*Principal investigators planning to work with Risk Group 1 biological materials only, without inclusion of recDNA/RNA procedures, are not subject to NIH oversight and do not need to complete any part of this application. Principal investigators with protocols identified as* ***exempt*** *from NIH guidelines based on NIH Guidelines Section III-F or Appendix C must complete Parts 1, 2, and 3 of this application. Principal investigators with protocols identified as* ***non-exempt*** *from NIH guidelines based on NIH Guidelines Sections IIIA-F must complete* ***all*** *applicable sections of this application.*

*Submit this application with the* ***Personnel Training Form*** *(available from the UWSP IBC website)**electronically to* *biosafety@uwsp.edu**. Protocols will be reviewed by the IBC and feedback provided in writing. Approved protocols expire after 3 years. If modifications are required, resubmit this form with changes highlighted for review and approval by the IBC. If laboratory personnel (non-PI) changes, submit a revised Personnel Training Form only. Investigators should keep a hard copy of the protocol in their lab for personnel to review. For additional questions, contact* *biosafety@uwsp.edu**.*

**Part 1: Principal Investigator(s) and Assurance Statement**

1. **Project Title: Project Type:** [ ]  Research [ ]  Teaching [ ]  Other

 **Date:**

[Fill-in]

Click or tap to enter a date.

**Review Type:** [ ] New Submission [ ] 3 Year Renewal [ ] Modification Form

**Protocol Number:** [Fill-in; **(SKIP if New)**]

Funding Agency (if applicable):

[Fill-in; **or SKIP if N/A**]

**Principal Investigator:** Email:

[Fill-in]

 Phone:

[Fill-in]

[Fill-in]

Department/Unit: Office (Building/Room):

[Fill-in]

[Fill-in]

**Co-Principal Investigator:** Email:

[Fill-in]

 Phone:

[Fill-in]

[Fill-in]

Department/Unit: Office (Building/Room):

[Fill-in]

[Fill-in]

*[Duplicate rows for additional co-PIs as needed; if no co-PIs are on this project,* ***DELETE the corresponding lines.****]*

1. By checking each item and 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](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html) (NIH Guidelines) as it relates to the biological agents/materials/recDNA/RNA 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), including the receipt of any of the substances outlined.

[ ]  I ensure that personnel under my oversight, including staff and students, have received training appropriate to their activities and have also received information on proper signage, potential biological hazards (as outlined in this protocol), manuals, MSDSs, and other information for these individuals to safely and effectively perform their 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, potentially hazardous spills, and know proper waste management and spill cleanup procedures.

[ ]  I will comply with all training and shipping requirements for transporting hazardous substances 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 it applies.

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

1. **Signatures:**

PI and/or Instructor: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Co-PI and/or Instructor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

*[Duplicate lines as needed, or* ***DELETE lines if appropriate.****]*

Department Chair/Supervisor:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

[ ] I am aware of this protocol and space/resources are available to support this project.

**Part 2: Categories and Experimental Design**

1. **Check all of the items below that will be used in your study, and check responses to follow-up questions if needed:**

[ ]  Recombinant DNA, Recombinant RNA, or Synthetic Nucleic Acids

Did you confirm your outlined recDNA/RNA materials are considered exempt by NIH Guidelines section III-F?

 [ ] Yes [ ] No *(If no, please verify, as you may not need to complete the entire application.)*

Do *any* of these recDNA/RNA materials require biosafety level-2 practices?

 [ ] Yes [ ] No *(If you are uncertain after performing a risk assessment, contact the IBC for assistance.)*

[ ]  Biological Materials (with possible biosafety concern; *perform a risk assessment, not everything needs reporting*)

Are *any* of the biological materials below: 1) capable of causing disease, 2) biohazardous (i.e., Risk Group 2, select agents and/or their toxins, etc.), 3) grown to ≥10 liters, or 4) manipulated using biosafety level-2 practices?

 [ ] Yes [ ] No

[ ]  Human or Non-Human Primate Cell Lines, Tissues, or Their Blood Products

[ ]  Living Animals (vertebrate or invertebrate), Animal Cell Lines, Tissues, or Their Blood Products

[ ]  Living Plants (exotic or grown with recombinant microbes/insect vectors), Plant Tissues, or Related Products

[ ]  Bacteria/Archaea, Viruses, Fungi, Protists, or Other Biological Materials (*not* marked above)

[ ]  Dual Use Research of Concern (DURC)

1. **Experimental Design:** Briefly describe the experimental design. Include a brief description of how the substances indicated above will be used in this protocol using language a non-expert would understand. Explain class objectives if this protocol is specifically designed for a teaching laboratory. Details can be provided elsewhere in this protocol.

[Fill-in]

1. **Teaching Activities:** Instructors are responsible for providing hazard communication to students and maintaining documentation that student training has occurred. **The IBC requires a copy of this training outline to be attached to the BPA form. The following elements should be covered with students:**
* Emergency procedures, personal protective equipment (PPE), lab etiquette and safety precautions, laboratory equipment use, and hazardous waste
* Any additional safety information specific to the activities conducted within the teaching laboratory
* Provide students with an electronic copy of the protocol that is followed for the teaching course
* Student should sign the Laboratory Safety Orientation Checklist or similar form acknowledging the training provided

A sample laboratory safety orientation checklist is available on the forms and documents page of our website.

**Part 3-1: Locations Used for Exempt Activities**

1. **List all locations** where the substances indicated in Part 2B are manipulated, stored/housed, decontaminated/sterilized, and prepared for disposal.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Building/Site** | **Room** | **Use of Room**(e.g. classroom, laboratory, animal housing, greenhouse, etc.) | **Containment Level**(e.g. BSL-1, ABSL-1, BSL-2, etc.) | **Containment Equipment**(e.g. BSC, fume hood) |
|  |  |  |  |  |

**ONLY COMPLETE THE FOLLOWING SECTIONS IF YOUR PROTOCOL IS NON-EXEMPT**

**Part 3-2: Locations Used for RG-2/Non-Exempt Activities**

1. **List all locations** where the substances indicated in Part 2B are manipulated, stored/housed, decontaminated/sterilized, and prepared for disposal.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Building/Site** | **Room** | **Use of Room**(e.g. classroom, laboratory, animal housing, greenhouse, etc.) | **Containment Level**(e.g. BSL-1, ABSL-1, BSL-2, etc.) | **Containment Equipment**(e.g. BSC, fume hood) |
|  |  |  |  |  |

1. List locations of **spill kits, sharps disposal, first aid kits,** **and biohazardous waste disposal** (if applicable)per location.

[**location name**:

 first aid kit = **(generally describe for each)**; spill kit = **( )**; sharps disposal = **( )**; biohazardous waste = **( )**;

*repeat for additional locations; omit or expand emergency clean-up / response materials where appropriate*]

1. Are pieces of containment equipment appropriately certified for the biosafety level practices indicated?

 *[~~STRIKETHROUGH~~ all options other than your intended response]* **Y / N / (N/A)**

1. Are **biohazardous signs** posted at entrances, on storage equipment, or other relevant equipment? **Y / N**

[If “no”, provide *general* descriptions of what still needs to be marked and what signs are needed; If “yes”, **SKIP**]

***NOTE:*** *Door signage must meet strict fire code policies; contact the BSO for coordinating proper door signs.*

1. Are any of the locations, including equipment, indicated above **shared with other users/groups**?  **Y / N**

If so, address any additional steps which have been taken to communicate potential hazards to these groups.

[Fill-in if “yes”; if “no”, **SKIP**]

***NOTE:*** *Issues regarding spaces/equipment which should not be shared with other groups may require the re-assignment of these locations by the department and/or college.*

1. **SPACES REQUIRING BSL-2 PRACTICES ONLY: Describe how access** to these substances, including all locations where they are stored/housed, manipulated, or prepared for disposal will be restricted from individuals not approved in the associated Personnel Training Form.

[Fill-in, **or SKIP if N/A**]

***NOTE:*** *Unauthorized access to such spaces must be reported to the IBC.*

1. **SPACES REQUIREING BSL-2 PRACTICES ONLY:** List locations of **emergency response information, emergency contacts, and biosafety paperwork** within the lab.

[Fill-in, **or SKIP if N/A**]

**Part 4: Recombinant Materials**

[ ]  **N/A:** Check here if such materials are not used in your experiments, and **SKIP to Part 5.**

1. If you intend to use **recombinant DNA, recombinant RNA, or synthetic nucleic acid molecules** in this protocol, indicate all categories from [NIH Guidelines, section III-A to](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.html#_Toc446948316) D that apply to your research. These categories are summarized on our [biosafety website, IBC Process](https://www3.uwsp.edu/acadaff/orsp/Pages/IBC-Process.aspx), which can be used to copy/paste/modify in the box below.

[Fill-in]

***NOTE:*** *You are not permitted to generate biological materials which would be designated as risk group-3 or -4 through the use of lower risk group materials in combination with recDNA/RNA (i.e., Staphylococcus aureus with multiple antibiotic resistance genes introduced).*

1. **Describe** the recDNA/RNA materials used in this protocol.

|  |  |  |  |
| --- | --- | --- | --- |
| **Name of Manipulated Genes / Sequences** (e.g., GFP, Ras, Ampicillinr) | **Description of Gene**(e.g., antibiotic resistance, oncogene, etc.)  | **Source Organism(s)**(*e.g., Enterococcus faecalis*, *Drosophila melanogaster )* | **Administered to:**(indicate both vector and/or organism) |
|  |  |  |  |

[Fill-in **ONLY** if the previous table cannot be used to adequately highlight the biosafety concern, **or SKIP if N/A**]

**Part 5: Biohazardous Biological Materials / Agents / Toxins**

1. Complete this section if you are working with **Human or Non-Human Primate Cell Lines, Tissues, or Their Blood Products**. ***NOTE:*** *Research involving human subjects requires IRB approval.*

[ ]  **N/A:** Check here if such materials are not used in your experiments, and then **SKIP to Part 5B.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Specific Material** | **Description of Material** | **BSL**  | **Fetal Derived?** Yes / No / N/A | **recDNA/RNA used? (Y/N);** (If Yes Section 4B ref.) | **Administered to:** (*ex. Mus musculus)* |
|  |  |  |  |  |  |

[Fill-in **ONLY** if the previous table cannot be used to adequately highlight the biosafety concern, **or SKIP if N/A**]

1. Complete this section if you are working with **Living Animals (vertebrate or invertebrate), Animal Cell Lines, Tissues, or Their Blood Products**. ***NOTE:*** *Research involving living vertebrates requires IACUC approval. Research involving living non-human primates is not allowed.*

[ ]  **N/A:** Check here if such materials are not used in your experiments, and then **SKIP to Part 5C.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Specific Animal / Material** | **General Description** | **BSL**  | **Transgenic?** Yes / No / N/A  | **recDNA/RNA used? (Y/N);** (If Yes Section 4B ref.) | **Housing / Containment Used** |
|  |  |  |  |  |  |

[Fill-in **ONLY** if the previous table cannot be used to adequately highlight the biosafety concern, **or SKIP if N/A**]

1. Complete this section if you will be working with **Living Plants (exotic or grown with recombinant microbes / insect vectors / etc.), Plant Tissues, or Related Products (with a biosafety concern).**

[ ]  **N/A:** Check here if such materials are not used in your experiments, and then **SKIP to Part 5D.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Name of Specific Plant / Material** | **General Description** | **BSL**  | **Transgenic?** Yes / No / N/A | **recDNA/RNA used? (Y/N);** (If Yes Section 4B ref.) | **Housing / Containment Used**  |
|  |  |  |  |  |  |

[Fill-in **ONLY** if the previous table cannot be used to adequately highlight the biosafety concern, **or SKIP if N/A**]

1. Complete this section if you will be working with **Bacteria/Archaea, Viruses, Fungi, Protists, Agents, Toxins, or Other Biological Materials** (not already described in **Sections 5A-C**, and also not considered exempt by NIH Guidelines III-F). ***NOTE:*** *You must state if these materials (or those listed in 5A-C) are known or suspected to contain blood borne pathogens.*

[ ]  **N/A:** Check here if such materials are not used in your experiments, and then **SKIP to Part 6.**

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Genus, species, relevant strains, or sample type** | **Description of Material** | **BSL**  | **recDNA/RNA used? (Y/N);** (If Yes Section 4B ref.) | **Administered to:** (*ex. Mus musculus)* |
|  |  |  |  |  |

[Fill-in **ONLY** if the previous table cannot be used to adequately highlight the biosafety concern, **or SKIP if N/A**]

[ ]  **N/A:** Check here if none of the above-listed types of materials are used in your experiments, and **SKIP to Part 6.**

**Part 6: General Risk Mitigation**

1. Conducting laboratory activities may result in contamination of laboratory equipment, laboratory spaces, and possibly personal exposure / breach of containment with these materials. Indicate how such risks will be mitigated.
2. List aerosol generating activities and how exposure/contamination/containment breach risks will be mitigated:

[Fill-in (i.e., centrifugation, vortexing, triteration, shaking, etc.)]

1. List PPE and special equipment used to reduce exposure/contamination/containment breach risks:

[Fill-in; if PPE or special equipment will vary depending upon which materials are handled, please specify]

1. Indicate how sharps will be safely manipulated and/or eliminated to reduce exposure risk:

[Fill-in, including both methods and equipment (refer to the biosafety manual for guidance), **or SKIP if N/A**]

1. Describe the locations of biological agent/toxins, logs for storage, manipulation, and decontamination/disposal:

[Fill-in, **or SKIP if N/A**]

1. Please indicate other major risk mitigation activities to maintain containment / decrease contamination as needed.

[Fill-in, **or SKIP if N/A**]

**Part 7: Dual Use Research of Concern**

[ ]  **N/A:** Check here if “DURC” does not apply to your experiments, and then **SKIP to Part 8.**

1. Complete this section if your described activities involve the potential to be used for nefarious purposes, also known as **Dual Use Research of Concern (DURC)**.
2. Briefly explain why this activity falls under “DURC” classification. Be sure to cross-reference which section and subsection contains the substances of concern (i.e., parts 4-B and 5-A if you are planning to use CRISPR/Cas 9 to modify the human genome in a cell line).

[Fill-in, **or SKIP if N/A**]

1. Justify why this activity should still be carried out.

[Fill-in, **or SKIP if N/A**]

1. Explain additional security measures that will be taken to document activities, record locations of any substances of concern, and further restrict access to the spaces where these activities take place.

[Fill-in, **or SKIP if N/A**]

**Part 8: Emergency Response**

1. **Exposure Awareness:** Before an accident occurs, explain how personnel will be made aware of potential risks and appropriate response to an exposure event.
2. Indicate possible routes of exposure per material where applicable:

[Fill-in (i.e., splash to the eye/mucous membranes, inoculation, ingestion, abrasion/cut, etc.),]

1. Briefly list possible consequences of an exposure (short-term or long-term; specific symptoms go in part 8B-iii):

[Fill-in (for each material capable of eliciting illness),]

1. Indicate the period of infectivity, shedding, or toxin latency:

[Fill-in (for each material capable of eliciting illness),]

1. Describe how personnel will be trained regarding possible exposures:

[Fill-in]

1. Describe where copies of this information will be kept and/or made accessible to personnel so information can be readily disseminated to health care providers / emergency responders in the event of an exposure.

[Fill-in]

1. **Response Procedure:** Provide a general response procedure to be followed if an individual is accidentally exposed to any of the recDNA/RNA, biological materials, or biological agents/toxins listed in this protocol.
2. Immediate response to an exposure:

[Fill-in]

1. Individuals to contact (including contact information) after an exposure:

[Fill-in]

1. Possible exposure symptoms (if they have been described or can be reasonably inferred):

[Fill-in]

***NOTE:*** *You are not required to report symptoms if none are known or could be reasonably inferred based on cases involving similar materials. However, you should still be aware of known symptoms/outcomes for risk assessment.*

1. Other information:

[Fill-in]

1. **Emergency Preparedness:** Complete this card and provide it to staff and students to best be prepared in the event of a medical emergency.

**Biological Material / Agent / Toxin / recDNA/RNA Exposed to:**

[Fill-in a different card for all separate items outlined in this protocol]

**Characteristics of Biological Material / Agent / Toxin / recDNA/RNA:**

[Fill-in (i.e., antibiotic resistances, toxicities, allergic response, etc.)]

**Common Symptoms if Known / Reasonably Inferred:**

[Fill-in, or indicate: **symptoms are currently unknown**]

***[Duplicate this box and modify for all substances with different exposure characteristics.]***

**Part 9: Safeguarding Visitors**

1. **Safeguarding Emergency Responders:** Describe the procedures used to safeguard emergency responders from encountering hazardous materials in the lab, including appropriate hazard communication signs, in the event of fire, medical emergency, etc.

[Fill-in]

1. **Safeguarding Non-Emergency Personnel:** Describe the procedures used to safeguard non-emergency personnel (i.e., custodial staff, IT, building maintenance crew/facilities services, equipment service vendors, etc.) from encountering hazardous materials in the lab, including appropriate hazard communication signs, pre-scheduling lab entry events, and routine surface decontamination schedules.

[Fill-in]

**Part 10: Waste Disposal, Spill Response, Surface Decontamination, and Laundry Service**

1. **Waste Disposal:** Different methods of decontamination and disinfection exist, but not all methods are equally appropriate. Refer to the biosafety manual for guidelines, and verify your chosen methods are appropriately matched to the materials you will use.
2. Describe the procedure used to dispose of liquid wastes:

[Fill-in the disinfectant used, its concentration, contact time, etc. (per liquid waste if using multiple methods)]

1. Describe the procedure used to dispose of solid wastes:

[Fill-in the chemical treatment used, autoclave cycle selected, waste collection coordinated, etc. (per solid waste if using multiple methods)]

1. **For Regulated Agent/Toxin Use ONLY:** Biological agents and/or their toxins are regulated, requiring logs of their receipt, use, and eventual disposal, including the removal of these substances by an authorized group. Describe any additional means of removing biological agents and/or their toxins by approved groups (i.e., service provided by the original authorized distributor, like ATCC).

[Fill-in, **or SKIP if N/A**]

1. **Spill Response:** Describe the method used to clean-up biological spills outside of containment.***NOTE:*** *MANY biological materials are NOT deactivated by ethanol alone.*

[Fill-in per material if using multiple methods]

***NOTE:*** *PIs are required to report incidents to the IBC within 24 hours. Incidents must be reported via the* ***Biosafety Incident Report Form****, found the IBC website, and submitted to* *biosafety@uwsp.edu**. Incidents in which responsible parties are unknown should still be reported to the BSO for appropriate follow-up and investigation. If an event requires medical care,* ***seek care immediately****. Employees or student workers should report injuries to HR within 24 hours.*

1. **Surface Decontamination:** Describe the method used to decontaminate biological wastes from equipment / laboratory surfaces / etc.

[Fill-in]

1. **Laundry Service:** Provide information on how laundry services are obtained for lab coats or other contaminated clothing (lab coats and contaminated clothing must not be laundered at home).

[Fill-in, **or SKIP if laundry services are not required, i.e., if lab coats or similar PPE are not required**]

**Part 11: Transportation and Shipping**

[ ]  **N/A:** Check here if none of your materials will be transported/shipped (**including between campus rooms/facilities**), and then **SKIP to Part 12.**

Complete this section if you **plan to ship or transport (both on or off campus)** biological agents/toxins, biological materials, and/or recDNA/RNA. ***NOTE:*** *The transport of biological agents/toxins is regulated and cannot be moved to another user group without strict prior authorization, even among known collaborators (both on and off campus).*

1. **Transport:** Describe the method of transporting biological materials through public spaces on campus.

[Fill-in (i.e., material is transported room-to-room in a sealed container, in addition to a secondary, hard walled container as outlined in the biosafety manual)]

1. **Shipping:** Describe the method of shipping biological materials and/or recDNA/RNA across campus or off campus.

[Fill-in, **or SKIP if N/A**]

***NOTE:*** *If biological agents/toxins, biological materials, and/or recDNA/RNA are to be transported to another location, these locations must be referenced under* ***part 3****; if they are to be transported to another lab, that PI must already have an approved protocol with these biological agents/toxins, biological materials, and/or recDNA/RNA indicated (additional requirements may need to be met for biological agents/toxins).*

**Part 12: Appendices**

1. **Additional Documents:** Attach any documents necessary for a full review of this application. Please do not attach documents from campus animal facilities; the IBC already has access to these documents. Examples of documents to attach include the following:
	* **Personnel Training Form (required)**
	* Lab manual(s), course materials, or syllabi
	* Other protocols describing experiment details related to materials handling
	* Plasmid/viral vector maps (backbone only required; type of insert is listed in Section 4B)

**References**

<https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/>

<https://www.cdc.gov/biosafety/publications/bmbl5/>

Adapted from: J. Keaton, K. Schill, S. Verbockel. 2017. IBC Protocol Application. UW-Oshkosh IBC