

# **JOHN D. DINGELL VA MEDICAL CENTER RESEARCH AND DEVELOPMENT RESEARCH APPLICATION**

**This packet contains the following:**

- 1. Guidelines for Submission of a Proposal**
- 2. Page 18 – Investigator Data (only fill out if you are a new investigator – this can be hand written)**
- 3. Research and Development Request to Review**
- 4. Research Safety Hazard Assessment Survey Form**
- 5. Conflict of Interest Information**
- 6. Data Use and Storage Agreement**
- 7. Data Security Checklist**
- 8. Abstract Form – limited to 500 words**
- 9. Budget Page Form – 2 parts (If no funds are designated for the proposal, a brief explanation must be included in the narrative under the topic "Budget.")**

**The VA Consent Form (VAF 10-1086), WSU Human Investigation Committee (HIC) application, Investigational Drug Information Record (VAF 10-9012), and Research Protocol Safety Survey (VAF 10-0398) form are available at [www.va.gov/detroitresearch](http://www.va.gov/detroitresearch), as well as information about required human protection training. WSU's AIC Form and the VA ACORP Form are available at <http://www.aic.wayne.edu/AICForms.html>. Both WSU and the VA have required animal training – WSU has required initial training at <http://rcr.wayne.edu/> and the VA also has an annual training requirement which can be completed at <https://www.citiprogram.org/default.asp>**

**If you have any questions or concerns please call (313) 576-1000, x61046**

## Guidelines for Submission of a Proposal

All proposed research studies performed at the VAMC must undergo review by the R&D Committee. All proposed human participant studies performed at the VAMC must also undergo review by the Clinical Investigation Committee, the human studies review subcommittee of the R&D Committee, prior to review by Wayne State University's Human Investigation Committee. All proposals involving animal studies must be reviewed by Wayne State University's Animal Investigation Committee (<http://www.aic.wayne.edu/>). If necessary, proposals will also be reviewed by the Subcommittee on Research Safety (SRS).

### 1. **CIC Review**

The purpose of the Clinical Investigation Committee (CIC) is to review all projects involving human subjects for a) scientific merit, b) ethics, 3) compliance with VA regulations and d) Impact of budget on VA resources. Based on these reviews, the CIC will determine one of the following: 1) approval to submit the application to the HIC for review, 2) not approved for submission to HIC – revisions required, or 3) not approved for submission. Approval of the CIC is necessary before the research can be submitted to the WSU HIC with all components required for evaluation of the protocol for the protection of human subjects.

### 2. **IACUC Review**

The IACUC reviews all protocols involving animal studies to ensure that all research and teaching protocols using live vertebrate animals are designed and carried out in a humane manner that complies with all applicable laws, policies, and guidelines. No animals can be purchased or used in experimental procedures without written AIC protocol approval.

### 3. **SRS Review**

The SRS reviews all research activities involving biological, chemical, physical, and radiation hazards for compliance with all applicable regulations, policies, and guidelines prior to submission for R&D funding. This includes a review of all research applications for funding that will be conducted at the VA facility or by VA personnel with VA funding located off-site.

### 4. **R&D Committee Review**

Once CIC & HIC approval, or AIC, and SRS (if appropriate) is received, the R&D Committee reviews proposals to ensure that they 1) exceed the minimum scientific standards for a study, and 2) do not impact adversely on the clinical or research facilities and personnel of the medical center. The Committee's goal is to facilitate the conduct of high-quality research by investigators. To that end, the Committee seeks to review the scientific, administrative and budgetary aspects of all proposals and provide whatever feedback (scientific, administrative, budgetary and editorial) is feasible in the time allotted. (VA Merit proposals for BLR&D/CSR&D services require just in time submission of compliance and/or approval documentation for human studies, animal studies, and biosafety. More information on this is available in the Research Office.)

### 5. **Timing of Submission of Proposals**

Each type of proposal within the VA Research Service has its own submission deadline. The appropriate deadline for each investigator should be clarified with the local research office by calling 313-576-1000, extension 64474. As a general rule, the CIC meets on the 4<sup>th</sup> Monday of the month and protocols are due by the 10<sup>th</sup> of the month. The R&D Committee meets on the first Tuesday of each month unless circumstances arise to necessitate a change in schedule. In order to review any application at its next meeting, the Research Office must receive it at least ten working days in advance. Exceptions must be granted by the Chairman of the CIC or the R&D. ***This is a minimum requirement that will be enforced.***

### 6. **Elements of Proposals Submitted for Committee Review**

Although the basic elements of any scientific proposals should be familiar to all investigators, the CIC and the R&D Committees receive a surprising number of proposals that either do not conform to standard format or lack some of the components generally considered essential. It is imperative that a proposal submitted to either committee be in appropriate format before it can be considered for review. This is both to expedite the review process on our part, as well as ensure that those elements, which will be deemed essential by any external review committee, are present.

Required submissions for FULL COMMITTEE CIC review **ORIGINAL AND THREE COPIES** of the following:  
For EXPEDITED submissions (contact the Research Office at 313-576-1000, ext. 61046 to see if the proposal qualifies) **ORIGINAL AND ONE COPY** of the following:

1. Request to Review Research Proposal
2. Budget & Clinical Impact Statement (**If no funds are designated for the proposal, a brief explanation must be included in the narrative under the topic "Budget."**)
3. Data Use Amendment and Data Security Checklist
4. Abstract – (500 words or less, on a separate sheet and on IBM formatted disk, under the following headings: Objectives, Research Plan, Methods, and if a basic science study, Clinical Relevance)
5. Complete Protocol
6. VA Consent Form (Form 10-1086)
7. A copy of the WSU Human Investigation Committee (HIC) application (including HIPAA form). Do not submit the original form it must go to the HIC with the CIC approval letter.
8. Completed VA Form 10-9012 (Investigation Drug Information Record), if applicable.

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

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**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 \_\_\_\_\_  
*(Enter Code From Table 4a)* Code \_\_\_\_\_ *If Code = 99, Enter Academic Rank (If Code #00, Skip to Item 5)*

b. University Administrative Title \_\_\_\_\_  
*(Enter Code From Table 4b)* Code \_\_\_\_\_ *If Code = 99, Enter University Administrative Title*

c. University Department \_\_\_\_\_  
*(Enter Name)*

d. University Section/Division \_\_\_\_\_  
*(If applicable, enter Name)*

e. University \_\_\_\_\_  
*(Enter Name)*

**5. Degrees:** (Check HIGHEST degrees only)  MD  Ph.D.  DDS/DMD  DVM  SCD  
 PharmD  Ed.D.  MPH  MA/MS  MN  
 MSW  BSN  RN  OTHER

**6. Diplomate Status, Board Certified**  Yes  No  Not Applicable  
*(See Instructions, item 6)*

**7. Specialty:** \_\_\_\_\_  
*(Enter Code from Table 7)* Code \_\_\_\_\_ *If Code = 99, Enter Specialty*

**8. Subspecialty:** \_\_\_\_\_  
*(Enter Code from Table 8)* Code \_\_\_\_\_ *If Code = 99, Enter Subspecialty*

**9. VA Employment:** (Check One)  Full-Time  
 Part-Time;  Hrs. /Week (If Part-Time, enter hrs/wk)  
 Consultant  Contract  WOC

**10. Salary Source:**  VA Funds Other Than R&D  Rehab R&D (Program 822)  
 Medical Research (Program 821)  Clinical Research (Program 829)  
 HSR&D (Program 824)  Not Salaried by VA

**11. Hospital Service:** \_\_\_\_\_  
Code \_\_\_\_\_ *If Code = 99, Enter Hospital Service*

**12. Primary Research Interest:** \_\_\_\_\_  
Code \_\_\_\_\_ *If Code = 99, Enter Primary Research Interest (Do not use Code 00)*

**13. Secondary Research Interest:** \_\_\_\_\_  
Code \_\_\_\_\_ *If Code = 99, Enter Secondary Research Interest*

**14. Research Involves:**  Human Immunodeficiency Virus  Any Other Retrovirus  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”

<b>Principal Investigator</b> <i>(Must be a VA employee):</i>	<b>Phone Number</b>	<b>Mailing Address</b>	<b>E-mail Address</b>
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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 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"/>	
Budget:	<input type="checkbox"/>	
Narrative:	<input type="checkbox"/>	
Conflict of Interest Certification	<input type="checkbox"/>	
Data Security Forms	<input type="checkbox"/>	
Research Safety Hazard Survey	<input type="checkbox"/>	
Human Studies Application:	<input type="checkbox"/>	<input type="checkbox"/>
Animal Studies Application:	<input type="checkbox"/>	<input type="checkbox"/>
Investigational Drug Form:	<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. <b>Telephone:</b> <i>(Office/Lab)</i>	3. <b>Mailing Address &amp; Routing Symbol</b>	4. <b>Email Address</b>
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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)*

\_\_\_\_\_  Check if at another VAMC  
*(Last name, First name, MI, Degree)                      (Social Security Number)*

\_\_\_\_\_  Check if at another VAMC  
*(Last name, First name, MI, Degree)                      (Social Security Number)*

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

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

<u>Source Code</u> <i>(4-digits)</i>	<u>Name if Funding Source Code ends in "99"</u>	<u>Admin Code</u> <i>(2-digits)</i>	<u>Name if Admin Code is "08"</u>
_____	_____	_____	_____

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

Human Subjects..... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Investigational Drugs ..... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	IND # _____
Animal Subjects..... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Investigational Devices .. <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	IND # _____
Radioisotopes..... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Biohazards..... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	

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

Agent Orange... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Females..... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>	Prisoners of War... <input type="checkbox"/> <i>Yes</i> <input type="checkbox"/> <i>No</i>
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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 on floppy disk; 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. **Data Security Checklist** and (if applicable) the authorization request to transport and utilize VA sensitive information outside protected environments
19. **Research Safety:** Please submit the one-page Research Safety Hazard Assessment Survey (below) or the **Research Protocol Safety Survey (VAF 10-0398)** – whichever is appropriate for this study.
20. **Lab Space:**  Yes  No **If Yes, Bldg. And Room:**
21. **Budget:** A Budget and Clinical Assessment Impact Statement must be submitted for any proposal that receives any form of financial assistance or involves institutional support in the form of medical procedures, pharmacy, etc. If no funds are designated for the proposal, a brief explanation must be included in the narrative under the topic "Budget."
22. **Please identify all the personnel who will work on this research project (including the PI).**

Name (first, last)  Signature (Required)	E-mail address	Phone number	Employer	Will administer and sign Informed Consent (Yes/No)?	*Dates Completed all required Human Studies Education <u>and</u> GCP Training

**\*All study members must complete WSU's on line training "Protection of Human Research Participants" available at [www.hic.wayne.edu](http://www.hic.wayne.edu) and GCP and Human Subjects Protection Training Through CITI at <https://www.citiprogram.org/default.asp>. Non-VA study members participating in human studies must also complete the human study application packet available at [www.va.gov/detroitresearch](http://www.va.gov/detroitresearch)**

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

<b>Principal Investigator</b>	<b>Signature</b>	<b>Date</b>
<b>Section Chief</b>	<b>Signature</b>	<b>Date</b>
<b>Service Chief</b>	<b>Signature</b>	<b>Date</b>

**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 a Research Protocol Safety Survey (VAF 10-0398). The RPSS must be accompanied by the “work proposed” section of your research proposal. If your work involves **ONLY** collection of human tissue, blood or body fluids, complete the section below. You will not need to complete VA Form 10-0398.

- a. If collecting clinical samples, where will the samples be analyzed?
- b. How will samples be transported?

**NOTE:** Federal regulations have established requirements for shipping materials of a potentially infectious nature. If samples will be shipped, the following requirements must be met:

- a. Shipping must be done only by personnel who have received approved training.
- b. Materials must be packaged in approved containers with required labeling.

Contact the Biosafety Officer for assistance.

6. <b>Personnel:</b> 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?	<b>SRS Use Only</b>
	<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 <b>NO</b> to any personnel, please explain:		
<b>PI Signature</b>		<b>Date</b>
<input type="checkbox"/> Exempt from Safety Review <input type="checkbox"/> Full Safety Review Conducted <input type="checkbox"/> VA Lab Regulated by CAP		
<b>TIMOTHY HADDEN, PH.D.</b> <b>Research Biosafety/Chemical Hygiene Officer</b>		<b>Date</b>

## 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 HIC Policy and Procedures Institutional Review Board & Institutional and Individual Financial Conflict of Interest (COI) at [www.research.wayne.edu/coi](http://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.

<b>PRINCIPAL INVESTIGATOR:</b>	
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



John D. Dingell VA Medical Center, Detroit, MI

DATA USE AND STORAGE AGREEMENT ADDENDUM

<b>Protocol:</b>	
1. USE - Describe briefly how protected health information will be used in this protocol.	
2. DISCLOSURE – Please identify all who will have access to the data.	
3. TRANSFER/TRANSMISSION – Is the data going to be taken elsewhere? Will it be electronically or physically sent somewhere else? If so what are the provisions for transporting the data securely?	
4. STORAGE – What are the provisions for data security in storage (locked offices, VA ISO approved secured computer system etc.)?	
5. IDENTIFIABLE DATA DESTROYED (PHI) – What are the provisions to destroy the identifiable data once it is no longer needed?	
<b>Investigator</b>	<b>Sponsor</b>

## Data Security Checklist for Principal Investigators

<b>Name of PI:</b>			
<b>Project:</b>			
<b>Yes</b>	<b>No</b>	<b>N/A</b>	<b>Specific Requirements</b>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All VA sensitive research information is used and stored within the VA.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	All copies of VA sensitive research information are used and remain within the VA.

**If you have answered Yes or N/A to both statements above, stop here.**

**If the original or copies of VA research information are removed from the VA the following apply:** Refer to [www.research.va.gov](http://www.research.va.gov) for definitions of research information.

Yes	No	N/A	Specific Requirements
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Permission to remove the data has been obtained from 1) your immediate supervisor, 2) your ACOS/R&D, 3) the VA Information Security Officer (ISO), and 4) the VA Privacy Officer.  <div style="text-align: center;">                       Data transportation                 </div>
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	A property pass for the equipment (Laptop etc.) has been obtained.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	The laptop or other portable media is encrypted and password protected. <b>Note:</b> Contact the VA ISO at your facility for encryption issues.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Data are not transmitted as an attachment to unprotected e-mail messages.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Names, addresses, and Social Security Numbers (real and scrambled) have been replaced with a code. <b>Note:</b> Names, addresses, and Social Security Numbers (real or scrambled) may only be maintained on a VA server and documentation of the procedure by which the data were coded must remain within the VA.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Data sent via mail or delivery service have been encrypted. <b>Note:</b> It is preferable to send data on CDs or other media by a delivery service where there is a "chain of custody".
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	For data that will reside on a non-VA server: The server has been certified and accredited as required by Federal Information and Security Management Act of 2002 (FISMA). <b>Note:</b> your facilities ISO should be consulted.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Access to the data is only by those who are authorized to access it and the access is related to VA-approved research.
<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Procedures for reporting theft or loss of sensitive data or the media such as a laptop, containing sensitive data are in place and familiar to the researcher and all others who have access to, use, store, or transport the data.

I certify to the best of my knowledge that all VA sensitive information associated with this research study will be used, stored and secured in accordance with all applicable VA and VHA policies and guidance.

Investigator Signature

Date

## **ABSTRACT**

**Please submit a hard copy and a floppy disk. The abstract must be limited to 500 words or less and organized under the following headings:**

**OBJECTIVE:**

**RESEARCH PLAN:**

**METHODS:**

**CLINICAL RELEVANCE:**

**BUDGET AND CLINICAL ASSESSMENT IMPACT STATEMENT  
JOHN D. DINGELL VA MEDICAL CENTER**

Protocol Title:		
IRB Approval Number:		
Sponsor:		
Principal Investigator:		
Anticipate Starting Date:	Anticipated Closing Date:	
Planned Number of Research Subjects Total:	Veterans	Non-Veterans
Planned Number of Non-Veteran Subjects Requiring Procedures:		

**I understand that the project must reimburse the VAMC for the procedures outlined below if they are performed on non-veterans or when performed on veterans above and beyond normal patient care.**

**If project funds are being managed by the VA non-profit, form must be signed by MDREF.**

<b>Executive Director, MDREF</b>	<b>Date</b>

**1. Fixed charges**

- a. IRB protocol review charge: **\$1800**                      Continuation review charge: **\$500**
- b. MDREF Administrative Fee: **%15**
- c. FHPP Fee: **%10**

**2. Pharmacy Charges:**



Pharmacy charges

A copy of the Pharmacy manual for this protocol must be provided to Pharmacy.

<b>Research Pharmacist</b>	<b>Date</b>

**3. Radiology Procedures:**                      Yes  No

# of Patients	X-ray Site		X-rays / Patient		Cost per X-ray		Total Cost	Standard of care
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Chief, Radiology Section</b>							<b>Date</b>	

**4. Nuclear Medicine Procedures:**                      Yes  No

# of Patients	Procedure		Procedure / Patient		Cost / Procedure		Total Cost	Standard of care
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Chief, Nuclear Medicine Section</b>							<b>Date</b>	

5. Other Ancillary or Specialty Tests Yes  No

# of Patients	Procedure		Procedure / Patient		Cost / Procedure		Total Cost	Standard of Care
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Chief,</b>							<b>Date</b>	

6. Inpatient hospital care for research study: Yes  No   
 (If yes, state anticipated # of patient days X # of patients x cost/day for research study purposes)

Patient Days		# of Patients		Cost / Day		Total Cost	
	X		X		=		
<b>Primary Care Ward:</b>				<b>Specialty Care Ward:</b>			

7. Clinical Laboratory Procedures: Yes  No

# of Patients	Procedure		Procedure / Patient		Cost / Procedure		Total Cost	Standard of Care
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
		X		X		=		<input type="checkbox"/> Yes <input type="checkbox"/> No
<b>Chief, Pathology &amp; Laboratory Service</b>							<b>Date</b>	

<b>Principal Investigator</b>	<b>Date</b>
<b>Research Service</b>	<b>Date</b>