Hello and thank you for accessing this form from the University of Maryland, Baltimore County Institutional Biosafety Committee web site.

Prior to submitting, please ensure that spelling and grammar are correct; this will assist in the timely review of this form during the IBC evaluation process. Complete all sections of the protocol application (indicate N/A in the section not applicable to your protocol). "See attached proposal" or “See the previous section” are not an acceptable responses.

Enter information by clicking the [ ]  box or typing in the **Click here to enter text.** area.

**Please go to UMBC** [**IBC website**](http://research.umbc.edu/biosafety-institutional-biosafety-committee/) **for all up-to date guidance and information regarding the below questions.**

**SECTION I: ADMINISTRATIVE INFORMATION**

PRINCIPAL INVESTIGATOR INFORMATION

Name: Click here to enter text. Department: Click here to enter text.

Email address: Click here to enter text. Phone: Click here to enter text.

Title of Research Project: Click here to enter text.

CATEGORY OF APPLICATION Please click the link for more information and choose the one that best describes this request

[**Full Committee Review**](http://research.umbc.edu/umbc-institutional-biosafety-committee-overview-2/#fullcom)**:** [ ]  **New** [ ]  **Updating Existing IBC approval**

[**Designated Member Review**](http://research.umbc.edu/umbc-institutional-biosafety-committee-overview-2/#desmem)**:** [ ]  **New Faculty startup** [ ]  **New Research Topic**

Note: If using a ***material transfer agreement*** to obtain materials described in this application, enter date when submitted to the Office of Technology Development (OTD): Click here to enter text.

EXTERNAL FUNDING INFORMATION (leave blank if not externally funded)

Name of PI on Grant:Click here to enter text.

Funding Agency/Source: Click here to enter text.

Project Dates: Click here to enter text.

Proposal or Award ID and Award Title: Click here to enter text.

Approval of this protocol is needed for grant application deadline? [ ]  Yes [ ]  No Deadline date: Click here to enter text.

As a federally funded institution, UMBC will hold all research conducted at the university to the same high standards as required by federally funded projects. One standard is performing congruency review of grant proposal application with any corresponding applications(s) reviewed and approved by the IBC. **Please attach a copy of the components of grant applications and contract proposals related to recombinant DNA and biohazardous materials use.** The ORPC will review research with recombinant DNA and biohazardous materials for congruency with respective components of grant application and contract proposals.

**SECTION II: INSTITUTIONAL & REGULATORY APPROVALS/ REVIEW**

|  |
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|  |
| **A. USE OF VERTEBRATE ANIMALS**Does this biosafety activity involve the use of animals? | [ ]  Yes [ ]  No | If Yes, please provide IACUC approval date: Click here to enter a date. Click on the [IACUC website](http://research.umbc.edu/institutional-animal-care-and-use-committee-animal-care-use/) for information and materials  |
| **B. USE OF HUMAN SUBJECTS**Does this biosafety activity involve the use of human subjects or human samples? | [ ]  Yes [ ]  No  | If yes, please provide the IRB approval date:Click here to enter a date.Click on the [IRB website](http://research.umbc.edu/institutional-review-board-human-subjects/) for information and materials  |
| **C. USE OF HAZARDOUS MATERIALS**Does this biosafety activity involve the use of radioactive materials, potentially pathogenic materials, infectious agents or biological toxins?  | [ ]  Yes [ ]  No  | If Yes, please provide ESH review date: Click here to enter a date.Click on the [ESH website](http://www.umbc.edu/safety) for information and materials |

**SECTION III: LOCATION OF ACTIVITIES**

|  |
| --- |
| LOCATION Approval of the proposed activity is given only for the locations listed below.  |
| Building | Room number(s) | Name and phone number of contact person at this site |  |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |  |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |  |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |  |
|  |
| Does any part of this activity occur at a non-UMBC facility or site? Yes [ ]  No [ ] If Yes, complete all of the following information for each non UMBC facility |
| Name and address of non-UMBC Facility | Contact Name, Title, Phone Number |
| Click here to enter text. | Click here to enter text. |
| Do any UMBC personnel associated with this activity physically participate in the activity at this non-UMBC facility? Yes [ ]  No [ ] If Yes, list the name(s) of these personnel Click here to enter text. |
| Are any hazardous or recombinant/synthetic NA materials transferred to your lab from this non-UMBC facility for this activity? Yes [ ]  No [ ] If Yes, write describe the materials transferred Click here to enter text.If using a ***material transfer agreement*** to obtain materials described in this application, enter date when submitted to the Office of Technology Development (OTD): Click here to enter text.  |
| Does this facility/or specific area where the work is conducted have an IBC approval for work at the appropriate biosaftey level? Yes [ ]  No [ ]  If Yes, what is the approved BSL? [ ]  BSL-1 [ ]  BSL-2**If work is conducted at a non UMBC facility, attach a copy of that institution’s IBC approval to this form** |

**SECTION IV. TYPE OF BIOLOGICALS AND BIOSAFETY ACTIVITY**

|  |
| --- |
| BIOHAZARDOUS AGENTS: Check all boxes that apply to this project.  |
| 1. [ ]  Arthropod (e.g., mosquitoes, ticks)
2. [ ]  Biohazardous agents (e.g. bacteria, viruses, prions)
3. [ ]  Cells or tissues (Animal source)
4. [ ]  Cells or tissues (Human or non-human primate source), blood, or body fluids, unfixed tissue including immortalized cell lines.
5. [ ]  Fungi
6. [ ]  Parasite (e.g., Plasmodium spp.)
7. [ ]  Recombinant or synthetic nucleic acidmolecules
8. [ ]  Toxin ([ ]  chemical or [ ]  biological product)
 | 1. [ ]  Use of expression vectors

[ ]  Yes viral vector [ ]  Yes cosmid, phagemid, plasmid vector1. [ ]  Virus - Animal
2. [ ]  Virus – Plant
3. [ ]  Other, list material below (e.g. *dura mater* from human, non-human primate, livestock, rickettsia, etc.)

Click here to enter text. |
| B. Check the appropriate boxes to indicate the sources of the materials listed above. |
|  [ ]  A commercial vendor - select all applicable [ ]  Addgene [ ]  ATCC [ ]  Stratagene [ ]  Promega  Other: Click here to enter text. **Provide the vendor or manufacturer order number:** Click here to enter text.[ ]  Isolation from environmental samples (water, soil, etc.) [ ]  Isolated from a plant or animal Colleagues and collaborators in: [ ]  Academia or [ ]  Industry [ ]   Specify:Click here to enter text.For each box checked in IV.B, provide the COMMON NAME, SCIENTIFIC NAME (genus & species, strain and/or Manufacturer’s kit name and product number) in the boxes below. Check each box that applies in the “SPECIFICS” column.  |
| COMMON NAME | SCIENTIFIC NAME (Genus & species, strain) | Yes No SPECIFICS |
| Click here to enter text. | Click here to enter text. | [ ]  [ ]  Special precautions or equipment (e.g. biosafety cabinets) required? (If yes, please describe): Click here to enter text. |
| Click here to enter text. | Click here to enter text. | [ ]  [ ]  Special precautions or equipment (e.g. biosafety cabinets) required? (If yes, please describe): Click here to enter text. |
| Click here to enter text. | Click here to enter text. | [ ]  [ ]  Special precautions or equipment (e.g. biosafety cabinets) required? (If yes, please describe): Click here to enter text. |
| Click here to enter text. | Click here to enter text. | [ ]  [ ]  Special precautions or equipment (e.g. biosafety cabinets) required? (If yes, please describe): Click here to enter text. |

*Please add additional pages to the end of this application, if required.*

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| C. PROPOSED BIOSAFETY LEVEL |
| What is the proposed Biosafety Level for this activity? [ ]  BSL-1 [ ]  BSL-2 | * Biosafety Level 1 involves well-characterized agents not known to consistently cause disease in healthy adult humans, and of minimal potential hazard to laboratory personnel and the environment.
* Biosafety Level 2 involves work with agents of moderate potential hazard to personnel and the environment.
* Biosafety Level 3 involves clinical, diagnostic, teaching, research, or production facilities in which work is done with indigenous or exotic agents that may cause serious or potentially lethal disease as a result of exposures by the inhalation route. **BSL-3 is not allowed at UMBC facilities.**
* Biosafety Level 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease. **BSL-4 is not allowed at UMBC facilities.**

Sources: [NIH Guidelines November 20](http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm)13 and [CDC BMBL 5th Edition](http://www.cdc.gov/biosafety/publications/bmbl5/index.htm)  |

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| D. RECOMBINANT OR SYNTHETIC NUCLEIC ACIDS |
| Does this research involve the use of recombinant or synthetic nucleic acidmolecules? [ ]  Yes [ ]  No  If yes, complete the below. |
| **Materials** | **Genus & species of organism / source of DNA** | **Specific source (e.g. tomato, environmental sample; or for *E. coli* and other cells supplied as part of commercial prep kit, list the origin of the cell line). Give reference, if applicable**  | **What is the nature of the DNA sequence of interest?** |
| Source of DNA[ ]  Plant[ ]  Animal[ ]  Other  | Click here to enter text. | Click here to enter text. | Click here to enter text. |
| **Expression vectors** | **Vector name(s)****(add additional spaces or attach a separate page if necessary)** | **Specify selection markers.****(Provide a gene map or give a reference from literature or commercial supplier if applicable.)**  | **Will the foreign gene be expressed? If yes, indicate the protein that will be produced and identify promotors** |
| Use of expression vectors?  [ ]  Yes [ ]  No[ ]  Viral vector  [ ]  Plasmid vector | Click here to enter text. | Click here to enter text. | Click here to enter text. |

*Please add additional pages to the end of this application, if required.*

E. CLASSIFICATION OF RECOMBINANT OR SYNTHETIC NA WORK UNDER THE NIH GUIDELINES

Refer to the [UMBC IBC website](http://research.umbc.edu/biosafety-institutional-biosafety-committee/) for the appropriate classification of your research

|  |  |
| --- | --- |
| [ ]   | **Section III-A, B & C:** Experiments that require NIH and IBC approval prior to initiation. This process is initiated by first submitting to Institutional Biosafety Committee (IBC) then to the NIH . The NIH may determine the level of containment. This process may take several months to complete. |
|[ ]  **Section III-D:** Experiments require IBC review before procuring materials to initiate experiments at UMBC. **Check** [ ]  **if transgenic animals will be used.** |
|[ ]  **Section III-E:** Experiments require IBC review before procuring materials to initiate experiments at UMBC. **Check** [ ]  **if transgenic animals will be used.** |
|[ ]  **Section III-F:** Experiments that are exempt under the NIH Guidelines and **do require** IBC review before procuring materials to initiate experiments at UMBC. **Check** [ ]  **if transgenic animals will be used.** |
|  | Under Section III-F , if using transgenic animals, check the following:[ ]  purchase or transfer of transgenic rodents. (Appendix C-VII) The purchase or transfer of transgenic rodents for experiments requiring Biosafety Level 1 containment.[ ]  generation of BSL-1 Transgenic Rodents via Breeding. (Appendix C-VIII) The breeding of two different transgenic rodents or the breeding of a transgenic rodent and a non-transgenic rodent with the intent of creating a new strain of transgenic rodent that can be housed at BSL-1 containment will be exempt from the NIH Guidelines if:(1) Both parental rodents can be housed under BSL-1 containment;And(2) neither parental transgenic rodent contains the following genetic modifications:i. incorporation of more than one-half of the genome of an exogenous eukaryotic virusfrom a single family of viruses; orii. incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat (LTR);and(3) the transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses. |

# SECTION V: DESCRIPTION OF ACTIVITY

A. LAY SUMMARY

In lay language, describe the experimental design and research objectives of the activity, with specific mention of the materials LISTED IN SECTION IV. Provide details that will allow a non-scientist to understand your work and assess the hazards and risks. Please define all acronyms at first use. Include an assessment of risks to personnel working on the research.

Click here to enter text.

B. PROCEDURES

Describe the procedures that you use for this activity. Provide this description with the intent of providing the IBC with a clear understanding of what you are doing IN TERMS OF THE MATERIALS LISTED IN SECTION IV. Include any activities which may produce aerosols, or which may increase the hazard of working with the biohazardous agent(s). Include both standard procedures (referred to by common names such as PCR), and novel procedures or significant modifications to standard procedures (which should be clearly described and/or a reference should be provided). List personal protective equipment (PPE) to be used.

Describe techniques, equipment and procedures to contain microorganisms:

a. Receiving and handling:

b. Containment in lab

c. Storage:

Click here to enter text.

C. SUBSTANCE DISPOSAL AND DECONTAMINATION PROCEDURES

Review the template language below describing the method of disposal of biohazardous substances and recombinant or synthetic nucleic acid transformed organisms (e.g., incineration, autoclaving, chemical disinfections). If chemical disinfectant other than a 10% dilution in water of 5.25.0% sodium hypochlorite (stock solution) is used, state chemical and concentration in the space provided. Note: Sodium hypochlorite solutions cannot be autoclaved.

**Inappropriate disposal of waste poses a potential for adverse environmental impact and regulatory enforcement action. We will follow UMBC procedure and regulations on disposal of solid lab waste, viable organisms waste DNA and materials containing recombinant or synthetic nucleic acid. All personnel will be trained by ESH in OSHA Hazard Communication, Laboratory Standard, and at least one person in our lab will be trained in UMBC Hazardous Waste Disposal.**

 **We decontaminate all solid waste (transformation products, spent agar plates) by autoclaving for 60 minutes.**

**We record autoclave use in a logbook containing the following information for each load:**

 **The date and time the cycle is engaged.**

 **The operator’s initials.**

 **Content (waste for decontamination, implements being sterilized, and liquids being sterilized.)**

 **Volume of the load, (e.g., bag size X number of bags).**

 **Cycle duration and type of load, i.e. 30-minute/liquid, 60-minute/dry.**

**We decontaminate liquid wastes and surfaces contaminated with liquid waste or cultures using a 10% volume/volume dilution of 5.25% sodium hypochlorite (household bleach) in water prior to disposal down the sanitary sewer. The resulting concentration is 0.525% sodium hypochlorite. We understand that the 10% hypochlorite solution will break down within a month, so we make up** [**a fresh dilution at least every day**](http://www.ors.od.nih.gov/sr/dohs/BioSafety/decon/Pages/decontamination.aspx)**. We track expiration by labeling the container with the date the solution was made.**

**We practice good housekeeping and package sharps in puncture-resistant containers manufactured for the purpose of sharps disposal and contain our waste in lined, rigid containers. We contact UMBC ESH for pick up of chemical waste and full sharp containers.**

Check here to indicate your research project will follow the above procedures [ ]

Specify any additional waste handling, decontamination, and disposal operations beyond those described above. (For example, household dish detergent may be used for some BSL-1 organisms instead of sodium hypochlorite.)

Click here to enter text.

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| D. EQUIPMENT |
| Do you use a biosafety cabinet (BSC) for this activity? [ ] Yes [ ]  No Do you use a chemical fume hood (CHF) for this activity? [ ] Yes [ ]  NoDo you use an autoclave for decontamination of laboratory waste? [ ] Yes [ ]  No  |
| If Yes to above, please check the appropriate box and fill in the information requested below.  |
|  | BUILDING | ROOM | ID INFO (e.g. MANUFACTURER, MODEL, SERIAL NUMBER) | TYPE OR CLASS | LAST ANNUAL CERT DATE \***MM/DD/YY** |
| [ ] BSC [ ]  CHF [ ]  Autoclave | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter a date. |
| [ ] BSC [ ]  CHF [ ]  Autoclave | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter a date. |
| [ ] BSC [ ]  CHF [ ]  Autoclave | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter a date. |
| [ ] BSC [ ]  CHF [ ]  Autoclave | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter a date. |

**\* Please contact Environmental Safety and Health to verify certification dates for BSC and CHF; Facilities Management for autoclave.**

**SECTION VI: PERSONNEL**

A. PERSONNEL

Provide the names of all persons (faculty, staff, post-doc, grad student, undergrad student, technician, or other person) working on this project. **All** personnel are required to take the below training prior to release of IBC approval. For each person provide most recent date of training completion.  **REMINDER: All training must be repeated annually. If you need information about training completion dates or have questions, please contact the ORPC.**

 [-----------Webnet Training---------------] [---------CITI Training-----]

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PERSONNEL  | [Lab Safety Training](http://research.umbc.edu/2041-2/)***Enter the date below*** | [Hazardous Communications](http://research.umbc.edu/2041-2/)***Enter the date below*** | [Bloodborne Pathogens](http://research.umbc.edu/2041-2/)***Enter the date below*** | [OSHA PPE Training](http://research.umbc.edu/2041-2/)***Enter the date below*** | [NIH rDNA Guidelines](http://research.umbc.edu/2041-2/)***Enter the date below*** |
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*Please add additional pages to the end of this application, if required.*

**SECTION VII: Principal Investigator Statement**

I certify that the information contained in the IBC application is accurate to best of my knowledge.

I agree to comply with all University and IBC requirements with regard to the use, handling, storage and disposal of biological agents and recombinant or synthetic nucleic acid molecules.

 I agree to follow the current *National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (November 2013)* and the recommendations from the CDC/NIH handbook, *Biosafety in Microbiological and Biomedical Laboratories, 5th Edition.*

I ensure that all research personnel listed on this application have completed all biosafety training modules and they are familiar with the hazards and symptoms of exposure relevant to the biological materials used within the laboratory. All laboratory personnel have been briefed on emergency procedures, good laboratory work practices, and the safe operation of laboratory equipment prior to the initiation of experimental work. Prior to the initiation of experimental work all vaccinations or medical surveillance requirements recommended by the IBC and ESH will be met.

I ensure that all personnel identified in this application are informed of UMBC’s safety guidance and plans including the [**UMBC Laboratory Safety Guide**](http://www.umbc.edu/safety/docs/umbc_laboratory_safety_guide.pdf)**,**  [**Chemical Hygiene Plan**](http://www.umbc.edu/safety/docs/Chemical_Hygiene_Plan_2013.pdf)**,**  [**Laboratory Spill Response**](http://www.umbc.edu/safety/docs/SPILL%20RESPONSE%20FOR%20LABORATORY%20PERSONNEL.pdf)and **[Bloodborne Pathogen Exposure Control Plan](http://www.umbc.edu/safety/bloodbornepathogens.html)**[.](http://www.umbc.edu/safety/bloodbornepathogens.html)

Personal protective equipment, necessary for experimental procedures, will be provided to all laboratory workers. All biosafety cabinets shall be maintained properly and certified ***annually*.**

I understand that if I or any of the project personnel have a financial interest related to the research or sponsor (e.g. payment for services, equity interests, etc.) that it must be disclosed according to [UMBC Conflict of Interest](http://www.umbc.edu/research/ORPC/coi_procedures_umbc.html) policy.

**I will notify UMBC Environmental Safety and Health (410-455-2918) in the event of the following:**

1. Accident resulting in inoculation, ingestion, and inhalation of biological agents or recombinant or synthetic nucleic acid molecules or any incident causing serious exposure of personnel or danger of environmental contamination. **It is an NIH requirement for any institution that receives NIH funding to report any accident involving the use of recombinant or synthetic nucleic acid molecules within 24 hours.**

2. Malfunction of biological and physical containment safety equipment (biosafety cabinet), or facility failure, which may compromise building engineering controls and the safety of the workers in the lab.

3. All experimental work has been completed.

I will not proceed with the experiment until I have received an official notice of approval from the IBC unless otherwise specified. I acknowledge that IBC approval granted by this application is non-transferable to any other UMBC researcher.

Principal Investigator Name:Click here to enter text. Date: Click here to enter a date.

By typing your name, email address and date, the investigator certify they will abide by all UMBC IBC policies and procedures and understand that no research activities will be conducted prior to obtaining the required approvals.

 Investigator’s Signature: Click here to enter text. Email: Click here to enter text. Date: Click here to enter a date.