View xForm - IBC Protocol Form

IBC Protocol Form v2.1

IBC Protocol Form Data Entry

A. Initial Demographics and Personnel

*** you can use the drop-down list above to temporarily skip past error messages. ***

Date for 180 day notice

9/14/2020

Submitter

Joseph, Elaine

Email: Elaine.Joseph@UToledo.Edu

A.1. What is the title of your project?

Title should reflect content and subject of project

A.2. Select the Principal Investigator by typing the first few letters of their last name into the box below and selecting the appropriate entry from the list.

Entered: 09/21/20 **By:** Joseph, Elaine **Internal:** No

This should be the PI or faculty member in charge of the protocol

Member, Board

Email: board.member@example.com **Phone:**

A.2.1. PI's Highest Biosafety Containment Level
BSL-2

A.3. P.I. Department

No answer provided.

If the P.I.'s department does not appear, it may be because it was either missing or incorrect in the KC or RSP system or the person was created using the automatic UTAD process, which does not have access to the person's department. A connection to update this data from Banner is in progress but will not be finished for a while.

A.4. If the P.I.'s department is missing above, please choose the department here.

No answer provided.

A.5. Study-Site Contacts

Add each member of your study team (other than the PI listed above) by typing part of their first or last name, email or Rocket Number into the space provided. Please add yourself if you will be a part of the study team and engaged in research. Remember to click "Save" at the end of the row when you have completed entry for that row.

Personnel Name	Highest Biosafety Containment Level

If you are unable to locate a UT-affiliated person in the drop down list to add to your study, ask the person to log into IRB Manager using their UTAD credentials. Within 5 minutes the person's contact record will available to add to the personnel table above.

IBC Biosafety Training for Researchers:

Contact	Expires (as of 10/20/2020)

IBC Laboratory Safety Training for Researchers:

Contact	Expires (as of 10/20/2020)

Calculate Title for Review Details

Title should reflect content and subject of project

B. Protocol Summary

*** you can use the drop-down list above to temporarily skip past error messages. ****

B.1. In a few sentences, briefly describe the purpose and objectives of your research.

The summary should be no more than two to three paragraphs at most and contain the purpose and objectives of the research. The summary should also state what you hope to achieve as a result of the project.

B.2. Briefly describe the types of experimental procedures that will be performed (e.g. Northern Blot, protein production, Flow Cytometry, etc.). Include any planned use of Core Facilities equipment.

This section should not only list the experimental procedures you plan to use, but also provide brief descriptions of those procedures. For example, "The cellular and molecular analysis will be through a quantitative real-time polymerase chain reaction (qRT-PCR). Briefly, cells from the disc will be collected and RNA will be extracted using TRIzol reagent (Thermo Fisher Scientific, US), and reverse transcription will be performed using the Omniscript RT kit (Qiagen, US) as per the manufacturer's instructions." Any procedures which will be done in a Core Facility (includes Flow Cytometry, Incucyte, IVIS, Laser Scanning Confocal Microscope,) needs an SOP. Generic SOPs are uploaded for you to modify here. It is also helpful for you to upload SOPs for complicated procedures, such as ELISA.

B.2.1. Attach SOP, if using a Core Facility

Rodent In Vivo Bioluminescence Imaging.docx	SOP	10/01/2020 11:01:34 AM ET
SOP for Confocal.docx	SOP	10/01/2020 11:01:35 AM ET
SOP for FACS.docx	SOP	10/01/2020 11:01:35 AM ET
SOP for InCucyte use.docx	SOP	10/01/2020 11:01:35 AM ET

B.3. Please list types of hazards to be used (e.g. viruses, bacteria, cell lines, human or animal tissues, etc.) including genes and vectors.

This section should contain a list of all the biohazards you are proposing to use in the project.

B.4. Address the potential sources of risk to personnel (aersol generation, needle sticks, etc.) and/or the environment and how these risks will be managed. Describe all safety precautions that will be used (e.g. biosafety cabinets, hand washing facilities, puncture resistant sharps container, personal protective equipment, etc.).

This section should list all the sources of risk to personnel based upon the procedures you are proposing (i.e., aerosol generation, needle sticks, etc.), specifically biohazards, as well as how you propose to minimize those risks. Please include such items such as the use of a biosafety cabinet during procedures, required personal protective equipment, safety needles (if appropriate), etc.

B.5. List all locations for experiments, plans for transportation of materials between laboratories (including Core Facilities), and secondary containment.

This should be a listing of all locations and information on how and if you will be transporting the biohazards or samples between these locations. If you are transporting samples, you must include secondary containment (i.e., another container to put the samples inside) during the transportation. This should be described here.

C. General Details

*** you can use the drop-down list above to temporarily skip past error messages. ****

C.1. Recombinant and Synthetic DNA are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are using recombinant DNA, viral vectors, plasmids, or synthetic DNA - excluding PCR primers

Yes

C.2. Infectious agents (bacteria, fungi, virus) are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are using bacteria, fungi, viruses (including viral vectors, such as lentivirus).

Yes

C.3. Tissues, fluids (incl. stem cells) or cell lines (human or animal) are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are using any tissues, fluids (i.e., blood, urine), or cell lines from humans or animals.

Yes

C.4. Non-Cellular Biohazards - Biological Nanoparticles and Biotoxins are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are using biological nanoparticles or biotoxins (i.e., microcystin, diphtheria toxin)

Yes

C.5. Live animals (vertebrate and invertebrate) are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if vertebrate or invertebrate transgenic animals are to be used. It should also be yes if vertebrate or invertebrate animals will be administered a biohazard.

Yes

C.6. Plants are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if transgenic plants or toxic or dangerous plants are involved, plants are to be genetically modified, or plant cells are to be used and modified by a biohazard or plasmid or viral vector.

Yes

C.7. Select agents are involved.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if any Federal Select Agents or Toxins are to be used.

Yes

C.8. On what campus(es) will work be performed?

No answer provided.

C.9. Please list all locations where research/procedures will occur.

Building	Room Number	Maximum Biosafety Level	Purpose (Check all that apply)

C.10. What is the highest containment level that applies to the work described in this protocol?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This is the highest Biosafety Level for this protocol. For example, any work with human tissue/fluids/cell lines would place the protocol at BSL-2. If you have any questions, please see the BMBL.
https://www.cdc.gov/labs/BMBL.html

No answer provided.

C.11. What is the highest risk group that applies to the work described in this protocol?

No answer provided.

Risk Group 1 (RG1): Agents not associated with disease in healthy adult humans
Risk Group 2 (RG2): Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3 (RG3): Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
Risk Group 4 (RG4): Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

D. Recombinant and Synthetic Nucleic Acids

*** you can use the drop-down list above to temporarily skip past error messages. ****

NIH GUIDELINES

D.1. Provide the following information about the DNA source(s). DO NOT LIST VECTORS, only genetic material to be inserted into vectors.

Source Type (^ = Name Required)	Name of Source^	Classification	Genus/Species/Subtype	Fraction of Genome	Name of Gene
Collegue Via MTA	name of colleague where DNA was obtained	Eukaryote	genus species (i.e. Human)	Whole Genome	name of gene
Commercial Vendor	name of vendor	Eukaryote	genus species (i.e., Human)	Whole Genome	name of gene

D.2. Information - Please consult the NIH GUIDELINES for research involving recombinant and synthetic nucleic acid molecules in answering the following.

D.2.1. Are any of the source organisms pathogenic to humans or other vertebrates?
No answer provided.

Consult Appendix B of the NIH GUIDELINES

D.2.2. Are you introducing antibiotic resistance into an infectious pathogen?
No answer provided.

D.3. Experiments - Check all the categories below that apply to the work you intend to do with recombinant DNA.

Protein Production

D.3.1. List ALL proteins to be produced and their known activity

Protein	Protein Activity/Enzymatic Activity
name of protein	protein activity

D.3.2. Are any of the above proteins known vertebrate toxins?

No answer provided.

D.4. Provide the following information about the vectors(s) being employed for this work.

Vector Types	Vector Name and Vendor Name/List	Transmissible?	Commercially Available?
Plasmid	name of vector/name of vendor	No	Yes

D.5. Provide the following information for each cell line used with vectors.

Source Type (^ = Name Required)	Name of Source^	Genus/Species/Subtype	Vector Associated	Materials Produced
Commercial Vendor	name of vendor	genus species (i.e., human)	list all vectors associated with this cell line	DNA Protein

D.6. Volume - What is the maximum volume of culture to be grown at any time?

Be advised that volumes greater than 10L will require more stringent oversight

No answer provided.

D.7. Risk Assessment - Consult the NIH GUIDELINES section II. Which risk group applies to the work in the recombinant and synthetic DNA portion of this research?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Risk Group is determined based upon the recombinant and synthetic DNA portion of the work (i.e., the rDNA, viral vector, and plasmid portions of the project). For example, work with lentivirus is Risk Group 2. Please see the NIH Guidelines linked above for more information on determining Risk Group. You must also list all of the health risks associated with working with these plasmids, viral vectors, etc. For example, lentiviruses can integrate a human host and causes disease and some lentiviruses can have ocogenic effects.

No answer provided.

Risk Group 1 (RG1): Agents not associated with disease in healthy adult humans
Risk Group 2 (RG2): Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3 (RG3): Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
Risk Group 4 (RG4): Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

D.7.1. Provide the specific citation to justify your choice. List section from the NIH guidelines and explain how it relates to the recombinant and synthetic DNA portion of this research.
No answer provided.

D.7.2. List all possible human health risks associated with the recombinant and synthetic DNA portion of this research.
This should list the human health risks associated with the recombinant DNA you are using. For example, "Acute infection with human lentiviruses can appear as non-specific “flu-like” and “mononucleosis-like” symptoms, including myalgia, arthralgia, diarrhea, nausea, vomiting, headache, hepatosplenomegaly, weight loss and neurological symptoms.
There is also the potential risk of oncogenesis based upon the nature of the transgene insert encoded by the vector."

D.8. Biosafety Containment Level - Consult Appendix G of the NIH GUIDELINES. Choose the appropriate biosafety level for procedures, equipment, and facilities for the recombinant and synthetic DNA portion of this research.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Biosafety level is chosen based upon the recombinant and synthetic DNA portion of the work (i.e., the rDNA, viral vector, and plasmid portions of the project). For example, work with lentivirus is Biosafety Level 2. Please see the NIH Guidelines linked above for more information on determining Biosafety Level.

No answer provided.

D.8.1. Provide the specific citation to justify your choice. List sections from the NIH guidelines.
No answer provided.

D.9. Waste/Disposal/Elimination - Select the appropriate disposal methods for materials used in this work.

No answer provided.

D.10. Decontamination - Select the appropriate methods for decontaminating instruments and work surfaces for this protocol.

No answer provided.

E. Infectious Material

*** you can use the drop-down list above to temporarily skip past error messages. ****

BMBL Guidelines

E.1. Provide the following information for each source of infectious material.

Source Type (^ = Name Required)	Name of Source^	Classification	Genus/Species/Subtype
Commercial Vendor	name of vendor	Eukaryote	name of species (i.e., dengue virus)
Lab Derived^	name of lab where originated	Eukaryote	name of species (i.e., lentivirus)

E.2. Risk Assessment - Please consult section II of the CDC-Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition. Which risk group applies to the work described in the infectious material portion of the protocol?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Risk Group is determined based upon the infectious material or bacteria, virus, and fungi used in the protocol. For examples, work with dengue virus would be Risk Group 2. Please use the BMBL to help determine Risk Group https://www.cdc.gov/labs/BMBL.html. In addition, please list all the health effects related to working with infectious materials.

No answer provided.

Risk Group 1 (RG1): Agents not associated with disease in healthy adult humans
Risk Group 2 (RG2): Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3 (RG3): Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
Risk Group 4 (RG4): Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

E.2.1. List section from the BMBL and explain how it relates to the infectious agent portion of this research.
No answer provided.

E.2.2. List all possible human health risks associated with the infectious agent portion of this research.
This should list the human health risks associated with the infectious materials you are using. For example, "Acute infection with human lentiviruses can appear as non-specific “flu-like” and “mononucleosis-like” symptoms, including myalgia, arthralgia, diarrhea, nausea, vomiting, headache, hepatosplenomegaly, weight loss and neurological symptoms.
There is also the potential risk of oncogenesis based upon the nature of the transgene insert encoded by the vector"

E.3. Biosafety Containment Level - Consult section IV of the CDC-BMBL. Choose the appropriate biosafety level for procedures, equipment, and facilities in the Infectious Material portion of the protocol.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Biosafety Level is determined based upon the infectious material or bacteria, virus, and fungi used in the protocol. For example, work with dengue virus would be BSL-2, per the BMBL under Arboviruses (Table 6 pg 251). Please use the BMBL to help determine Biosafety Level https://www.cdc.gov/labs/BMBL.html.

No answer provided.

E.3.1. List relevant sections from the BMBL to justify your biosafety level and briefly explain your justification.
No answer provided.

E.4. Waste/Disposal/Elimination - Select the appropriate disposal methods for materials used in this work.

No answer provided.

E.5. Decontamination - Select the appropriate methods for decontaminating instruments and work surfaces for this protocol.

No answer provided.

E.6. Contingency Plans - Describe all contingency plans in place in the event of spill/escape/personnel exposure. State if you have received your UT Safety and Health-issued spill kit.

This section should include plans your lab has in place for spills - including clean up and notification of EHRS where appropriate. This section should also address plans if personnel are exposed (treatment, reports, etc.). If you do not have a UToledo spill kit, please notify EHRS and get one as soon as possible.

F. Human/Animal Tissues and Cell Lines

*** you can use the drop-down list above to temporarily skip past error messages. ****

(Including stem cells - NOTE HSCRO committee approval is required for human stem cells)

BMBL Guidelines

F.1. Provide the following information for each source of tissue and/or cell line.

Source Type (^ = Name Required)	Name of Source^	Classification	Genus/Species/Subtype
Collegue Via MTA	name of colleague where material was obtained	Body Fluids	human blood
Commercial Vendor	name of vendor (i.e., ATCC)	Cells/Cell Line	Human cancer cells (for example)

F.2. Risk Assessment - Please consult section II of the CDC-Biosafety in Microbiological and Biomedical Laboratories (BMBL) 5th edition. Which risk group applies to the tissue and cell lines portion of your protocol?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Risk Group is determined based upon the human or animal tissue/fluids/cell lines used in the protocol. For examples, work with human materials would be Risk Group 2. Please use the BMBL to help determine Risk Group https://www.cdc.gov/labs/BMBL.html. In addition, please list all the health effects related to working with these materials.

Entered: 10/01/20 **By:** Joseph, Elaine **Internal:** No

As a note, human tissues/cells/body fluids and transformed animal cell lines are performed at Risk Group 2 per Appendix H

No answer provided.

Risk Group 1 (RG1): Agents not associated with disease in healthy adult humans
Risk Group 2 (RG2): Agents associated with human disease which is rarely serious and for which preventive or therapeutic interventions are often available
Risk Group 3 (RG3): Agents associated with serious or lethal human disease for which preventive or therapeutic interventions may be available
Risk Group 4 (RG4): Agents likely to cause serious or lethal human disease for which preventive or therapeutic interventions are not usually available

F.2.1. List section from the BMBL Guidelines and explain how it relates to the tissues and cell cultures portion of this research.
No answer provided.

F.2.2. List all possible human health risks associated with the tissues and cell cultures portion of this research.
This should list the human health risks associated with the tissues/cells/body fluids you are using. For example, "human cells/body fluids can carry a variety of blood borne pathogens including HIV, HCV, HBV, HTLV, EBV, HPV and CMV."

F.3. Consult section IV of the CDC-BMBL Guidelines. Choose the appropriate biosafety containment level for procedures, equipment, and facilities described in the tissue and cell lines portion of your protocol.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Biosafety Level is determined based upon the human or animal tissue/fluids/cell lines used in the protocol. For examples, work with human materials would be BSL-2. Please use the BMBL to help determine Biosafety Level https://www.cdc.gov/labs/BMBL.html. In addition, please list all the health effects related to working with these materials.

Entered: 10/01/20 **By:** Joseph, Elaine **Internal:** No

As a note, human tissues/cells/body fluids and transformed animal cell lines are performed at BSL 2 per Appendix H

No answer provided.

F.3.1. List relevant sections from the BMBL Guidelines to justify your biosafety level choice and briefly describe your justification.
No answer provided.

F.4. Waste/Disposal/Elimination - Select the appropriate disposal methods for materials used in this work.

No answer provided.

F.5. Decontamination - Select the appropriate methods for decontaminating instruments and work surfaces for this protocol.

No answer provided.

F.6. Contingency Plans - Describe all contingency plans in place in the event of spill/escape/personnel exposure. State if you have received your UT Safety and Health-issued spill kit.

This section should include plans your lab has in place for spills - including clean up and notification of EHRS where appropriate. This section should also address plans if personnel are exposed (treatment, reports, etc.). If you do not have a UToledo spill kit, please notify EHRS and get one as soon as possible.

F.7. Are animal tissues or cell lines taken from live vertebrate animal?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if the animal materials you are working with are either taken from a UToledo protocol or from another universities IACUC protocol.

Yes

F.7.1. Please provide pending and/or approved IACUC Protocol numbers.

IACUC Number

Please input IACUC numbers for old protocol numbers as 123456-12 and new numbers as 400011 for example.

F.7.2. Please provide title(s) for unsubmitted IACUC Protocols.
another university's protocol

F.8. Are human tissues or cell lines taken from human subjects?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be use if the human materials you are working with came from human subjects.

No answer provided.

G. Non-Cellular Biohazards - Biological Nanoparticles and Biotoxins

*** you can use the drop-down list above to temporarily skip past error messages. ***

G.1. Provide the following information for each source of biological nanoparticle or biotoxin.

Source Type (^ = Name Required)	Name of Source^	Classification	Genus/Species/Subtype-or-Name
Field Isolate	name of area where collected	Biological Toxin	genus species (i.e., microcystin)
Commercial Vendor	name of vendor	Biological Nanoparticle	genus species (i.e., magnetite)

G.2. Please describe the biological nanomaterials and how they will be utilized.

This section should describe the biological nanoparticle and how you will be using it in your project. Only biological nanoparticles should be listed and described in the IBC protocol.

G.3. Please describe the biotoxins, your current inventory, how they will be utilized, and any safety measures you will use.

This section should list and describe the biotoxins, how much you have, how you will use them in your research, and the safety measures you have in your laboratory.

H. Animals

*** you can use the drop-down list above to temporarily skip past error messages. ***

BMBL Guidelines

NIH Guidelines

H.1. Does your project include experiments that involve non-rodent whole animals whose genome has been altered by introduction of DNA into the germ line (i.e., transgenic animals)?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are purchasing, using, breeding, or maintaining non-rodent transgenic animals. This includes invertebrate transgenic animals.

Yes

H.1.1. Describe the use of non-rodent transgenic animals in your rDNA experiments. Explain the timeline of use in logical, chronological order. Also include the species and methods that will be used to make the transgenic animals.
No answer provided.

H.1.2. Describe the nature of the transgene.
No answer provided.

H.2. Does your project include experiments that involve breeding rodents from two strains, where the parental strain contains one of the following:
a) incorporation of more than one-half of the genome of an exogenous eukaryotic virus from a single family of viruses
b) incorporation of a transgene that is under the control of a gammaretroviral long terminal repeat
or
the rodent that results from the breeding contains more than one-half of an exogenous eukaryotic virus from a single family of viruses?

Yes

H.2.1. Describe the use of transgenic rodents in your rDNA experiments. Explain in logical, chronological order. Include also the species and methods that will be used to make the transgenic rodents.
No answer provided.

H.3. Will this protocol involve recombinant DNA-derived, biohazardous, or infectious materials; or select agents/toxins to be used in or on living vertebrate/invertebrate animals?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are injecting recombinant DNA, plasmids, viral vectors, biohazards, or infectious materials into a living animal - this includes invertebrate animals.

Yes

H.3.1. State briefly the general objectives of the project involving biohazardous/infectious agent use as they pertain to animal research subjects.

This should be a one to two paragraph summary of the objectives of the project only as it relates to animal research.

H.3.2. Will animals be housed or treated in DLAR?

Yes

H.3.2.1 - Explain below what will be done to the animals treated in DLAR.
This should be a brief description of the animal procedure as it pertains to biological hazards.

H.3.2.1.1 - What is the total period of time animals will reside in DLAR after the first treatment?
No answer provided.

H.3.2.1.2. What is the expected duration of treatments?
No answer provided.

H.3.2.1.3. What is the typical number of animals being treated and residing in DLAR?
No answer provided.

H.3.2.1.4 - What is the anticipated maximum number of animals being treated and residing in DLAR?
No answer provided.

H.3.2.1.5 - Describe how/when biohazardous agents will be transported to/from DLAR and how/where they will be stored.
No answer provided.

H.3.3. Will animals be treated outside DLAR?

No answer provided.

H.3.4 Will hazardous material be shed (ie fur, skin sloughing,etc) or excreted (feces, urine, saliva, nasal discharge) by an animal?

No answer provided.

H.3.4.3. Provide a list of citations supporting your answer above.
No answer provided.

H.3.5. For recombinant DNA based agents consult Appendix Q of NIH GUIDELINES. For infectious agents, biohazardous agents, select agents or toxins consult section V of CDC-Biosafety in Microbiological and Biomedical Laboratories 5th edition. Choose the appropriate biosafety level for procedures, equipment, and facilities for the animal portion of your research protocol.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

For this section, the Animal Biosafety Level is determined based upon the agents being administered to the animals. If you are administering recombinant DNA, plasmids, or viral vectors consult the NIH Guidelines. If you are administering other biohazards, consult the BMBL.

No answer provided.

H.3.5.1. List relevant section of the NIH guidelines to justify your ABSL level.
No answer provided.

H.3.6. Decontamination - Select the appropriate methods for decontaminating instruments and work surfaces for this protocol.

No answer provided.

H.3.7. Personal Protective Equipment.

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

The personal protective equipment level selected should match the Animal Biosafety Level of the project.

ABSL 2

ABSL2 Help Text

Personal Protective Equipment	Hands	Body/Skin	Head	Face/Eye Splash	Face/Eye Vapor
ABSL2	**Nitrile**	**Disposable Gown Shoe covers**	**Hair net**	**Surgical mask (inside BSC), N95 (outside BSC)**	**Surgical mask (inside BSC), N95 (outside BSC)**

H.3.8. Does the animal portion of this protocol involve ONLY invertebrate species?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

If your project involves vertebrate animals, this question should be NO. You must have an IACUC approved protocol from UToledo or another institution to proceed.

No answer provided.

I. Plants

*** you can use the drop-down list above to temporarily skip past error messages. ****

I.1. Are you creating genetically engineered plants or using plants with microorganisms or insects containing recombinant DNA?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This should be yes if you are either creating transgenic plants or using plants that are associated with transgenic microorganisms or transgenic insects.

Yes

I.1.1. Explain Below

No answer provided.

I.2. Are you deliberately releasing recombinant DNA-modified plants into the environment?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

If you are planning to release transgenic plants into the environment, you must have a USDA APHIS permit.

Yes

I.2.1. Please Explain
No answer provided.

I.2.2. Please provide USDA APHIS Field test permit number (if pending, put "pending")
No answer provided.

I.3. Are you using poisonous or dangerous plants?

Entered: 09/17/20 **By:** Joseph, Elaine **Internal:** No

This section should be yes if you are planning on working with poisonous or dangerous plants. Some of these may require permits. You should also describe safety precautions for working with these plants.

Yes

I.3.1. Please describe PPE, including Biosafety Containment practices and list all permits obtained.
No answer provided.

I.4. List all plant species to be used, BSL level, and locations in the table below.

Plant Genus Species	Has this plant been altered? How?	BSL Level	BSL-P (Plant) Level

BSL-P1 is recommended for all experiments with transgenic plants and associated agents that have no or limited threat potential. For example: transgenic plants that are not noxious weeds or agents that have no recognized potential for rapid dissemination. Examples of agents worked with at BSL-1P include Agrobacterium tumefaciens and Rhizobium spp.

BSL-P2 is recommended for transgenic plants that are noxious weeds, plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent, plants associated with transgenic non-exotic microbe that has a recognized potential for serious detrimental impact on managed or natural ecosystems, or plant pathogens that have a recognized potential for serious detrimental impact on managed or natural ecosystems. Examples of agents worked with at BSL-2P include: Meliodogyne incognita (root-knot nematode), Pepino mosaic virus (PepMV), Pectinophora gossypiella (Pink bollworm), and Pseudomonas syringae

BSL-P3 is recommended for transgenic plants, plant pathogens, or other organisms that have a recognized potential for significant detrimental impact on the environment. This category also applies to non-genetically engineered plant research that involves exotic infectious agents capable of causing serious environmental harm. Experiments using transgenic plants or organisms that contain genes coding for vertebrate toxins are also likewise conducted at BSL-P3

J. Select Agents

*** you can use the drop-down list above to temporarily skip past error messages. ***

Work with Federal Select Agents and Toxins requires approval from the Dual Use Research of Concern (IRE) Committee. Forms can be found on their website.

J.1. List all the select agents and toxins to be used on this project.

Select Agent(s) or Toxin(s) (Genus Species)	Vaccine Available?	Largest Volume In Possesion

Stage awaiting acceptance