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**IBC Biosafety Protocol Application**

*Submit the completed form and attachments to the Office of Research & Sponsored Programs via email at* *grants@uwlax.edu**.*

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| **Section I: Principal Investigator & Project Overview** |

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| **A. Principal Investigator (PI)** |
| Name[[1]](#footnote-2): | Click or tap here to enter text. | Department: | Click or tap here to enter text. |
| Email: | Click or tap here to enter text. | Employee Classification: | Choose an item. |

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| **B. Project Overview** |
| Project Title:  | Click or tap here to enter text. |
| Course Number & Name[[2]](#footnote-3): | Click or tap here to enter text. |
| Project Type: | [ ] Research[ ] Teaching | Application Type: | [ ] New [ ] Renewal [ ] Revision[[3]](#footnote-4)If a renewal or revision: Protocol number: Click or tap here to enter text. Summarize change(s): Click or tap here to enter text. List revised protocol section(s): Click or tap here to enter text. |
| Funding:  |
| Is this project associated with external award(s)? | [ ] Yes [ ] No | If yes, complete information below. |
| Sponsor | Status | Award # (if current) | Start Date | End Date |
| Click or tap here to enter text. | [ ] Current [ ] Pending | Click or tap here to enter text. | Click or tap to enter a date. | Click or tap to enter a date. |
| Click or tap here to enter text. | [ ] Current [ ] Pending | Click or tap here to enter text. | Click or tap to enter a date. | Click or tap to enter a date. |
| Location(s):List all locations where biological materials will be used, stored, or handled. Add lines if needed. |
| Building | Room Number | Containment and/or Storage Equipment (e.g., biosafety cabinet refrigerator, freezer, dewar) |
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| **C. Project Summary** |
| Provide a brief description of the research project(s) in which the materials and/or organisms addressed in Section II will be used. |
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| **Section II: Biological Materials** |

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| **A. Recombinant Materials** |
| Complete this section if working with any recombinant or synthetic DNA/RNA materials. Provide the following information, and expand the table if needed:* Gene name(s) and acronym(s)
* All pertinent biological activities of the encoded protein(s) (e.g., normal biological function, oncogenic potential, toxicity) – If unknown, indicate “unknown” and explain. Address the suspected nature of the gene, if any.
* Biological source/origin (genus and species)
* Risk group (RG) of the source organism(s) – see [ABSA Risk Group Database](https://my.absa.org/Riskgroups)
* Vector(s) (bacterial plasmid, virus, or other vector)
* Host(s) (genus, species, strain, tissue, cell line) that the recombinant material might be inserted into
* Risk group (RG) of the host – see [ABSA Risk Group Database](https://my.absa.org/Riskgroups)

If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Name of Gene or Gene Fragment** | **Nature of Gene** | **Source Organism(s)** | **RG of Source Organism** | **Vector(s)** | **Host Administered to** | **RG of Host** |
| 1.  |  |  |  |  |  |  |
| 2.  |  |  |  |  |  |  |

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| a. For each material listed in the table above, indicate all categories from the [NIH Guidelines, Section III](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm#_Toc3457031) that apply. |
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| b. Attach plasmid maps as part of the protocol in Section VI: Attachments. |

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| **B. Microorganisms, Viruses, & Prions** |
| Complete this section if working with any prokaryotes, fungi, virus, viral vectors, or prions. Provide the following information, and expand the table if needed:* Organism name(s) (genus, species, strain), name of virus(es), and/or prion name(s) and natural host(s)
* Whether the agent is a human, animal, and/or plant pathogen (and if a plant pathogen, whether it is indigenous to Wisconsin) – if none apply, enter “n/a”
* Risk group (RG) – see [ABSA Risk Group Database](https://my.absa.org/Riskgroups)
* Biosafety level (BSL) – see [UWL Biosafety Manual](https://www.uwlax.edu/globalassets/offices-services/grants/ibc/biosafety-manual.pdf), Summary of Biosafety Levels
* Any rDNA (plasmid, virus, DNA fragment, or other vector)
* Host (genus, species, strain, cell lines) exposed to the microbial agent

If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Organism, Name of Virus, or Prion Name & Natural Host** | **Human, Animal, or Plant Pathogen** | **RG** | **BSL** | **rDNA Added?** *(If yes, indicate identity from II.A.)* | **Administered to host?***(If yes, reference protocol section)* |
| 1.  |  |  |  |  |  |
| 2.  |  |  |  |  |  |

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| a. If the identity of your microbial agents, viruses, or prions is unknown, please explain. |
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| b. If any of the microbial agents, viruses, or prions are pathogenic, indicate the host(s) organism(s) at risk of infection. |
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| c. Will any of the microorganisms be grown in volumes of 10 liters or more? If so, indicate which and the volume. |
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| d. In protocol section III.A., address the following information for each microorganism, virus, or prion: Describe the safety procedures personnel will use to protect themselves from exposure and appropriate response if accidental exposure occurs. Address both collection and research if applicable. |

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| **C. Human and Non-Human Animal Tissues, Cell Lines, & Blood Products** |
| Complete this section if working with any human-derived materials *or* non-human animal-derived materials that are infectious, potentially infectious, or recombinant. Provide the following information, and expand the table if needed:* Type of material used (species, strain, technical name)
* Source
* Risk group (RG) – see [ABSA Risk Group Database](https://my.absa.org/Riskgroups)
* Biosafety level (BSL) – see [UWL Biosafety Manual](https://www.uwlax.edu/globalassets/offices-services/grants/ibc/biosafety-manual.pdf), Summary of Biosafety Levels
* Any vector (bacterial plasmid, virus, or other vector) that will be delivered into the sample – if applicable, indicate identity from other protocol sections
* Host (genus, species, strain) to which the samples will be applied – if applicable, reference protocol section

If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Type of Material** | **Source** | **RG** | **BSL** | **Exposed to biological material or rDNA?** | **Administered to host?** |
| 1.  |  |  |  |  |  |
| 2.  |  |  |  |  |  |

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| a. Does the material contain a known infectious agent? |
| [ ]  Yes [ ]  No |
| b. If administering nucleic acids, toxins, nanoparticles, microbes, viruses, or other biohazardous material to animals, describe the route of delivery.  |
|  |
| c. In protocol section III.A., address the following information for each material listed above: Describe the safety procedures personnel will use to protect themselves from exposure and appropriate response if accidental exposure occurs. |
| d. **All work involving live (non-fixed) human-derived materials (e.g., blood or blood components, tissues, secretions), cell lines, and/or bloodborne pathogens must comply with the OSHA Bloodborne Pathogens Standard** (29 CFR 1910.1030). If this is applicable to your project, contact [Environmental Health & Safety](https://www.uwlax.edu/ehs/) to ensure compliance with annual training and other UWL [Bloodborne Pathogens Program](https://www.uwlax.edu/ehs/policies-and-procedures/) requirements. |

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| **D. Biological Toxins** |
| Complete this section if working with any toxin(s) of biological origin. Provide the following information, and expand the table if needed:* Biological toxin name(s) and acronym(s) if appropriate, biological source/origin (genus species)
* Median lethal dose (LD50) as ng/kg
* Risk group (RG) – see [ABSA Risk Group Database](https://my.absa.org/Riskgroups)
* Biosafety level (BSL) – see [UWL Biosafety Manual](https://www.uwlax.edu/globalassets/offices-services/grants/ibc/biosafety-manual.pdf), Summary of Biosafety Levels
* Whether toxin is a CDC Select Agent (see [CDC Select Agents and Toxins List](https://www.selectagents.gov/sat/list.htm))
* If the gene encoding the toxin will be cloned into a vector (bacterial plasmid, virus, or other vector), or host (genus, species, strain) that the toxin or recombinant materials containing the toxin gene might be inserted into
* Maximum amount administered to each type of recipient at one time (e.g., 0.1 ng)

If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Biological Toxin and Source Organism** | **LD50**(ng/kg) | **RG** | **BSL** | **Select Agent?**(Y/N) | **Administered to host?**(Y/N; if yes, reference protocol section) | **Max Amount Administered** (at one time) |
| 1.  |  |  |  |  |  |  |
| 2.  |  |  |  |  |  |  |

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| a. In protocol section III.A., address the following information for each biological toxin: Describe the safety procedures personnel will use to protect themselves from exposure and appropriate response if accidental exposure occurs. |
| b. For CDC Select Agent Toxins, address the following information in protocol section III.A. Include information for both collection and research if applicable.* 1. Maximum amount of toxin inventory and how you will document inventory (permissible amounts of select toxins are listed on the [CDC website](https://www.selectagents.gov/sat/permissible.htm))
	2. How the toxin will be stored securely
	3. For toxins that will be reconstituted from a powder, how select toxins will be reconstituted (should be conducted inside containment, e.g., chemical fume hood, biological safety cabinet)
	4. How each toxin will be inactivated (Appendix H of the [BMBL](https://www.cdc.gov/labs/BMBL.html) describes inactivation procedures)
	5. List aerosol generating activities and how an exposure risk will be mitigated
	6. Indicate if sharps will be used in procedures involving toxins.
	7. If administering the toxin to live animals, describe the route of delivery and maximum dose.
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| **E. Vertebrate & Invertebrate Animals** |
| Complete this section if working with any vertebrate or invertebrate animals administered biological materials. Work with vertebrate animals additionally requires [IACUC](https://www.uwlax.edu/iacuc/) review and approval before initiating work. Provide the following information, and expand the table if needed:* Animal common name and genus species
* Risk group (RG) – see [ABSA Risk Group Database](https://my.absa.org/Riskgroups)
* Animal Biosafety Level (ABSL) – see [UWL Biosafety Manual](https://www.uwlax.edu/globalassets/offices-services/grants/ibc/biosafety-manual.pdf); [BMBL](https://www.cdc.gov/labs/BMBL.html) Section V, and [NIH Guidelines, Appendix M](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm#_APPENDIX_M._PHYSICAL)
* Whether animal is transgenic
* Biological materials administered to the animals – type of materials, quantity, and method of administration
* Housing – type of housing for animals (e.g., static microisolators, rack system), and building(s) and room number(s) where animals will be housed

If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Vertebrate or Invertebrate**(Common name; Genus species) | **RG** | **ABSL** | **Transgenic?**(Y/N) | **Biological Materials Administered**(Type, Quantity, Method of Administration) | **Housing**(Type, Building & Room Number(s)) |
| 1.  |  |  |  |  |  |
| 2.  |  |  |  |  |  |

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| a. Indicate routes of shedding for any biological material administered (e.g., feces, urine, saliva, respiratory droplets, bites). |
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| b. List PPE used to reduce exposure risk when personnel handle the animal(s) listed. |
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| c. Indicate the period of infectivity and shedding for any biological materials administered. |
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| d. List aerosol generating activities involving biological materials and how an exposure will be mitigated. |
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| e. Address any additional information that would facilitate a complete biosafety review. |
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| **F. Plants & Soils** |
| Complete the relevant table(s) in this section if working with any of the following:* Plants that are recombinant (transgenic), exotic, or grown in association with pathogenic or recombinant microbes or pathogenic or recombinant small animals (insects, etc.)
* Foreign soils or domestic soils from counties listed under federal quarantine by the USDA to another US location (see the [USDA APHIS federal domestic soil quarantines map](https://www.aphis.usda.gov/plant_health/permits/organism/soil/downloads/Fed-SoilRegs.pdf))

For Plant Biosafety Levels, see the [UWL Biosafety Manual](https://www.uwlax.edu/globalassets/offices-services/grants/ibc/biosafety-manual.pdf) and [NIH Guidelines, Appendix L](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm#_APPENDIX_P._PHYSICAL). If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Plant**(Common name, Genus species) | **Plant Biosafety Level** | **Transgenic?**(Y/N) | **Biological Materials Administered** | **Growth Location**(e.g., greenhouse, growth chamber location) |
| 1.  |  |  |  |  |
| 2.  |  |  |  |  |

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| **Soil Source Location** | **Foreign or Quarantined Domestic?** | **Destination Location** | **Estimated Quantity** | **“Active” or Sterilized Soil?** |
| 1.  |  |  |  |  |
| 2.  |  |  |  |  |

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| a. If applicable, describe how pathogenic organisms will be stored. |
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| b. If applicable, describe when and how pathogenic organisms will be disposed of at the termination of the study. |
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| Additional permits and approvals: * The import of foreign plant material requires a permit from the USDA. If applicable, approved permits must be attached to this protocol. See [USDA APHIS plant import information](https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information).
* The import of foreign soils into the continental US requires a permit from the USDA. If applicable, approved permits must be attached to this protocol. See [USDA APHIS soil import and permit information](https://www.aphis.usda.gov/aphis/ourfocus/planthealth/import-information/permits/plant-pests/SA_Soil/soil-permits-home).
* The movement of domestic quarantined soil requires authorization by the local APHIS office. If applicable, approval must be attached to this protocol. Contact [USDA APHIS PPQ](https://www.aphis.usda.gov/aphis/ourfocus/planthealth/ppq-program-overview/ct_sphd) for information regarding quarantine status, soil regulations, or movement eligibility.
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| **Section III: Safety Precautions & Waste Disposal** |

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| **A. Safety Precautions** |
| Address the following information as applicable:* Describe the methods for handling materials and/or organisms addressed in Section II.
* If you will be employing Biosafety Level 2, 3, or 4 materials, provide additional information about investigator experience, adequacy of facility design and containment equipment, personnel practices, decontamination and disposal, staff training, and chemical hygiene considerations.
* Address any additional required information as directed in relevant subsections from Section II.
* All laboratories using hazardous chemicals must take actions to minimize exposure to hazardous chemicals as defined in the [UWL Chemical Hygiene Program (CHP) and Hazard Communication Policy](https://www.uwlax.edu/ehs/policies-and-procedures/). The Chemistry & Biochemistry and Microbiology Departments have department-specific CHPs. Hazardous chemical means any chemical that is classified as a physical hazard or a health hazard, a simple asphyxiant, combustible dust, pyrophoric gas, or hazard not otherwise classified. Contact Environmental Health and Safety for additional information.
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| **B. Waste Disposal & Terminal Inactivation** |
| In the table below, describe the method of disposal of hazardous substances, animal wastes and carcasses, and residual human substances (e.g., incineration, autoclaving, chemical disinfection). If chemical disinfectant is used, state kind and concentration. Is autoclave monitored with a biological indicator (e.g., spore strips)? If more space is needed than provided in the table below, include an attachment with additional information in Section VI. |

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| **Substance** | **Disposal method** | **Description of procedure** |
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| **Section IV: Personnel** |

In the table below, identify all personnel, including students, who will be working on the biological materials described in this protocol. Copies of required CITI training completion certificates for the PI and all individuals listed below must be included as an attachment (see Section VI. Attachments). For training requirements, see the [IBC website](https://www.uwlax.edu/grants/institutional-bio-safety-committee/).

*Teaching laboratory courses:* Students enrolling in laboratory courses do not need to be listed below and are not required to complete CITI training modules unless directed by the instructor. Instead, summarize the training provided to students who will be involved in the course (e.g., hands-on training, instructor-based training, online learning) and include the summary as an attachment (see Section VI. Attachments).

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| **Name** | **Personnel Type** | **Project Role****(e.g., PI, co-PI, research assistant)** |
|  | Choose an item.  |  |
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| **Section V: PI Assurances** |

I certify that the information contained in this application is accurate and complete. I am familiar with and agree to abide by the [NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm) (current edition), CDC [Biosafety in Microbiological and Biomedical Laboratories](https://www.cdc.gov/labs/BMBL.html) (current edition), and University of Wisconsin-La Crosse (UWL) [Biosafety Manual](https://www.uwlax.edu/globalassets/offices-services/grants/ibc/biosafety-manual.pdf). Also, I agree to abide by the following requirements:

1. I will not initiate any biological research subject to the guidance and guidelines mentioned above until that research has been registered, reviewed, and approved by the UW-La Crosse (UWL) Institutional Biosafety Committee (IBC). The purview of the UWL IBC includes biological research involving recombinant or synthetic nucleic acids; biological agents and pathogens; human cells, tissues, materials and embryonic stem cells; non-human animal-derived cells, tissues, materials, or samples that are infectious, potentially infectious, or recombinant; animals or plants that are recombinant, exotic, and/or grown in association with pathogens, biological toxins, and/or recombinant materials; select agents and toxins; biological toxins; dual use research of concern (DURC) agents and toxins; and the use of any of these in animal or plant research.
2. I will assure that personnel, including animal care staff or other laboratory support staff, have received appropriate information, including signage, about the biological hazards of the research outlined in this application by making available copies of approved protocols, Biosafety Manuals, and Biological Research Registrations that describe the potential biohazards and precautions to be taken to prevent exposures or release to the laboratory or the environment.
3. I will ensure that laboratory personnel understand the procedures for dealing with incidents and spills of biological materials and know the appropriate waste management procedures.
4. I will work with appropriate university personnel to comply with all training and shipping requirements for the transport of hazardous biological materials (e.g., [export controls regulations](https://kb.uwlax.edu/123473), US Department of Transportation (DOT) [49 CFR 171-178](https://www.ecfr.gov/current/title-49/subtitle-B/chapter-I/subchapter-C), [International Civil Aviation Organization](https://www.utikad.org.tr/images/Mevzuat/icaotechnicalinstructionsforthesafetransportofdangerousgoodsbyair-9608.pdf) (ICAO), [International Air Transport Association](https://www.iata.org/en/programs/cargo/dgr/) (IATA), US Department of Agriculture (USDA) [9 CFR 122](https://www.aphis.usda.gov/aphis/ourfocus/importexport/organism-vectors)).
5. I will comply with the OSHA [Bloodborne Pathogen Standard 29 CFR 1910.1030](https://www.osha.gov/laws-regs/regulations/standardnumber/1910/1910.1030) if my research includes human cells, tissues, materials, or embryonic stem cells.
6. I will ensure that all laboratory personnel working with biological materials are listed on this application.
7. I will assure that I along with all laboratory personnel have completed all required biosafety training and that their training records are up to date.
8. I assure that all laboratory spaces associated with the research and/or instruction described in this application are listed.
9. I am familiar with and understand my responsibilities as a Principal Investigator as outlined in [Section IV-B-7](https://osp.od.nih.gov/wp-content/uploads/NIH_Guidelines.htm#_Toc3457063) of the NIH Guidelines.
10. I will assure adequate supervision of personnel and will correct work errors and conditions that could result in breaches of the guidelines and regulations pertaining to this research as listed above.

I understand that failure to adhere to all related requirements may result in penalties outlined in federal and state regulations, sponsor guidelines, and institutional policies such as the IBC Noncompliance Policy.

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|  | Click or tap to enter a date. |
| **Principal Investigator Signature** | **Date** |

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| **Section VI: Attachments** |

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| **A. Training** |
| Attach copies of the required CITI training completion certificates for the PI and all individuals, including students, listed in Section IV. Personnel. For training requirements, see the [IBC website](https://www.uwlax.edu/grants/institutional-bio-safety-committee/).*Teaching laboratory courses:* Students enrolling in laboratory courses are not required to complete CITI training modules unless directed by the instructor. Instead, summarize the training provided to students who will be involved in the course (e.g., hands-on training, instructor-based training, online learning) and include the summary as an attachment or in the space below. |
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| **B. Supporting Materials** |
| Attach plasmid maps and/or any other supporting materials as instructed by applicable subsections in Section II. |

1. Only a UWL faculty or staff member may be listed as the PI on a Biosafety Protocol Application. All other project personnel, including students, must be listed in Section IV. Personnel. [↑](#footnote-ref-2)
2. If lab courses involve recombinant materials, they are subject to NIH Guidelines, and a protocol is required. Lab courses involving other biological materials but not recombinant materials are recommended to submit a protocol but are not required to do so. [↑](#footnote-ref-3)
3. For revisions to research elements, biological materials used, and/or locations, complete this form. For personnel or award modifications, submit the IBC Personnel & Award Modification Form. [↑](#footnote-ref-4)