INSTRUCTIONS FOR

Washington State University

**Biosafety Approval Form (BAF)** - **THIS FORM MUST BE TYPED**

1. **What is a BAF:** A BAF is a document describing a Principal Investigators (PI’s) activities with [potentially biohazardous material](https://biosafety.wsu.edu/potentially-biohazardous-materials/) at WSU that, when approved by the WSU Institutional Biosafety Committee (IBC), provides authorization to utilize designated material(s) for the specified activities.

2. **Who should complete a BAF:** A BAF must be completed by a WSU-affiliated PI, including a USDA/ARS PI, who currently has or plans to possess, store, work with, or transport infectious agents, or biological material that requires a federal permit, recombinant or synthetic DNA/RNA; transgenic animals, microbes and plants; human or primate tissues/fluids including established cell lines, select agents and biological toxins. If post-doctoral fellows and visiting scholars plan to work with potentially biohazardous material, they must submit the BAF under the auspices of a WSU-affiliated PI.

3. Why a BAF must be completed: Per WSU policy all work with potentially biohazardous agents must receive authorization from the WSU IBC prior to receiving the material or beginning work. Whether funded or not, you must submit a BAF for IBC review and approval. Federal regulations and guidelines require that work with potentially biohazardous material at institutions receiving federal funds have IBC’s that oversee these projects.

1. Assistance in preparing a BAF: Contact WSU Biosafety Officer (BSO): Levi O’Loughlin ([levi.oloughlin@wsu.edu](mailto:levi.oloughlin@wsu.edu), 335-1585). Note that the BSO does not process submissions. All submissions must be sent to [ibc@wsu.edu](mailto:ibc@wsu.edu).
2. BAF timeline & approval: For submission deadline information click [here](https://biosafety.wsu.edu/meeting-schedule/). The IBC reviews and votes on each BAF at committee meetings. IBC approval is valid for up to three years. As the expiration date approaches, courtesy renewal notifications are sent. However, it is the responsibility of the PI to maintain approval by submitting a [BAF](https://biosafety.wsu.edu/forms-templates-inspection-checklists/) renewal prior to the expiration date.

6**. BAF amendment:** Any change to an approved BAF requires the submission of an amendment request (or possibly a new BAF). There is no separate amendment form. All changes are to be incorporated into the BAF and highlighted. If you would like assistance, contact the BSO at 335-1585 prior to sending an amendment request.

1. **Review and approval of Lab Biosafety Level (BSL), Animal Biosafety Level (ABSL) and Plant Biosafety Level (BSLP) facilities:** The [Office of Research Assurances](http://www.ora.wsu.edu/), (ORA) maintains a list of approved facilities/BAF’s and also conducts reviews of facilities. BSL1 and BSL2 facilities are reviewed, at minimum, every three years. BSL3 facilities must be reviewed annually. BAF-associated facility approvals are provided by the ORA.
2. **Review and approval of the Biosafety Manual (BSM) and Exposure Control Plan (ECP):** The BSO meets with the PI and lab personnel to prepare the BSM and ECP upon submission of the BAF. BSM’s and Research ECP’s are reviewed by the BSO for each initial submission and with each amendment and renewal. The BSO will provide approval for BSM‘s and ECP’s, and a copy will be maintained by the ORA.
3. **Submitting the BAF:** Send by email to [ibc@wsu.edu](mailto:ibc@wsu.edu). The source file is preferred, no need to scan or convert to PDF. The original submission email must be sent from the WSU email of the Principal Investigator (PI). Signature of the PI is not necessary if submitted in this manner (the submission email is sufficient authentication). Co-Investigators, Laboratory contacts and facility administrators should be copied on the submission, as well.
4. **Appropriate Biosafety Level guidelines:** There are several guidelines available to assist in determining appropriate risk groups for biological materials and biosafety levels for containment purposes. Below are listings to pertinent guidelines and their respective website links (CDC, NIH and ISB). The CDC guidelines are generally appropriate for work with infectious agents. The NIH guidelines refer primarily to work with recombinant or synthetic nucleic acids. The ISB guidelines are for plant containment information.
5. **Training & Education:** Prior to beginning work with potentially biohazardous material, the PI must ensure that all individuals involved with this work are appropriately trained and have read and are following appropriate practices and procedures.
6. **Compliance with CDC/APHIS** [**Biological Select Agent**](https://www.selectagents.gov/sat/list.htm)**s and Toxins Registration Standard:** A PI whose activities involve any of the select agents or toxins (at greater than the exempt level- see section 8 in this document) must clearly indicate such usage by checking the “YES” box in that section. Select agents require special registration with CDC or APHIS for facilities and investigators to be approved. To mitigate Biosecurity risks these BAF’s are hand delivered to the ORA Director or BSO.
7. **References for determining which E. coli strains are K12 or K12 derivatives:**

[**http://openwetware.org/wiki/E.\_coli\_genotypes**](http://openwetware.org/wiki/E._coli_genotypes)

[**http://aem.asm.org/cgi/reprint/61/11/4135?view=long&pmid=8526531**](http://aem.asm.org/cgi/reprint/61/11/4135?view=long&pmid=8526531)

[**http://cgsc.biology.yale.edu/**](http://cgsc.biology.yale.edu/)

**Definitions:**

**ABSL-1, 2 & 3**: Animal Biosafety Level “X”

**Appropriate Biosafety Levels:** These are levels deemed appropriate to the biological materials and activities as demonstrated by outside standard references including but not limited to Centers for Disease Control and Prevention (CDC), National Institutes of Health (NIH), and United States Department of Agriculture (USDA)/Animal and Plant Health Inspection Service (APHIS). If this information is limited or inconclusive a full risk assessment will be performed. The IBC has the final authority to set appropriate Biosafety Levels.

**ASAF:** Animal Subject Approval Form

**BL1-N, BL2-N, BL3-N:** Animal Biosafety Level “X” – Animals (NIH)

**BSL -1, 2 & 3:** Biosafety Level “X”

**BL1-P, 2-P & 3-P:** Biosafety Level “X”-Plants (NIH)

**IBC:** Institutional Biosafety Committee

**Infectious Agents:** Includes all infectious material (e.g., bacteria, fungi, parasites, prions, viruses, and viroids) which can cause disease in humans, animals, or plants, or cause environmental or agricultural impact.

**ISB:** Information Systems for Biotechnology

**NIH**: National Institutes of Health

**OSP:** Office of Science Policy

**Oncogenic Viruses:** Viruses capable of inducing neoplasms in their hosts.

**Potentially Biohazardous Material (includes all the categories below):**

* Recombinant or Synthetic Nucleic Acids (r/sNA)
* Genetically modified organisms (GMO). Including, but not limited to:
  + Animals, plants, invertebrates, and/or other organisms created by WSU employees or in/on WSU property,
  + Genetically modified whole plants.
  + Transgenic field trials and plantings of, any genetically modified organism to be introduced into the environment even those commercially available and not requiring APHIS permits (by WSU personnel and/or on WSU property)
  + Field testing of plants engineered to produce pharmaceutical and industrial compounds,
* Any organisms requiring federal permits (APHIS, CDC, FDA, EPA…),
* Pathogens/infectious agents (human, animal, plant and other),
* Select/Biological Agents and Toxins (CDC and USDA),
* Human & non-human primate blood and blood products, body fluids, and tissue,
* Work with animals or vectors known or suspected to be reservoirs of BL2 or BL3 infectious agents when such work increases potential exposure risks to personnel or other animals,
* Oncogenic viruses used in conjunction with animals.

**Prions:** Infectious proteinaceous particles associated with transmissible spongiform encephalopathies in animals and humans.

**Recombinant or Synthetic Nucleic Acids (r/sNA):** According to NIH Section I-B i) molecules that are constructed outside living cells by joining natural or synthetic DNA or RNA segments to DNA or RNA molecules that can replicate in a living cell, or ii) molecules that result from the replication of those described in (i) above.

**Select Agents & Toxins:** Agents listed in the Code of Federal Regulations (including, but not limited to, 42 CFR Part 73, 7 CFR Part 331, and 9 CFR Part 121) and are capable, if released, of generating a serious public health crisis or are high-consequence livestock pathogens. Transfer of select agents is limited and controlled by the Federal Select Agent Program.

Washington State University

Biosafety Approval Form (BAF)

**Section 1a: Basic contact information – BAF Administration**

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| Application status: | | | | | | | | | | ORSO # (if avail.): | | |  | | |  | | For IBC use only – Do not mark in this area | | | | | | | |
|  | New Submission | | | | | | | |  | |  | | | | | | BAF #: | |  | | | | | |
|  |  | | | | | | | |  | |  | | | | | |  | |  | | | | | |
|  | Renew BAF # | | | |  | | |  | | | | | | | | | Received Date: | | | Version Date: | | | | |
|  |  | | | |  | | | |  | | | | | | | |  | |  | | | | |  |
|  | Amend BAF # | | | |  | | | If checked, highlight the changes. | | | | | | | | | | | | | | | | |
|  | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Project Title: | | | |  | | | | | | | | | | | | | | | | | | | | | |
| Principal Investigator: | | | | | | |  | | | | | | | | Title & WSU ID #: | | | |  | | | | | | | |
| Department: | | | |  | | | | | | | | | | Building: | | |  | | | | | Office# | |  | | |
| Phone: | | |  | | | | | Fax: | |  | E-mail address: | | | |  | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Co-Investigator: | | | | |  | | | | | | | | | | Title & WSU ID#: | | | |  | | | | | | | |
| Department: | | | |  | | | | | | | | | | Building: | | |  | | | | | Office# | |  | | |
| Phone: | | |  | | | | | Fax: | |  | E-mail address: | | | |  | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | | | | | | | | | | | | |
| Lab contact: | | | |  | | | | | | | | | | | Title & WSU ID #: | | | |  | | | | | | | |
| Department: | | | |  | | | | | | | | | | Building: | | |  | | | | | Lab # |  | | | |
| Phone: | | |  | | | | | Fax: | |  | E-mail address: | | | |  | | | | | | | | | | | |

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| --- |
| **Principal Investigator’s Certification:**  I certify that I have read the following statements and agree that I and all listed participants will abide by those statements:   1. Ensure that listed personnel have received or will receive appropriate training in safe laboratory practices and procedures for this project *before any work begins* and at least annually thereafter. Also, all listed personnel who have occupational exposure to bloodborne pathogens will be trained annually (EH&S provides this training). 2. Follow health surveillance practices as required in the biosafety laboratory manual and inform those working on the protocol about appropriate emergency assistance information for their location(s). 3. Inform EH&S (335- 3041) and the BSO of any research-related accident or illness as soon as possible after its occurrence. For USDA-ARS employees, contact Occupational Safety and Health Specialist (335-7766). Complete and submit a university incident report form. See [SPPM S25.20](https://policies.wsu.edu/prf/index/manuals/2-00-contents/2-24-reporting-accidental-injuries-work-related-illnesses/) for instructions on filling out this form; 4. Submit in writing a request for approval from the IBC of any significant modifications to the study, facilities, or procedures; and 5. Adhere to all applicable federal, state, local, and WSU regulations, guidelines, or contracts, as IBC approval does not supersede other regulations, guidelines, or contracts. |

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| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Signatures\*: | | | | | | | | | | | | | |
|  | Principal Investigator: |  | | | | | | | | Date: |  | | | |
| \* Signatures are only necessary if not submitted from Principal Investigator’s WSU email | | | | | | | | | | | | | | |
| **For IBC use only:** | | | **IBC-BSL level approval** |  | **BSL-1** | |  | **BSL-1+** |  | **BSL-2** |  | **BSL-2+** |  | **BSL-3** |
| Do not mark in this area | | | **IBC-ABSL approval** |  | **ABSL-1** | |  | **ABSL-1+** |  | **ABSL-2** |  | **ABSL-2+** |  | **ABSL-3** |
|  | | | **IBC BSLP approval** |  | **BSL-1P** | |  | **BSL-1+P** |  | **BSL-2P** | | | | |
|  | | | **IBC Coordinator/BSO Signature:** | | |  | | | | | | | | |

**Section 1b: Basic contact information - Lab Personnel**

List all project personnel (PI, Associates, and technicians who will be involved in conducting the procedures or have access to the biological materials). This information is intended to inform the IBC of the training and background of key personnel. This is an IBC oversight activity required by the NIH Guidelines.

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **NAME** | **WSU ID #** | **ROLE ON PROJECT**  **(e.g., PI, Graduate Student, Postdoctoral Scholar)** | **TRAINING & EXPERIENCE RELATED TO PROCEDURES PERFORMED** | | | | | |
|  |  | **Principal Investigator (PI)** |  | **Beginner** |  | **Intermediate** |  | **Advanced** |
|  |  |  |  | **Beginner** |  | **Intermediate** |  | **Advanced** |
|  |  |  |  | **Beginner** |  | **Intermediate** |  | **Advanced** |
|  |  |  |  | **Beginner** |  | **Intermediate** |  | **Advanced** |
|  |  |  |  | **Beginner** |  | **Intermediate** |  | **Advanced** |

Additional rows may be added with the TAB key

**Section 2: Description of research and facilities used (This section must be completed)**

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| **A.** | **In Lay Language, briefly describe your Goals and Aims of the research project, as if addressed towards a general audience (do not provide a grant proposal). Provide definitions or explanations of technical terms and jargon:** | | | | | | |
| **B.** | **Briefly describe your Plan of Work describing all activities in respect to biological agents used to accomplish the goal and aims described above. Include a brief explanation of research methods, microbiological practices, and laboratory procedures in lay language. Provide definitions or explanations of technical terms and jargon:** | | | | | | |
| **C.** | **Will vertebrate animals be involved?** | **No** |  | **Yes** |  | ASAF Number: |  | |
|  | | | | | | | | |
| **D.** | **Will non-vertebrate animals be involved?** | **No** |  | **Yes** |  |  |  | |
|  | | | | | | | | |
| **E.** | **Will human subjects directly or indirectly (samples) be used?** | **No** |  | **Yes** |  | IRB Number: |  | |
|  | | | | | | | | |
| **F.** | **Will plants be used?** | **No** |  | **Yes** |  |  | | |

**G. Appropriate Biosafety Levels**:

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | **Laboratory Containment:** | BSL-1 |  | BSL-2 | |  | BSL-3 |  | other |  |  |
|  |  | If ‘Other,’ explain: | | |  | | | | | | |
|  |  |  | | |  | | | | | | |
| 2. | **Animal Containment:** | ABSL-1 |  | ABSL-2 | |  | ABSL-3 |  | other |  |  |
|  |  | If ‘Other,’ explain: | | |  | | | | | | |
|  |  |  | | |  | | | | | | |
| 3. | **Plant Containment:** | BSL1-P |  | BSL2-P | |  | BSL3-P |  | other |  |  |
|  |  | If ‘Other,’ explain: | | |  | | | | | | |

**H Location of facilities where biological agents are used for this project (See Example in Red):**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Campus** | **Name of Building or Field Plot** | [**Facility ID #**](https://facilities.wsu.edu/facilities-services-administration/space-management/facility-roster/)**:** | **Room #(s)** | **BSL**  **(1-3)** | **ABSL**  **(1-3)** | **BSL-P**  **(1-3)** | **Species of Animals housed in these rooms**  **or location** | **Species of Plants housed in these rooms or location** |
| Pullman | Neill Hall | 0070 | 419 |  | **1** |  | Mice | None |
|  |  |  |  |  |  |  |  |  |
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| **I. Please check Yes or No for each of the following categories that apply (do not leave any blank):** | | | | | | |
| Yes |  |  | No |  |  | **Infectious agents (animal, human, or plant);** If yes, complete **section 3.** |
|  |  |  |  |  |  |  |
| Yes |  |  | No |  |  | **Generating and handling recombinant or synthetic nucleic acids (r/sNA) or using cells, organisms and viruses containing such molecules;** If yes, complete **section 4.** |
|  |  |  |  |  |  |  |
| Yes |  |  | No |  |  | **Human or primate blood, body fluids, cells, cell lines, and tissues;** If yes, complete **section 5**. |
|  |  |  |  |  |  |  |
| Yes |  |  | No |  |  | **Transgenic plants;** if yes, complete **sections 4 & 6.** |
|  |  |  |  |  |  |  |
| Yes |  |  | No |  |  | **Transgenic animals;** If yes, complete **sections 4 & 7.** |
|  |  |  |  |  |  |  |
| Yes |  |  | No |  |  | **Select agents and/or toxins;** If yes, complete **sections 3 & 8.** |

**Section 3: Infectious agents and biological toxins**

**For definition of BSL classifications refer to Biosafety in Microbiological and Biomedical Laboratories (**[**BMBL**](https://www.cdc.gov/labs/BMBL.html)**) or the** [**NIH Guidelines**](https://biosafety.wsu.edu/documents/2023/01/nih-guidelines-04-2019.pdf) **for use of r/sNA.**

1. **List all Agents and toxins (additional rows may be added with the TAB key)**

|  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Infectious Agent** | **Toxin** | Human Hazard\* | | Animal Hazard | | **Plant Hazard** | | **Human Vaccines Available** | | **BSL Level** | | |
| **YES** | **NO** | YES | NO | YES | NO | YES | NO | 1 | 2 | 3 |
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\*If organism is non-pathogenic to humans check NO.

1. **Briefly answer the following questions in the boxes provided below (if applicable):**

|  |  |
| --- | --- |
| **1.** | **Briefly describe experimental design and goals with the infectious agents and/or toxins:** |
|  |
| **2.** | **What is the source of the agent, toxin, or potentially biohazardous material?** |
|  |
| **3.** | **What is your assessment of the biohazardous potential? Include vaccines that will be required (if applicable).** |
|  |
| **4.** | **What containment procedures will be used when transporting agents within and between facilities? Provide an example of the double-containment used when transporting agents outside of the primary laboratory facility.** |
|  |
| **5.** | **What is the method of terminal inactivation of the biological agent (autoclave, chemical inactivation, compost, steam sterilization technology – STI, incineration)?** |
|  |
| **6.** | **What is the disposal method for inoculated animals (including animal bedding and waste) or plants?** |
|  |
| **7.** | **List all materials that require federal permits & include copies of these permits with this application.** |
|  |

**Section 4: Recombinant or Synthetic Nucleic Acid (r/sNA) molecules**

Note: Descriptions in the table below are summarized from the [**NIH Guidelines**](https://biosafety.wsu.edu/documents/2023/01/nih-guidelines-04-2019.pdf), contact the BSO for questions.

1. NIH Review Category & Subcategory: ***Check all the categories, subcategories and information that apply.***

|  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Category** | | | **Oversight** | **Includes / Subcategories** | | | | | | |
| **III-A** | | | **NIH Director & IBC** | Studies that involve the deliberate transfer of drug resistance to microorganisms (not known to acquire the trait naturally) that can compromise the use of the drug to control the microorganism and its disease in humans, veterinary medicine or agriculture. Contact BSO for special instructions. | | | | | | |
|  |  |  |
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| **III-B** | | | **NIH/OSP & IBC** | Studies that involve the deliberate formation of recombinant or synthetic nucleic acid molecules containing genes for the *biosynthesis* of toxin molecules lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight Contact. BSO for special instructions. | | | | | | |
|  |  |  |
|  | | |
| **III-C** | | | **IRB & IBC** | Experiments involving human gene transfer (recombinant or synthetic DNA, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into one or more human subjects. Contact BSO for special instructions. | | | | | | |
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|  | | |
| **III-D** | | | **IBC approval before initiation** |  | | | | | | |
|  |  | **D-1**: Experiments using Risk Group 2 or higher agents as host-vector systems (*e.g.,* lentiviral) | | | | |
|  | |
|  |  |  |  |  | **D-2**: Experiments in which DNA from Risk Group 2 or higher agents is cloned into non-pathogenic prokaryotic or lower eukaryotic host-vector systems | | | | |
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|  |  | **D-3:** Experimentsin which r/sNA is introduced with infectious or defective viruses in the presence of helper virus in tissue culture systems. | | | | |
|  |  |
|  | |  | Yes |  | No | Experiment is likely to enhance pathogenicity |
|  | | | | | | |
|  | |  | Yes |  | No | Experiment extends the host range |
|  |  |  | | | | |
|  |  | **D-4:** Experiments involving *whole* *animals* in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line and experiments involving viable recombinant *or* synthetic nucleic acid molecule-modified *microorganisms tested on whole animals*. (This section does not include generation or breeding transgenic rodents, see Section III-E). For more information, see [Animal experiments covered under the NIH guidelines](https://biosafety.wsu.edu/documents/2023/01/nih-guidelines-animal-activities-table.pdf). | | | | |
|  | |
|  | |  | Yes |  | No | Fraction of viral genome utilized may lead to productive infection. |
|  | | | | | |
|  | |  | Yes |  | No | r/sNA source is greater than 2/3 eukaryotic viral genome. |
|  | | | | | |
|  |  | **D-5:** Experiments to genetically engineer plants by recombinant or synthetic nucleic acid molecule 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 recombinant or synthetic nucleic acid molecules (typically risk group 2 or higher: BSL2 or BSL2-P) | | | | |
|  |  |
|  |  | **D-6:** Experiments involving more than 10L of culture of organisms containing r/sNA molecules.  **D-7:** Experiments involving influenza viruses generated by recombinant or synthetic methods. | | | | |
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| **III-E** | | | **IBC approval simultaneous with initiation** |  | | | | | | |
|  |  | **E-1:** Experiments involving the formation of r/sNA molecules containing no more than two-thirds of the genome of any eukaryotic virus (cells must lack helper virus for the families of defective viruses used). This category is used for all routine r/sNA cloning or gene expression with low risk agents (*e.g.,* *E. coli* cloning strains). | | | | |
|  |  |  |  |  |
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|  | | |  | |  |  |  |  |  |
|  |  | **E-2:** Experiments involving nucleic acid molecule-modified whole plants, and/or experiments involving recombinant or synthetic nucleic acid molecule-modified organisms associated with whole plants (typically group 1: BSL1 or BSL1-P). | | | | |
|  |  |
|  |  | **E-3:** Experiments involving the generation of risk group 1 (*e.g., ABSL-1*) rodents in which the animal's genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or nucleic acids derived therefrom, into the germ-line (transgenic rodents). See III-D4 for experiments requiring BSL-2 or higher containment and practices. | | | | |
|  |  |
| **III-F** | | | **WSU policy requires BAF submittal for review and IBC approval simultaneous with initiation** |  |  | Exempt by NIH Guidelines, including synthetic nucleic acids that: (1) can neither replicate nor generate nucleic acids in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication), and (2) are not designed to integrate into DNA, and (3) do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight. (Provide descriptions of experiments that use r/sNA molecules and information from the NIH Guidelines that verifies exemption in the narrative of section 2). | | | | |
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**Recombinant r/sNA information below to be filled out for Category III-A through III-F work.**

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. **Please check Yes or No for each of the following statements:** | | | | | | |
| **1.** | Yes |  |  | No |  | I am inserting or using foreign DNA or RNA into a vector, organism, or cell/cell line to clone or express it. |
| **The DNA or RNA to be cloned or expressed:** | | | | | | |
| **2.** | Yes |  |  | No |  | Is from a Risk Group 3 agent. |
|  |  |  |  |  |  |  |
| **3.** | Yes |  |  | No |  | Represents more than two-thirds of the genome of a Risk Group 1 or 2 organisms that have not been determined to be exempt by NIH Guidelines. |
|  |  |  |  |  |  |  |
| **4.** | Yes |  |  | No |  | Encodes a known oncogene. |
|  |  |  |  |  |  |  |
| **5.** | Yes |  |  | No |  | Encodes a control element that may extend the host range. |
|  |  |  |  |  |  |  |
| **6.** | Yes |  |  | No |  | Encodes molecules or genes for the biosynthesis of such molecules known to be toxic to vertebrates at  LD50 of less than 100 ng/kg body weight. |
| **The vector I am using for introducing a foreign DNA or RNA into the host:** | | | | | | |
| **7.** | Yes |  |  | No |  | Is from a Risk Group 3 agent. |
|  |  |  |  |  |  |  |
| **8.** | Yes |  |  | No |  | Is a Risk Group 1 or 2 virus that infects eukaryotic cells and contains more than two-thirds of the viral genome. |

**If you checked Yes for any of the above statements, please complete the following r/sNA information.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
|  | | | **Biosafety Level** | | |
| 1. **Host, vector, and gene biosafety information (as applicable):** | | | **1** | **2** | **3** |
| 1. Host(s): |  | |  |  |  |
| If applicable, include plants/animals to be transformed | |  |
| 2. Vector(s)\*: |  | |  |  |  |
|  |  | |
| 3. Gene(s), DNA, or RNA involved (e.g., cloned or expressed)#: |  | |  |  |  |
|  |  | |
| 4. DNA/RNA source(s): |  | |  |  |  |
|  |  | |

\* List the type of vector systems used (e.g., plasmid, lentiviral, adenoviral, CRISPR/Cas9 vectors, etc.) and provide vector names or descriptions (e.g., backbone, resistance markers, etc.). If multiple vectors are used, provide a representative example of vector names for each type. # Provide names of genes or families with relevant examples. **Section 5: Human or Primate Blood, body fluids, cells, cell-lines, and tissues**

A. Human blood, body fluids, cells, and tissues must be treated as though containing infectious agents.

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 1. |  | **Blood** |  |  | **Vendor/Collaborator:** |  |
|  |  |  |  |  |  |  |
| 2. |  | **Body fluids** | **List type:** |  | **Vendor/Collaborator:** |  |
|  |  |  |  |  |  |  |
| 3. |  | **Cells/tissues** | **List type:** |  | **Vendor/Collaborator:** |  |
|  |  |  |  |  |  |  |
| 4. |  | **Primary Cell Lines** | **List type:** |  | **Vendor/Collaborator:** |  |
|  |  |  |  |  |  |  |
| 5. |  | **Established Cell lines** | **List type:** |  | **Vendor/Collaborator:** |  |

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| 6. | Do any of the cells, tissues, or cell lines have characterized agents? |  | Yes |  | No | **If Yes, Fill out Section 3** |

7. Use of human or primate blood, body fluids, cells, and tissues may require a Bloodborne (BBP) Pathogen Exposure Control Plan (ECP), bloodborne pathogen training, and offer to provide personnel vaccinations (contact EH&S at 335-3041).

|  |  |  |  |
| --- | --- | --- | --- |
| a. | Has a BBP ECP been completed? |  | Yes |
|  |  |  |  |
| b. | Has your BBP ECP been reviewed and approved by the BSO? |  | Yes |
|  |  |
| c. | Are systems in place to ensure lab personnel BBP training? |  | Yes |
|  |  |
| d. | Are systems in place to ensure lab personnel are offered required Hepatitis-B Virus (HBV) vaccinations? (Not applicable for established cell lines except those of liver origin) |  | Yes |  | N/A |
|  |  |  |  |

Please note: Use and/or collection of human blood, body fluids, cells, or tissues may require human subjects’ approval from the WSU [IRB](http://www.irb.wsu.edu/).

**Section 6: Transgenic plants**

The [NIH Guidelines](https://biosafety.wsu.edu/documents/2023/01/nih-guidelines-04-2019.pdf) require that transgenic plant activities be reported to the IBC. Transgenic plant projects requiring only BSL-1 containment may be initiated simultaneously with submission of this form to the IBC. All other transgenic plant research requires IBC review and approval prior to initiation of the research. Please refer to the NIH Guidelines or contact the BSO for additional information. Note: The Agricultural Research Center (ARC) has requested to be kept informed of all transgenic plant research outside the laboratory at WSU. The ORA will forward a copy of any BAF that includes research with transgenic plants to be introduced into the field to the ARC for their records. This will not affect review and approval by the IBC.

**A. *Please check Yes or No for each of the following categories and fill in appropriate boxes***

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  | Yes |  | No | 1. | Transgenic whole plants will be maintained in the laboratory, greenhouse, or growth chamber. | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 2. | Transgenic whole plants will be introduced into the field. | | | | | | | | | | | | | | | | |
|  | | | |  | |  | | | | | | | | | | | | | | | |
| a. | | If a pharmaceutical or bioactive industrial compound will be synthesized in a food or feed crop, state | | | | | | | | | | | | | | | |
| the reason for choosing that crop: | | | |  | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
| b. | | Describe information gained from lab and growth chamber or greenhouse experiments that would be | | | | | | | | | | | | | | | |
| relevant to assessing potential risks from field tests: | | | | | | |  | | | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| c. | | Describe procedures to monitor for and eliminate any volunteer plants: | | | | | | | | |  | | | | | | |
|  | | | | | | | | | | | | | | | | | |
| d. | | How close is the field planting to other plants where gene flow or cross pollination could occur? | | | | | | | | | | | | | | | |
|  | | | | | | | | | | | | | | | |
|  | Less than 100 feet |  | Less than one mile | | | |  |  | | | | | | | |
|  | |  | |  |  | | | |  |  | | | | | | | |
|  | |  | Less than 100 yards |  | Greater than one mile | | | |  |  | | | | | | | |
|  | |  | |  |  | |  | | | | | | | | | | |
|  | |  | Not applicable |  | Explain: | |  | | | | | | | | | |
|  | |  | |  |  | |  | | | | | | | | | | |
| e. | | Have bordering farms been made aware of the transgenic field release? | | | | | | | | | | Yes |  | No |  |  | |
|  | |  | | | | | | | | | |  |  |  |  |  | |
| f. | | I agree to adhere to all federal guidelines as outlined in the attached copy of the APHIS approval/permit | | | | | | | | | | Yes |  | No |  |  | |
|  |  |  |  |  | |
|  | |  | | | | | | | | | |  |  |  |  |  | |
| g. | | A planting map with GPS coordinates and bordering field planting information has been attached. | | | | | | | | | | Yes |  | No |  |  | |
|  |  |  |  |  | |
|  | |  | | | | | | | | | |  |  |  |  |  | |
|  | Yes |  | No | 3. | Is the recombinant plant a noxious weed? | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 4. | Can the recombinant plant interbreed with weeds in the area? | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 5. | Does the recombinant plant have recognized potential for detrimental environmental impact on managed or natural ecosystems? | | | | | | | | | | | | | | | | |
|  |  |  |  |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 6. | Does the recombinant DNA work contain a complete genome of a non-exotic infectious agent? | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 7. | Does the recombinant DNA work contain the genome of an exotic infectious agent? | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 8. | Could this work reconstitute the genome of an infectious agent in a plant? | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 9. | Does this work involve exotic infectious agents with potentially detrimental environmental impact? | | | | | | | | | | | | | | | | |
|  |  |  |  |  |  | | | | | | | | | | | | | | | | |
|  | Yes |  | No | 10 | Contains an exogenous toxin? If yes, please describe: | | | | | | |  | | | | | | | | | |

**B. Please complete the questions below:**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 1. | What physical and or biological containment conditions will be implemented? | | |  | |
|  |  | | | |  |
| 2. | How will biological material be decontaminated or inactivated? | | | |  |
|  | | | | | |
|  | Autoclave | | | |
|  | | | | |
|  | Chemical | | | |
|  | | | | |
|  | Composting | | | |
|  | | | | |
|  | Desiccation | | | |
|  | | | | |
|  | Chopping / Mincing | | | |
|  | | | | |
|  | Steam Sterilization Technology - STI | | | |
|  | | | | |
|  | | | | |
|  | Incineration | | | |
|  | | | | |
|  | Other – Please Explain |  | | |

**Section 7: Transgenic animals**

**A. This section is to be completed for any transgenic vertebrate or non-vertebrate animal.**

**Exception:** Projects involving the purchase, transfer and use of transgenic rodents in BSL-1 experiments are not required to fill out this form. Breeding of BSL-1 rodent colonies within the same genetic lineage is also exempt if:

* Both parental rodents can be housed under BSL-1 containment; **and** neither parental transgenic rodent contains either of the following genetic modifications:
  + Incorporation of more than one-half of the genome of a eukaryotic virus from a single family of viruses; **or**
  + Incorporation of a transgene that is under the control of a gammaretroviral terminal repeat (LTR); **and**
* The transgenic rodent that results from this breeding is not expected to contain more than one-half of an exogenous viral genome from a single family of viruses.

|  |
| --- |
|  |

**This research utilizes only rodents that meet this exception.**

|  |
| --- |
|  |

**This exception does not apply to the animals involved in this research.**

**B. For transgenic animal research (not excepted as described above) complete the following section:**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 1. | Source of animal: | | | |  | | | |
|  |  | | | | | | |  |
| 2. | Animal decontamination upon termination of experiment:   |  |  |  | | --- | --- | --- | |  | | | |  | | |  | Composting | |  | | |  | Steam Sterilization Technology - STI | |  | | |  | Incineration | |  | | |  | | | | | | | | |  |
|  | | |  |  | | | | |
|  | Other- Please specify: | |  | | |
|  | |  | | | |  | | |
|  |  | | | | | |  | |
| 3. | If breeding BSL-1 rodent colonies with other genetic lines describe the genetic make-up of both lineages that will be used for breeding: | | | | | | | |
|  | | | | | |

|  |  |
| --- | --- |
| **C.** | **Briefly list all transgenic animals utilized in this research:** |

**Section 8: Select agents and toxins**

Select agents require registration with the Federal Select Agent Program (FSAP) administered by WSU ORA. Both the CDC and USDA APHIS oversee the program and approve research utilizing these agents. Additional information on Select Agents and Toxins can be found on the [Biosafety Website](https://biosafety.wsu.edu/potentially-biohazardous-materials/) or the [FSAP](https://www.selectagents.gov/index.htm) (A list of excluded agents and toxins are found [here](https://www.selectagents.gov/sat/exclusions/index.htm)). Contact the BSO prior to submitting a BAF.

**A. PLEASE CHECK BOXES BELOW INDICATING SELECT AGENTS & TOXINS USED IN YOUR LABORATORY.**

**HHS Select Agents and Toxins**

|  |  |  |  |
| --- | --- | --- | --- |
|  |  | | |
|  | Abrin (over 1000mg) | | |
|  | *Bacillus cereus* Biovar *anthracis* | | |
|  | Botulinum neurotoxins (over 1mg)  Botulinum neurotoxin producing species of *Clostridium* | | |
|  |
|  | Short, paralytic alpha conotoxins containing the following amino acid sequence X1CCX2PACGX3X4X5X6CX7 (over 100 mg)  *Coxiella burnetii*  Crimean-Congo haemorrhagic fever virus | | |
|  |
|  |
|  | Diacetoxyscirpenol (over 10,000mg)  Eastern Equine encephalitis virus | | |
|  |
|  | Ebola viruses  *Francisella tularensis* | | |
|  |
|  | Lassa fever virus  Lujo virus | | |
|  |
|  | Marburg virus | | |
|  | Mpox virus | | |
|  | Reconstructed 1918 influenza virus | | |
|  | Ricin (over 1000mg) | | |
|  | *Rickettsia prowazekii* | | |
|  | SARS-associated coronavirus (SARS-CoV) | | |
|  | SARS-CoV/SARS-CoV-2 chimeric viruses resulting from any deliberate manipulation of SARS-CoV-2 to incorporate nucleic acids coding for SARS-CoV virulence factors | | |
|  | Saxitoxin (over 500mg) | | |
|  | South American haemorrhagic fever viruses. | | |
|  |  |  |  |
|  |  |  | Chapare |
|  |  |  | Guanarito |
|  |  |  | Junin |
|  |  |  | Machupo |
|  |  |  | Sabia |
|  | Staphylococcal enterotoxins A,B,C,D,E subtypes (over 100mg)  T-2 toxin (over 10,000mg)  Tetrodotoxin (over 500mg) | | |
|  |
|  |
|  | Tick-borne encephalitis complex (flavi) viruses | | |
|  |  |  |  |
|  |  |  | Far Eastern subtype |
|  |  |  | Siberian subtype |
|  | Kyasanur Forest disease virus  Omsk hemorrhagic fever virus  Variola major virus (Smallpox virus) | | |
|  |
|  |
|  | Variola minor virus (Alastrim) | | |
|  | *Yersinia pestis* | | |

**Overlap Select Agents and Toxins**

|  |  |
| --- | --- |
|  |  |
|  | *Bacillus anthracis*  *Bacillus anthracis* Pasteur strain |
|  |
|  | *Brucella abortus* |
|  | *Brucella melitensis* |
|  | *Brucella suis* |
|  | *Burkholderia mallei* |
|  | *Burkholderia pseudomallei* |
|  | Hendra virus |
|  | Nipah Virus |
|  | Rift Valley fever virus |
|  | Venezuelan equine encephalitis virus |

**USDA Select Agents and Toxins)**

|  |  |
| --- | --- |
|  |  |
|  | African horse sickness virus |
|  | African swine fever virus |
|  | Avian influenza virus |
|  | Classical swine fever virus |
|  | Foot and mouth disease virus |
|  | Goat pox virus |
|  | Lumpy skin disease virus |
|  | *Mycoplasma capricolum* |
|  | *Mycoplasma mycoides* |
|  | Newcastle disease virus |
|  | Peste Des Petits Ruminants virus |
|  | Rinderpest virus |
|  | Sheep pox virus |
|  | Swine vesicular disease virus |

**USDA Plant Protection and Quarantine (PPQ) Select Agents and Toxins**

|  |  |
| --- | --- |
|  |  |
|  | *Coniothyrium glycines (formerly Phoma glycinicola and Pyrenochaeta glycines)*  *Peronosclerospora philippinensis (Peronosclerospora sacchari)* |
|  |
|  | *Ralstonia solanacearum*  *Rathayibacter toxicus* |
|  |
|  | *Schlerophthora rayssiae* |
|  | *Synchytrium endobioticum* |
|  | *Xanthomonas oryzae* |