

# Protocol Form CrosswalkIndiana University Institutional Biosafety Committee (IBC)

v.11.18.2022

This guide can be used as a tool for investigators, lab staff, IBC members, and IBC staff when transferring information from a previously approved IBC protocol on a Word document to the Kuali Protocols online system. Users can refer to the sections of their Word document, in the left column, to see where information should be entered in Kuali Protocols, in the right column. Use the table of contents below or “ctrl+F” (Windows) or “Cmd+F” (Mac) to search for a section of the Word IBC form. Please contact the IBC Office at IBC@iu.edu if you have any questions.

## Contents

[Section I. General Project Details 2](#_Toc113359835)

[Section II. Research Description 7](#_Toc113359836)

[Research Description 7](#_Toc113359837)

[Section III. Experiments Covered by the NIH Guidelines 7](#_Toc113359838)

[NIH Covered Experiments 7](#_Toc113359839)

[Section IV. Viral Vectors (recombinant viruses) 12](#_Toc113359840)

[Viral Vector(s) 12](#_Toc113359841)

[Section V. Biological Materials and Toxins 15](#_Toc113359842)

[Biological Material(s) 15](#_Toc113359843)

[Section VI. Potential Dual Use 17](#_Toc113359844)

[Dual Use Research of Concern (DURC) 17](#_Toc113359845)

[Section VII. Select Agents and Toxins 18](#_Toc113359846)

[Select Agents and/or Toxins 18](#_Toc113359847)

[Section VIII. Human Gene Transfer (HGT) 18](#_Toc113359848)

[Section IX. Use of Whole Animals in Research 19](#_Toc113359849)

[Animal(s) 19](#_Toc113359850)

[Section X. Recombinant or Synthetic Nucleic Acid Molecules in Plants 23](#_Toc113359851)

[Plant(s) 23](#_Toc113359852)

[Section XI. Biosafety Level/Containment Selection 25](#_Toc113359853)

[Lab Practices 25](#_Toc113359854)

[Section XII. Personal Protective Equipment (PPE) & Laboratory Practices 32](#_Toc113359855)

[Lab Practices 32](#_Toc113359856)

[Section. XIII. Decontamination and Waste Disposal Procedures 34](#_Toc113359857)

[Lab Practices 34](#_Toc113359858)

[Section. XIV. Reporting 35](#_Toc113359859)

[Section. XV. Investigator Statement & Signature 35](#_Toc113359860)

[PI Agreement 35](#_Toc113359861)

[Lab Practices in Kuali Protocols 35](#_Toc113359862)

|  |  |
| --- | --- |
| Word Document Sections | Kuali Protocols Sections |
| Section I. General Project Details |
| **Sec. I-A. Principal Investigator (PI) Information** | **General Information** |
| Principal Investigator (PI) | **General Information - Principal Investigator** – Search using “Last, First” name or by IU Username. |
| Position | n/a |
| Email | Populated by Kuali Protocols when **Principal Investigator** is entered. Stored in “**Research Personnel**” section. |
| Phone | Populated by Kuali Protocols when **Principal Investigator** is entered. Stored in “**Research Personnel**” section. |
| Campus | n/a |
| Department | **General Information - Department Name** –Populated by Kuali Protocols when Principal Investigator is entered. Do not delete the automatically populated Department Name.  |
| Campus/Office Address | n/a |
| **Sec. I-B. Additional Contact Information**Alternate/Administrative ContactOther Alternate/Administrative ContactEmergency Lab Contact | **Permissions tab*** Click “**+Add User**” to add any Alternate, Administrative, or Emergency Contact who are **not** also listed as personnel working in your lab. For example, if you would like for your Clinical Trial Coordinator to be included on correspondence related to your IBC protocol, add them in the Permissions tab. An IU email address is required in order to access Kuali Protocols.
	+ **Name Column:** Search using “Last, First” name or by IU Username.
	+ **Roles & Permissions:** Read-Only access allows the user to log in and view the IBC Protocol. Full Access allows the user to make changes to the protocol by submitting amendments and renewals, and to respond to requested revisions.
	+ Click “**Add**” to save the new user and their associated permissions.

**Note:*** You may change a user’s Permission Type at any time by logging in to Kuali Protocols, navigating to the Permissions tab on your protocol, and clicking the “Permission Type” next to their name.

You may remove a user from your protocol Permissions at any time by logging in to Kuali Protocols, navigating to the Permissions tab on your protocol, and clicking the “X” by the user’s name. * Kuali Protocols does not distinguish between Alternate, Administrative, or Emergency contacts.
 |
| **Sec. I-C-1. Protocol Information** | **General Information, General Questionnaire** |
| This submission is a: New Research Protocol5 Year ResubmissionNew Teaching Protocol | **General Questionnaire - Select Protocol Type:** Researchn/aTeachingCore Facility |
| Submission #, Amendment, Annual Continuing Review | Generated automatically by Kuali Protocols. |
| Project Title | **General Information - Protocol Title** |
| **Sec. I-C-2. Submissions Record** |  |
| **Sec. I-C-2.c. Submissions Record Table** |  |
| Submission # | Generated automatically by Kuali Protocols. |
| Date Submitted | Generated automatically by Kuali Protocols. |
| Submission Type (Major Amendment/Minor Amendment/Continuing Review/Continuing Review and Major Amendment, Continuing Review and Minor Amendment) | On previously approved protocols in the Kuali Protocols system, users will see the following options in the right-hand side navigation pane:* **Amend** – Allows the user to make changes and updates to the IBC Protocol
* **Renew** – Allows the user to submit an annual renewal of the IBC Protocol
* **Renew & Amend** – Allows the user to make changes and updates as well as submit an annual renewal of the IBC Protocol
 |
| Submission Summary | **Amendment**When taking the **Amend** or **Renew & Amend** actions, users will briefly summarize the proposed change(s) to their IBC Protocol in the **Amendment** section.  |
| Date Approved | Generated automatically by Kuali Protocols. |
| **Sec. I-D. Other Compliance Committee Approvals** | **Other Approvals** |
| Animal Research (IACUC)Human Subjects Research (IRB)Veterans Affairs (VA) Research | * Click “**+Add Line**” to add all “Other Compliance Approval” information related to your IBC Protocol.
	+ **Review Type**: Animal Research (IACUC), Human Subjects Research (IRB), Veterans Affairs Research (VA)
	+ **Protocol Status**: Pending, Approved
	+ **Protocol #**: Enter number of related protocol. This is a required field. If your pending protocol has not yet been submitted for review, “TBD”.
	+ **Protocol Title**: Enter title of related protocol.
	+ **PI of record if different than IBC PI**: Search using “Last, First” name or by IU Username.
	+ Click “**Done**” to save each entry.
* All entries should be entered individually.
 |
| **Sec. I-E. Funding** | **Funding** |
| Internal Funding | **Internal Funding** checkbox |
| External Funding: Agency, Grant Number | **External Funding Agency**\* |
| VA Funding: Grant Number | **VA Funding**\* |
|  | \*Selecting “**External Funding Agency**” or “**VA Funding**” will trigger the “Instructions to add or update additional grant numbers” list.* Click “**+Add Line**” to add all external or VA funding information related to your IBC Protocol.
	+ **Grant Number**
	+ **Agency**
	+ Click “**Done**” to save each entry.
* All entries should be entered individually.
 |
| **Sec. I-F. Investigators** | **Research Personnel** |
|  | **Personnel List**All biological research personnel should be entered in this section. Individuals who need access to the IBC Protocol, but are not performing biological research, should be added to the **Permissions** tab. **Note:** * An IU email address is required to access IBC Protocols in Kuali Protocols. If you have non-IU personnel, the protocol should be saved as a PDF and made available to lab members without Kuali Protocols access.
 |
| For IU PersonnelLast Name, First Name <E-mail Address>TitleJob DescriptionTraining Checkboxes: NIH Guidelines, Bloodborne Pathogens, Biosafety, N95 Fit Test, Dual Use, Other | * Click “**+Add Line**” to add each individual to your IBC Protocol.
	+ **Person:** Search using “Last, First” name or by IU Username.
		- If you cannot find someone, refer to the IU Directory to ensure that their name or username is entered correctly.
	+ **Email Address:** Populated by Kuali Protocols when **Person** is entered.
	+ **Title:** Enter title related to this IBC Protocol (e.g., “Lab Manager,” or “Research Technician”)
	+ **Job Description:** Enter a brief description of the work that the individual will perform on this IBC Protocol (e.g., aliquoting viral stocks, animal husbandry)
	+ **Researcher Role:**
		- **Principal Investigator:** Faculty member who is responsible for the oversight of the lab. This role is automatically assigned by Kuali Protocols.
		- **Co-Investigator:** A faculty member who collaborates closely with the PI regarding the leadership of lab.
		- **Personnel:** Lab member (i.e., student, staff, or faculty) who performs experiments or assists with other work covered by the protocol.
	+ **Permissions:**
		- Full Access allows the user to make changes to the protocol by submitting amendments and renewals, and to respond to requested revisions.
		- Read-Only access allows the user to log in and view the IBC Protocol.
	+ **Training:** For each individual listed, check the training that is required for your IBC Protocol. IUEHS Biosafety Training is required for all personnel on all protocols and is automatically applied to each individual. You will be able to see training completions in real-time.
	+ Click “**Done**” to save each entry.
 |
| For Non-IU Personnel | “Are there any affiliated personnel you are unable to add because they were not found in the drop-down list?” * Click “**+Add Line**” to add each non-IU individual to your IBC Protocol.
	+ **List first and last name**
	+ **Email**
	+ **Institution**
	+ **Role**
	+ Click “**Done**” to save each entry.
 |
| For IU Health Services and/or Groups (for Clinical Trials) | “Will any IU Health Services and/or Groups (e.g., CCRC, CTL, BMT Nurses, IDS, Blood Bank, or CTSL) handle or administer investigational products covered by this IBC protocol?”* Click “**+Add Line**” to add each IU Health Service or Group to your IBC Protocol.
	+ **Service or Group**
	+ **Services Provided**
	+ Click “**Done**” to save each entry.
* Check the attestation box (**I ensure that all staff from the above listed IU Health Services and Groups…**)
 |
| Investigator Acknowledgement | By entering personnel in the **Research Personnel** section, the PI assumes responsibility for ensuring that all personnel have completed the necessary training requirements before beginning experiments.  |
| **Sec. I-G. Research Locations** | **Location(s)** |
| BuildingRoom #Research Activities PerformedBiosafety Level | “Where will this research be conducted?”* Click “**+Add Line**” to add each research location where you will conduct work related to this IBC protocol.
	+ **Building**
	+ **Room #**
	+ **Research Activities Performed**
	+ **Biosafety Level**
	+ Click “**Done**” to save each entry.

**Note:*** If you are performing the same task in multiple rooms in the same building, you may list them all in one entry.
* If you are performing multiple tasks at the same biosafety level in one room, you may list them all in one entry. If the biological safety levels vary, please use separate entries (e.g., an entry for BL-2 tasks and an entry for BL-1 tasks).
 |
| Field Work | “Will any of your research be performed in the field (e.g., sample collection; work with wild animals or animal material)?”* If **Yes** is selected, click “**+Add Line**” to add each field site location where you will conduct work related to this IBC protocol.
	+ **Where will this research be conducted?**
		- If **United States** is selected: select **State**
	+ **Research Activities Performed**
	+ **Biosafety Level**
	+ Click “**Done**” to save each entry.
 |
| Section II. Research Description | Research Description |
| **Sec. II-A. Overall rationale for research in layman’s terms** | Users can copy and paste text into the “Overall rationale for research in layman’s terms” text box.  |
| **Sec. II-B. Description of planned experiments** | Users can copy and paste text into the “Description of planned experiments”**Note:*** This section does not support the use of tables or images. If you would like to include an image (e.g., vector map, plasmid map), include it in the attachments section.
 |
| Section III. Experiments Covered by the NIH Guidelines | NIH Covered Experiments |
|  | This section is triggered by answering yes to one of the following questions in the **General Questionnaire**:* “Will Recombinant or Synthetic Nucleic Acid Molecules be used in this research?”
* “Will Viral Vectors be used in this research?”
* “Will this research involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants?”
* “Will these animals be genetically modified (e.g., tg/ko/ki), will you be making genetic modifications to the animals, or will you introduce recombinant material into the animals?”
 |
| III-A. Experiments that Require NIH Director Approval and Institutional Biosafety Committee (IBC) Approval Before Initiation | No general III-A checkbox |
| III-A-1: Major Actions under the NIH Guidelines |  |
| III-A-1-a: The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally (See Section V-B, Footnotes and Reverences of Sections I-IV of the NIH Guidelines), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will require the NIH Director approval | III-A-1-a: The deliberate transfer of a drug resistance trait to micro-organisms that are not known to acquire the trait naturally (See Section V-B, Footnotes and Reverences of Sections I-IV of the NIH Guidelines), if such acquisition could compromise the ability to control disease agents in humans, veterinary medicine, or agriculture, will require the NIH Director approval |
| **III-B. Experiments that require NIH Office of Science Policy (OSP) and IBC Approval Before Initiation** | No general III-B checkbox |
| III-B-1: Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight | III-B-1 Experiments Involving the Cloning of Toxin Molecules with LD50 of Less than 100 Nanograms per Kilogram Body Weight |
| II-B-2: Experiments that have been Approved (Under Section III-A-1-a) as Major Actions under Sec. III-A-1-a of the NIH Guidelines | III-B-2 Experiments that have been Approved (Under Section III-A-1-a) as Major Actions under Sec. III-A-1-a of the NIH Guidelines |
| **III-C. Experiments Involving Human Gene Transfer that Require IBC Approval Prior to Initiation** | No general III-C checkbox |
| 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-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. Experiments that Require IBC Approval Before Initiation** | No general III-D checkbox |
| III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines) | III-D-1: Experiments using Risk Group 2 (RG2), Risk Group 3 (RG3), Risk Group 4 (RG4), or Restricted Agents as Host-Vector Systems (See Section II-A, Risk Assessment, of the NIH Guidelines)* If III-D-1 is checked, the **III-D-1 Category** will open below the full III-D section. Please review the category and select the box if relevant to your research. The category is:
 |
|  | * Experiments using RG2 or RG3 recombinant or synthetic nucleic acid molecule modified microbes in any animal (transgenic or otherwise).
 |
| III-D-2: Experiments in which DNA from RG2, RG3, RG4, or Restricted Agents is Cloned into Nonpathogenic Prokaryotic or Lower Eukaryotic Host-Vector Systems | III-D-2: Experiments in which DNA from RG2, RG3, RG4, 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-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: Experiments Involving Whole Animals: | III-D-4: Experiments With Whole Animals Involving Recombinant or Synthetic Nucleic Acid MoleculesIf III-D-4 is checked, a list of **III-D-4 Categories** will open below the full III-D section. Please review each category and select the box(es) relevant to your research. The categories include: |
| * Involving whole animals in which the animal’s genome has been altered by stable introduction of recombinant or synthetic nucleic acid molecules, or
* DNA derived therefrom, into the germ-line (transgenic animals other than rodents), or
* Experiments involving viable recombinant or synthetic nucleic acid molecule-modified microorganisms tested on whole animals, including rodents Appendix M: Experiments involving large animals
 | * Purchase or transfer of Transgenic Animals other than BL-1 Rodents
* Breeding of Transgenic Animals other than BL-1 Rodents
* Creation of Transgenic Animals other than BL-1 Rodents
* Experiments with Transgenic Animals
* Experiments with recombinant or synthetic nucleic acid molecules in an animal (transgenic or otherwise)
 |
| III-D-5: Experiments involving whole plants at BL-2 or higher practices | III-D-5: Experiments involving whole plants at BL-2 or higher practices |
| III-D-6: Experiments involving more than 10 liters of culture (in one container) | III-D-6: Experiments involving more than 10 liters of culture (in one container) |
| III-D-7: Experiments involving influenza viruses generated by recombinant or synthetic methods | III-D-7: Experiments involving influenza viruses generated by recombinant or synthetic methods |
| **III-E. Experiments that Require IBC Notice Simultaneous with Initiation** ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required. | III-E. ALL experiments not included in Sections III-A, III-B, III-D, III-F, and their subsections are non-exempt from the NIH Guidelines and fall under Section III-E. All Such experiments may be conducted at BL-1. The IBC reviews and approves all such proposals, but IBC review and approval prior to initiation of the experiments is not required. |
| III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus.  | III-E-1: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than 2/3 of the genome of any Eukaryotic virus. |
| III-E-2: Experiments involving whole plants at BL-1 or BL-2. | III-E-2: Experiments involving whole plants at BL-1 or BL-2. |
| III-E-3: Experiments involving transgenic rodents: involving the generation of 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. Only experiments that require BL1 containment are covered under this section; experiments that require BL2 or higher containment fall under section III-D-4 above.  | III-E-3: Experiments involving transgenic rodents: involving the generation of 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. Only experiments that require BL1 containment are covered under this section; experiments that require BL2 or higher containment fall under section III-D-4 above. |
| **III-F**. **Experiments that are exempt from the *NIH Guidelines*** | No general III-F checkbox. |
| III-F-1: Uses synthetic nucleic acids that:1. Can neither replicate nor generate nucleic acids that can replicate in any living cell, 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 of body weight.
 | III-F-1: Uses synthetic nucleic acids that: A) Can neither replicate nor generate nucleic acids that can replicate in any living cell, and B) Are not designed to integrate into DNA, and C) Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram of body weight. |
| III-F-2: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated to render them capable of penetrating cellular membranes  | III-F-2: Those that are not in organisms, cells, or viruses and that have not been modified or manipulated 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-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: Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or closely related strain of the same species), or when transferred to another host by well-established physiological means | III-F-4: Those that consist entirely of nucleic acids from a prokaryotic host, including its indigenous plasmids or viruses when propagated only in that host (or closely related strain of the same species), or when transferred to another host by well-established physiological means |
| III-F-5: Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species) | III-F-5: Those that consist entirely of nucleic acids from a eukaryotic host including its chloroplasts, mitochondria, or plasmids (but excluding viruses) when propagated only in that host (or a closely related strain of the same species) |
| III-F-6: Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent | III-F-6: Those that consist entirely of DNA segments from different species that exchange DNA by known physiological processes, though one or more of the segments may be a synthetic equivalent |
| 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-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: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below) | III-F-8: Those that do not present a significant risk to health or the environment, as determined by the NIH Director, with the advice of the RAC, and following appropriate notice and opportunity for public. (You MUST check one of the Appendix C exemptions below)If III-F-8 is checked, a list of **Appendix C – Exemptions Under Section III-F-8** will open below the full III-F section. Please review each category to select the boxes relevant to your research. Those categories include: |
| * Appendix C-I: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture

**Host-Vector System Exemptions:*** Appendix C-II: Escherichia coli K-12 Host-Vector Systems\*
* Appendix C-III: Saccharomyces Host-Vector Systems\*
* Appendix C-IV: Kluyveromyces Host-Vector Systems\*
* Appendix C-V: Bacillus subtilis OR Bacillus licheniformis Host-Vector Systems\*
* Appendix C-VI: Extrachromosomal Elements of Gram Positive Organisms\*

\*Exemptions do not apply to experiments described in Section III-B which require NIH OSP and IBC approval before initiation or experiments involving DNA from Risk Groups 3, 4, or restricted organisms.**Transgenic Rodent Exemptions:*** Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1
* Appendix C-VIII: Generation of BL1 transgenic rodents via breeding
 | * Appendix C-I: Experiments involving the formation of recombinant or synthetic nucleic acid molecules containing no more than ½ of the genome of any Eukaryotic viral genome that are propagated and maintained in cells in tissue culture
* Appendix C-II: Escherichia coli K-12 Host-Vector Systems\*
* Appendix C-III: Saccharomyces Host-Vector Systems\*
* Appendix C-IV: Kluyveromyces Host-Vector Systems\*
* Appendix C-V: Bacillus subtilis OR Bacillus licheniformis Host-Vector Systems\*
* Appendix C-VI: Extrachromosomal Elements of Gram Positive Organisms\*
* Appendix C-VII: The purchase or transfer of transgenic rodents at BL-1
* Appendix C-VIII: Generation of BL1 transgenic rodents via breeding
 |
| **Sec. III-B. Recombinant DNA (rDNA) and Synthetic Nucleic Acid Molecule Information** | **Recombinant DNA** This section is triggered by answering yes to one of the following questions in the **General Questionnaire**:* “Will Recombinant or Synthetic Nucleic Acid Molecules be used in this research?”
* “Will Viral Vectors be used in this research?”
* “Will this research involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants?”
* “Will these animals be genetically modified (e.g., tg/ko/ki), will you be making genetic modifications to the animals, or will you introduce recombinant material into the animals?”
 |
| * Source Species of inserted DNA
* Plasmid and/or Vector(s) (recombinant viruses) to be used
* Host(s) to be used (please include all intermediate hosts)
* What is the gene or transcription product
* Is it known to be harmful (e.g. Oncogenic, Toxic, Mutated Gene) to researcher or environment?
 | * Click “**+Add Line**” to add each type of recombinant DNA or synthetic nucleic acid you plan to use.
	+ **Source Species of inserted DNA**
	+ **Plasmid and/or Vector (recombinant virus) to be used**
	+ **Host to be used**
	+ **What is the gene or transcription product?**
	+ **Is it known to be harmful (e.g., oncogenic, toxic, mutated gene) to the researcher or environment?**
		- If **Yes** is selected: **Please describe**
	+ Click “**Done**” to save each entry.
 |
| Section IV. Viral Vectors (recombinant viruses) | Viral Vector(s) |
|  | This section is triggered by answer yes to the following questions in the **General Questionnaire:** * “Will Viral Vectors be used in this research?” If yes, then:
* “Please select the type of Viral Vectors(s) you plan to use.”
* “Adeno Associated Viral Vectors (AAVs)
* “Lentiviral Vectors”
* “Non-AAV, Non-Lentiviral Vectors”
 |
| **Sec. IV-A. Adeno Associated Viral Vectors** | **Adeno Associated Viral Vectors** |
| * List all AAV Vectors
* Promoter and encoded gene
* Is encoded gene tumorigenic or a toxin?
* Made with helper virus or helper plasmid?
* Produced in human or insect cells?
* If produced in human cells has it been purified?
* Source of virus?
* Information previously entered in Sec. XI: Biosafety Level/Containment Selection
 | * Click “**+Add Line**” to add each Adeno Associated Viral Vector you plan to use.
	+ **AAV vector**
	+ **Promoter and encoded gene**
	+ **Is encoded gene tumorigenic or a toxin?**
	+ **Made with helper virus, helper plasmid, or helper cell lines?**
	+ **Produced in human or insect cells:**
		- If **human** is selected: **Has it been purified?**
	+ **Source of viral particles:**
		- **Produced in lab**
		- If **Made by collaborator lab** is selected: **Collaborator Name and Institution**
		- If **Commercially bought** is selected: **Name of Company**
	+ **Will use in whole animals?** If **checked**, then select **Animal Containment:**
		- Injection of AAV, containing toxic or oncogenic inserts, into animals. All work will remain at BSL-2/ABSL-2.
		- Injection of AAV, not containing toxic or oncogenic inserts, into animals. Animal housing may drop to ABSL-1 after 72 hours. Necropsy and postmortem tissue handling of animals receiving direct injection of AAV vectors (as described above) can be performed under BSL1 conditions 72 hours after final injection.
		- Injection of AAV, not containing toxic or oncogenic inserts, into animals. The IBC will consider lowering the biosafety level for animal housing to ABSL-1 on a case-by-case basis based on the following criteria: a.) The nature of the transgene expression: Transgenes expressing oncogenic protein or toxin require BSL-2/ABSL-2. b.) Whether or not the vector is generated using adenovirus or any other helper virus of human origin c.) Identification of the cell line in which the vector is propagated. d.) A description of purification procedures (e.g., column chromatography, etc.) and/or documentation from the source of the vector (investigator or vector core facility) that describes purification procedures. e.) Animal bedding must be decontaminated prior to disposal for the first 72 hours after final injection and first cage change. Necropsy and postmortem tissue handling of animals receiving direct injection of AAV as described above can be performed under BSL-1 conditions 72 hours after final injection.
	+ Click “**Done**” to save each entry.
 |
| **Sec. IV-B. Lentiviral Vectors** | **Lentiviral Vectors** |
| * List all Lentiviral vectors
* 2nd’, 3rd, or 4th generation?
* If 2nd generation, please provide the plasmid map information as an addendum to this protocol. Also, list the packaging plasmids used.
* If 2nd generation, please describe tests to confirm replication incompetence.
* Is encoded gene tumorigenic or a toxin?
* Is TAT encoded on any system component? If yes, please describe.
* Source of viral particle
* Will you use >10 liters of culture in one container?
* Information previously entered in Sec. XI: Biosafety Level/Containment Selection
 | * Click “**+Add Line**” to add each Lentiviral Vector you plan to use.
	+ **Lentiviral vector**
	+ **Generation**
		- If 2nd generation is selected:
			* List the packaging plasmids used, and attach plasmid map information in the Attachments section
			* Describe tests to confirm replication incompetence
	+ **Is encoded gene tumorigenic or a toxin?**
	+ **Is TAT encoded on any system component:**
		- If yes, please describe TAT encoding.
	+ **Source of viral particles:**
		- **Produced in lab)**
		- If **Made by collaborator lab** is selected: **Collaborator Name and Institution**
		- If **Commercially bought** is selected: **Name of Company**
	+ See **Lab Practices** section for **Large Scale** containment level and best practices.
	+ **Will use in whole animals:** If **checked**, then select:
		- Lentivirus transduced mouse cells will be injected into animals. All work can remain at BSL-1/ABSL-1.
		- Injection of lentiviral vector directly into an animal. Animal housing may drop to ABSL-1 after 72 hours.
		- Injection of lentiviral vector-transduced human cells into animals or injected lentiviral vector into animals engrafted with human cells. All work will remain at BSL-2/ABSL-2.
	+ Click “**Done**” to save each entry.
 |
| **Sec. IV-C. Non-AAV, Non-Lentiviral Vectors** | **Non-AAV, Non-Lentiviral Vectors** |
| * List all Non-AAV, Non-Lentiviral vectors
* Describe tests to confirm replication incompetence
* Are you using any helper viruses or packaging/producer cell lines?
* List any essential genes that have been deleted, added, or modified from the vector/packaging system
* Is encoded gene tumorigenic or a toxin?
* Does the viral vector have an expanded host range or increase tissue tropism compared to wild-type virus?
* Source of viral particles. If you amplify or produce your own viral particle stock, please indicate “produced in your lab.”
* Will you use >10 liters of culture in one container?
 | * Click “**+Add Line**” to add each Non-AAV, Non-Lentiviral Vector you plan to use.
	+ **List all non-AAV, non-lenti viral vectors**
	+ **Describe tests to confirm replication incompetence**
	+ **Are you using any helper viruses or packaging/producer cell lines?**
	+ **List any essential genes that have been deleted, added, or modified from the vector/packaging system.**
	+ **Encoded Gene Status:** Tumorigenic, A toxin, non-Tumorigenic/Non-Toxic
	+ **Does the viral vector have an expanded host range or increase tissue tropism compared to wild-type virus?**
		- If **Yes** is selected: **Please describe**
	+ **Source of viral particles:**
		- **Produced in lab**
		- If **Made by collaborator lab** is selected: **Collaborator Name and Institution**
		- If **Commercially bought** is selected: **Name of Company**
	+ See **Lab Practices** section for **Large Scale** containment level and best practices.
	+ Click “**Done**” to save each entry.
 |
| Section V. Biological Materials and Toxins | Biological Material(s) |
|  | This section is triggered by answering yes to the following question in the **General Questionnaire:** * “Will Biological Materials be used in this research?”
 |
| **Sec. V-A. Biological Materials Table*** Biological Material
* Source
* Not currently collected on Word Document
* Infectious Host Range (RG2 and higher)
* Check if Zoonotic
* Risk Group (RG)
* Containment Level/Biosafety Level (BL)
* Potential Routes of Transmission
	+ Injection
	+ Ingestion
	+ Inhalation
	+ Direct contact with open wound or mucous membranes
 | * Click “**+Add Line**” to add each biological material you plan to use.
* **Biological Material** – This field is a type-ahead list. Your selection in this field determines which other fields require your input. For example, if you select a Biological Toxin in this field, you will be required to answer questions related to Biological Toxins.
* **Where will you obtain this material?**
	+ **My lab**
	+ **Collaborator lab**
		- If selected: **Collaborator Name and Institution**
	+ **Vendo**r
		- If selected: **Biological Material Vendor**
	+ **Clinical sample(s)**
	+ **Field collection**
* If **this experiment will involve >10 L of culture (in one container)** is selected, **attach** specialized spill procedures in the Attachments section
* **Infectious Host Range** – This field only becomes visible if BSL-2 or higher is selected for “**Containment/Biosafety Level.**”
* **Is this material zoonotic?**
* **Risk Group**
* **Containment/Biosafety Level**
* **Potential Routes of Transmission** – This field only becomes visible if BSL-2 or higher is selected for **Containment/Biosafety Level.**
	+ Injection
	+ Ingestion
	+ Inhalation
	+ Direct contact with open wound or mucous membranes
* **Sharps are restricted with this material**
* Click “**Done**” to save each entry.
 |
| **Sec. V-A. Question 1: Should exposure occur, list all potential risk associated with exposure.** | **Potential Risks Associated with Exposure** – This field only becomes visible if BSL-2 or higher is selected for **Containment/Biosafety Level.** |
| **Sec. V-A. Question 2: Are you using Biological Toxins?**If yes, then:* LD50 of biological toxin
* Symptoms of exposure to toxin
* Toxin inactivation procedures
* Total amount of any non-Select Agent toxin
* Engineering device used for reconstituting toxin
* Engineering device used for administering toxin to animals
 | **Biological Toxin**These fields only become visible when a biological toxin is entered.* LD50 of biological toxin
* Symptoms of exposure to toxin
* Toxin inactivation procedures
* Total amount of any non-Select Agent toxin
* Engineering device used for reconstituting toxin
* Will this toxin be used in animals?
	+ If Y**es:** select **Engineering device used for administering toxin to animals**
 |
| **Sec. V-A. Question 3: Are you using Transactive or Infectious Proteins (e.g. Prion Proteins)?**If yes, then:* Protein
* Agent
* Cellular Target
* Hazards of Exposure
 | **Transactive Infectious Protein**These fields only become visible when a Transactive or Infectious Protein is entered.* Protein
* Agent
* Cellular Target
* Hazards of Exposure
 |
| **Sec. V-B. Risk Group 2 and Higher Material** | **Potential Risks** These fields only become visible when a non-human, non-viral vector, BSL-2 or higher biological material is entered in the Biological Material(s) table. |
| **Sec. V-B. Question 1: Do you plan to use Risk Group 2 material, other than human materials or viral vectors?**If yes, then:* Biological Material
* Infectious dose (if known), conditions ID50 determined, and citation
* Highest Volume and Concentration used at Any Time
* Route of transmission for ID50
* High-risk aerosol-generating procedures
	+ Sonication
	+ Centrifugation
	+ Large culture growth (>1L)
	+ Other (e.g., vortexing, homogenizing)
 | If you are using a non-human, non-viral vector, BSL-2 or higher material, then:* Not required to be entered a second time
* **Infectious dose (if known), conditions ID50 determined, and citation**
* **Highest Volume and Concentration used at Any Time**
* **Is this a high risk aerosol-generating procedure?** If **yes**, then:
	+ Sonication
	+ Centrifugation
	+ Large Culture Growth (>1L)
	+ Other (e.g., vortexing, homogenizing)
 |
| **Sec. V-B. Question 2: Will you deviate from standard containment and decontamination practices listed in section XI after each procedure?**If yes, please describe.  | **Will you deviate from standard containment and/or decontamination practices with this material?*** If **yes**, then **Describe the proposed modified containment and/or decontamination practices you intend to use.**
 |
| Section VI. Potential Dual Use | Dual Use Research of Concern (DURC) |
|  | This section only becomes available if certain nonattenuated agents or toxins are listed in the Biological Material(s) section.  |
| **Sec. VI. Question 1: Please check any of the nonattenuated agents or toxins that will be used in this protocol:*** Avian influenza virus (highly pathogenic)
* Bacillus anthracis
* Botulinum neurotoxin
* Burkholderia mallei
* Burkholderia pseudomallei
* Ebola virus
* Foot-and-mouth disease virus
* Francisella tularensis
* Marburg virus
* Reconstructed 1918 influenza virus
* Rinderpest virus
* Toxin-producing strains of Clostridium botulinum
* Variola major virus
* Variola minor virus
* Yersinia pestis
 | * Click “**+Add Line**” to add each DURC agent you plan to use.
* **Agent:** Relevant agents listed in the **Biological Material(s)** section will appear in the **Agent** dropdown list
 |
| Will your research enhance the harmful consequences of the agent or toxin: | * **Will your research enhance the harmful consequences of the agent or toxin?**
 |
| Will your research disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification: | * **Will your research with this agent disrupt immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification?**
 |
| Will your research add resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies: | * **Will your research with this agent add resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitate their ability to evade detection methodologies?**
 |
| Will your research increase the stability, transmissibility, or the ability to disseminate the agent or toxin: | * **Will your research with this agent increase the stability, transmissibility, or the ability to disseminate the agent or toxin?**
 |
| Will your research alter the host range or tropism of the agent or toxin: | * **Will your research with this agent alter the host range or tropism of the agent or toxin?**
 |
| Will your research enhance susceptibility of a host population to the agent or toxin: | * **Will your research with this agent enhance susceptibility of a host population to the agent or toxin?**
 |
| Will your research generate or reconstitute an eradicated or extinct agent or toxin listed above: | * **Will your research with this agent generate or reconstitute an eradicated or extinct agent or toxin?**
 |
| If you answered yes to any of the questions above, have you completed the required DURC training?: | Answering “**Yes**” to any of the above questions will trigger the DURC training requirement. Please select “**Dual Use Research of Concern**” training from the training options in the **Research** **Personnel** section for all personnel working with the DURC agent. |
|  | * Click “**Done**” to save each entry.
 |
| Section VII. Select Agents and Toxins | Select Agents and/or Toxins |
|  | This section only becomes available if agents from the CDC USDA Federal Select Agent Program are listed in the Biological Material(s) section. |
| **Sec. VII.** * **Question 1: For any select agents and/or toxins being used in this protocol, please list and contact the Biosafety Office**
* **Question 2: Please list the largest amount of exempt select agent toxin investigator will have in their possession at any given time**
* **Will this protocol be identifying any select agents and/or toxins in humans, soil, or the environment?**
 | * Click “**+Add Line**” to add each select agent or toxin you plan to use.
* **Agent:** Relevant agents listed in the **Biological Material(s)** section will appear in the **Agent** dropdown list
* **What is the largest amount of exempt select agent or toxin you will have in your possession at any given time?**
* **Will this protocol be identifying any select agents and/or toxins in humans, soil, or the environment?**
	+ If yes, then **Provide a description of the sample source(s).**
* Click “**Done**” to save each entry.
 |
| Section VIII. Human Gene Transfer (HGT) |  |
|  | There is no standalone HGT section in Kuali Protocols.**General Questionnaire**:* “Will this research involve the deliberate transfer of recombinant or synthetic nucleic acid molecules, or DNA or RNA derived from recombinant or synthetic nucleic acid molecules, into human research participants?”

**Personnel List:*** “Will any IU Health Services and/or Groups (e.g., CCRC, CTL, BMT Nurses, IDS, Blood Bank, or CTSL) handle or administer investigational products covered by this IBC protocol?

**Attachments Section:*** Informed Consent
* Investigator Brochure
* Sponsor Protocol
 |
| Section IX. Use of Whole Animals in Research | Animal(s) |
|  | This section is triggered by answering yes to the following question in the **General Questionnaire:** * “Will animals be used in this research?”
 |
| **Sec. IX. Question 1: Please list all animal species (vertebrates, invertebrates, genetically modified, or non-genetically modified).** | * Click “**+Add Line**” to add each animal species and related experiments you plan to conduct.
* **Species** (dropdown menu)
	+ If the species selected requires IACUC coverage you will be prompted to select a protocol number in the **List the corresponding IACUC protocol for this experiment** field.
	+ Note, if your corresponding IACUC protocol is pending and you did not enter a protocol number, this field will appear blank. In the Other Approvals section, either enter the pending protocol number or “TBD” if the protocol has not been submitted.
* **Species Type:** Wild-type; Genetically Modified (If you plan to use both wild-type and GM strains of the same species, for the same experiment, you may check both boxes in this section.)
 |
| **Sec. IX. Question 2: Are any biological materials used in research with animals? Please make sure to include all materials listed in Sec. V if being used with animals.** If yes, then:* This protocol involves the use of wild-type or attenuated microbial pathogens in animals.
* This protocol involves the use of xenografts.
* This protocol involves the use of transfected or transduced cells inoculated into animals.
* Other; please describe:
 | * **Will this protocol involve biological agents or recombinant DNA or synthetic nucleic acid molecules used with this species?** If **yes**, then:
* Click “**+Add Line**” to add agent you plan to use with the selected species.
* **Agent Type:**
	+ **Biological Material:** Thislist pulls from the agents you listed in the Biological Material(s) section of the form. Select **Biological Material** if you are using any of the following: non-modified biological materials, viral vectors, or modified human or mouse cell lines with whole animals.
		- **Is this agent genetically modified?**
	+ **rDNA or Synthetic Nucleic Acid:** This list pulls from the agents you listed in the Recombinant DNA section of the form. Select rDNA or Synthetic Nucleic Acid for all other genetically modified material used with whole animals.
* **How will this agent be used with animals?**
	+ The use of wild-type or attenuated microbial pathogens in animals
	+ The use of xenografts
	+ The use of xenografts with genetically modified cells
	+ The use of transfected or transduced cells inoculated into animals
	+ The direct administration of nucleic acids, viral vectors, or plasmid vectors into animals
	+ The use of allografts
		- If **Other**, then **Describe other agent use.**
 |
| **Sec. IX. Question 3: What is the route of administration (e.g., IV) and how will materials be administered (e.g., microinjection pump)?** | **What is the route of administration (e.g., IV) and how will materials be administered (e.g., microinjection pump)?** |
| **Sec. IX. Question 4: What containment is utilized while administering materials?*** Biosafety Cabinet
* N95 Respirator
* Other; please complete question 5.
 | * + What containment is utilized while administering materials?
		- Biosafety Cabinet
		- Chemical Fume Hood
		- N95 Respirator
		- Other; If **Other**, please answer the questions below
		- Not Applicable
 |
| **Sec. IX. Question 5: Please include the following (if other was marked in question 4)*** Material Volume
* Concentration
* Pressure of Injection (if known)
* Total number of injections at one time
 | * + - * If “**Other**” was selected above:
			* Material Volume
			* Concentration
			* Pressure of Injection (if known)
			* Total number of injections at one time
* Click “**Done**” to save each entry.
 |
| **Sec. IX. Question 6: Are any recombinant or synthetic nucleic acid molecules used in research with animals?** If yes, then:* This protocol involves the direct administration of nucleic acids or viral or plasmid vectors to animals.
* Other; please describe:
 | This question is answered above under **Agent Type** and **How will this agent be used with animals?** |
| **Sec. IX-A. Genetically Modified Mammalian and/or Avian Animals** | This section is triggered based on your answers to the following questions:* **Species:** If a mammal or bird is selected; and
* **Species Type:** if “Genetically Modified (tg/ko/ki)” is selected
 |
| **Sec. IX-A. Question 1: Will genetically-modified rodents be used in this research project?** If yes, then: * Complete the table in question 4 only if new germline strains are created by methods other than breeding or if lines are biohazardous.
 | **Genetically Modified Rodents** – This section is triggered based on your answer to the following questions: * **Species:** If a rodent is selected; and
* **Species Type:** If “Genetically Modified (tg/ko/ki)” is selected
* **Will genetically modified rodents be produced in your lab by means other than breeding?** If **yes**, then:
	+ **Strain Name**
	+ **The following method(s) will be used to make the transgenic animals:**
		- Microinjection of gene into fertilized oocytes
		- Insertion of gene(s) into embryonic stem cells microinjected into oocytes
		- Use of vectors to transfect oocytes
		- Other method(s):
			* If **Other method(s)**, then add **Describe Other Method(s).**
 |
| **Sec. IX-A. Question 2: Will non-rodent, genetically-modified, mammalian/avian animals be used in this research project?** If yes, then: * Complete the table in question 4 only if new germline strains are created or if lines are biohazardous.
 | **Genetically Modified, Non-Rodent, Mammalian or Avian Animal** – This section is triggered based on your answer to the following questions: * **Species:** If a non-rodent mammal or bird is selected; and
* **Species Type:** If “Genetically Modified (tg/ko/ki)” is selected
 |
| **Sec. IX-A. Question 3: Are genetically-modified rodents produced with the assistance of the IU Genome Editing Center?** If yes, then:* Yes, the following method(s) will be used to make the transgenic animals:
	+ Microinjection of gene into fertilized oocytes
	+ Insertion of gene(s) into embryonic stem cells microinjected into oocytes
	+ Use of vectors to transfect oocytes
	+ Other method(s), please include description
 | **Genetically Modified Rodents** – This section is triggered based on your answer to the following questions: * **Species:** If a rodent is selected; and
* **Species Type:** If “Genetically Modified (tg/ko/ki)” is selected
* **Will genetically modified rodents be produced with the assistance of the IU Genome Editing Center (IUGEC)?** If **yes**, then:
	+ Strain Name
	+ The following method(s) will be used to make the transgenic animals:
		- Microinjection of gene into fertilized oocytes
		- Insertion of gene(s) into embryonic stem cells microinjected into oocytes
		- Use of vectors to transfect oocytes
		- Other method(s):
			* If **Other method(s)**, then **Describe Other Method(s).**
 |
| **Sec. IX-A. Question 4: Genetically-modified, Mammalian/Avian Table: Please complete if you are using any non-rodent genetically-modified mammalian/avian animal or if you are creating genetically modified rodents in your lab by means other than breeding. Please include any mice being created via the IU Genome Editing Center. Add any animals that are purchased/bred that are expressing a hazardous biological agent (i.e. whole toxin or virus).** | **Genetically Modified, Non-Rodent, Mammalian or Avian Animal** – This section is triggered based on your answer to the following questions: * **Species:** If a non-rodent mammal or bird is selected; and
* **Species Type:** If “Genetically Modified (tg/ko/ki)” is selected
 |
| * Animal Species
* How your lab refers to this strain
* Original Source of Animal
* Knockout (KO), Knock-In (KI), Transgene (T)
* Gene Modified
* Potential Hazard(s)
* Biological Source of Gene
 | * How does your lab refer to this strain?
* Original source of Animal
* Knockout (KO), Knock-In (KI), Transgenic (Tg)
* Gene Modified (added or removed)
* Potential Hazard(s)
* Biological Source of Gene
 |
| **Sec. IX-B. Genetically Modified, Non-Mammalian/Non-Avian Animals** |  |
| **Sec. IX-B. Question 1: Are genetically modified, non-mammalian/non-avian Animals being used?** If yes, then: | **Genetically Modified, Non-Mammalian or Non-Avian Animal** – This section is triggered based on your answer to the following questions: * **Species:** If a non-mammal or non-avian animal is selected; and
* **Species Type:** If “Genetically Modified (tg/ko/ki)” is selected
 |
| * Please describe in Sec. II
 | * **Will this protocol involve biological agents or recombinant DNA or synthetic nucleic acid molecules used with this species?** If **yes**, then:
* Click “**+Add Line**” to add agent you plan to use with the selected species.
* **Agent Type:**
	+ **Biological Material:** Thislist pulls from the agents you listed in the Biological Material(s) section of the form. Select Biological Material if you are using any of the following: non-modified biological materials, viral vectors, or modified human or mouse cell lines with whole animals.
		- **Is this agent genetically modified?**
	+ **rDNA or Synthetic Nucleic Acid:** This list pulls from the agents you listed in the Recombinant DNA section of the form. Select rDNA or Synthetic Nucleic Acid for all other genetically modified material used with whole animals.
* **How will this agent be used with animals?**
	+ The use of wild-type or attenuated microbial pathogens in animals
	+ The use of xenografts
	+ The use of xenografts with genetically modified cells
	+ The use of transfected or transduced cells inoculated into animals
	+ The direct administration of nucleic acids, viral vectors, or plasmid vectors into animals
	+ The use of allografts
	+ Other
		- If **Other**, then **Describe other agent use.**
* **What is the route of administration (e.g., IV) and how will materials be administered (e.g., microinjection pump)?**
* **What containment is utilized while administering materials?**
	+ Biosafety Cabinet
	+ Chemical Fume Hood
	+ N95 Respirator
	+ Other; If **Other**, please answer the questions below
	+ Not Applicable
		- If “**Other**” was selected above:
		- Material Volume
		- Concentration
		- Pressure of Injection (if known)
		- Total number of injections at one time
 |
| **Sec. IX-B. Question 2: Are the genetically modified, non-mammalian/non-avian animals used in this project known to be harmful (e.g. Oncogenic, Toxic) to the researcher and/or the environment?** If **yes**, then:* Please describe in Section II
 | * **Are the genetically modified, non-mammalian/non-avian animals used in this project known to be harmful (E.g.: Oncogenic/Toxic) to the research and/or environment?**
 |
| **Sec. IX-B. Question 3:** **How will the non-mammalian/non-avian animals be used?**  | This information is captured in the Research Description and in the sections described above.  |
| **Sec. IX-B. Question 4:** **For insect work, what measures are being taken to ensure that animals are not being released?**  | * **For insect work, what measures are being taken to ensure that animals are not being released?**
 |
|  | * Click “**Done**” to save each entry.
 |
| Section X. Recombinant or Synthetic Nucleic Acid Molecules in Plants | Plant(s) |
|  | This section is triggered by answering yes to one of the following questions in the **General Questionnaire**:* “Will any plants or arthropods associated with plant disease be used in this research?”
* “Will these plants or arthropods be genetically modified/transgenic, will you be making genetic modifications to the plants or arthropods, or will you introduce recombinant material into the plants or arthropods?”
 |
| **Sec. X. Question 1: Please list all plant species used in your research:** | * Click “**+Add Line**” to add each plant species and related experiments you plan to conduct.
	+ **Plant Species Name, Genus, and Common Name**
	+ **Plant Species Type:** Genetically modified; Wild-type
	+ **Will this protocol involve recombinant DNA or synthetic nucleic acid molecules used with this species?.**
* Click “**Done**” to save each entry.
 |
| **Sec. X. Question 2: Please check all types of experiments that apply:****BL1-P experiments:** * Planned experiments use recombinant or synthetic nucleic acid molecule-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area
* Planned experiments use whole plants and recombinant or synthetic nucleic acid molecule-modified non-exotic microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., Rhizobium spp. and Agrobacterium spp.)
 | **BL1-P experiments:** * Planned experiments use recombinant or synthetic nucleic acid molecule-modified plants that are not noxious weeds or that cannot interbreed with noxious weeds in the immediate geographic area
* Planned experiments use whole plants and recombinant or synthetic nucleic acid molecule-modified non-exotic microorganisms that have no recognized potential for rapid and widespread dissemination or for serious detrimental impact on managed or natural ecosystems (e.g., Rhizobium spp. and Agrobacterium spp.)
 |
| **BL2-P experiments:** * Planned experiments use plants modified by recombinant or synthetic nucleic acid molecules that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.
* Planned experiments use plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent.
* Planned experiments use plants associated with recombinant or synthetic nucleic acid molecule- modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems.
* Planned experiments use plants associated with recombinant or synthetic nucleic acid molecule-modified exotic microorganisms that have no recognized potential for serious detrimental impact on managed or natural ecosystems.
* Planned experiments use recombinant or synthetic nucleic acid molecule-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant or synthetic nucleic acid molecule-modified microorganisms associated with them if the recombinant or synthetic nucleic acid molecule-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems.
 | **BL2-P experiments:** * Planned experiments use plants modified by recombinant or synthetic nucleic acid molecules that are noxious weeds or can interbreed with noxious weeds in the immediate geographic area.
* Planned experiments use plants in which the introduced DNA represents the complete genome of a non-exotic infectious agent.
* Planned experiments use plants associated with recombinant or synthetic nucleic acid molecule- modified non-exotic microorganisms that have a recognized potential for serious detrimental impact on managed or natural ecosystems.
* Planned experiments use plants associated with recombinant or synthetic nucleic acid molecule-modified exotic microorganisms that have no recognized potential for serious detrimental impact on managed or natural ecosystems.
* Planned experiments use recombinant or synthetic nucleic acid molecule-modified arthropods or small animals associated with plants, or with arthropods or small animals with recombinant or synthetic nucleic acid molecule-modified microorganisms associated with them if the recombinant or synthetic nucleic acid molecule-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems.
 |
| **BL3-P experiments:*** Planned experiments use exotic infectious agent with recognized potential for serious detrimental impact on managed or natural ecosystems.
* Planned experiments use cloned genomes of readily transmissible exotic infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in planta.

Planned experiments use microbial pathogens of insects or small animals associated with plants if the recombinant or synthetic nucleic acid molecule-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems. | **BL3-P experiments:*** Planned experiments use exotic infectious agent with recognized potential for serious detrimental impact on managed or natural ecosystems.
* Planned experiments use cloned genomes of readily transmissible exotic infectious agents with recognized potential for serious detrimental effects on managed or natural ecosystems in which there exists the possibility of reconstituting the complete and functional genome of the infectious agent by genomic complementation in planta.

Planned experiments use microbial pathogens of insects or small animals associated with plants if the recombinant or synthetic nucleic acid molecule-modified organism has a recognized potential for serious detrimental impact on managed or natural ecosystems. |
| Section XI. Biosafety Level/Containment Selection | Lab Practices ([Click here for a list of all Lab Practices in Kuali Protocols](#LabPracticesKP)) |
| **Sec. XI-A. Please check the highest appropriate physical containment level for the proposed research.** | **Check the highest appropriate physical containment level for the proposed research.** |
| Biohazards or recombinant DNA: * BL-1
* BL-2
* BL-3
 | Biohazards and/or Recombinant or Synthetic Nucleic Acid Molecule Research* BSL-1
* BSL-2
* BSL-3
 |
| Animal Research:* ABL-1
* ABL-2
* ABL-3
 | Animal Research* ABSL-1
* ABSL-2
* ABSL-3
 |
|  | Large Scale: This section is triggered when “This experiment will involve >10 L of culture (in one container)” is selected in the **Biological Material(s)** section.* BSL-1
* BSL-2
 |
|  | * If “Large Scale” BSL-1 is selected, a list of practices will open below the General Practices section. Please review the options and select the box(es) relevant to your research:
	+ **Large Scale General Practices**
		- Cultures of viable organisms containing recombinant or synthetic nucleic acid molecules shall be handled in a closed system or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge) which is designed to reduce the potential for escape of viable organisms.
		- Culture fluids shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant or synthetic nucleic acid molecules have been inactivated by a validated inactivation procedure.
		- Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which minimizes the release of aerosols or contamination of exposed surfaces.
		- Exhaust gasses removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air (HEPA) filters or by other equivalent procedures to prevent the release of viable organisms.
		- Lab will deviate from one of the practices above.
			* If checked, then “**Describe deviation”.**
* If “Large Scale” BSL-2 is selected:
	+ **Large Scale General Practices**
	+ Cultures of viable organisms containing recombinant or synthetic nucleic acid molecules shall be handled in a closed system or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge) which is designed to reduce the potential for escape of viable organisms.
	+ Culture fluids shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant or synthetic nucleic acid molecules have been inactivated by a validated inactivation procedure.
	+ Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which minimizes the release of aerosols or contamination of exposed surfaces.
	+ Exhaust gasses removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air (HEPA) filters or by other equivalent procedures to prevent the release of viable organisms.
	+ Rotating seals and other mechanical devices directly associated with a closed system used for propagation and growth of viable organisms containing recombinant or synthetic nucleic acid molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to high efficiency particulate air (HEPA) filters or by other equivalent treatment devices.
	+ Primary containment equipment contains sensing devices that monitor the integrity of containment during operations.
	+ A closed system used for propagation and growth of viable organisms containing recombinant and synthetic nucleic acid molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment for research or production activities.
	+ The universal biosafety sign shall be posted on each closed system and primary containment equipment.
	+ Lab will deviate from one of the practices above.
		- If checked, then **Describe deviation**.
 |
| Lentiviral vector Containment:* BL-1/ABL-1: Lentivirus transduced mouse cell that will be injected into animals
* BL-2: Cell culture work, no delivery into animals
* BL-2/ABL-2: Injection of lentiviral vector directly into an animal. Animal housing may drop to ABL-1 after 72 hours.
* BL-2/ABL-2: Injection of lentiviral vector-transduced human cells into animals or injected lentiviral vector into animals engrafted with human cells.
 | See the Lentiviral Vector section. Containment for Lentiviral Vectors used with animals is entered along with each vector you will use.  |
| Adeno-associated vector containment:* BL-2: Cell culture work, no delivery into animals
* BL-2/ABL-2: injection of AAV, containing toxic or oncogenic inserts, into animals. All work will remain at BL-2/ABL-2. Please list the specific AAVs requiring ABL-2 housing:
* BL -2/ABL-2: injection of AAV, not containing toxic or oncogenic inserts, into animals. Animal housing may drop to ABL-1 after 72 hours. Necropsy and postmortem tissue handling of animals receiving direct injection of AAV vectors (as described above) can be performed under BL1 conditions 72 hours after final injection.
* BL-2/ABL-1: injection of AAV, not containing toxic or oncogenic inserts, into animals. The IBC will consider lowering the biosafety level for animal housing to ABL-1 on a case-by-case basis based on the following criteria:
	+ The nature of the transgene expression: Transgenes expressing oncogenic protein or toxin require BL-2/ABL-2
	+ Whether or not the vector is generated using adenovirus or any other helper virus of human origin
	+ Identification of the cell line in which the vector is propagated
	+ A description of purification procedures (e.g.: column chromatography, etc.) and/or documentation from the source of the vector (investigator or vector core facility) that describes purification procedures
	+ Animal bedding must be decontaminated prior to disposal for the first 72 hours after final injection and first cage change. Necropsy and postmortem tissue handling of animals receiving direct injection of AAV as described above can be performed under BL-1 conditions 72 hours after final injection.
 | See the Adeno Associated Viral Vector section. Containment for Adeno Associated Viral Vectors used with animals is entered along with each vector you will use.  |
| **Sec. XI-B. Biosafety Level 1** | This section is triggered by selecting “**BSL-1**” under **Biohazards and/or Recombinant or Synthetic Nucleic Acid Molecule Research**BL-1 Containment and Lab Practices will be selected in the following sections:* General Practices
* Non-Animal Research Personal Protective Equipment (PPE)
* Engineering Devices
* Health Surveillance/Immunization
* Laboratory Practices
* Laboratory Access
* Lab and Surface Disinfectant
* Equipment Disinfectant
* Solid Waste
* Liquid Waste
 |
| Follow Practices described belowDeviate from practices described below, please explain:* Personal Protective Equipment (PPE): PPE such as gloves, safety glasses and a laboratory coat should be worn whenever biological work is conducted in the laboratory. No sandals are allowed in the laboratory. No open-toed shoes, ballet flats, shorts, or short skirts are allowed in the laboratory for all biosafety levels.
* Handwashing: Hands must be washed immediately or as soon as feasible after removing gloves or other personal protective clothing.
* Use of Sharps: Minimize the use of and exposure to sharps in the workplace. Never recap, bend, or shear needles. As often as possible, replace glassware with less damaging materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
* Food and Beverage: Eating, drinking, storing food and drink for human consumption, smoking, applying cosmetics or lip balm and handling contact lenses in the laboratory or other work areas is prohibited. This prohibition shall be well posted.
* Aerosol Generation: Any procedures that could potentially generate aerosols or other inhalation hazards must be performed in a manner that will minimize airborne pathogen transmission.
* Proper Labeling: Place a color-coded label incorporating the universal biohazard symbol on any potentially contaminated equipment or work surface to warn others of biohazard contamination that may not be easily visible. This includes freezers, refrigerators, and incubators.
* Autoclave Safety: Always wear heat-resistant gloves, goggles or safety glasses, and a laboratory coat when opening an autoclave. Be sure to allow the superheated steam to exit before attempting to remove the contents.
* Spills: Always clean spills from the periphery of the spill towards the center, after placing paper towels over the spill. Make sure that the cleaning materials are disposed of in an appropriate manner. Report all spills to the Biological Safety Office.
* Mouth Pipetting: Mouth pipetting may lead to accidental ingestion of biological specimens and is strictly prohibited.
* Decontamination Procedures: A fresh 0.5 – 1 percent sodium hypochlorite (a 1 to 10-20 dilution of household bleach) will be used to decontaminate equipment, work surfaces, and liquid waste. In locations where bleach would cause corrosion, an iodophor (e.g., Wescodyne) will be used to decontaminate. All solid waste shall be autoclaved prior to disposal.
* Local Transport of Biological Materials: All biological materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities.
* Storage: All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space (e.g., freezers and refrigerators).
 | * **Non-Animal Research Personal Protective Equipment (PPE):** Closed toe shoes, Long pants or skirts that cover the legs, Gloves, Laboratory Coat, Eye Protection, Face Shield, Other
	+ If **Other**, then **Describe other PPE used**
* **General Practices:** Hands will be washed immediately or as soon as feasible after removing gloves or other personal protective clothing as well as before exiting the laboratory.
* **Laboratory Practices:** Needles and syringes are not recapped or reused, Sharps containers are only 2/3 full before disposal.
* **General Practices:** No eating, drinking, storing food and drink for human consumption will occur in the laboratory or other work areas. This prohibition shall be well posted. No smoking, applying cosmetics or lip balm, and/or handling of contact lenses in the laboratory or other work areas will occur.
* **General Practices:** All experiments will be performed in a manner to reduce aerosol generation
* **General Practices:** Any potentially contaminated equipment or work surface will have a color-coded label incorporating the universal biohazard symbol including freezers, refrigerators, and incubators.
* **General Practices:** Spills will be reported to the Environmental Health & Safety, Biosafety Program. If there is a spill it will be cleaned from the periphery of the spill towards the center and paper towels will be placed over the spill. All cleaning materials will be disposed of in an appropriate manner.
* **General Practices:** No mouth pipetting will occur. Mouth pipetting may lead to accidental ingestion of biological specimens.
* **Lab and Surface Disinfectant:** 10% commercial bleach (0.5% sodium hypochlorite) with 10 minutes contact time; **Solid Waste:** Materials will be appropriately autoclaved; Puncture resistant container with biohazard symbol: autoclaved prior to disposal; **Liquid Waste:** Commercial bleach (equivalent to .5% sodium hypochlorite), with 30 minutes contact time
* **Laboratory Practices:** Lab will transport biological materials outside of laboratory; Transported in a closed, rigid, leakproof container with biohazard symbol; Transported in other container; Materials will be shipped
	+ If **Transported in other container**, then **Describe other container**
* **General Practices:** All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space.
 |
| **Sec. XI-C. Biosafety Level 2** | This section is triggered by selecting “**BSL-2**” under **Biohazards and/or Recombinant or Synthetic Nucleic Acid Molecule Research**BL-2 Containment and Lab Practices will be selected in the following sections:* General Practices
* Non-Animal Research Personal Protective Equipment (PPE)
* Engineering Devices
* Health Surveillance/Immunization
* Laboratory Practices
* Laboratory Access
* Lab and Surface Disinfectant
* Equipment Disinfectant
* Solid Waste
* Liquid Waste
 |
| Follow Practices described below **in addition to** the Biosafety level 1 practices listed aboveDeviate from practices described below, please explain:* Use of Sharps: Minimize the use of and exposure to sharps in the workplace. Never recap, bend or shear needles. As often as possible, replace glassware with less damaging materials such as plastic. Keep sharps containers readily available in all locations where sharps waste may be generated. In order to avoid accidental injury, do not overfill sharps containers.
* Attention to sharps; use of safety needles when possible
* Local Transport of Infectious Materials: All infectious materials transported to and from the laboratory will be enclosed in a primary container with a sealed lid or top, which will then be enclosed in a secondary leak-proof, rigid container (e.g., a Coleman cooler) appropriately labeled with biohazard symbol. A responsible lab employee shall escort any specimens transported to and from off-campus satellite facilities. Packaging and labeling must comply with the IATA dangerous goods or DOT hazardous materials regulations.
* Bloodborne Pathogens: All PIs using human blood or blood products, unfixed tissue, body fluids or organ or cell cultures of human origin will follow the procedures outlined in the IU Bloodborne Pathogen Exposure Control Plan.
* No plants shall be allowed in the laboratory.
* Transport of Select Agents/Toxins: EH&S must be notified of all transfers or shipments off campus.
* The PI is responsible for developing laboratory SOPs and training laboratory staff in specific procedures.
* Procedures with a potential for creating aerosols or splashes must be conducted inside a biological safety cabinet or with other appropriate personal protective equipment as determined by the Biosafety Office (BSO).
 | * **Laboratory Practices:** Needles and syringes are not recapped or reused, Sharps containers are only 2/3 full before disposal.
* **Laboratory Practices:** Lab will transport biological materials outside of laboratory; Transported in a closed, rigid, leakproof container with biohazard symbol; Transported in other container; Materials will be shipped
	+ If **Transported in other container**, then **Describe other container**
* **Personnel List:** Select Bloodborne Pathogens training; **PI Agreement**
* **General Practices:** No non-protocol associated plants will be allowed in the laboratory unless previously approved by the Environmental Health & Safety, Biosafety Program. If plants are approved for lab space they cannot leave the lab and must be autoclaved.
* **Personnel List:** Select Bloodborne Pathogens training; **PI Agreement**
* **General Practices:** All experiments will be performed in a manner to reduce aerosol generation
 |
| **Sec. XI-C. Biosafety Level 3** | This section is triggered by selecting “**BSL-3**” under **Biohazards and/or Recombinant or Synthetic Nucleic Acid Molecule Research** |
| Follow Practices described below **in addition to** the Biosafety level 1 and 2 practices listed aboveDeviate from practices described below, please explain:All BL3 procedures, training and safety precautions have been documented and reviewed by the Biosafety Office. | BL-3 Containment and Lab Practices will be selected in the following sections:* General Practices
* Non-Animal Research Personal Protective Equipment (PPE)
* Engineering Devices
* Health Surveillance/Immunization
* Laboratory Practices
* Laboratory Access
* Lab and Surface Disinfectant
* Equipment Disinfectant
* Solid Waste
* Liquid Waste
 |
| Section XII. Personal Protective Equipment (PPE) & Laboratory Practices | Lab Practices |
| **Sec. XII-A. Personal Protective Equipment (PPE) and Safety Equipment****Non-Animal Research*** Gloves
* Eye Protection
* Laboratory Coat
* Face Shield
* Surgical Mask
* Respirator
* Chemical Fume Hood (only if being used for biological work)
* Biosafety Cabinet
* Other PPE
 | **Non-Animal Research Personal Protective Equipment (PPE)*** Gloves
* Eye Protection
* Laboratory Coat
* Face Shield
* Surgical Mask
* Respirator: N95 (BSL-2 and BSL-3 only)
* Respirator: PAPR (BSL-2 and BSL-3 only)

**Engineering Devices*** Chemical Fume Hood (only select if required for biological work)
* Biosafety Cabinet

**Non-Animal Research Personal Protective Equipment (PPE)*** If **Other**, then **Describe other PPE used**
 |
| **Animal Research (Vertebrate research only)*** Gloves
* Eye Protection
* Disposable Gown
* Face Shield
* Surgical Mask
* Respirator
* Method of animal containment/caging
 | **Animal Research Personal Protective Equipment (PPE) and Safety Equipment** * Gloves
* Eye Protection
* Disposable Gown
* Face Shield
* Surgical Mask
* Respirator: N95
* Respirator: PAPR
 |
| **Hypoxia Chamber*** My lab is using a hypoxia chamber. If checked, please complete the questions below. If yes, then:
	+ Make/Model of Chamber:
	+ Please describe any in-house modifications to chamber:
	+ Agents that will be used inside the chamber:
	+ Procedures that will occur within the chamber (including duration):
	+ Decontamination Procedure:
	+ Spill Procedures:
 | **Engineering Devices*** **Hypoxia Chamber**
	+ Make/Model of Chamber
	+ Describe any in-house modifications to chamber
	+ List agents that will be used inside the chamber
		- Click “**+Add Line**” to add each agent
		- These agents will pull from the **Biological Material(s)** list you entered earlier in the form.
	+ Describe procedures that will occur within the chamber and the duration of those procedures
	+ Describe decontamination procedures
	+ Describe spill procedures
 |
| **Sec. XII-B. Laboratory Practices** |  |
| * Needles and syringes are not recapped or reused
* Restrictions on the use of sharps while working with the following agent(s):
* Sharp containers are only 2/3 full before disposal
* Chemical restraint (animals)
* Physical Restraint (animals)
* Biological material transported outside of the laboratory in rigid container with lid and biohazard symbol
* Biological material transported outside of the laboratory in other container (describe):
* Vertexing/mixing/centrifugation performed in tightly capped tubes
* Centrifugation performed in aerosol containment capsules (Check box if Inhalation is checked as a Route of Transmission in Sec. V-A.)
* Specialized spill procedures required (Check box if Inhalation is checked as a Route of Transmission in Sec. V-A.): Evacuate immediate area for 30 minutes, post signage on all entrances and notify IUEHS Biosafety
* Pipetting in Biosafety Cabinet for work requiring BSL-2 or higher containment
* Other Techniques performed in Biosafety Cabinet:
* Other Techniques performed on bench top:
 | * **Laboratory Practices:** Needles and syringes are not recapped or reused
* **Biological Materials:** Please note where sharps are restricted when entering each agent into the Biological Material(s) section.
* **Laboratory Practices:** Sharps containers are only 2/3 full before disposal
* **Animal Restraint:** Chemical Restraint
* **Animal Restraint:** Physical Restraint
* **Laboratory Practices:** Lab will transport biological materials outside of laboratory
	+ **How will biological materials be transferred outside of the laboratory?**
		- Transported in a closed, rigid, leakproof container with a biohazard symbol
		- Transported in other container
			* **Describe other container**
		- Materials will be shipped
* **Laboratory Practices:** Vortexing/mixing/centrifugation performed in tightly capped tubes
* **Laboratory Practices:** Centrifugation performed in aerosol containment capsules
* **General Practices:** Specialized spill procedures are required: Evacuate immediate area for 30 minutes, post signage on all entrances and notify IUEHS Biosafety (BSL-2 and BSL-3 only)
* Pipetting in Biosafety Cabinet for work requiring BSL-2 or higher containment (BSL-2 and BSL-3 only)
* Other Techniques performed in Biosafety Cabinet
	+ **Describe other procedures to be performed in Biosafety Cabinet**
* Other Techniques performed on Bench Top
	+ **Describe other procedures to be performed on Bench Top**
 |
| **Sec. XII-C. Laboratory Access** | **Laboratory Access** |
| * Limited to personnel listed on protocol
* Locked laboratories with limited public access
* Limited to personnel trained for specific procedure
* Other:
 | * Limited to personnel listed on protocol
* Locked laboratories with limited public access
* Limited to personnel trained for specific procedure
* Other
	+ **Describe other laboratory access**
 |
| **Sec. XII-D. Health Surveillance/Immunization** | **Health Surveillance/Immunization** |
| * Hepatitis B Vaccine offered
* Orthopoxviruses (vaccinia and others)
* Other Vaccine:
* Custom health surveillance/immunization program:
* Serum sample banking: Consult with Environmental Health and Safety - Biological Safety Office (BSO)
 | * Hepatitis B vaccine offered
* Orthopoxviruses (vaccinia and others)
* Other vaccine(s)
	+ List other vaccine(s)
* Custom health surveillance/immunization program:
	+ **Describe the custom health surveillance/immunization program**
* Serum sample banking: Consult with Environmental Health and Safety - Biological Safety Office (BSO)
 |
| Section. XIII. Decontamination and Waste Disposal Procedures | Lab Practices |
| **Sec. XIII-A. Lab or Surface Disinfectant** | **Lab and Surface Disinfectant** |
| * 10% commercial bleach (0.5% sodium hypochlorite) with 10 minutes contact time
* 70% Ethanol with 10 minutes contact time
* Other Disinfectant:
	+ Contact Time:
	+ Concentration:
 | * 10% commercial bleach (0.5% sodium hypochlorite) with 10 minutes contact time
* 70% ethanol with 10 minutes contact time
* Other disinfectant
	+ **Other disinfectant name, concentration, and contact time**
 |
| **Sec. XIII-B. Solid Waste** | **Solid Waste** |
| * Materials will be autoclaved for a minimum of 15 minutes, at 121°C, under 15 psi (pounds per square inch)
* Chemical Inactivation:
	+ Chemical:
	+ Contact Time:
* Other:
* Mammalian/avian animal carcasses are frozen, EHS is contacted to pick them up and dispose of them (Bloomington)
* Animal carcasses are returned to animal facility for disposal (IUPUI)
* Animal carcass, including invertebrate, disposal, Other:
 | * Materials will be appropriately autoclaved
* Puncture resistant container with biohazard symbol: autoclaved prior to disposal
* Chemical inactivation
	+ **Chemical name and contact time**
* Other
	+ **Describe other solid waste disposal**
* **Animal Carcass Waste Disposal**
	+ Mammalian/avian animal carcasses are frozen, EHS is contacted to pick them up and dispose of them (Bloomington)
	+ Animal carcasses are returned to animal facility for disposal (IUPUI)
	+ Other animal carcass disposal, including invertebrate(s)
 |
| **Sec. XIII-C. Liquid Waste** | **Liquid Waste** |
| * Commercial bleach (equivalent to .5% sodium hypochlorite), with 30 minutes contact time
* Other:
 | * Commercial bleach (equivalent to .5% sodium hypochlorite), with 30 minutes contact time
* Other
	+ **Describe other liquid waste disposal**
 |
| **Sec. XIII-D. Infectious Sharps** |  |
| * Puncture resistant container with a biohazard symbol: autoclaved prior to disposal
 | **Solid Waste:** Puncture resistant container with biohazard symbol: autoclaved prior to disposal |
| **Sec. XIII-E. Equipment Decontamination Procedure** | **Equipment Disinfectant** |
| * Please detail how you will decontaminate equipment:
 | * Please detail how you will decontaminate equipment
 |
| Section. XIV. Reporting Section. XV. Investigator Statement & Signature | PI Agreement |
|  | * Check acknowledgement box
 |

|  |
| --- |
| Lab Practices in Kuali Protocols |
| **General Lab Practices** | **BSL-1** | * Hands will be washed immediately or as soon as feasible after removing gloves or other personal protective clothing as well as before exiting the laboratory.
* No eating, drinking, storing food and drink for human consumption will occur in the laboratory or other work areas. This prohibition shall be well posted.
* No smoking, applying cosmetics or lip balm, and/or handling of contact lenses in the laboratory or other work areas will occur.
* No non-protocol associated plants will be allowed in the laboratory unless previously approved by the Environmental Health & Safety, Biosafety Program. If plants are approved for lab space they cannot leave the lab and must be autoclaved.
* Any potentially contaminated equipment or work surface will have a color-coded label incorporating the universal biohazard symbol including freezers, refrigerators, and incubators.
* All infectious materials to be stored will be clearly labeled with the universal biohazard symbol as will the storage space.
* Spills will be reported to the Environmental Health & Safety, Biosafety Program. If there is a spill it will be cleaned from the periphery of the spill towards the center and paper towels will be placed over the spill. All cleaning materials will be disposed of in an appropriate manner.
* No mouth pipetting will occur. Mouth pipetting may lead to accidental ingestion of biological specimens.
* All experiments will be performed in a manner to reduce aerosol generation
* Long hair will be restrained so that it cannot contact hands, specimens, containers, or equipment
* The lab will deviate from one of the practices above
 |
| **BSL-2** | * Specialized spill procedures are required: Evacuate immediate area for 30 minutes, post signage on all entrances and notify IUEHS Biosafety
 |
| **BSL-3** | * All BL-3 procedures, training and safety precautions have been documented and reviewed by the BL-3 IBC Sub-Committee and the Biological Safety Office.
 |
| **Non-Animal Research Personal Protective Equipment (PPE)** | **BSL-1** | * Closed toe shoes
* Long pants or skirts that cover the legs
* Gloves
* Laboratory Coat
* Eye Protection
* Face Shield
* Other
 |
| **BSL-2** | * Respirator: N95
* Respirator: PAPR
* Surgical Mask
 |
| **BSL-3** | * Surgical Gown
* Tyvek
 |
| **Engineering Devices** | **BSL-1, BSL-2, BSL-3** | * Chemical Fume Hood (only select if required for biological work)
* Biosafety Cabinet
* Hypoxia Chamber
 |
| **Health Surveillance/Immunization** | **BSL-2, BSL-3** | * Hepatitis B Vaccine offered
* Orthopoxviruses (vaccinia and others)
* Other Vaccine(s)
* Custom health surveillance/immunization program
* Serum sample banking: Consult with Environmental Health and Safety - Biological Safety Office (BSO)
 |
| **Laboratory Practices** | **BSL-1** | * Lab will transport biological materials outside of laboratory
* Needles and syringes are not recapped or reused
* Sharps containers are only ⅔ full before disposal
* Vortexing/mixing/centrifugation performed in tightly capped tubes
 |
| **BSL-2, BSL-3** | * Centrifugation performed in aerosol containment capsules
* Pipetting in Biosafety Cabinet for work requiring BSL-2 or higher containment
* Other Techniques performed in Biosafety Cabinet
* Other Techniques performed on Bench Top
 |
| **Laboratory Access** | **BSL-1** | * Locked laboratories with limited public access
* Limited to personnel listed on protocol
* Other
 |
| **BSL-2, BSL-3** | * Limited to personnel trained for specific procedure
 |
| **Lab and Surface Disinfectant** | **BSL-1, BSL-2, BSL-3** | * 10% commercial bleach (0.5% sodium hypochlorite) with 10 minutes contact time
* 70% Ethanol with 10 minutes contact time
* Other Disinfectant
 |
| **Solid Waste** | **BSL-1, BSL-2, BSL-3** | * Materials will be appropriately autoclaved
* Puncture resistant container with biohazard symbol: autoclaved prior to disposal
* Chemical Inactivation
* Other
 |
| **Liquid Waste** | **BSL-1, BSL-2, BSL-3** | * Commercial bleach (equivalent to .5% sodium hypochlorite), with 30 minutes contact time
* Other
 |
| **Animal Research Personal Protective Equipment (PPE) and Safety Equipment** | **ABSL-1, ABSL-2, ABSL-3** | * Closed toe shoes
* Long pants or skirts that cover the legs
* Gloves
* Disposable Gown
* Laboratory Coat
* Eye Protection
* Face Shield
* Respirator: PAPR
* Respirator: N95
* Surgical Mask
* Other
 |
| **Animal Restraint** | **ABSL-1, ABSL-2, ABSL-3** | * Chemical Restraint
* Physical Restraint
 |
| **Animal Carcass Waste Disposal** | **ABSL-1, ABSL-2, ABSL-3** | * Mammalian/avian animal carcasses are frozen, EHS is contacted to pick them up and dispose of them (Bloomington)
* Animal carcasses are returned to animal facility for disposal (IUPUI)
* Other animal carcass disposal, including invertebrate(s)
 |
| **Large Scale General Practices** | **BSL-1** | * Cultures of viable organisms containing recombinant or synthetic nucleic acid molecules shall be handled in a closed system or other primary containment equipment (e.g., biological safety cabinet containing a centrifuge) which is designed to reduce the potential for escape of viable organisms.
* Culture fluids shall not be removed from a closed system or other primary containment equipment unless the viable organisms containing recombinant or synthetic nucleic acid molecules have been inactivated by a validated inactivation procedure.
* Sample collection from a closed system, the addition of materials to a closed system, and the transfer of culture fluids from one closed system to another shall be conducted in a manner which minimizes the release of aerosols or contamination of exposed surfaces.
* Exhaust gasses removed from a closed system or other primary containment equipment shall be treated by filters which have efficiencies equivalent to high efficiency particulate air (HEPA) filters or by other equivalent procedures to prevent the release of viable organisms.
* Lab will deviate from one of the practices above.
 |
| **BSL-2** | * Rotating seals and other mechanical devices directly associated with a closed system used for propagation and growth of viable organisms containing recombinant or synthetic nucleic acid molecules shall be designed to prevent leakage or shall be fully enclosed in ventilated housings that are exhausted through filters which have efficiencies equivalent to high efficiency particulate air (HEPA) filters or by other equivalent treatment devices.
* Primary containment equipment contains sensing devices that monitor the integrity of containment during operations.
* A closed system used for propagation and growth of viable organisms containing recombinant and synthetic nucleic acid molecules shall be permanently identified. This identification shall be used in all records reflecting testing, operation, and maintenance and in all documentation relating to the use of this equipment for research or production activities.
* The universal biosafety sign shall be posted on each closed system and primary containment equipment.
 |