# Section 1: Principal Investigator, Overview, and Assurance Statement

## Type: [ ]  Research [ ]  Teaching *Indicate as appropriate*

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| **Principal Investigator / Instructor**: *Name of main principal investigator* |
| Department / Division: *Primary appointment*  | Building / Lab Room: *Main location (other locations*  *entered later)* |
| Phone No: *Main phone of contact* | Email: *Campus email address* |
| **Co-Principal Investigator / Instructor**: *Enter co-principal investigator or enter “N/A” if none* |
| Department / Division: *Primary appointment* | Building / Lab Room: *Main location (other locations*  *entered later)* |
| Phone No: *Main phone of contact* | Email: *Campus email address* |
| **Project title or Course Name:** *Title of the project or name of the course* |
| **Type of Review:** [ ]  New Submission [ ]  3 Year Renewal [ ]  Revision (attach modification form)*Indicate as appropriate* |
| **Protocol Identification Number for Renewal or Revision** (if applicable):*Protocol number of the existing project if this application is for a renewal or revision of that project* |
| **Funding Source** (if applicable): *Name of the source of funding* |

## Overview: All researchers or instructors planning to work with biological agents, biological toxins, viruses, pathogens, recombinant DNA or synthetic nucleic acids must complete all applicable sections of this form. Sections that do not apply to the intended work may be left blank. Once a protocol is reviewed and registered by the IBC, an IBC Modification Request Form and a revised protocol should be submitted to request approval for any changes to the protocol. Approved protocols expire after three years.

Submit completed form electronically to biosafety@uwosh.edu. Investigators should keep a copy of the protocol in their records as well as placing a copy in their lab or shared drive for all staff listed on this protocol to review. You may find the [IBC Biological Safety Protocol Companion Guide](https://uwosh.edu/sponsoredprograms/ibc/forms/) and [IBC Companion Help Guide Video](https://uwosh.edu/sponsoredprograms/ibc/forms/) helpful for preparing your application.

## Principal Investigator or Instructor Assurance Statement:

*This Assurance Statement must be filled out, signed, and dated.*

By signing below, I am agreeing that:

[ ]  The information provided is true and accurate. I acknowledge I have familiarized myself with the [NIH
Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](http://osp.od.nih.gov/sites/default/files/resources/NIH_Guidelines_PRN_1-sided.pdf) (NIH Guidelines) as it relates to the biological materials described in this application and I am aware that my intended work will be subject to these guidelines and the [*Biosafety in Microbiological and Biomedical Laboratories manual*](https://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf) (BMBL).

[ ]  I will not begin any of the procedures or activities outlined in this protocol until I have received approval by the Institutional Biosafety Committee (IBC).

[ ]  I ensure that personnel under my oversight, including staff and students, have received training appropriate to their work activities and have also received information on proper signage, potential biological hazards (as outlined in this protocol), manuals, SOP’s, and other information for these employees to safely and effectively perform their job duties. I also will ensure that these personnel keep up-to-date training records of all training received.

[ ]  I will ensure that personnel under my oversight understand procedures for dealing with incidents and biological material spills and know proper waste management and spill cleanup procedures.

[ ]  I will comply with all training and shipping requirements for the transportation of hazardous biological materials following DOT 49 CFR 171-178, International Civil Aviation Organization (ICAO) and International Air Transport Association (IATA).

[ ]  I will comply with the OSHA Bloodborne Pathogen Standard 29 CFR 1910.1030 if I plan to work with human-derived materials such as cells, tissues, organs or embryonic stem cells.

[ ]  I ensure that all spaces where the intended work will be conducted are listed in this protocol.

Signature of PI and/or Instructor: *Signature of the main principal investigator* Date: *Date of signature*

Signature of Co-PI and/or Instructor: *Signature of the co-principal investigator, if applicable*
Date: *Date of signature, if a co-principal investigator’s signature is present*

# Section 2: Biological Material Categories and Experimental Design

## Biological Material Categories:

**Check all of the materials below that will be used in your study**:

[ ]  Recombinant DNA (rDNA or Nucleic Acid Molecules) (Section 5)

[ ]  Bacteria, Viruses, Viral Vectors, Fungi, Prions (Section 6)

[ ]  Human/Non-Human Primate (NHP) Cell Lines, Tissues or Blood Products (Section 7A)

[ ]  Animal Cell Lines, Tissues, or Blood Products (Section 7B)

[ ]  Biological Toxins (Section 8)

[ ]  Live Animals (vertebrate or invertebrate) (Section 9)

[ ]  Plants (exotic or grown in association w/ pathogenic or recombinant microbes/animals) (Section 10)

## Experimental Design: Briefly describe the experimental design. Include a brief description of how the materials indicated above will be used in this protocol using language a non-expert would understand. Explain the class objective if this is a protocol specifically for a teaching laboratory.

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| * *Enter a brief and general description of the types of experiments/procedures which will be conducted using the all the biological materials indicated in Section 2 A*
* *Use language which a non-expert of your area of study who has a scientific background can understand*
* *Spell out all acronyms when first used*
* *Do not provide a risk assessment in this section*
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# Section 3: Personnel, Responsibilities, and Training

## Personnel, Responsibilities, and Training: Identify all personnel (including PI, Co-PI, lab personnel, students) who will be working with any of the biological materials described on this protocol, indicate the training they have received, and their responsibilities under this protocol. For training requirements, see the [Biosafety website](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-training/). Please reserve discussion on training for teaching activities to Section B below.

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| **Name** |  | **Responsibilities** | **Training Completed** | **Date Completed** |
| *List all personnel who will be involved with the research or teaching project described in this application* |  | *e.g., project oversight, shipping, culture of microorganisms, tissue culture, animal work, general lab work* | *e.g., CITI trainings, BBP, Biosafety Awareness, rDNA, Shipping Hazardous Materials, Instructor Safety Training, etc. Training requirements may be located on the* [*IBC Training Page*](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-training/)*.* | *Date the training was completed* |
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**Additional Information:** Indicate the following:

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| 1. *Individual(s) responsible for training all incoming laboratory personnel: This would be the PI or a lab member whom the PI has determined to be knowledgeable enough to all hazards associated to the biological materials and related procedures; this may be more than one individual.*
2. *Individual(s) responsible for training- Years of experience for handling the biological materials indicated on this protocol: This information provides a reviewer with an understanding of the amount of relevant experience that the trainer(s) have which qualifies them as a competent trainer.*
3. *How and where completed training is documented: Training should be documented and stored in a location where all lab members have access. This will be verified during a routine lab inspection.*
4. How will research personnel/students be given access to this protocol: *For example, will a hard copy of the protocol be available in a binder in the laboratory or will they have access to an electronic copy of the protocol?*
5. *Other information: Include any additional information which you feel would facilitate a sufficient biosafety review.*
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## Training for Students for Teaching Activities: (Note: complete the section only if this protocol covers teaching activities). Provide a summary of the training provided to students who will be involved with the classroom activities. Include any hands-on training, instructor-based training, or online learning and how it is documented. Attach any class safety documents students sign as an appendix.

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| * *Ignore this section if this protocol does not relate to teaching activities*
* *An Example Lab Safety Orientation Checklist for Teaching Activities may be found* [*here*](http://grants.uwosh.edu/sample-page/research-compliance/institutional-biosaftey-committee-ibc/ibc-forms/)*.*
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# Section 4: Locations

## Locations: List all locations where biological materials are used, stored, or handled.

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| **Building** | **Room** | **Use of Room**(e.g. classroom, laboratory, animal housing, storage) | **Containment Level**(e.g. BL-1, ABSL-1) | **Containment Equipment**(e.g. BSC, fume hood) |
| 1.*e.g., Halsey* | *All rooms should have their own entry* | *e.g. classroom, laboratory, animal housing, storage* | *e.g. BL-1, ABSL-1* | *e.g. BSC, fume hood* |
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# Section 5: NIH Guidelines and Recombinant Materials

## NIH Guidelines: If you intend to use rDNA materials or synthetic nucleic acid molecules in protocol, indicate all citations from Section III of the NIH Guidelines which apply to your research. If you will not be working with rDNA or synthetic nucleic acids, indicate N/A:

*Contact biosafety@uwosh.edu for help answering questions regarding NIH Guidelines citations*

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|[ ]  III-A-1 | The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire that trait naturally, if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. |
|[ ]  III-B-1 | Deliberate formation of rDNA containing genes for the biosynthesis of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. |
|[ ]  III-B-2 | Experiments that have been Approved (under Section III-A-1-a) as Major Actions under the NIH Guidelines and determined by NIH/OBA. |
|[ ]  III-C-1 | Experiments involving the Deliberate Transfer of Recombinant or Synthetic Nucleic Acid Molecules, or DNA or RNA Derived from Recombinant or Synthetic Nucleic Acid Molecules, into One or More Human Research Participants. |
|[ ]  III-D-1 | Experiments using Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents as Host-Vector Systems. |
|[ ]  III-D-2 | Experiments in which DNA from Risk Group 2, Risk Group 3, Risk Group 4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems. |
|[ ]  III-D-3 | Experiments involving the Use of Infectious DNA or RNA Viruses or Defective DNA or RNA Viruses in the Presence of Helper Virus in Tissue Culture Systems |
|[ ]  III-D-4 | Stable introduction of rDNA into an animal genome or testing of rDNA-modified microorganisms in whole animals. |
|[ ]  III-D-5 | Experiments to genetically engineer plants by rDNA methods, to use such plants for other experimental purposes (e.g., response to stress), to propagate such plants, or to use plants together with microorganisms or insects containing rDNA. |
|[ ]  III-D-6 | Experiments involving more than 10 Liters of Culture (in a single vessel)**If > 10L, Indicate Biological Material(s) Here:** |
|[ ]  III-D-7 | Experiments involving Influenza Viruses |
|[ ]  III-E | Experiments not included in Sections III-A, III-B, III-C, III-D, III-F and their subsections |
|[ ]  III-E-1 | Formation of rDNA molecules containing no more than 2/3 of any eukaryotic viral genome |
|[ ]  III-E-2 | Experiments with genetically modified plants |
|[ ]  III-E-3 | Experiments involving the generation of transgenic rodents |
|[ ]  III-F-1 | Those synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase. Example: PCR falls under category III-F-1 |
|[ ]  III-F-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-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-4 | rDNA molecules consisting entirely of DNA from a prokaryotic host including its indigenous plasmids or viruses where propagated only in that the host (or a closely related strain of the same species) or transferred to another host by know physiological means. |
|[ ]  III-F-5 | rDNA molecules consisting entirely of DNA from a eukaryotic host (including mitochondria, chloroplasts, or plasmids but excluding viruses) when propagated only in that host or a closely related strain of the same species. |
|[ ]  III-F-6 | rDNA molecules consisting entirely of DNA segments from different species that exchange DNA by known physiological processes and are described in Appendix A. |
|[ ]  III-F-7 | Those genomic DNA molecules that have acquired a transposable element provided the transposable element does not contain any recombinant and/or synthetic DNA |
|[ ]  III-F-8 | Experiments not posing significant risk to health or the environment, as determined by the NIH Director, and are described in Appendix C of the NIH Guidelines.*If you selected III-F-8, there must be at least one reference for Appendix C selected below***Appendix C Reference**:[ ]  C-I: Recombinant or Synthetic Nucleic Acid Molecules in Tissue Culture[ ]  C-II: *E. coli* K-12 Host-Vector Systems *Non-K-12 strains fall under Section III-E*[ ]  C-III: *Saccharomyces* Host-Vector Systems[ ]  C-IV: *Kluyveromyces* Host-Vector Systems[ ]  C-V: *Bacillus subtilis* or *Bacillus licheniformis* Host-Vector Systems[ ]  C-VI: Extrachromosomal Elements of Gram Positive Organisms[ ]  C-VII: The Purchase or Transfer of Transgenic Rodents[ ]  C-VIII: Generation of BL1 Transgenic Rodents via Breeding |

## Recombinant Materials: Describe the Recombinant or Synthetic DNA/RNA materials used in this protocol. Attach plasmid maps to the end of this protocol. NOTE: it is not necessary to list antibiotic resistance genes in this subsection.

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|  **Name of Gene or****Gene Fragment**(e.g., microtubulin, GFP, Ras, Ampicillinr) | **Nature of Gene**(e.g., oncogene, toxin, transcription factor, tracking)  | **Source Organism**(*e.g., Enterococcus faecalis*, *Drosophila melanogaster )* | **Administered to**(e.g., *Enterococcus faecalis*, *Mus musculus*) |
| 1. *e.g., microtubulin, GFP, Ras, Ampicillinr* | *e.g., oncogene, toxin, transcription factor, tracking* | *e.g., Enterococcus faecalis, Drosophila melanogaster* | *e.g., Enterococcus faecalis, Mus musculus, Lentiviral vector* |
| 2. *Do not include plasmid vector DNA; only the insert DNA; ignore marker genes found on a plasmid* | *If nature of gene is not known, indicate “Unknown” and the suspected nature of the gene (if any)* | *Source organisms for antibiotic resistance genes are not required* |  |
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# Section 6: Bacteria, Viruses, Viral Vectors, Fungi, and Prions

## Bacteria: Complete this subsection if working with any prokaryotes.

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| **Genus and Species** | **RG** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1. *Indicate Genus and Species of Bacteria and strain (if known)* | *Indicate Risk Group. See* [*ABSA Risk Group Database*](https://my.absa.org/Riskgroups) | *Indicate Biosafety Level* | *Indicate “Y” or “N”; list rDNA entry which has been described in Section 5B (e.g., #5,#8)* | *e.g., Mus musculus, cell culture* |
| 2.*If unknown, indicate Family and/or source of bacteria* |  |  | *If this is a knockout organism, indicate “Y” and indicate the nature of the knockout gene here* |  |
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**Additional Information**: Provide additional information that is relevant to the bacteria listed.

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| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate possible routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed bacteria. Note: laboratory research procedures may provide different routes of exposure than what may be the normal route found in nature. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of an exposure: If there are disease causing organisms listed, list the associated diseases; indicate any populations which may be at risk (e.g., women who are pregnant)*
3. *List aerosol generating activities and how an exposure will be mitigated: e.g., centrifugation is an aerosol generating activity and can be mitigated with the use of centrifuge safety cups and opening centrifuge buckets in containment (for work at BSL-2 or greater); pipetting is an aerosol generating activity which can be mitigated with use of aerosol barrier pipette tips.*
4. *Indicate any antibiotic resistance markers used in Risk Group 2 or greater bacteria: Indicate the antibiotic resistance and which bacteria will have them; this is of special concern for pathogenic organisms where post-exposure medical treatment may be affected.*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
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### Viruses: Complete this section if you are working with any viruses (not including viral vectors).

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| **Name of Virus** | **RG** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(Cell Culture, *Mus musculus, Zea mays*) |
| 1. *Indicate scientific name of virus (e.g., Influenza A)* | *Indicate Risk Group See* [*ABSA Risk Group Database*](https://my.absa.org/Riskgroups) | *Indicate Biosafety Level* | *Indicate “Y” or “N”; list rDNA entry which has been described in Section 5B (e.g., #5,#8)* | *e.g., Cell Culture, Mus musculus, Zea mays* |
| 2. *If unknown, indicate Family and/or source of virus* |  |  | *If this is a knockout organism, indicate “Y” and indicate the nature of the knockout gene here* |  |
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**Additional Information**: Provide additional information that is relevant to the viruses listed.

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| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate possible routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed virus. Note: laboratory research procedures may provide different routes of exposure than what may be the normal route found in nature. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of exposure: If there are disease causing organisms listed, list the associated diseases; indicate any populations which may be at risk (e.g., women who are pregnant)*
3. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity and can be mitigated with the use of centrifuge safety cups and opening centrifuge buckets in containment (for work at BSL-2 or greater); pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
4. *Indicate any drug resistance traits engineered into any virus Risk Group 2 or greater: Indicate the drug resistance and which virus will have them; this is of special concern for pathogenic organisms where post-exposure medical treatment may be affected.*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
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### Viral Vectors: Complete this section if you are working with any viral vectors.

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| **Viral Vector** | **Generation of Vector**(e.g., 3rd) | **RG** | **BSL** | **rDNA Listed in Section 5B**(e.g., #5, #8) | **Administered to**(Cell Culture, *Mus musculus, Zea mays*) |
| 1.*e.g., Lentivirus, Adenovirus, Adeno-Associated Virus* | *e.g., 3rd* | *Indicate Risk Group (e.g., Lentivirus is RG3) See* [*ABSA Risk Group Database*](https://my.absa.org/Riskgroups) | *Indicate Biosafety Level* | *List rDNA entry which has been described in Section 5B (e.g., #5,#8)* | *Cell Culture, Mus musculus, Zea mays* |
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**Additional Information**: Provide additional information that is relevant to the viral vectors listed.

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| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate possible routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed viral vector. Note: laboratory research procedures may provide different routes of exposure than what may be the normal route found in nature, and many viral vectors have been pseudotyped to expand their wild-type host range. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of exposure: If viral vectors will be used to alter the functioning of their intended target, indicate any potential outcome an exposure could have on a person. Also, oncogenesis is a possible outcome if the viral vector functions by randomly integrating DNA into the genome of cell.*
3. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity and can be mitigated with the use of centrifuge safety cups and opening centrifuge buckets in containment; pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
4. *Other information: Include any additional information which you feel would facilitate a complete biosafety review (e.g., replication incompetent viral vectors)*
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### Fungi: Complete this subsection if working with any fungi.

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| **Fungi**(Common Name; Genus species) | **RG** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1. *Indicate Genus and Species of Fungi and strain (if known)* | *Indicate Risk Group See* [*ABSA Risk Group Database*](https://my.absa.org/Riskgroups) | *Indicate Biosafety Level* | *Indicate “Y” or “N”; list rDNA entry which has been described in Section 5B (e.g., #5,#8)* | *e.g., Mus musculus* |
| 2. *If unknown, indicate Family and/or source of virus* |  |  | *If this is a knockout organism, indicate “Y” and indicate the nature of the knockout gene here* |  |
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 **Additional Information**: provide additional information that is relevant to the fungi listed.

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| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate possible routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed fungi. Note: laboratory research procedures may provide different routes of exposure than what may be the normal route found in nature. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of exposure: If there are disease causing organisms listed, list the associated diseases; indicate any populations which may be at risk (e.g., women who are pregnant).*
3. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity which can be mitigated with the use of centrifuge safety cups and opening centrifuge buckets in containment; pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
4. *Indicate any antibiotic resistance markers used in Risk Group 2 or greater fungi: Indicate the drug resistance and the fungi which will have them; this is of special concern for pathogenic organisms where post-exposure treatment may be affected.*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
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### Prions: Complete this subsection if working with any prions.

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| **Common Name and Affected Species** | **RG** | **BSL** | **Recombinant** (Y/N) | **Administered to**(e.g., *Mus musculus)* |
| 1. *e.g., Scrapie; Ovis aries* | *Indicate Risk Group See* [*ABSA Risk Group Database*](https://my.absa.org/Riskgroups) | *Indicate Biosafety Level* | *Indicate “Y” or “N”* | *e.g., Mus musculus* |
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**Additional Information**: Provide additional information that is relevant to the prions listed.

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| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate possible routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed prions. Note: laboratory research procedures may provide different routes of exposure than what may be the normal route found in nature. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of exposure: If it listed prion can cause human disease, list the associated disease in humans. If the prion is recombinant indicate the possible effects of its altered nature.*
3. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity which can be mitigated with the use of centrifuge safety cups and opening centrifuge buckets in containment; pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
4. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
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# Section 7: Human/Non-Human Primate, and Animal Cell Lines, Tissues, or Blood Products

## Human / Non-Human Primate Cell Lines, Tissues or Blood Products: Complete this subsection if working with any human or non-human primate derived materials. List the type of material used. Example: list “human pancreatic cells” and not specific human pancreatic cell lines such as “AKT2” or “HTB-134” unless the specific cells pose a unique hazard.

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| **Type of Material** | **Fetal Derived?** (Y/N) | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1.*e.g., “human pancreatic cells”; you do not need to list specific cell lines like “AKT2” unless they pose a unique hazard* | *This question enables the tracking of fetal tissue use on campus* | *Indicate Biosafety Level* | *Indicate “Y” or “N”; list rDNA entry which has been described in Section 5B (e.g., #5,#8)* | e.g., *Mus musculus* |
| 2.*By listing the general cell type it makes it possible to add similar cells without needing an amendment to your IBC application* |  |  |  |  |
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**Additional Information**: Provide additional information that is relevant to the cells, tissues or blood

products listed.

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| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate possible routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed materials. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of exposure: Per OSHA all human derived materials are potentially infectious; old world monkey cells are also considered to be potentially infectious.*
3. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity which can be mitigated with the use of centrifuge safety cups and opening centrifuge buckets in containment; pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
4. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

## Animal Cell Lines, Tissues or Blood Products: Complete this subsection if working with any animal cell lines, tissues or blood products. List the type of material used; example: list “mouse pancreatic cells” and not specific mouse pancreatic cell lines such as “CRL-2151” or “CRL-2135” unless the specific cells pose a unique hazard.

|  |  |  |  |
| --- | --- | --- | --- |
| **Type of Material** | **BSL** | **rDNA?**(Y/N; If “Y” include Section 5B reference) | **Administered to**(e.g., *Mus musculus)* |
| 1. *e.g., “mouse pancreatic cells”; you do not need to list specific cell lines like “CRL-2151” unless they pose a unique hazard* | *Indicate Biosafety Level* | *Indicate “Y” or “N”; list rDNA entry which has been described in Section 5B (e.g., #5,#8)* | e.g., *Mus musculus* |
| 2. *By listing the general cell type it makes it possible to add similar cells without needing an amendment to your IBC application* |  |  |  |
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| 9. |  |  |  |
| 10. |  |  |  |

**Additional Information**: Provide additional information that is relevant to the cells, tissues or blood

products listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate potential routes of exposure (e.g., aerosol, sharps injury, splash) which may occur while performing procedures with the above listed materials. Indicate the PPE which personnel will be required to wear.*
2. *List possible consequences of exposure: Describe possible consequences which may result from exposure (e.g., primary sheep placental cells may pose a risk for the Q-fever causing bacterium associated this particular source material)*
3. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity which can be mitigated with use of centrifuge safety cups and opening centrifuge buckets in containment; pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
4. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

# Section 8: Biological Toxins

## Biological Toxins: Complete this subsection if working with any toxins of biological origin.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Biological Toxin** | **LD50**(ng/kg) | **BSL** | **Select Toxin?** (Y/N) | **Administered to**(e.g., *Mus musculus)* | **Max Amount Administered**(at one time) |
| 1. *List toxin name* | *ng/kg* | *Indicate Biosafety Level* | *As determined by the CDC/HHS/USDA*[here](https://www.selectagents.gov/selectagentsandtoxinslist.html) | *e.g., Mus musculus, cell culture* | *Indicate maximum amount administered to each type of recipient* |
| 2. *e.g., botulinum toxin* | *1ng/kg* | *2* | *Y* | *Mus musculus* | *0.1 ng* |
| 3. |  |  |  |  |  |
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**Additional Information**: Provide additional information that is relevant to the biological toxins listed.

|  |
| --- |
| 1. *Indicate routes of exposure and list PPE used to reduce exposure risk: Objectively indicate potential routes of exposure (e.g., aerosol sharps injury splash) which may occur while performing procedures with the above listed toxins. Indicate the PPE which personnel will be required to wear.*
2. *For each Select Toxin- Indicate maximum amount of toxin in inventory, and where inventory is documented: Permissible amounts of select toxins can be found* [here](https://www.selectagents.gov/PermissibleToxinAmounts.html)*; it is required to maintain an accurate inventory for select toxins.*
3. *Describe how each toxin will be inactivated: Appendix H of the* [BMBL 5th Edition](https://www.cdc.gov/biosafety/publications/bmbl5/bmbl.pdf) *describes inactivation procedures.*
4. *For toxins that will be reconstituted from a powder- describe process for reconstitution: Procedures with powdered toxins will pose a unique hazard and should be conducted inside containment (e.g., chemical fume hood, biological safety cabinet)*
5. *List aerosol generating activities and how an exposure risk will be mitigated: e.g., centrifugation is an aerosol generating activity which can be mitigated with use of centrifuge safety cups and opening centrifuge buckets in containment; pipetting is an aerosol generating activity which can be mitigated by using aerosol barrier pipet tips.*
6. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

# Section 9: Vertebrate and Invertebrate Animals

## Vertebrates: Complete this subsection for vertebrate animals administered biological materials. Note: IACUC approval will also need to be obtained prior to initiating work.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Vertebrate**(Common Name; Genus species) | **Animal Biosafety Level** | **Transgenic?** (Y/N) | **Biological Materials Administered**(Section 5B ref) | **Housing**(e.g., *static microisolators, rack system)* |
| 1. *e.g., Sheep; Ovis aries* | *Indicate Animal Biosafety Level (ABSL)* | *Indicate “Y” or ”N”* | *List biological materials administered; include a reference to section 5B if applicable* | *e.g., static microisolators, rack system* |
| 2. |  |  |  |  |
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**Additional Information**: Provide additional information that is relevant to vertebrate animals listed.

|  |
| --- |
| 1. *Indicate routes of shedding for any biological material administered: e.g., feces, urine, saliva, respiratory droplets, bites.*
2. *List PPE used to reduce exposure risk: List PPE which personnel will be required to wear when handling the vertebrate(s) listed.*
3. *Indicate the period of infectivity and shedding for any biological material administered: List period in hours (e.g., 96 hours, lifetime of animal) for each animal being administered a biological material.*
4. *List aerosol generating activities involving biological materials and how an exposure will be mitigated: e.g., changing animal bedding is an aerosol generating activity which can be mitigated by using a biological safety cabinet. It is not necessary to list aerosol generating activities if biological materials are NOT being administered.*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

## Invertebrates: Complete this subsection if working with any animals that are invertebrates. Note: Notify the IACUC of invertebrate animal use via the [IACUC Invertebrate Notification Survey](https://oshkosh.co1.qualtrics.com/jfe/form/SV_cBhgw9qSUjamWNv).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Invertebrate**(Common Name; Genus species) | **Animal Biosafety Level** | **Transgenic?** (Y/N) | **Biological Materials Administered**(Section 5B ref)  | **Housing**(e.g., *petri dish, aquarium)* |
| 1. *e.g., Mosquito; Aedes aegypti* | *Indicate Animal Biosafety Level (ABSL)* | *Indicate “Y” or ”N”* | *List biological materials administered; include a reference to section 5B if applicable* | e.g., *petri dish, aquarium* |
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**Additional Information**: Provide additional information that is relevant to invertebrate animals listed.

|  |
| --- |
| 1. *Indicate routes of exposure for any biological material administered: e.g., bites*
2. *List PPE used to reduce exposure risk: List PPE which personnel will be required to wear when handling the invertebrate(s) listed.*
3. *Indicate the period of infectivity and shedding for any biological material administered: List period in hours (e.g., 96 hours, lifetime of animal) for each animal being administered a biological material.*
4. *List aerosol generating activities involving biological materials and how an exposure risk will be mitigated: e.g., changing aquarium water is an aerosol generating activity which can be mitigated by using a respirator.*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

# Section 10: Plants

## Plants: Complete this subsection if working with any exotic plants, plants which are grown in association with pathogenic or recombinant microbes, or pathogenic or recombinant animals (e.g., insects).

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Plant** (Common Name; Genus species) | **Plant Biosafety Level** | **Transgenic?** (Y/N) | **Biological Materials Administered**(Section 5B ref) | **Growth Location**(e.g., *greenhouse, growth chamber location)* |
| 1.*Watermeal; Wolffia angusta* | *Indicate Plant Biosafety Level (e.g.,BL1-P)* | *Indicate “Y” or ”N”* | *List biological materials administered; include a reference to section 5B if applicable* | *e.g., specific greenhouse / growth chamber location* |
| 2. |  |  |  |  |
| 3. |  |  |  |  |
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**Additional Information**: Provide additional information that is relevant to vertebrate animals listed.

|  |
| --- |
| 1. *Indicate routes of exposure for any biological material administered: e.g., skin*
2. *List PPE used to reduce exposure risk: List PPE which personnel will be required to wear when handling the plant(s) listed*
3. *Indicate precautions used to contain transgenic plants: e.g., screens on greenhouse windows to prevent arthropods from removing pollen from greenhouse.*
4. *List aerosol generating activities involving biological materials and how an exposure risk will be mitigated: e.g., grinding infected plant material is an aerosol generating activity which can be mitigated with the use of a fume hood or biological safety cabinet.*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

# Section 11: Emergency Response

## Emergency Response: Provide a general response procedure to be followed if an individual is accidentally exposed to any of the materials listed in this protocol. The IBC should be notified as soon as possible (within 72 hours) by submitting an [IBC Incident Report Form](https://uwosh.edu/sponsoredprograms/ibc/forms/). Consider the consequences of an accidental exposure (e.g., splash to the eye or mucous membranes, inoculation) which might occur during work with the materials outlined in this protocol.

|  |
| --- |
| 1. *Immediate response to an exposure: e.g., wash exposed skin with soap and water for 15 minutes, flush exposed eyes in eyewash for 15 minutes.*
2. *Individuals to contact (including contact information) after an exposure: e.g., PI, senior lab member, student health services (for students).*
3. *Who will be contacted if the incident occurs after regular business hours: Include name and contact information.*
4. *Possible exposure outcomes to materials listed in this protocol: Summarize possible illnesses including those which may affect particular groups (e.g., women who are pregnant).*
5. *Other information: Include any additional information which you feel would facilitate a complete biosafety review.*
 |

# Section 12: Waste Disposal, Spill Response, Surface Decontamination, and Laundry Service

## Waste Disposal: There are two recommended methods to dispose of biological waste, depending on the waste type:

* **Liquid Waste**: expose liquids to 10% bleach for 30 minutes prior to disposal in the sanitary sewer**.**
* **Solid Waste**: autoclave solid waste minimally at 121°C /30 minutes / 2 ATM.

**Do you plan to use the recommended waste disposal method indicated above for all materials (not including vertebrate animals) listed in this application?**

[ ]  **Yes** [ ]  **No**

If “no" was selected above: describe the method used to dispose of the biological wastes which will not be disposed of using the above indicated methods:

|  |
| --- |
| *Alternative methods other than what are described above are acceptable; other chemical disinfectants approved by the EPA can be used to dispose of liquid waste and other solid waste methods could be used if desired (e.g., incineration). EPA approved disinfectants may be found* [*here*](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants)*.* |

## B. Spill Response: The following is the recommended procedure for decontaminating a spill outside of containment:

1. Notify supervisor and lab members of spill and close off area to traffic; for large spills of >100ml, leave room for 30 minutes to allow for aerosols to settle.
2. Remove all contaminated clothing and place in biohazard bag for autoclaving, wash any exposed skin with soap and water, and wash exposed eyes for 10 minutes in eyewash.
3. Contact Local Medical Service (Mercy Medical or Aurora Occupational Health Provider). If an exposure requires emergency medical attention (Call 911).
4. Contact University Police (414-1212) if necessary to request assistance limiting access to spill.
5. Put on any required PPE (do not attempt cleanup if adequate PPE is not available).
6. Cover the spill with absorbent material (e.g., paper towel).
7. Prepare fresh bleach solution (at least 10%).
8. Gently pour bleach solution on spill (starting from outside of spill).
9. Add more paper towels as necessary to contain liquid.
10. Allow 30 minutes contact time for bleach to decontaminate spill.
11. Clean-up any broken glass with dust pan or forceps and dispose in glass waste container; any glass not yet decontaminated can be placed in a container (e.g., beaker) for decontamination with a 10% bleach solution.
12. Clean up paper towels and dispose in a biological waste container.

**Do you plan to use the recommended spill clean-up method indicated above for all materials (not including vertebrate animals) listed in this application?**

[ ]  **Yes** [ ]  **No**

If “no" was selected above: describe the method used to clean up biological spills outside of containment:

|  |
| --- |
| *Indicate any deviations from the above procedure.*  |

## **C. Surface Decontamination:** The following is the recommended procedure for decontaminating surfaces which may have been exposed to biological materials:

1. Apply at least 10% bleach to surface and allow to air dry.
2. Apply 70% EtOH or water to surface to remove bleach residue.

For decontamination of the biological safety cabinets or other stainless steel surfaces, Periodox RTU is recommended:

1. Apply PeridoxRTU (no need to dilute; contact time=10 minutes).
2. Apply 70% EtOH or water to surface to remove residue if needed.

**Do you plan to use the recommended surface decontamination method for all surfaces and equipment which may have been exposed to any of the materials listed in this application?**

[ ]  **Yes** [ ]  **No**

If “no" was selected above: describe the method used to dispose of the biological wastes that will not be disposed of using the above indicated method. Note: Alternative disinfectants used must be [EPA approved disinfectants](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants), please explain:

|  |
| --- |
| *Bleach alternatives may be used, if they are approved disinfectants by the EPA, to decontaminate the biological materials described on this application. EPA approved disinfectants may be found* [*here*](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants)*.* |

### D. Laundry Service: Provide information on how laundry services are obtained for lab coats or other contaminated clothing (lab coats contaminate clothing shall not be laundered at home):

|  |
| --- |
| [ ]  3rd party Service: [ ]  In-House Services, Location:[ ]  Disposable Lab Coats Used[ ]  Other (describe):  |

# Section 13: Transport and Shipping

Complete this section if you plan to transport public spaces on campus or ship biological materials. Please review the [Biohazard Materials Shipping Guide](https://uwosh.edu/sponsoredprograms/ibc/forms/) for more details.

### Inter-Campus Transport: The following is the recommended method for transport of biological materials through public spaces:

1. Place biological material in a 1° and 2° container.
2. Place absorbent materials between 1° and 2° container sufficient to absorb contents of 1° container.
3. Place biohazard sticker on outermost container if transporting biohazardous material.

**Do you plan to use the recommended method to transport biological materials through public spaces?**

[ ]  **Yes** [ ]  **No** [ ]  **N/A** (will not be transporting materials on campus)

## Off-Campus Shipping: The following is the recommended method for shipping biological materials (See Department Shipping Representative or Biohazard Materials Shipping Guide):

1. Place biological material in a 1° and 2° container
2. Place absorbent materials between 1° and 2° container sufficient to absorb contents of 1° container
3. Place 1° and 2° container into 3° container
4. Place applicable shipping label(s) on outside of 3° container

**Do you plan to use the recommended method to ship biological materials?**

[ ]  **Yes** [ ]  **No** [ ]  **N/A, will not ship biological materials off-campus**

If “no" was selected above: describe the method used to transport or ship biological materials:

|  |
| --- |
| *Describe any deviations from the above recommended methods for transport and shipping biological materials. The recommended shipping method is compliant with DOT requirements; therefore, any deviations for shipping would need to meet or exceed DOT requirements.* |

1. **Have you Completed** [**Shipping Training Requirements**](https://uwosh.edu/sponsoredprograms/ibc/training/) **and is your certification current?**

[ ]  **Yes** [ ]  **No**[ ]  **N/A** (will not be transporting materials on campus)

# Section 14: Biological Material Storage Only

## Biological Material Storage Only: List all biological materials which will not be actively used, and which will only be maintained in storage: (Note: IBC approval will be needed to actively use these materials in the future.)

|  |  |  |  |
| --- | --- | --- | --- |
| **Biological Material** | **rDNA?**(Y/N/NA) | **Select Agent or Toxin** (Y/N/NA) | **Storage Location**(e.g., Building, Room, Freezer, Refrigerator) |
| 1. *Describe the biological material as it would be listed in its corresponding section above* | *Indicate “Y”, “N” or ”NA”* | *Indicate “Y”, “N” or ”NA”* | *e.g., Building, Room, Freezer, Refrigerator* |
| 2. *e.g., tetrodotoxin* | *NA* | *Y* | *Halsey 601; Northwest freezer* |
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| 4. |  |  |  |
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# Section 15: Additional Documents

## Additional Documents: Attach any documents necessary for a full review of this application. Please do not attach SOP’s for campus animal facilities; the IBC already have access to these documents.

Examples of documents to attach include the following:

* Lab manual(s)
* Standard Operating Procedures (SOP’s) describing experiment details related to materials handling
* Plasmid vector maps (backbone only required; type of insert is listed in Section 5B)
* Viral vector plasmid maps