**Institutional Biosafety Committee Application Review Checklist**

|  |  |  |  |
| --- | --- | --- | --- |
| **PI Name:** |  | | |
| **Protocol Title:** | |  | |
| **Protocol Number:** | | |  |

**Type of Application** (please select)New SubmissionRenewal Protocol

Teaching Application  Research Application

|  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| **Section 1: Principal Investigator, Overview, Assurance Statement** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Yes** | **No** |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Contact information is complete | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Assurance is signed, boxes are checked | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | |
| **Section 2: Biological Material Categories & Experimental Design** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Biological materials selected in Part A are mentioned in Part B | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | Experimental design is easily understandable (acronyms spelled out, common language used, etc) | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | |
| **Section 3: Personnel, Responsibilities, Training** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | All training certificates are attached to the application | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | |
|  |  | PI provides in-person training documentation; is attached | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
|  |  | Personnel responsibilities correspond with proper training received | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  |  | Training is documented, all personnel have access to materials | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | |
|  |  | Personnel responsible for training is listed and qualified (explains qualifications) | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  |
|  |  | Student and Teaching activities receive adequate training | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **Teaching Applications ONLY:** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI selects “Teaching” on Cover Page 1 | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI lists training provided to students | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI indicates which class students are participating in | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | |
|  |  | PI provides Lab Safety Orientation Checklist as related to work being conducted, attached to protocol | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | |
| **Section 4: Locations** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | All rooms to be utilized are listed | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | All rooms have their own entry | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Containment levels are accurate | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI indicates adequate containment equipment per containment level | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
|  |  | PI indicates containment equipment is in good working condition, certified | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
|  |  | PI indicates signage is appropriately placed, and accurate based on containment level; attached | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
|  |  | PI states lab space is appropriate for work being conducted | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | |
| **Section 5:** [**NIH Guidelines**](https://osp.od.nih.gov/biotechnology/nih-guidelines/) **& Recombinant Materials** | | | | | | | | | | | | | | | **N/A (PI not working with recombinant materials)** | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI indicated use of recombinant materials | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Items selected in this section match categories selected in Section 2 | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  |  | All rDNA experiments listed in protocol are referenced in this section | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | |
|  |  | Enhanced containment required-Materials listed: | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Proper NIH citations are selected for work (if not, indicate in comments) | | | | | | | | | | | | | | | | | | | **Correct citation:** | | | | | | | | | | | | | | | |
|  |  |  | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
| **Section 6: Bacteria, Viruses, Viral Vectors, Fungi & Prions** | | | | | | | | | | | | | | | **N/A (PI not working with materials)** | | | | | | | | | | | | | | | | | | | | | |
|  |  | [Risk Group](https://my.absa.org/Riskgroups)/Biosafety Levels are appropriate | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Routes of exposure are listed | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PPE is appropriate to work being conducted | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Possible consequences of exposure are accurately listed | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Antibiotic/drug resistance is noted; virus is listed; exposure is properly mitigated | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Is respirator fit testing required? | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Aerosol generating activities are listed & are properly mitigated | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | Common language is used; genus & species names are accurate | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | Is rDNA being administered? Check for pathogenicity, host range, treatment options | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
| **Section 7: Human/Non-Human Primate, Animal Cell Lines, Tissues or Blood Products** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
| **N/A (PI not working with materials)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | All cell lines are listed by category, not specific cell line names | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Risk Group/Biosafety Levels are appropriate | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Routes of exposure are listed | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PPE is appropriate to work being conducted | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Possible consequences of exposure are accurately listed | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Aerosol generating activities are listed & are properly mitigated | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | Common language is used; genus & species names are accurate | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | Is rDNA being administered? Check for pathogenicity, host range, treatment options | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
| **Section 8: Biological Toxins** | | | | | | | | | | | | | | | **N/A (PI not working with materials)** | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Toxins are appropriately identified | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | [Risk Group](https://my.absa.org/Riskgroups)/Biosafety Levels are appropriate | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Routes of exposure are listed | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PPE is appropriate to work being conducted | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Possible consequences of exposure are accurately listed | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Aerosol generating activities are listed & are properly mitigated | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |
|  |  | Select toxins do not exceed [CDC Permissible Amounts](https://www.selectagents.gov/PermissibleToxinAmounts.html) | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | |
|  |  | PI states Inventory is documented accurately: amount, location | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | Toxins are appropriately deactivated; see BMBL 5th Edition | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Toxins are reconstituted inside of containment; procedures listed | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | |
| **Section 9: Vertebrate & Invertebrate Animals** | | | | | | | | | | | | | | | **N/A (PI not working with materials)** | | | | | | | | | | | | | | | | | | | | | |
|  |  | IACUC committee approval initiated | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Common language is used; name, genus, species are correct | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Animal Biosafety Level reflects biological materials administered | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |
|  |  | Is rDNA being administered? Check for pathogenicity, host range, treatment options, NIH Guideline referenced | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
|  |  | Animal housing is appropriate | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Period of infectivity is listed appropriately: Lifetime (animals administered HSM ) v. 72hrs (animals administered viral vector) | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |
|  |  | Routes of shedding biological material is accurately listed | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
|  |  | PPE is appropriate to work being conducted | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Routes of exposure are listed | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Possible consequences of exposure are accurately listed | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Aerosol generating activities are listed & are properly mitigated | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
| **Section 10: Plants** | | | **N/A (PI not working with materials)** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Common language is used; name, genus, species are correct | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Plant Biosafety Level is accurate | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Is rDNA being administered? Check for pathogenicity, host range, NIH Guideline referenced | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Precautions to contain transgenic plants are appropriate; screens on greenhouses, short life of plants, etc. | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | |
|  |  | Housing is appropriate for plant life listed | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Biological materials administered are listed; included NIH reference | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | |
|  |  | Routes of exposure are listed | | | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Possible consequences of exposure are accurately listed | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Aerosol generating activities are listed & are properly mitigated | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | |
|  |  | PPE is appropriate to work being conducted | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | | | |
| **Section 11: Emergency Response** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI has received appropriate training for emergency response | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | |
|  |  | PI provides emergency response for exposures from sharps | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | PI provides emergency response for exposure to eyes or body | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | PI lists individuals to contact in event of exposure | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | Possible exposure outcomes are listed objectively | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | |
|  |  | PI provides response for after-hours exposures | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  |  | Overt exposures to recombinant materials BSL-2 or higher are immediately reported (to PI, IBC, BSO) | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
| **Section 12: Waste Disposal, Spill Response, Surface Decontamination & Laundry Service** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Section is filled completely | | |  | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI will use recommended waste disposal method | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | |
|  |  | PI listed alternative waste disposal method; approved by [EPA](https://www.epa.gov/pesticide-registration/selected-epa-registered-disinfectants), is validated & meets/exceeds standard procedure | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | | |
|  |  | PI will use recommended spill response method | | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | |
|  |  | PI listed alternative spill response method; procedure provides same amount of protection | | | | | | | | | | | | | |  | | | | | | | | | | | | | | | | | | | | |
|  |  | PI will use recommended surface decontamination method | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | PI will use alternative surface decontamination method; alternative chemicals approved by EPA for biological materials listed in application | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | |
|  |  | PI indicates laundry service; lab coats are not laundered at home | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | |
| **Section 13: Transport & Shipping** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI indicates use of recommended transport method | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Alternate transport methods will be used because standard method is not suitable; PI must provide detail | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | PI indicates use of recommended shipping method | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | | | |
|  |  | Alternate shipping method will be used because standard method is not available; PI must provide detail, meets DOT standards | | | | | | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | |
|  |  | PI has initiated a Material Transfer Agreement | | | | | | | | | | | | | Date: | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI has received appropriate training for transport/shipping | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
| **Section 14: Biological Material Storage Only** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | PI indicated storage only for some or all biological materials in possession | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Recombinant biological materials in storage are referenced in Section 5A: NIH Guidelines | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Toxins are inventoried | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Housing locations are appropriate for RG/BSL level | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Common language is used | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
| **Section 15: Additional Documents** | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | | |
|  |  | Plasmid vector map (backbone only required) | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Viral vector plasmid maps | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Training documents | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |
|  |  | Additional documents attached: | | | | | | | | | | | | | | | | | | | | | | | |  | | | | | | | | | | |

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| --- | --- | --- | --- | --- | --- | --- |
| **Reviewer:** | | | | **Date Reviewed:** | | |
|  | **Approve as Submitted** |  | **Request Changes (to secure approval)** | |  | **Request additional reviewer** |
|  | **Request convened IBC** |  | **Changes are minor points of order or clarification** | |  | **Revisions requested for re-review** |
| **Review Category:** | | | | | | |
| **Comments:** | | | | | | |