

**Providence VA Healthcare System
Research Safety Continuing Review/Study Closure**

Version 6.10.2015

1. Principal Investigator, Name and Degree :				
2. Project Title:				
3. Date of Submission:				
4. Project is <u>Active</u> and you are submitting a Continuing Review:	<input type="checkbox"/> Please complete the remainder of the form.			
Project is <u>Terminated</u> and you are submitting a Study Closure:	<input type="checkbox"/> Please complete the following 3 items: a) Provide a final abstract with progress results on page 4. b) Provide the disposition of each chemical, bacteria, tissue culture, used in this protocol. Please specify if they are to be disposed of or used for other/future studies c) Sign/date this form (no other information is required).			
5. Location(s) where this project will be conducted:		Building(s)/Room(s):		
<input type="checkbox"/> Other(s): Please list: (The committee reserves the right to ask for documentation of safety authorization from other facilities.)				
6. For projects involving laboratory procedures, please provide:				
a. List all personnel working on this project and check the appropriate box. Any individual no longer working on this project is considered "Inactive". "Existing" personnel were listed on the New Protocol or last Continuing Review form. *Required training/documents should be on file with the Research Training Coordinator*				
	Name	NEW	EXISTING	INACTIVE
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
7. The following items are required to be submitted by the PI for Continuing Reviews and Approval to the Subcommittee on Research Safety:				
A.	An updated VA-Abstract using lay persons terms describing methodology, procedures, and findings to date. Please date the abstract.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
B.	A copy of the <u>original</u> , approved, signed Research Protocol Safety Survey Form (Biosafety Form - VA Form 10-0398) Form. If unavailable/missing, please notify the Research Safety Office immediately.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
C.	A copy of all Standard Operating Procedures (SOP's) for the study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
D.	A copy of all approved Amendments, if any, to the above Research Protocol Safety Survey Form (Biosafety Form).	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
E.	A copy of the laboratory Chemical Inventory. Please <u>highlight/identify</u> all chemicals used in this study.	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A
F.	Is the Research Chemical Hygiene Plan (CHP) available in your specific laboratory?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> N/A

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8. The research continues to involve the following:					If you would like to change an item, check Amendment and submit a revised Research Safety Form for approval.
A.	Biological Hazards (Microbiological or viral agents, pathogens, toxins, select agents as defined in 42 CFR 72.6, or Animals)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
B.	Human or Non Human Cell or Tissue Samples (including cultures, tissues, blood, other bodily fluids or cell lines)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
C.	Recombinant DNA	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
a.	Procedures are limited to PCR	<input type="checkbox"/> Yes	<input type="checkbox"/> No		
D. Chemicals					
(1)	Toxic Chemicals (including heavy metals)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(2)	Flammable, explosive, or corrosive chemicals	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(3)	Carcinogenic, mutagenic, or teratogenic chemicals	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(4)	Toxic compressed gases	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(5)	Acetylcholinesterase Inhibitors or Neurotoxins	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
E.	Controlled Substances	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
F. Ionizing Radiation					
(1)	Radioactive materials	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(2)	Radiation generating equipment	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
G. Nonionizing Radiation					
(1)	Ultraviolet Light	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(2)	Lasers (Class 3b or Class 4)	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
(3)	Radiofrequency or microwave sources	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	
H.	Transport of Biological Substances	<input type="checkbox"/> Yes	<input type="checkbox"/> No	<input type="checkbox"/> Amendment	

I. Radioactive Materials (RAM) (If use of Radiation Permit)

Does your research involve the use of radioactive materials? YES NO

If YES, please answer the following:

1. Are you currently the: "Primary Authorized User (AU)" listed on the Permit? YES NO OR
Are you a "Supervised Individual" (i.e. "listed co-worker") listed on the permit? YES NO

2. Who is the AU by whom you are designated as a "Supervised Individual to use RAM?"

3. List all "Supervised Individuals" who will actually be using RAM on this protocol.

4. List all radionuclides and max quantities to be used in this protocol.

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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 bio-hazardous 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 bio-hazardous materials, chemicals, radioisotopes, and physical hazards. A chemical inventory of all Occupational Safety and Health Administration (OSHA) and Environmental Protection (EPA) regulated hazardous chemicals is attached to this survey.

Required: Principal Investigator Printed Name and Signature

Date

AUTHORIZED USER CERTIFICATION – IF USE OF RADIATION PERMIT

I certify that I am the Authorized User on the Radiation Permit and have reviewed this protocol.

Authorized User Printed Name and Signature (applicable only if using radioactive materials - RAM)

Date

Certification of Research Training Approval

A complete list of training documents pertaining to the **safety training required for this proposal** has been reviewed. A database containing an accurate listing of required training and date of completion is maintained in the Research Office is current, and available upon request.

Research Training Coordinators Printed Name and Signature (applicable only if there is a safety component) Date

Certification of Research Safety Officer's Approval

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

Research Safety Officer's Signature (applicable only if there is a safety component and chemicals are involved)

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 bio-hazardous materials, chemicals, radioisotopes, and physical hazards. Copies of any additional surveys used locally are available from the Research and Development (R&D) Office.

Radiation Safety Officer (if applicable)	sign and print	Date
Facility Safety Officer	sign and print	Date
Chair, Subcommittee on Research Safety	sign and print	Date
Chair, Research & Development Committee	sign and print	Date

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Providence VAMC Abstract

Title of Study:

Principal Investigator: _____ Date: _____

(Please use layperson terms and verbiage when describing your research)

Instructions: An electronic abstract (<500 words) in this format is required for each type of submission. **(For SRS Committee Review:** This document, **with original signatures**, and all other SRS submission requirements should be emailed to Candace.Shuman@va.gov and ALL originals placed in her mailbox in Building 35).

OBJECTIVE

RESEARCH PLAN

METHODS

CLINICAL RELEVANCE (basic science studies only).

PROGRESS

LIST OF ABBREVIATIONS AND ACRONYMS USED: Provide a list and definition of the abbreviations and acronyms used in the abstract.