Risk Assessment Summary **IBC-09-000** *(to be assigned by EHS)*

PI Name, Dept., Position, Phone # and Fax #

 "Protocol Title"

Subcommittee Review By: *(To be assigned by IBC)*

**Protocol summary:**  *(A summary, in* ***lay*** *terms, of the proposed project which highlights the safety measures to be taken when conducting experimentation. As an attachment please also provide a copy of your “methods” and any relevant copies of citations or articles. Please define* ***all*** *acronyms.)*

**Biological agents involved:**

Viruses- Specific name, strain, concentration, bioengineered safety controls, source info.

Bacteria- Specific name, strain, quantity, bioengineered safety controls, source info.

Fungi- Specific name, strain, quantity, bioengineered safety controls, source info.

Parasites Specific name, quantity, bioengineered safety controls, source info.

Cell lines/strains Specific name, strain, quantity, bioengineered safety controls, source info.

Human Subjects Purpose for use, systems to be used, CPHS Approval #

Animals Specific name, strain, housing, bioengineered safety controls, source, AWC Approval #

(Transgenic/ KO)

For recombinant DNA, please complete the following table:

|  |  |
| --- | --- |
| **Biological agents** | Agent, strain, concentrations to be used, source info |
| **Manipulations**  | Example: Cloning of protein X into adenoviral vector |
| **Agent characteristics** | Antibiotic resistance? Toxin producing? Unique strain characteristics? Bioengineered safety controls? |
| **Source of inserted DNA sequence** | Please list |
| **Nature of inserted DNA sequence** | Example: Structural gene |
| **Host(s) to be used** **Vector(s) to be used** | Example: Host - rat cardiomyocytes and HEK 293; Example: Vector - adenovirus serotype V vector |
| **Expression of foreign gene, if so protein produced** | Example: Proteins associated with programmed cell death and cardiolipin synthesis: cardiolipin synthase and BLC2 |
| **BSL Level** | BSL-? |

*Please copy and paste this table for more space or multiple rDNA constructs.*

**Applicable Regulations/Guidelines/References:** NIH Guidelines for Research Involving Recombinant DNA Molecules (April 2002) as amended, CDC-NIH Biosafety in Microbiological and Biomedical Laboratories (5th Ed., 2007), and UTHSC-H Biosafety Manual.

**Biosafety Level (BSL):** BSL-?

**NIH Guidelines** (<http://oba.od.nih.gov/oba/rac/guidelines_02/NIH_Guidelines_Apr_02.htm> )**:**

*Please refer to the NIH Guidelines for PI’s document and indicate appropriate section* (<http://www.uth.tmc.edu/safety/biological_safety.html>).

Section III-

**AWC/CPHS approval:** *(Please list AWC/CPHS approval numbers related to this protocol)*

**Personnel:** *(Please list each person who will be participating on the project along with a summary of education, experience and training as it relates to the use of the proposed biological agents. Please indicate where applicable all persons not employed through UTHSC-Houston.)*

**Protective equipment:** *(Please provide a summary of your intended personal protective equipment including locations and certification dates for biological safety cabinets.)*

**Location of work:** *(Room #’s for all work areas, storage, animal housing, autoclave locations, and BSC locations)*

**Biological waste disposal:**  *(Describe waste disposal / disinfection practices and methods for transport of waste through the facility for disposal.)*

**Lab Status:** *(To be determined by EH&S)*

**Shipping Infectious Substances (if any):** *(Please indicate whether you intend to ship or receive infectious substances. Please note crossing any public road is considered shipping, and this includes hand carrying samples to or from UT- MDACC.)*

**Conditions (if any):** *(To be determined by IBC and EH&S. Required training such as Basic Lab Clinical Safety and Bloodborne Pathogens training are most often cited here.)*

**Date received (for review):** *(Date application is received by EH&S.)*

**Projected start date:** *(Your projected start date.)*