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| IBC Use Only | |
| Date Received: | BSL: |
| Protocol #:      IBC meeting date | |
| Approved?  Yes  No Date | |

**WESTERN UNIVERSITY**

**INSTITUTIONAL BIOSAFETY COMMITTEE**

**Registration of Research Involving the Use of Biological Materials**

**INSTRUCTIONS:**

**All submissions** – must be typed. E-mail the completed Word doc form to [IBC@westernu.edu](mailto:IBC@westernu.edu)  For questions or additional information email David Sanchez, Ph.D. at [sanchezd@westernu.edu](mailto:sanchezd@westernu.edu). Keep a copy of your submitted application for your records.

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| **SECTION I: GENERAL PROJECT INFORMATION** | | | |
| **APPLICATION STATUS:**   New  Renewal (every 3 yrs), previous IBC #: | | | |
| **Title of Protocol**: | | |  |
| Principal Investigator’s Name (last, first): | | Degree: | |
| Department: | | Position:  If not Faculty, you must identify a Faculty Sponsor and complete the information below | |
| Campus Address: | Email: | Emergency Phone: | Fax: |
| Office Phone: | | | Lab Phone: |
| Co-Principal Investigator’s Name (last, first): | | Degree: | |
| Department: | | Position: | |
| Campus Address: | Email: | Emergency Phone: | Fax: |
| Office Phone: | | Lab Phone: | |
| Alternate Contact Name (e.g., lab supervisor, etc): | | Email of Alternate Lab Contact: | |
| Office Phone or Lab Phone: | | Fax: | |
| Faculty Sponsor’s Name (Required if not faculty): | | Degree: | |
| Department: | | Email: | |

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| **COMMITTEE PARTNERS** | **Yes** | **N/A** | **Protocol #** | **Approval Date** |
| IRB (Institutional Review Board) for use of human subjects |  |  |  |  |
| ESCRO (Embryonic Stem Cell Research Oversight) |  |  |  |  |
| IACUC (Animal Research Committee) |  |  |  |  |
| Radiation Safety Committee |  |  |  |  |
| Other (specify): |  |  |  |  |
| Other (specify): |  |  |  |  |

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| **SECTION II: GENERAL SUMMARY OF PROJECT** | | |
| **Mark the materials that will be used in this project:** | **YES** | **NO** |
| Use of Recombinant DNA, gene transfer, host vector systems |  |  |
| Use of Infectious Agents (Bacteria, Virus, Yeast, Fungus, Prions, & Parasitic Agents) |  |  |
| Use of Human subjects |  |  |
| Use of Human/Nonhuman Primate Material (including blood, bodily fluids, tissues, excretions, secretions, or primary and established cell lines) |  |  |
| Use of transgenic or other genetically modified whole animals |  |  |
| Use of animals or animal specimens known to be reservoirs / vectors of zoonotic diseases |  |  |
| Use of CDC Select Agent or Toxins |  |  |
| Other (specify): |  |  |

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| **SECTION III: LABORATORY PERSONNEL** | | |
| **Name (Last, First)** | **Position Title** | **Describe responsibilities for this protocol** |
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| **SECTION IV: OCCUPATIONAL HEALTH/ IMMUNIZATIONS PROGRAM** |
| In accordance to the *NIH Guidelines* and CDC Biosafety in Microbiological and Biomedical Laboratories (5th ed):   * All persons entering the laboratory must be advised of the potential hazards and meet specific entry/exit requirements. * Laboratory personnel must be provided medical surveillance and offered appropriate immunizations for agents handled or potentially present in the laboratory. |
| 1. Identify how prospective workers/current workers will be educated about the biohazard(s) listed in this protocol. |
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| 1. If any, describe additional medical surveillance for personnel who are more vulnerable to infection with the agents listed in this protocol (e.g., non-vaccinated individuals, immunodeficient workers or non-immune pregnant female workers). |
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| 1. Describe applicable health surveillance/immunization programs that will be recommended or implemented for this protocol. *The IBC upon review may change any of these items based on currently available federal, state, and local occupational health. recommendations.* |
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| 1. In case of an exposure incident, describe the procedure that will be implemented for personnel to obtain consultation and treatment. |
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| **SECTION V: LOCATIONS OF STUDY** | | |
| 1. List ALL locations for this study and describe the general purpose of the room as it pertains to this protocol. | | |
| **Building** | **Room #** | **Describe Room Functions (i.e., tissue culture, animal handling, centrifuging, greenhouse**) |
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| **SECTION VI: RESEARCH DESCRIPTION** |
| The IBC is made up of a diverse group of members. It is therefore important to use language useful for a scientific evaluation as well as general enough to be understood by members with non-scientific backgrounds. Provide sufficient information to evaluate the work for the purposes of determining an appropriate biohazard risk assessment. **Copies from grant applications or abstracts will not be accepted.** |
| **1. List all Project/Grant Title(s):** |
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| **2. Please identify the source(s) of funding that will be used to support the research:** |
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| 1. **Provide a brief non-technical description and objectives of the research project that will enable the committee to fully understand your project. If this is a renewal, provide updated information.** |
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| **4. Describe in detail the procedures and techniques to be used in the research project. If applicable, incorporate description of any biohazards, animal work (in vivo and/or ex vivo), human subjects, or use of radiological materials. *Pay special attention to how biohazard risk will be minimized. Describe laboratory techniques that will be employed to contain biohazards and prevent spillage, needle sticks, aerosol formation (especially spills during centrifugation), contamination, and human exposure.*** |
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| 1. **Describe the laboratory safety procedures in detail. Disinfection should be performed using a 1:10 dilution of household bleach (use this language: final concentration of 0.5% sodium hypochlorite). Ensure that the following topics are covered thoroughly and answered next to the corresponding letters:**   **a. Waste disposal procedures**  **b. Type of disinfection and contact time**  **c. Personal protective equipment.**  **d. Engineered sharps protection used (safety needles, etc)** |
| a.       b.  c.  d. |
| 1. **Describe how materials will be safely transported to/from the laboratory. This includes if material is being transported between building on campus or between rooms in the same location. Generally describe all primary and secondary containers. If materials will be shipped to/from campus from off site, confirm that appropriate governmental permits have been obtained.** |
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| **SECTION VII: NIH GUIDELINES ASSESSMENT FOR RESEARCH INVOLVING RECOMBINANT DNA (rDNA)** |
| Mark the appropriate section(s) that describes this project. If experiment does not fall into any of these categories, contact David Sanchez, Ph.D. at (909) 469-8479 or [IBC@westernu.edu](mailto:IBC@westernu.edu). |
| III-A-1-a: The deliberate transfer of a drug resistance trait to microorganisms that are not known to acquire the trait naturally if such acquisition could compromise the use of the drug to control disease agents in humans, veterinary medicine, or agriculture. (Note that antibiotic resistance markers used for selecting and propagating plasmids in *E. coli* are not included.) |
| III-B-1: Experiments involving the cloning of toxin molecules with LD50 of <100ng per kg body weight (e.g., microbial toxins such as botulinum toxin, tetanus toxin). |
| III-C-1: Experiments involving the deliberate transfer of rDNA, or DNA or RNA derived from rDNA, into one or more human research participants.  **NOTE: Attach response to Points to Consider: Appendix M of the NIH Guidelines and submit any supplemental documents such as investigator brochure, clinical study, correspondence with NIH, etc.** |
| III‑D-1-a Introduction of rDNA into Risk Group 2 (RG-2) agents.  III‑D-1-b Introduction of rDNA into Risk Group 3 (RG-3) agents.  III‑D-2-a Experiments in which DNA from RG- 2, RG- 3 agents, or RG-4 agents is transferred into nonpathogenic prokaryotes or lower eukaryotes.  III‑D-3-a Use of infectious RG-2 viruses, or defective RG-2 viruses in the presence of helper virus.  III‑D-3-b Use of infectious RG-3 viruses, or defective RG-3 viruses in the presence of helper virus may be conducted at BL3 containment.  III‑D-3-d Use of infectious restricted pox viruses, or defective restricted poxviruses in the presence of helper virus shall be determined on a case-by-case basis following NIH/OBA review. A USDA permit is required for work with plant or animal pathogens.  III-D-3-e Use of infectious viruses, or defective viruses in the presence of helper virus, not covered in Sections III-D-3-a through III-D-3-d.  ***rDNA Involving Whole Animal***  III‑D-4-a rDNA, or DNA or RNA molecules derived therefrom, from any source except for greater than two‑thirds of eukaryotic viral genome may be transferred to any non‑human vertebrate or any invertebrate organism and propagated under conditions of physical containment comparable to BSL1 or BSL1‑N and appropriate to the organism under study. Animals that contain sequences from viral vectors, which do not lead to transmissible infection either directly or indirectly as a result of complementation or recombination in animals, may be propagated under conditions of physical containment comparable to BSL1 or BSL1-N and appropriate to the organism under study. Experiments involving the introduction of other sequences from eukaryotic viral genomes into animals are covered under Section III-D-4-b. Investigator must demonstrate that the fraction of the viral genome being utilized does not lead to productive infection.  III‑D-4-b Experiments involving rDNA, or DNA or RNA derived therefrom, involving whole animals, including transgenic animals, and not covered by Sections III-D-1 or III-D-4-a, may be conducted at the appropriate containment determined by the IBC.  III‑D-4-c-1 Experiments involving the generation of transgenic rodents that require BSL1 containment.  III‑D-4-c-2 Purchase or transfer of transgenic rodents is exempt from the “NIH Guidelines”, but register with the IBC (Form 4).  III‑D-6 Experiments involving more than 10 liters of culture. The appropriate containment will be decided by the IBC. |
| III‑E‑1 Experiments involving the formation of rDNA molecules containing no more than 2/3 of the genome of any eukaryotic virus (All viruses from a single Family being considered identical.) may be propagated and maintained in cells in tissue culture using BSL1.  **III-E-2-b-(5)** Experiments with rDNA-modified arthropods or small animals associated with plants, or with arthropods or small animals with rDNA-modified microorganisms associated with them if the rDNA-modified microorganisms have no recognized potential for serious detrimental impact on managed or natural ecosystems.  **II‑E-3** Experiments involving the generation of rodents in which the animal’s genome has been altered by stable introduction of rDNA, or DNA derived therefrom, into the germ0line (transgenic rodents). |
| **Section III-F EXEMPT EXPERIMENTS**  III‑F‑1 Synthetic nucleic acids that are not replication-competent or integration competent.  III‑F‑2 Naked rDNA molecules that are not within organisms, cells, or viruses.  III‑F‑3 An exact rDNA copy of a naturally existing DNA molecule.  III‑F-4 rDNA molecules that consist entirely of DNA from one prokaryotic host, when propagated only in that host.  III‑F‑5 rDNA molecules that consist entirely of DNA from one eukaryotic host, when propagated only in that host (but excluding viruses).  III‑F‑6 rDNA molecules that consist entirely of DNA segments from different species that exchange by known physiological processes.  III‑F‑7 Genomic DNA molecules that have acquired a natural transposable element.  III‑F‑8 Classes of experiments described in Appendix C, including: Appendix C-I (Recombinant or Synthetic Nucleic Acid Molecules in  Tissue Cultures); Appendix C-II (Escherichia coli K-12 Host-Vector Systems); Appendix C-III (Saccharomyces Host-Vector Systems);  And other appendices. |
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| **SECTION VIII: RECOMBINANT DNA/ VECTOR STUDIES** | | | |
| **1. Vector Source**  (check all that apply): | PI’s Laboratory  Commercial Vendor  Other (specify – PI’s Name and/or facility): | | |
| ***Host(s)***  ***Indicate the host into which the recombinant material (rDNA, RNA, or virus) will be introduced. (i.e., E.coli, mouse, human, virus)*** | | **Vector(s)**  **Which of the following host vector system will be used for this research? (i.e. bacterial plasmids, baculovirus, viruses)** | **DNA Sequence(s)**  **List names of genes segments of DNA that will be studied** |
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| 1. **Will an attempt be made to purify any of the foreign gene product(s) encoded by the gene?**   Yes No |
| 1. **If yes, indicate which foreign gene product will be purified and describe the procedure for purification:** |
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| 1. **If a virus-derived vector system that is engineered to be replication-incompetent will be used, please explain below how this has been achieved using details, maps, references, etc. Also, describe how you will assure that your vector material is free from contamination by replication-competent virus (RCV).** |
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| **SECTION IX: INFECTIOUS MATERIALS** | | | | | | |
| **If working with any of the following materials, list each item separately for containment determination (attach additional page if needed):** | | | | | | |
| **Name of Material**  **(Identify genus, species, strain, or known contaminants, etc)** | **Risk Group** | **Source**  **(i.e. Clinical specimen, commercial vendor [be sure to list actual vendor name], Lab, Collaborator)** | **Biosafety Level** | **Animal Experiment** | | **Large Scale (>10L of culture)** |
| **Host Species** | **Containment**  **(ABSL1 – 3)** |
| **e.g. Lentivirus (3rd generation)** | **2** | **Commercial Vendor (be sure to list actual vendor name)** | **BSL2** | **Mouse**  **Rat** | **ABSL2**  **ABSL2** | **N/A** |
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| **SECTION X: HUMAN/ NON HUMAN PRIMATE MATERIAL** | | | | | | |
| **List Human/ Non Human Primate Material – must be handled under BSL-2 Conditions**  As indicated in the Cal-OSHA Bloodborne Pathogen Standard, all employees with occupational exposure to any of the materials listed above must complete annual Bloodborne Pathogens training. | | | | | | |
| **Material – List each material per line**  *e.g. Established cell line* | **Type**  *e.g. HEK* | **Source**  *e.g. Human* | **Origin of materials**  *e.g. Clinical specimens, commercial vendor, primate center, field)* | **Known Pathogens**  *e.g. None* | **Building**  *e.g. HPC* | **Room**  **Number**  *e.g.123* |
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| **SECTION XI: TRANSGENIC/ GENETICALLY MODIFIED ANIMALS** |
| **Describe (procedure and technique) how the transgenic animal will be created. If this involves viral vector constructs, complete the rDNA section of this application.** |
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| **Identify the location where the transgenic animal will be created. If off-site, provide the institution name and address.** |
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| **For each transgenic animal created, provide the following information:**  **Species, Gene Name and Function, the Biological Source of the gene, Type, source of the transgenic animals, the associated hazard, and the precautions animal handlers must follow to prevent accidental exposure.** |
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| **SECTION XII: SELECT AGENTS AND TOXINS** |
| *Attach a Material Safety Data Sheet (MSDS) or provide a web link for each agent* |

**To obtain the latest Select Agent list:** [**http://www.selectagents.gov/agentToxinList.htm**](http://www.selectagents.gov/agentToxinList.htm)

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| Agent/Toxin Name | Viable | | Genomic Material | | rDNA | Small Animal | Large Animal | Large Scale | Lab Area | Storage Area | Lab Safety Level\* | How is agent/ toxin obtained | Provide name and address of vendor/ collaborator | Facility agent ID | Amount Purchased | Physical stage of agent | Beginning concentration | Final concentration  use | |
| e.g. Ricin | **Indicate with an “X” for each agent** | | | | | | | | Building/Room | Building/Room |  | Purchased |  |  |  |  |  |  | |
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| 1. Yes | | No | | Will you be working with isolates/concentrates or recombinant DNA of any Select Agents as part of your work with these Select Agent Toxins? | | | | | | | | | | | | | | |
| 1. Yes | | No | | Have you transferred the Select Agent outside the U.S. during the past 3 years? | | | | | | | | | | | | | | |

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| 1. **Describe the type of work being done with Select Agent(s) listed above (1-2 sentences only)** |
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| 1. **Describe how access is controlled to the lab area where Select Agent(s) are used** |
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1. Physical Security (check all apply):

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| **a. Means to limit access to buildings with Select Agents and Toxins:**  Locks Card access system Biometric system  Intrusion detection system Other (describe): | **b. Means to limit access to rooms with Select Agents and Toxins:**  Locks Card access system Biometric system Intrusion detection system  Other (describe): |
| **c. Means to limit access to Select Agents and Toxins inside the room:**  Locked incubators, refrigerators, freezers, etc.  Locked box inside incubators, refrigerators, freezers, etc. Biometric system  Card access system Intrusion detection system  Other (describe): | **d. Means to monitor access to areas where Select Agents and Toxins are used or stored**  Electronic logs of access Manual sign in logs Video camera surveillance  Other (describe): |

***Use your mouse instead of the tab button to go in between question 6-10***

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| 1. **Describe how adequate training and proficiency testing for personnel working with the Select Agents is ensured.** |
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| 1. **Describe the dilution procedures.** |
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| 1. **Describe the safe handling and disposal procedures that will be used for this agent.** |
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| 1. **Where are Select Agent(s) stored (e.g., location of refrigerators, freezers, other storage)?** |
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| 1. **Describe the air handling system for the laboratory where work will be performed (e.g., single pass or recirculation, type of**      **filters, method for handling safety cabinet & fume hood exhaust).** |
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| **SECTION XIII: Executive session. In exceptional cases the IBC may conduct the review of the protocol in executive session, with only the committee members present. Do you have any special reason that makes confidentiality essential and would require a closed meeting? If so please provide justification.** |
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| **SECTION XIV: PROGRESS REPORT – MUST BE COMPLETED IF THIS IS A RENEWAL** |
| **Please indicate the statement that applies to your project:**  **1.**  **YES**  **NO  NOT APPLICABLE Have any adverse events occurred in the last approval period?**  **2.  YES  NO  NOT APPLICABLE Have there been any overt spills related to this protocol?**  **If yes, please provide details of events (including notification being sent to the IBC) and what was done to prevent this type of event from recurring?**    **3.  YES  NO Have there been any accidental exposures related to this protocol, not limited to your lab staff?**  **If yes, please provide details of events (including notification being sent to the IBC and/or Worker’s Compensation) and what was done to prevent this type of event from recurring?**    **4.  YES  NO Has there been accidental release to the environment of any of the regulated biohazard agent including transgenic animals/plants related to this protocol?**  **If yes, please provide details of events (including notification being sent to the IBC and/or other oversight committees) and what was done to prevent this type of event from recurring?**    **5.  YES  NO Were any of these events described above reported to the IBC immediately following the incidents? If no, please explain.** |

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| **SECTION XV: PRINCIPAL INVESTIGATOR’S ASSURANCE** | |
| 1. I attest that the information contained in the attached application is accurate and complete to the best of my knowledge. 2. I agree to comply with the requirements pertaining to the possession, use, transfer, and disposal of all regulated biologically hazardous materials in accordance to all applicable federal, state, and local laws and regulations and Western University policies and procedures. 3. I have read and understand my responsibilities as Principal Investigator outlined in Section IV-B-7 of the NIH Guidelines and agree to comply with these responsibilities. 4. I attest that prior to the start of this project, all persons involved (including my collaborators) will be:  * adequately trained in good microbiological techniques and practices, * have received instruction on any specific hazards associated with the project and worksite, * aware of any specific safety equipment, practices, and behaviors required for the procedures and use of the facilities, and * familiar with appropriate emergency procedure response (e.g., spills, accidental exposure, environmental release) to ensure safety will be followed.  1. I hereby adopt the current edition of CDC/NIH Biosafety in Microbiological and Biomedical Laboratories as the principal biosafety manual for my laboratory with laboratory specific standard operating procedures, or, I will provide a supplemental manual in addition to, or in place of, the CDC/NIH manual as deemed necessary or when specifically requested by the IBC. I understand that this biosafety manual must be approved by the IBC before research can commence. 2. I will abide by the reporting requirements and submit a report to the IBC for activities that may include, but not limited to the following:  * All accident that results in exposure to the infectious agents or recombinant DNA or danger of environmental contamination. * All spills outside a physical containment equipment (e.g., outside biosafety cabinet, outside centrifuge, etc). * All problems pertaining to operation, implementation of containment safety procedures or equipment, facility failure, or breach in security (facility and/or biological agent). * Any new information bearing on the Guidelines such as technical information relating to hazards and safety procedures or innovations.  1. I understand my responsibility with regard to laboratory safety and certify that the protocol as approved by the IBC will be followed during the period covered by this research project. I certify that no work will be initiated or modified until approval has been issued by the IBC, other appropriate oversight committees and all sponsoring agency requirements have been met. | |
| **Signature of Principal Investigator (must be original)** | **Date:** |
| **Signature of Faculty Sponsor (Required if PI is non-Western University faculty)** | **Date:** |