

JOHN D. DINGELL VA MEDICAL CENTER
Animal and/or Basic Science
RESEARCH AND DEVELOPMENT
RESEARCH APPLICATION

Required submissions for FULL COMMITTEE review ORIGINAL AND ONE COPY of the following:

1. **Request to Review Research Proposal**
2. **Abstract – (500 words or less, on a separate sheet and also email to either robert.molitoris@va.gov or patricia.fox2@va.gov under the following headings: Objectives, Research Plan, Methods, and if a basic science study, Clinical Relevance)**
3. **Complete Protocol**
4. **A copy of the WSU IACUC forms, if an animal study.**

WSU's IACUC Form and the VA ACORP Form are available at <http://iacuc.wayne.edu/forms-and-documents.php>.

Both WSU and the VA have required animal training – WSU has required initial training and the VA has required annual training at www.citiprogram.org.

If you have any questions or concerns please call (313) 576-1000, x64474.

New Investigators: Please complete and submit an Investigator Data Sheet (Below).

DO NOT COMPLETE AND SUBMIT THIS FORM IF YOU NOW OR IN THE PAST HAVE HAD AN ACTIVE VA STUDY.

DEPARTMENT OF VETERANS AFFAIRS
Research and Development Information System
Investigator Data 553 Detroit, MI

COMPLETE ONLY IF NEW INVESTIGATOR (PAGE 18) (fill in by hand)

1. Name: (Last) _____ (First) _____ (MI) _____ (Degree) _____	2. SSN _____
3. VA Title:	
4. University Appointment:	
a. Academic Rank <i>(Enter Code From Table 4a)</i>	Code _____ <i>If Code = 99, Enter Academic Rank (If Code #00, Skip to Item 5)</i>
b. University Administrative Title <i>(Enter Code From Table 4b)</i>	Code _____ <i>If Code = 99, Enter University Administrative Title</i>
c. University Department	_____ <i>(Enter Name)</i>
d. University Section/Division	_____ <i>(If applicable, enter Name)</i>
e. University	_____ <i>(Enter Name)</i>
5. Degrees: <i>(Check HIGHEST degrees only)</i>	<input type="checkbox"/> MD <input type="checkbox"/> Ph.D. <input type="checkbox"/> DDS/DMD <input type="checkbox"/> DVM <input type="checkbox"/> SCD <input type="checkbox"/> PharmD <input type="checkbox"/> Ed.D. <input type="checkbox"/> MPH <input type="checkbox"/> MA/MS <input type="checkbox"/> MN <input type="checkbox"/> MSW <input type="checkbox"/> BSN <input type="checkbox"/> RN <input type="checkbox"/> OTHER
6. Diplomate Status, Board Certified <i>(See Instructions, item 6)</i>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Not Applicable
7. Specialty: <i>(Enter Code from Table 7)</i>	Code _____ <i>If Code = 99, Enter Specialty</i>
8. Subspecialty: <i>(Enter Code from Table 8)</i>	Code _____ <i>If Code = 99, Enter Subspecialty</i>
9. VA Employment: <i>(Check One)</i>	<input type="checkbox"/> Full-Time <input type="checkbox"/> Part-Time; <input type="checkbox"/> Hrs. /Week <i>(If Part-Time, enter hrs/wk)</i> <input type="checkbox"/> Consultant <input type="checkbox"/> Contract <input type="checkbox"/> WOC
10. Salary Source:	<input type="checkbox"/> VA Funds Other Than R&D <input type="checkbox"/> Rehab R&D <i>(Program 822)</i> <input type="checkbox"/> Medical Research <i>(Program 821)</i> <input type="checkbox"/> Clinical Research <i>(Program 829)</i> <input type="checkbox"/> HSR&D <i>(Program 824)</i> <input type="checkbox"/> Not Salaried by VA
11. Hospital Service:	_____ Code _____ <i>If Code = 99, Enter Hospital Service</i>
12. Primary Research Interest:	_____ Code _____ <i>If Code = 99, Enter Primary Research Interest (Do not use Code 00)</i>
13. Secondary Research Interest:	_____ Code _____ <i>If Code = 99, Enter Secondary Research Interest</i>
14. Research Involves: <input type="checkbox"/> Human Immunodeficiency Virus <input type="checkbox"/> Any Other Retrovirus <input type="checkbox"/> Recombinant DNA	
15. Mailing Address: _____	
16. Email Address: _____	
Investigator's Signature _____	Date _____

INVESTIGATOR CODES FOR PAGE 18

Table 5a - Academic Rank - The default Academic Rank for each Series is shown. If actual rank is different, or code is 06, enter name.

01 = Instructor Series	03 = Assistant Professor Series	05 = Professor Series	00 = None
02 = Lecturer Series	04 = Associate Professor Series	06 = Resident/Fellow/Trainee/Other	

Table 5b - University Administrative Title: The default University Administrative Title for each Series is shown. If actual title is different, or code is 99, enter name.

01 = Department Chair Series	02 = Division Chief Series	03 = Dean Series
99 = Other (Specify)	00 = None	

6. DIPLOMATE STATUS, BOARD CERTIFIED: Physicians, Dentists, and Psychologists - Check YES or NO

Table 7 - Specialty - Select Board or area of training or expertise. If 99 are selected, enter name in space provided.

01 = Allergy & Immunology	70 = Emergency Medicine	34 = Nursing	51 = Physiology
66 = Anatomic Pathology	16 = Endodontics	35 = Obstetrics/Gynecology	52 = Plastic Surgery
67 = Anatomic & Clinical Pathology	17 = Engineering	71 = Occupational Medicine	53 = Preventive Medicine
02 = Anatomy	18 = Epidemiology	36 = Oncology	54 = Public Health
03 = Anesthesiology	19 = Family Practice	37 = Operations Research	55 = Prosthodontics
04 = Anthropology	20 = General Practice	38 = Ophthalmology	56 = Psychiatry
05 = Audiology	21 = Genetics	39 = Optometry	57 = Psychology
06 = Biochemistry	22 = Geriatrics	40 = Oral Pathology	73 = Radiation Oncology
07 = Bioengineering	23 = Health Care Administration	41 = Oral Surgery	58 = Radiology
08 = Biology	24 = Health Economics	42 = Orthopedic Surgery	59 = Rehabilitative Medicine
09 = Biophysics	25 = Histology	43 = Osteopathy	60 = Social Work
10 = Biostatistics	26 = Immunology	44 = Otolaryngology	61 = Sociology
11 = Chemistry	27 = Internal Medicine	45 = Pathology	62 = Speech Pathology
68 = Clinical Pathology	28 = Mathematics	46 = Pediatrics	63 = Surgery (General)
12 = Colon & Rectal Surgery	29 = Medical Illustration	47 = Periodontics	64 = Thoracic Surgery
13 = Dentistry (General)	30 = Microbiology	48 = Pharmacology	99 = Other (Specify)
14 = Dermatology	31 = Neurological Surgery	49 = Pharmacy	
69 = Diagnostic Radiology	32 = Neurology	72 = Physical Medicine & Rehabilitation	
15 = Dietetics	33 = Nuclear Medicine	50 = Physics	

Table 8 - Subspecialty - Physicians - Enter code for ONE Board or area of training, or 00 (Not applicable). If 99 is selected, enter name. Non-physicians - enter 00.

29 = Addiction Psychiatry	08 = Endocrinology	39 = Medical Microbiology	23 = Physiological Psychology
01 = Administrative Medicine	09 = Experimental Psychology	40 = Medical Oncology	24 = Public Health
03 = Allergy	10 = Forensic Pathology	41 = Medical Toxicology	25 = Pulmonary Disease
30 = Cardiac Electrophysiology	35 = Forensic Psychiatry	16 = Metabolism	26 = Rheumatology
04 = Cardiovascular Disease	11 = Gastroenterology	17 = Nephrology	44 = Sports Medicine
05 = Child Psychiatry	12 = General Preventive Medicine	18 = Neuropathology	27 = Therapeutic Medicine
31 = Clinical & Laboratory Immunology	36 = Geriatric Medicine	19 = Neuropsychology	28 = Therapeutic Radiology
32 = Clinical Neurophysiology	37 = Geriatric Psychiatry	20 = Occupational Medicine	45 = Vascular Surgery
06 = Clinical Psychology	38 = Hand Surgery	42 = Nuclear Radiology	99 = Other (Specify)
33 = Clinical Care Medicine	13 = Hematology	43 = Pain Management	00 = Not Applicable
34 = Dermatopathology	14 = Immunology	21 = Pediatric Allergy	
07 = Diagnostic Radiology	15 = Infectious Disease	22 = Pediatric Cardiology	

Table 11 - Hospital Service: Select code for the hospital service with which the investigator is identified and/or from which salary is paid. If salaried from VA research funds, enter code 09, 13, or 27.

01 = Administration	36 = Extended Care	17 = Nursing	25 = Radiology
02 = Ambulatory Care	09 = HSR&D	38 = Ophthalmology	26 = Rehabilitation Medicine
34 = Anesthesiology	37 = Geriatrics	39 = Otolaryngology	27 = Rehabilitation R&D
03 = Audiology & Speech Pathology	10 = GRECC	18 = Outpatient Clinic	28 = Recreation
04 = Chaplain	11 = Intermediate Care	19 = Pathology	30 = Social Work
05 = Dental	12 = Laboratory	20 = Pharmacy	31 = Spinal Cord Injury
35 = Dermatology	13 = Medical Research	21 = Prosthetics	32 = Surgery
06 = Dietetics	14 = Medical	22 = Psychiatry	40 = Urology
07 = Domiciliary	15 = Neurology	23 = Psychology	33 = Voluntary
08 = Education	16 = Nuclear Medicine	24 = Pulmonary Disease	99 = Other (Specify)

Table 13 & 14 - Primary and Secondary Research Interests: Select codes that best define general areas of primary and secondary interests. Do NOT use 00 for primary research interest.

01 = Aging	11 = Drug Dependence	52 = Neuropsychology	29 = Radiology
02 = Alcoholism	45 = Emergency Medicine	21 = Nuclear Medicine & Radiation	61 = Rehabilitation
38 = Ambulatory Care	12 = Endocrinology & Metabolism	22 = Nutrition	30 = Rehabilitative Medicine
03 = Anesthesiology	46 = Epidemiology	23 = Nursing	31 = Respiration & Pulmonary Disease
04 = Audiology & Speech Pathology	13 = Gastroenterology	24 = Oral Biology	32 = Rheumatology
05 = Basic Sciences	47 = Geriatrics	25 = Oncology	33 = Social Work
06 = Behavioral Sciences	48 = Health Care	53 = Ophthalmology	62 = Spinal Cord Injuries
07 = Biochemistry	49 = Health Economics	26 = Orthopedic Surgery	34 = Surgery
39 = Bioengineering	50 = Health Services	27 = Pathology	63 = Urology
40 = Biomechanics	14 = Hematology	54 = Pharmacology	64 = Vascular Surgery
08 = Cardiovascular Disorders	15 = Immunology	55 = Pharmacy	35 = Veterinary Medicine
41 = Clinical Epidemiology	16 = Infectious Diseases	28 = Podiatry	36 = Virology
09 = Clinical Pharmacology	51 = Medical Education	56 = Post Traumatic Stress Disorder	37 = Vision
42 = Computer Science	17 = Mental Health	57 = Preventive Medicine	99 = Other (Specify)
43 = Critical Care	18 = Molecular Biology	58 = Prostatic Disease	00 = None
44 = Dental Implants	19 = Nephrology	59 = Prosthetics	
10 = Dermatology	20 = Neurology & Neurobiology	60 = Psychiatry	

JOHN D. DINGELL VA MEDICAL CENTER RESEARCH AND DEVELOPMENT “REQUEST TO REVIEW”

Principal Investigator <i>(Must be a VA employee):</i>	Phone Number	Mailing Address	E-mail Address
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Project Title *(Maximum length: 142 characters, including spaces)*

Is this submitted for a “Just-in-Time Review?”
(Subcommittee reviews not required until project is funded. Yes No)

Does this proposal involve the creation of a database or tissue repository for FUTURE use? Yes No
If the answer is yes, you must contact the Research Compliance Officer (ext 64467) for more information.

Project Coordinator:	Phone No:	Mailing Address:	E-mail Address:
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Important: The following elements, where applicable, must be submitted prior to review by the R&D Committee:

	<u>Submitted</u>	<u>Not Applicable</u>
Request to Review Research Proposal:	<input type="checkbox"/>	
Narrative/Abstract:	<input type="checkbox"/>	
Complete Protocol	<input type="checkbox"/>	
Conflict of Interest Certification	<input type="checkbox"/>	
Research Safety Hazard Survey	<input type="checkbox"/>	
Animal Studies Application:	<input type="checkbox"/>	<input type="checkbox"/>
Radioisotope Application:	<input type="checkbox"/>	<input type="checkbox"/>
Research Safety Application:	<input type="checkbox"/>	<input type="checkbox"/>

Space Utilization Authorization:

Space to be used: Room(s):

Request to Review Research Proposal

(Last First MI Degree)

1. Principal Investigator/Program Director:

2. **Telephone:** (Office/Lab)

3. **Mailing Address & Routing Symbol**

4. **Email Address**

5. **VA Appointment:** Full-time Part-time WOC Consultant Contract

6. **Status of PI in Proposal:** (01 = Awardee or Initiator 02 = Not Awardee, Responsible VA Investigator)

7. **Type of Submission:** New Renewal of Active Project

If Renewal, complete a and b: a) Enter 4-digit number of active project _____ b) Has title changed? Yes No

8. **Project Title:** (Maximum length: 142 characters, including spaces--72 Characters for Merit Review)

9. **Co-Principal Investigators:** (Must have a VA appointment and must be designated a Co-PI in application. Do Not enter Co-Investigator)

_____ (Last name, First name, MI, Degree)

_____ (Social Security Number)

Check if at another VAMC

_____ (Last name, First name, MI, Degree)

_____ (Social Security Number)

Check if at another VAMC

10. **Anticipated Starting Date:** (mm/dd/yy)

11. **Funding Source and Fund Administration:**

Source Code
(4-digits)

Name if Funding Source Code ends in "99"

Admin Code
(2-digits)

Name if Admin Code is "08"

12. **Project Uses:** (Mark each item and submit completed forms. If Animal Subjects is Yes, Complete Item 15.)

Human Subjects Yes No Investigational Drugs..... Yes No IND #

Animal Subjects..... Yes No Investigational Devices .. Yes No IND #

Radioisotopes..... Yes No Biohazards Yes No

13. **Research Focus:** (Mark each item.)

Agent Orange... Yes No

Females..... Yes No

Prisoners of War... Yes No

14. **Key Words:** (Minimum 3, maximum 6. Use Mesh terms only. Enter one term per line) <http://www.nlm.nih.gov/mesh/meshhome.html>

1 _____	4 _____
2 _____	5 _____
3 _____	6 _____

15. **Animal Subjects Used:** (Species and, if applicable, strain. Enter one species and its strain per line.)

1 _____	4 _____
2 _____	5 _____
3 _____	6 _____

Request to Review Research Proposal

16. **Abstract:** (Submit by email to either robert.molitoris@va.gov ; see instructions— < 500 words and organized under the following headings: Objectives, Research Plan, Methods, and if a basic science study, Clinical Relevance.)

17. **Conflict of Interest:** (Please complete the Conflict of Interest Statement that is attached to this application)

18. **Research Safety:** Please submit the one-page Research Safety Hazard Assessment Survey (below) and the **Research Protocol Safety Survey (VAF 10-0398)** .

19. **Lab Space:** Yes No **If Yes, Bldg. And Room:**

20. **Please identify all the personnel who will work on this research project (including the PI).**

Name (first, last)	E-mail address	Phone number	Employer	Is all required VA training complete?

WSU's IACUC Form and the VA ACORP Form are available at <http://iacuc.wayne.edu/forms-and-documents.php>. Both WSU and the VA have required animal training at www.citiprogram.org

22. **Institutional Approvals:** (Original signatures required at time of submission for R&D Committee review)

Principal Investigator	Signature	Date
Section Chief	Signature	Date
Service Chief	Signature	Date

If this is the First Research Proposal submitted at this Medical Center, also submit an Investigator Data Sheet (Page 18).

**Research Safety Hazard Assessment Survey
Research Safety Committee
JOHN D. DINGELL VA MEDICAL CENTER**

Principal Investigator:

Email Address:

Project Title:

Building:

Room:

Phone Number:

**This form must be included with your application to the VA R&D Committee.
Please check all boxes that apply to your research protocol.
Give a brief summary for each item checked.**

- A.** Ionizing Radiation: radioactive materials generating equipment
- B.** Microbial/Viral Agents
- C.** Chemicals (toxic, flammable, explosive, corrosive, carcinogenic, neurotoxins)
- D.** Recombinant DNA
- E.** Other cell lines, pathogens, toxins, select agents
- F.** Poisonous, toxic, venomous animals/plants
- G.** Physical agents (UV light, Lasers, Radiofrequency or microwaves, electricity, trauma, etc.)
- H.** Controlled Substances
- I.** Animals (must submit VA ACORP form with WSU addendum)
- J.** Human tissue, blood, other body fluids (must submit VA Human Studies Application)

If you checked one or more boxes above, you must complete the following form: Research Protocol Safety Survey (VAF 10-0398). The RPSS must be accompanied by the “work proposed” section of your research proposal.

6. Personnel: List the names of all personnel, co-investigators and collaborators who will work with the PI on this research proposal. List non-VA personnel only if working in a VA laboratory.	Has person received safety training specific for this project?	SRS Use Only
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A	
If NO to any personnel, please explain:		
PI Signature	Date	
<input type="checkbox"/> Exempt from Safety Review <input type="checkbox"/> Full Safety Review Conducted <input type="checkbox"/> Reviewed by SRS Chair		
TIMOTHY HADDEN, PH.D. Research Biosafety/Chemical Hygiene Officer/SRS Chairperson	Date	

RESEARCH PROTOCOL SAFETY SURVEY

This form must be accompanied by a copy of the “work proposed” section of your research proposal.

PRINCIPAL INVESTIGATOR (PI):
PROJECT TITLE:
DATE OF SUBMISSION:
VA FUNDED? (circle) YES NO
LIST VA AND NON-VA LOCATIONS WHERE THIS PROTOCOL WILL BE CONDUCTED:

1. DOES THIS RESEARCH INVOLVE THE USE OF ANY OF THE FOLLOWING?

- a. Biological Hazards
 - (1) Microbiological or viral agents, pathogens, toxins, select agents as defined in Title 42 Code of Federal Regulations (CFR) 72.6, YES NO
 - (2) animals YES NO

- b. Human or non-human cell or tissue samples (including cultures, tissues, blood, other bodily fluids or cell lines) YES NO

- c. Recombinant deoxyribonucleic acid (DNA) YES NO

- d. Chemicals:
 - (1) Toxic chemicals (including heavy metals) YES NO
 - (2) Flammable, explosive, or corrosive chemicals YES NO
 - (3) Carcinogenic, mutagenic, or teratogenic chemicals YES NO
 - (4) Toxic compressed gases YES NO
 - (5) Acetylcholinesterase inhibitors or neurotoxins YES NO

- e. Controlled Substances YES NO

- f. Ionizing Radiation:
 - (1) Radioactive materials YES NO
 - (2) Radiation generating equipment YES NO

- g. Nonionizing Radiation:
 - (1) Ultraviolet Light YES NO
 - (2) Lasers (class 3b or class 4) YES NO
 - (3) Radiofrequency or microwave sources YES NO

If the answer to any of these questions is YES, complete all sections of this survey that apply.
 If all answers are NO, a documented review by the local Subcommittee on Research Safety is still required prior to submission. If the research involves the use of human subjects or human tissues, Institutional Review Board (IRB) review is required. **NOTE:** Use of animals also requires submission of an Institutional Animal Care and Use Committee (IACUC)-approved Animal Component.

2. BIOLOGICAL HAZARDS

- a. Does this research protocol involve the use of microbiological or viral agents, pathogens, toxins, poisons or venom? YES NO

If **NO**, skip to the section on **Cells and Tissue Samples**.

If **YES**, list all Biosafety Level 2 and 3 agents or toxins used in your laboratory. It is the responsibility of each PI to:

(1) Consult either:

(a) The National Institutes of Health (NIH)-Center for Disease Control and Prevention (CDC) publication entitled Biosafety in Microbiological and Biomedical Laboratories or

(b) The CDC online reference (<http://www.cdc.gov>)

Have you reviewed this website?

Yes Date

No

(2) And identify the Biosafety Level (also called Risk Group) for each organism, agent, or toxin. Enter it into the following table.

Organism, Agent, or Toxin Biosafety Level**

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

- b. Are any of the biohazardous agents listed above classified as a “Select Agent” by the Centers for Disease Control? YES NO

3. BIOLOGICAL HAZARDS – Description of Use (*Note: Photocopy this page, as necessary.*)

a. Identify the microbiological agent or toxin (name, strain, etc.):

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b. If this is a Select Agent (42 CFR 72.6), provide the CDC Laboratory Registration # and the date of the CDC inspection:

--	--

c. Indicate the largest volume and/or concentration to be used:

--

d. Indicate whether antibiotic resistance will be expressed, and the nature of this antibiotic resistance:

--

e. Describe the containment equipment (protective clothing or equipment, biological safety cabinets, fume hoods, containment centrifuges, etc.) to be used in this research:

f. Describe the proposed methods to be employed in monitoring the health and safety of personnel

involved in this research:

4. CELLS and TISSUE SAMPLES

- a. Will personnel work with human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES NO
If yes, specify:
- b. Will this study represent a potential biohazard for lab personnel? NA YES NO

If yes, specify the potential hazard and precautions employed to protect personnel in the laboratory:

- c. Will personnel work with animals or animal blood? YES NO

NOTE: If these studies involve animals, the Animal Component of Research Protocol (ACORP) must be completed.

- d. If this study involves use of animals, specify precautions employed to protect personnel working in the laboratory:

5. RECOMBINANT DNA

- a. Are procedures involving recombinant DNA used in your laboratory? YES NO
If **NO**, skip to next section.

- b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES NO

(1) If **YES**, your recombinant DNA studies are exempt from restrictions described in the NIH Guidelines for Research Involving Recombinant DNA Molecules.

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

(a) Consult the current NIH Guidelines for Research Involving Recombinant DNA Molecules which can be found at the Internet site: http://oba.od.nih.gov/rdna/nih_guidelines_oba.html

(b) Identify the experimental category of their recombinant DNA research.

c. Description of Recombinant DNA Procedures:

(1) Identify the NIH classification (and brief description) for these recombinant DNA studies:

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(2) Biological source of DNA insert or gene:

--

(3) Function of the insert or gene:

--

(4) Vector(s) used or to be used for cloning (e.g., pUC18, pCR3.1):

--

(5) Host cells and/or virus used or to be used for cloning (e.g., bacterial, yeast or viral strain, cell line):

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6. USE OF CHEMICALS

a. Has the use of chemicals in your laboratory been reviewed by an appropriate committee or subcommittee in the past 12 months? YES NO

b. Are personnel knowledgeable about the special hazards posed by:

(1) Carcinogens? NA YES NO

(2) Teratogens and Mutagens? NA YES NO

(3) Toxic gases? NA YES NO

(4) Neurotoxins? NA YES NO

(5) Reactive and potentially explosive compounds? NA YES NO

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

7. CONTROLLED SUBSTANCES



Controlled Substances

a. Have you reviewed this list? Yes Date _____ No

b. Does your research involve the use of any substance regulated by the Drug Enforcement Agency?

Yes No If yes, list controlled substances to be used:

c. Are all Schedule II and III drugs stored in a double-locked vault? NA YES NO

8. RADIOACTIVE MATERIALS

Does this research involve the use of radioactive materials?

YES NO

If YES, provide the following:

a. Identity of radioactive source (s):	
b. Radiation Safety Committee Approval (date):	

9. PHYSICAL HAZARDS

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan? YES NO

b. Do employees receive annual training addressing physical hazards? YES NO

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
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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	Date
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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 surveys used locally are available from the Research and Development (R&D) Office.

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

Conflict of Interest

The policy of the VA is to ensure that the welfare of human subjects and the integrity of research will not be compromised, or appear to be compromised, by competing institutional interests or obligations. Objectivity in research is a key component of any research project. One method for maintaining objectivity is to have **all** individuals involved in research design, development, or data evaluation/analysis disclose any potential and/or real financial conflict of interest. This includes all personnel working on this proposal.

Examples of relevant relationships for potential conflict of interest include but are not limited to:

- (1) receiving past, current, or expecting future income in the form of salary, stock or stock options/warranties, equity, dividends, royalties, profit sharing, capital gain, forbearance or forgiveness of a loan, interest in real or personal property, or involvement in a legal partnership with the sponsor
- (2) receiving past, current, or expecting future income in the form of consulting fees, honoraria, gifts, gifts to the University, or payments resulting from seminars, lectures, or teaching engagements, or service on a non-federal advisory committee or review panel
- (3) serving in a corporate or for-profit leadership position, such as executive officer, board member, fundraising officer, agent, member of a scientific advisory board, member of a scientific review committee, or member of a data safety monitoring committee, regardless of compensation
- (4) inventor on a patent or copyright involving technology/processes/products licensed or expected to be licensed to the sponsor.

See Policy and Procedures Institutional Review Board & Institutional and Individual Financial Conflict of Interest (COI) at www.research.wayne.edu/coi, MCNM 11R-4, Institutional Conflict of Interest (COI) in Research, and Research Service Policy #8, Conflict of Interest Policy.

If any response below is "yes," there must be a "Financial Conflict of Interest Detailed Disclosure Form" submitted to the R&D Committee at the time of this protocol submission and then annually or when changes occur; if this form is not submitted, the protocol cannot be approved.

The form and more information are available through the Research Office. For additional information please call 313-576-1000, x61046.

PRINCIPAL INVESTIGATOR:	
SIGNATURE:	
Do you, your spouse or domestic partner, or any of your dependent children have a potential and/or real financial conflict of interest with the sponsor of this project, including all secondary sources?	<input type="checkbox"/> No <input type="checkbox"/> YES
Are you aware of any potential and/or real financial conflict of interest with the sponsor of this project, involving your supervisor, service chief or the John D. Dingell VA Medical Center?	<input type="checkbox"/> No <input type="checkbox"/> YES
Are you aware of any potential and/or real financial conflict of interest with the sponsor of this project, involving co-investigators, other key personnel (which could include collaborators, fellows, residents, research assistants, etc.) and/or their spouses, domestic partners, or dependent children?	<input type="checkbox"/> No <input type="checkbox"/> YES

ABSTRACT

Please submit a hard copy and email a copy to either robert.molitoris@va.gov. The abstract must be limited to 500 words or less and organized under the following headings:

OBJECTIVE:

RESEARCH PLAN:

METHODS:

CLINICAL RELEVANCE: