |  |  |

Does this cell line contain latent, adventitious, or inherent microorganisms or virus (e.g., HEK and adenovirus)?

[ ]  Yes [ ]  No

## Animals

**Will this protocol use animals?**

[ ]  Yes - COMPLETE this section. (NOTE: you may also need IACUC approval. See the [IACUC website](https://umaine.edu/research-compliance/animal-care/).)

 [ ]  Vertebrate

 [ ]  Invertebrate

[ ]  No - SKIP this section. Proceed to [Section III.F.](#_Plants_and_Derived)

### List all animal species and research locations

| **Animal Species/Strains** | **Location of Animal Research** | **ABSL Designation** |
| --- | --- | --- |
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### Hazards from Animals

Do any of the strains or manipulated animals present a hazard that would require more than ABSL-1 (BSL1-N) housing?

[ ]  Yes

[ ]  No

### List all transgenic animals

Include animals to be acquired and/or breeding/crossbreeding. If none, indicate N/A or leave blank

| **Background Strain** | **Line Designation to be Crossed** | **Source of Line** |
| --- | --- | --- |
|  |  |  |
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### Description of transgenic animals

| **Please check all boxes that apply**: |
| --- |
| III.E.5.a |[ ]  The animals contain more than one-half of the genome of an exogenous eukaryotic virus. |
| III.E.5.b |[ ]  If crossbreeding, the offspring have transgenes under the control of LTR and contain more than one-half of the exogenous viral genome |
| III.E.5.c |[ ]  Transgenes are under control of gamma-retroviral long terminal repeat (LRT). |

### Acquisition and Breeding of Transgenic Animals

| **Please check all boxes that apply:** |
| --- |
| III.E.6.a |[ ]  Transgenic animals will be purchased | Vendor:  |
| III.E.6.b |[ ]  Transgenic animals will be generated in-house |
| III.E.6.c |[ ]  A colony of transgenic animals will be maintained |
| III.E.6.d |[ ]  Transgenic animals will be cross-bread to generate new strains |

### Will biological materials\* be inserted/inoculated/introduced?

\*If biological material is infectious, use of BSC, negative pressure and restricted entry during manipulation is REQUIRED

[ ]  Yes [ ]  No

If YES, please describe.

|  |
| --- |
| Click or tap here to enter text. |

### Will there be a potential of biological material being shed from the animal?

[ ]  Yes [ ]  No

If YES, please describe.

|  |
| --- |
| Click or tap here to enter text. |

### Does animal waste/bedding require decontamination?

[ ]  Yes [ ]  No

If YES, ATTACH reference and recommended protocol.

### Will you use venomous, dangerous, endangered, or threatened wild animals?

[ ]  Yes

 [ ]  Venomous

 [ ]  Dangerous

 [ ]  Endangered

 [ ]  Threatened

[ ]  No

If YES:

* + - 1. LIST in box below, AND
			2. ATTACH a description of PPE and Biosafety Containment, AND
			3. ATTACH a copy of the permits from DLNR, CITES/NFWS

|  |
| --- |
|  |

## Plants and Derived Biological Materials

### Will this protocol use plants, including plant parts, plant cell lines, but excluding fungi?

[ ]  Yes – COMPLETE this section.

[ ]  Whole Plant

[ ]  Plant Part

[ ]  Plant cell lines

[ ]  No – SKIP this section. Proceed to [Section IV](#_Experimental_Design).

### Will you ONLY use commercially available de-regulated transgenic plants?

[ ]  Yes [ ]  No

### Will biological materials be inserted/inoculated/introduced?

[ ]  Yes [ ]  No

If YES, please describe.

|  |
| --- |
| Click or tap here to enter text. |

### List all plant species and research locations.

| **Plant Species**(include genus species or variety) | **Has this plant been altered?****How?** | **Location of Research** | **Greenhouse /Screen house****(Yes/No)** | **BSL of Greenhouse** | **Growth Chamber/****Room** (Location) |
| --- | --- | --- | --- | --- | --- |
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IF field testing, provide location (field allocation no., GPS location of all four corner points)

|  |
| --- |
| **Field Location:** Click or tap here to enter text. |

### Will you be using poisonous, dangerous, endangered, or threatened plants?

[ ]  Yes

 [ ]  Poisonous

 [ ]  Dangerous

 [ ]  Endangered

 [ ]  Threatened

[ ]  No

If YES:

1. LIST in box below
2. ATTACH a description of PPE and Biosafety Containment
3. ATTACH a copy of the permits from DLNR, CITES/NFWS

|  |
| --- |
| Click or tap here to enter text. |

# Experimental Design

Provide a concise description or summary of your project procedures, placed in sequential order of performance.
*Please do not attach entire protocols.*

|  |
| --- |
| Click or tap here to enter text. |

# Risk Assessment

## Risk Group Classification

The PI should review the [NIH Guidelines (PDF)](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.pdf) Appendix B, and propose a risk group.

|  |
| --- |
|[ ]  Does not apply. No microorganisms, pathogens, or biomaterial are being used that will cause human, plant, or animal disease. |
|[ ]  **RG1**: Agents that are not associated with disease in healthy adult humans. This group includes a list of animal viral etiologic agents in common use. These agents represent no or little risk to an individual and no or little risk to the community. |
|[ ]  **RG2**: Agents that are associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available. These agents represent a moderate risk to an individual but a low risk to the community. |
|[ ]  **RG3**: Agents that are associated with serious or lethal human disease for which preventive or therapeutic interventions may be available. These agents represent a high risk to an individual but a low risk to the community. |
|[ ]  **RG4**: Agents that are likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available. These agents represent a high risk to the individual and a high risk to the community. **NO RG4 RESEARCH IS AUTHORIZED AT THE UNIVERSITY OF MAINE SYSTEM.** |

## Host Range of the Biological Material(s)

Complete this question ONLY IF RG2 or RG3 selected above. Otherwise, leave blank or mark N/A.

|  |
| --- |
| Click or tap here to enter text. |

## Support for Risk Classification

Identify biosafety risks. What would be the impact of a release to the environment? Extract, condense and describe the pertinent biosafety content from your protocol. Cite supporting references and/or URLs as needed.

|  |
| --- |
| Click or tap here to enter text. |

## Hazardous Process?

[ ]  Centrifuge [ ]  Sharps [ ]  Animal [ ]  Injection

[ ]  Sonication [ ]  Tissue Harvesting [ ]  Pipetting [ ]  None

|  |
| --- |
| [ ]  Other (describe)Click or tap here to enter text.  |

## Possible Exposure Routes?

[ ]  Ingestion [ ]  Percutaneous (i.e., needle puncture) [ ]  Direct Contact

[ ]  Mucous Membrane [ ]  Inhalation [ ]  None

|  |
| --- |
| [ ]  Other (describe)Click or tap here to enter text.  |

# Risk Management

## Designated Work Areas

| **Building** | **Room Number** | **Biosafety Designation** (BSL-, ABSL-, BL-P, BL-N…) | **Date of Most Recent Biosafety Inspection** |
| --- | --- | --- | --- |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |

## Movement and Storage

Concisely describe protocol-specific movement and secure storage plans.

|  |
| --- |
| Click or tap here to enter text.      |

## Personnel and Training

List all personnel involved in the protocol. Under “Personnel Type,” please list the individual’s level or role in the protocol, such as PI, postdoc, student (undergraduate, graduate, etc.), lab technician, etc.

| **Name** | **Personnel Type**  |
| --- | --- |
|  |  |
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Please review and check the following boxes to indicate understanding of training responsibilities and requirements:

[ ]  Online CITI training is required per the [Training for Biosafety guidance on the ORC website](https://umaine.edu/research-compliance/biosafety/training/). *The PI must be fully trained before obtaining IBC approval.*

[ ]  Hands-on training of personnel is the responsibility of the PI.

[ ]  All required personnel training must be completed within 3 months of protocol approval; training must be documented in the files maintained in the lab and be made available for inspection as requested.

## Personal Protective Equipment (PPE)

Please consider all PPE use, as needs can vary depending on the activity (ex. animal work, etc.).

[ ]  Safety Glasses/Goggles [ ]  Gloves [ ]  Lab Coat [ ]  Disposable Lab Gown

[ ]  Hair Bonnet [ ]  Disposable Booties [ ]  Surgical Mask [ ]  N-95 Respirator\*

[ ]  PAPR\*

\*Requires respirator use clearance, fit testing, and training.

Please describe PPE used for the project (including any additional PPE not listed in checkboxes above).

|  |
| --- |
| Click or tap here to enter text.     |

## Engineering Controls

[ ]  Biosafety Cabinet [ ]  Fume Hood Centrifuge [ ]  Rotor Covers

|  |
| --- |
| [ ]  Other (describe)Click or tap here to enter text. |

## Equipment Certifications

| **Type of Equipment** | **Manufacturer/Model** | **Location** | **Last Certification Date** |
| --- | --- | --- | --- |
| **Biosafety Cabinet** |  |  |  |
| **Any HEPA equipment** |  |  |  |
| **Aerosol generating equipment** |  |  |  |
| **Autoclave** |  |  |  |
| How often is an autoclave quality control test (biological indicator test) performed?[ ] Annually [ ]  Quarterly [ ]  Monthly [ ] Not routine |
| TYPE of Biological Indicator: [ ]  spore [ ]  Class 5 integrator  |
| **Laminar Flow Clean Bench** |  |  |  |
| DO NOT USE a Laminar Flow Clean Bench for Infectious Agents. Laminar Flow Clean Benches are not for worker or environmental protection. They are for product protection only. |

## Decontamination and Waste Disposal

In addition to any attached protocol-specific information, describe how biohazardous materials, waste, carcasses, and bedding will be disinfected and disposed. Include type of chemical disinfectant, concentration, and time.

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| Click or tap here to enter text. |

# Incident Response Plan

## Does a written protocol-specific incident response plan exist?

(Examples of incidents would include spill, exposure, injury, fire reporting, security breech, etc.)

[ ]  Yes (Note: if yes, the plan does NOT need to be attached with this form.)

[ ]  No

## Occupational Health Program

| **Item #** | **Question** | **Yes** | **No** |
| --- | --- | --- | --- |
| VII.B.1 | Are personnel enrolled in an occupational health or medical surveillance program? |[ ] [ ]
| VII.B.2 | Respiratory protection occupational health program (required for any person using a respirator) |[ ] [ ]
| VII.B.3 | Blood-borne pathogen training and HepB vaccine |[ ] [ ]
| VII.B.4 | Other (vaccine, medical surveillance, etc.) |[ ] [ ]

# Tier 1 Select Agents and Toxins

**Does this research use Tier 1 select agents and/or toxins?** (see [Select Agents and Toxins List](https://www.selectagents.gov/SelectAgentsandToxinsList.html))

☐ Yes ☐ No

# Dual Use Research of Concern (DURC)

Biological research is considered ‘dual-use research of concern’ (DURC) if the methodologies, material, or results could be used in a manner to cause public harm. To ensure all research is given due consideration as to whether the planned experiments include DURC, the following questions must be answered.
(See [NIH Dual Use Research of Concern](https://oir.nih.gov/sourcebook/ethical-conduct/special-research-considerations/dual-use-research))

| **Item #** | **Dual Use Questionnaire** | **Yes** | **No** |
| --- | --- | --- | --- |
| IX.1 | Will an intermediate or final product of your research make a vaccine less effective or ineffective? |[ ] [ ]
| IX.2 | Will the intermediate or final product of your research confer a drug resistance trait to microorganism(s) in the study that could compromise the use of appropriate or conventional drugs to control these microorganism(s) as disease agents in humans, veterinary medicine, or agriculture? |[ ] [ ]
| IX.3 | Will your work enhance the virulence of a pathogen or render a non-pathogen virulent? |[ ] [ ]
| IX.4 | Will the results of your work increase the transmissibility of any pathogen? |[ ] [ ]
| IX.5 | Will your research result in the alteration of the host range of the pathogen? |[ ] [ ]
| IX.6 | Will your research result in an intermediate or final product that may prevent or interfere with the diagnosis of infection or disease? |[ ] [ ]
| IX.7 | Does your research enable weaponization\* of an agent or toxin? |[ ] [ ]
| IX.8 | Will synthetic biology\*\* techniques be used to construct a pathogenic organism, toxin or potentially harmful intermediate product? |[ ] [ ]
| IX.9 | Even if your planned research does not involve any of the above eight criteria, and recognizing that your work product or results of your research could conceivably be misused, is there the potential for your data/product to be readily used to cause public harm? |[ ] [ ]

\*In this context, weaponization refers to the enhanced dispersion, deliverability, survivability or pathogenesis of a potentially harmful agent or toxin.

\*\*Synthetic biology includes, but is not limited to, techniques of molecular biology, chemistry, and genetics that would allow for the *de novo* synthesis or reverse engineering of genes, gene products or entire functional organisms.

# Federal/State Permits and Other Approvals

## Federal and State Permits

**Do the activities/materials for this project require a federal/state permit?**
[ ]  Yes [ ]  No

If YES:

1. COMPLETE the table below with the permit information, AND
2. ATTACH a copy of the current permits
* There will be No Authorization without a copy of the permit or authorization.
* For NEW protocols, if a permit is pending, you must submit a copy of the final approved permit to the Biosafety Office before you may begin work.

For RENEWAL protocols, please provide most current approved permit with the protocol form.

| **Type (CDC, USDA)** | **Permit #** | **Biological Materials listed on permit** | **Importation / Inoculation** | **Exp. Date** |
| --- | --- | --- | --- | --- |
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## Other UMaine Review Committee Approvals

**Is this work subject to any of the following?**

[ ]  IACUC

[ ]  IRB

[ ]  Radiation Safety (Risk and Safety Management [RSM])

[ ]  Chemical and Physical Hazards (RSM)

[ ]  Export Control

If YES to any of the above, please provide basic information in the table below. The PI should submit applications to these other review entities as appropriate.

| **Protocol #** | **Protocol Title** | **Exp. Date** |
| --- | --- | --- |
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# Miscellaneous

| **Item #** | **Question** | **Yes** | **No** |
| --- | --- | --- | --- |
| XI.1 | Will your experiments involve large scale culture? (bioreactors or >10 Liters in one container) |[ ] [ ]
| XI.2 | Will your experiments involve transfer of an antibiotic resistance gene into the host in addition to those contained in vectors? |[ ] [ ]
| XI.3 | Will you be using human pluripotent stem cells derived from human embryos (human embryonic stem cells) or human fetal tissue (human embryonic germ cells)? |[ ] [ ]
| XI.4 | Will your research/experiment involve the need to share confidential or proprietary information? |[ ] [ ]
| XI.5 | Will your research/experiment involve the need to transfer materials and/or data to other institutions, organizations, or foreign countries? |[ ] [ ]

If YES to ANY of the above question, please ATTACH additional information.

**The information provided may be shared with other institutional programs and offices for their review and assessment. It is intended that the disclosure of information to other UMaine compliance entities will not interfere with the independent IBC review and approval process.**

# Certification

As Principal Investigator, I understand the risks associated with recombinant and synthetic nucleic acid molecules, use of biologically hazardous materials (human pathogens, human blood, body fluids, or tissues, animal pathogens, blood, body fluids or tissues, plant pathogens), and imported biological materials.

I will notify the [UMaine Office of Research Compliance and Institutional Biosafety Officer](https://umaine.edu/research-compliance/biosafety/#contact) immediately should related activity produce an unanticipated product that increases virulence or toxicity, or otherwise confers a phenotypic change that could be biologically hazardous. Furthermore, I certify I have read the relevant sections of the NIH Guidelines and CDC/USDA requirements (see links above), have or will have appropriately trained and advised my staff of the requirements outlined in the NIH Guidelines or CDC/USDA requirements prior to initiation of the project, acknowledge I have reviewed this form, and I am responsible for this project.

I am familiar with and agree to abide by all provisions of UMaine IBC, US CDC, Maine BLS, NIH, USDA, and other applicable State and Federal guidelines/regulations pertaining to the proposed project. I understand that I bear the responsibility for ensuring that all personnel are adequately trained and informed of any risks with the research activity.

I agree to comply with all applicable requirements pertaining to:

* Reporting of all personnel exposures of regulated biological material
* Reporting any transgenic/knockout/knock-in/ biological material release/escape.
* Transport/transfer of for import/export of biological commodities

**The information in this application is accurate and correct.**

|  |  |  |
| --- | --- | --- |
| **Principal Investigator (Print)**Click or tap here to enter text. | **Principal Investigator (Signature)** | **Date**Click or tap to enter a date.   |

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| --- | --- | --- |
| **FOR IBC USE ONLY**Approver name(s): Click or tap here to enter text.Approval date: Click or tap here to enter text.Exempt status:[ ]  Exempt[ ]  Not ExemptApproval types: [ ]  DNA[ ]  Class II Infectious AgentsBSL Designation: Click or tap here to enter text.Biohazard Summary:

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| Click or tap here to enter text. |

Notes:

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| Click or tap here to enter text. |

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