

RESEARCH PROTOCOL SAFETY SURVEY

PRINCIPAL INVESTIGATOR (PI):

PROJECT TITLE:

SUBMISSION DATE:

HSC #:

Protocol #:

LIST VA AND NON-VA LOCATIONS WHERE THIS RESEARCH WILL BE CONDUCTED:

South Texas Veterans Health Care System, Rooms:

University of Texas Health Science Center, Rooms:

Other:

Does the protocol involve any of the following?

- | | | |
|--|-----|----|
| 1. Biological Hazards (microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6, or animals) | YES | NO |
| 2. Cells, Tissue, Blood and Other Body Fluids | | |
| (a) Human cells (including cell lines), tissue samples, and body fluids (including blood) | YES | NO |
| (b) Animal cells (including cell lines), tissue samples, and body fluids (including blood) | YES | NO |
| 3. Recombinant and/or Synthetic Nucleic Acid Molecules | YES | NO |
| (a) Is this a human gene therapy study? | YES | NO |
| (i) If yes, complete UT IRB Form Q-1 and provide all documents listed under checklist for human gene therapy studies. | | |
| 4. Chemical Hazards (excluding medications) | | |
| (a) Toxic chemicals (including heavy metals) | YES | NO |
| (b) Flammable, explosive, or corrosive chemicals | YES | NO |
| (c) Carcinogenic, mutagenic, or teratogenic chemicals | YES | NO |
| (d) Toxic compressed gases | YES | NO |
| (e) Acetylcholinesterase inhibitors or neurotoxins | YES | NO |
| (f) Inhalation anesthetics | YES | NO |

5. Controlled Substances (substances regulated by the Drug Enforcement Agency- DEA)	YES	NO
6. Medications with the potential to cause harm to those admixing or administering them (including chemotherapeutic agents, caustic agents, teratogenic agents)	YES	NO
7. Ionizing Radiation (research personnel exposure only):		
(a) Radioactive materials	YES	NO
(b) Radiation generating equipment	YES	NO
8. Nonionizing Radiation (research personnel exposure only):		
(a) Ultraviolet light	YES	NO
(b) Lasers (Class 3B or Class 4)	YES	NO
(c) Radiofrequency or microwave sources	YES	NO
9. Physical Hazards:		
(a) Are any research personnel DELINQUENT in annual training addressing physical standards?	YES	NO

Note: Physical hazards are addressed in the facility Occupational Safety and Health Plan. All employees must receive annual training addressing physical standards.

If all answers are NO the PI must sign the Acknowledgement of Responsibility and Knowledge on the last page and submit pages 1 & 2 with the signature page for review and approval by the local Subcommittee on Research Safety.

If the answer to any of the above questions is YES, complete all applicable sections of this survey, the PI must sign the Acknowledgement of Responsibility and Knowledge on the last page and all pages must be submitted for review and approval by the local Subcommittee on Research Safety.

NOTE: R&D Committee and all appropriate subcommittee (i.e. IRB, IACUC) approvals are required prior to initiation of the protocol.

1. BIOLOGICAL HAZARDS

Does your research involve the use of microbiological or viral agents (including those used to express exogenous nucleic acids), pathogens, toxins, poisons, or venom YES NO

Provide location where microbiological or viral agents will be used here:

If **NO**, skip to the section on **CELLS, TISSUES, BLOOD AND OTHER BODY FLUIDS**

If **YES**,

- (a) Provide location where microbiological or viral agents will be use here:

- (b) It is the responsibility of each PI to:
 - i. Consult either:
 1. The National Institutes of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or
 2. The CDC Guidelines online reference (<http://www.cdc.gov>);
 - ii. Identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin;
 - iii. Enter requested information in the following table. Note if you have more than one toxin, organism or agent, use a separate page to describe the remainder:
- (c) Please fill out chart on next page (4)

Organism, Agent, or Toxin	Biosafety Level* (also called Risk Group)	If a select agent**; provide the CDC Lab Reg # and the date of CDC inspection	Largest volume or concentration to be used	Indicate if antibiotic resistance will be expressed in the organism or agent, and the nature of this antibiotic resistance	Describe the containment equip (specify protective clothing or equipment, biological safety cabinets, fume hoods, containment centrifuges, etc) to be used in this research	Describe the proposed methods to be employed in monitoring the health and safety of personnel involved in this research

*For **each Biosafety Level 2 or 3 agent or toxin** listed, provide the additional requested information. (Description of Biosafety Levels 2 and 3 can be found in Appendix A.)

**Select Agents (42 CFR 72.6) are classified by The Centers for Disease Control

2. CELLS, TISSUES, BLOOD AND OTHER BODY FLUIDS

Will this study involve working with human or animal blood, body fluids, organs, tissues, cell lines, or cell clones (check all that apply). Do any of those above check boxes present a biohazard? YES NO

(1) Specify all the potential biohazards exposures from this research:

(2) Specify the precautions that will be used to protect personnel from these biohazards (check all that apply): mask gloves gown goggles

other, specify

3. RECOMBINANT AND/OR SYNTHETIC NUCLEIC ACID MOLECULES

Does this protocol involve the use of recombinant and/or synthetic nucleic acid molecules?
YES NO

If **NO**, skip to the section on **CHEMICAL HAZARDS**

If **YES**, Is this a human gene therapy study? YES NO

If **YES**, complete UT IRB Form Q-1 and provide all documents listed under checklist for human gene therapy studies

If **NO**, are recombinant and/or synthetic nucleic acid molecules procedures for this protocol limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES NO

If **YES**, your recombinant and/or synthetic nucleic acid molecules studies are exempt from restrictions described in the *NIH Guidelines for Research Involving Recombinant DNA Molecules*.

If **NO**, it is the responsibility of each PI to:

a) Provide location and room # for conducting this portion of research:

b) Consult the current *NIH Guidelines for Research Involving Recombinant and/or Synthetic Nucleic Acid Molecules* which can be found at the Internet site <https://osp.od.nih.gov/biotechnology/nih-guidelines/>

c) Identify the experimental category of their recombinant and/or synthetic nucleic acid molecules research.

d) Describe the recombinant and/or synthetic nucleic acid molecules procedures

e) Enter requested information in the following table:

Brief description and NIH classification for these recombinant and/or synthetic nucleic acid molecules procedures	Biological source of Recombinant and/or synthetic nucleic acid molecules insert or gene	Function of the insert or gene	Vector(s) used or to be used for cloning (e.g., pUC18, pCR3.1)	Host cells and/or virus used or to be used for cloning (e.g., bacterial, yeast or viral strain, cell line)

4. CHEMICAL HAZARDS

Does this protocol involve the use of **hazardous** chemicals? YES NO

If **NO**, skip to the section on **CONTROLLED SUBSTANCES**

If **YES**:

(1) Complete the following table or use plain bond paper attachment for additional chemicals and provide location for where hazardous chemicals will be used in your research:

List all hazardous chemicals to be utilized in this protocol	List the precautions that will be used to protect research personnel from the potential chemical exposure	Describe the standard operating procedure (SOP) for use and disposal. If necessary provide attachment.

(2) Are research personnel knowledgeable about the special hazards posed for all the above listed chemical hazards?

YES NO

(3) Are all chemicals listed above on your submitted "laboratory chemical inventory" on file in the VA Research and Development Office?

YES NO

(4) Has the use of chemicals in your laboratory been reviewed by an appropriate committee or subcommittee within the past 6 months? YES NO

***NOTE:** Submission of the laboratory chemical inventory is required for local review.*

5. CONTROLLED SUBSTANCES

Does this protocol involve the use of any substance regulated by the Drug Enforcement Agency?

YES NO

If **NO**, skip to the schedule on MEDICATIONS

If **YES**, provide location where controlled substances will be used:

***NOTE:** The schedule of controlled substances can be found at the Internet site <http://www.usdoj.gov/dea/pubs/schedule.pdf>.*

Acknowledgement of Responsibility and Knowledge

I certify that my research studies will be conducted in compliance with and full knowledge of Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. I further certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OSHA) and Environmental Protection Agency (EPA)-regulated hazardous chemicals is attached to this survey.

Principal Investigator's Signature

Date

This safety survey does not have safety issues as verified by Research office and the SRS Administrator and does not require safety committee review: Research Office: _____

Administrator: _____

Certification of Safety Officer's Approval

A complete list of chemicals to be used in the proposal has been reviewed. Appropriate occupational safety and health, environmental, and emergency response programs will be implemented on the basis of the list provided.

Safety Officer's Signature

TERRY MEEKER, REM, CHMM

Date

Certification of Research Approval

The safety information for this application has been reviewed and is in compliance with Federal, State, and local policies, regulations, and CDC-NIH Guidelines governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional review forms used locally are available from the Research and Development (R&D) Office.

ELIZABETH FERNANDEZ, PhD
Chair, Subcommittee on Research Safety

Date

ROBERT CLARK, M.D.
Chair, Research and Development Committee

Date

CLINTON ABELL, MHP
Radiation Safety Officer (if applicable)

Date

TERRY MEEKER, REM, CHMM
Facility Safety Officer

Date