

APPLICATION FOR INITIAL REVIEW OF RESEARCH—VA CIRB PROTOCOL

Durham VA Health Care System Research and Development

Durham VA Medical Center, Building 5

OFFICE USE	DATE VERIFIED COMPLETE:	COMMITTEE APPROVAL(S) REQUIRED: Subcommittee on Research Safety <input type="checkbox"/> Radiation Safety Committee <input type="checkbox"/> Research and Development Committee <input type="checkbox"/>	PROTOCOL NUMBER (MIRB#):

Contents of Initial Review Application for VA Central IRB Approved Projects

**Asterisk indicates required documents for all initial review applications for studies under the purview of VA CIRB.*

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|---|--|
| <input type="checkbox"/> DVAHCS Application for Initial Review—VA CIRB Protocols* | <input type="checkbox"/> Packing and Shipping of Biological Specimens |
| <input type="checkbox"/> Abstract* | <input type="checkbox"/> Standard Operating Procedure (SOP) for Using Human blood and Tissue |
| <input type="checkbox"/> Protocol* | <input type="checkbox"/> Blood Collection Competency Checklist |
| <input type="checkbox"/> VA CIRB Approved Complete LSI Initial Review Application Packet* | <input type="checkbox"/> Vital Sign Competency Checklist |
| <input type="checkbox"/> VA Form 10-0398 Research Protocol Safety Survey* | <input type="checkbox"/> ORD Offsite Waiver Request |
| <input type="checkbox"/> VA CIRB Approved complete PI/SC Initial Review Approval Packet (<i>if the LSI is also the PI/SC</i>) | <input type="checkbox"/> Authorization to Use, Process, Store or Transmit Sensitive Information Outside VA Owned or Managed Facilities (<i>If conducting research off-site or in a non-VA owned or leased space</i>) |
| <input type="checkbox"/> Research Scope of Practice | Investigator Data--Page 18 (<i>if new PI</i>) |
| <input type="checkbox"/> VA Form 10-9012 Investigational Drug Record | |
| <input type="checkbox"/> Letter(s) of Support | |

Project Title:

A. Local Site Investigator Information

Local Site Investigator:

Email:

Phone Number:

Service:

B. Research Coordinator Information Not Applicable

Research Coordinator:

Email:

Phone Number:

C. Location

Location of where research activities will take place (*check all that apply*):

- Durham VA Medical Center
- Community Based Outpatient Clinic(s) (e.g., Raleigh CBOC I, II, III)
- Greenville Health Care Center
- Hillandale Clinics I or II
- MIRECC/Croasdaile
- VA leased space at Mutual Life Building / Legacy Tower (e.g., HSR&D, CSPEC, etc.)
- Non DVAHCS owned or leased space¹. Describe:

¹ For research activities taking place at non-VA owned or leased locations, an *Authorization to Use, Process, Store or Transmit Sensitive Information Outside VA Owned or Managed Facilities* (VASI Memo) may be required. An ORD Partial or Full Off-site Waiver may also be required. Contact the Research Office for more information.

D. Funding

<input type="checkbox"/> VA funded research	<input type="checkbox"/> Non-VA funded research	<input type="checkbox"/> Unfunded	
Source Code: (link to codes)	Name (if -99 code):	Admin Code:	Name (if Code is 08):
VACO Project number (for codes 0997, 9022, 9024):			

E. Project Overview

1. The Local Site Investigator is also serving as the Principal Investigator / Study Chair? <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, include the PI/SC initial review approval packet, in addition to the LSI Initial Review approval packet.</i>										
2. The DVAHCS is serving as the coordinating center? <input type="checkbox"/> YES <input type="checkbox"/> NO										
3. All research personnel working on this study have a Research Scope of Practice on file in the Research Office or submitted with this application? <input type="checkbox"/> YES <input type="checkbox"/> NO										
4. This study involves FDA Regulated Drugs, Devices, or Other Products <input type="checkbox"/> YES ² <input type="checkbox"/> NO										
5. If the study has an IND or IDE, complete the table below. <i>Check here if N/A:</i> <input type="checkbox"/>										
<table border="1"><thead><tr><th>Drug or Device Name</th><th>IND or IDE # (if Applicable)</th></tr></thead><tbody><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr><tr><td> </td><td> </td></tr></tbody></table>	Drug or Device Name	IND or IDE # (if Applicable)								
Drug or Device Name	IND or IDE # (if Applicable)									
6. Non-Veterans (<i>excluding VA employees</i>) will be enrolled. <input type="checkbox"/> YES <input type="checkbox"/> NO										
7. The study will likely enroll the following categorically vulnerable populations: <input type="checkbox"/> <i>Not applicable</i> <input type="checkbox"/> Children (<i>MCD approval required</i>) <input type="checkbox"/> Incompetent to provide consent <input type="checkbox"/> Prisoners (<i>CRADO Waiver required</i>) <input type="checkbox"/> Pregnant women (<i>MCD approval required; does not include women who might become pregnant</i>)										

F. Subcommittee Review(s) Not Applicable

1. This study has safety concerns: <i>SRS review may be required.</i> <input type="checkbox"/> Human Tissue <input type="checkbox"/> Genetic strains <input type="checkbox"/> Chemicals <input type="checkbox"/> Biohazards <input type="checkbox"/> Class 3b/4 Lasers <input type="checkbox"/> Radionuclides <input type="checkbox"/> Other:
2. Radiation Safety Committee Review is required: <input type="checkbox"/> YES <input type="checkbox"/> NO <i>If yes, Radiation Safety Committee review and approval should occur prior to submitting the initial review packet to the Research Office.</i>

G. Departmental Support Not applicable

1. The study will require support from the following Durham VAHCS departments or services: <i>Check all that apply. A letter of support is required from the department(s).</i> <input type="checkbox"/> Pharmacy <input type="checkbox"/> Clinical Laboratory <input type="checkbox"/> Surgery <input type="checkbox"/> Nursing <input type="checkbox"/> Nuclear Medicine <input type="checkbox"/> Radiology <input type="checkbox"/> Other:

H. Keywords (list a minimum of 3 keywords relevant to the project):

1.
2.
3.

² A Letter of Support from Pharmacy Service is required.

I. Comments *Please provide additional information that may help the reviewer as s/he reviews this application.*

J. Supervisor Signature(s)

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Service Chief Printed Name	
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Signature of Service Chief	Date
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Supervisor Printed Name	
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Signature of Supervisor (if different than Service Chief)	Date

K. Principal Investigator Verification

1. Considering all the above information, the risks in this project are outweighed by the benefits.

2. All information provided on this form and any required supplemental initial review documents are truthful and accurate to the best of my knowledge.

3. All project team members will be trained on applicable project procedures and all VA and other requirements pertaining to human subject protections as befits their roles, scope of practice, and responsibilities prior to participating in the project.

4. As local site investigator for this study, I acknowledge that I have the primary and ultimate responsibility for protecting the rights and welfare of research participants at this site and that I understand the ethical principles of human subjects protections and Good Clinical Practice.

5. I have the competencies and the resources to conduct the research outlined in this application and I attest that the application is scientifically and ethically sound.

6. Initiation of research activities cannot begin until I receive written notification of approval form Research and Development Committee and the Associate Chief of Staff for Research and Development.

Local Site Investigator Signature	Date
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RESEARCH OFFICE USE ONLY

Subcommittee on Research Safety (SRS) Not applicable

SRS RECOMMENDED ACTION: <input type="checkbox"/> Approve without modifications <input type="checkbox"/> Approve with minor modifications <input type="checkbox"/> Table (Requires Substantive Changes) <input type="checkbox"/> Disapprove	COMMENTS:
<hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> SRS Committee Member Signature Date	

Research and Development Committee (R&DC)

R&DC RECOMMENDED ACTION: <input type="checkbox"/> Approve without modifications <input type="checkbox"/> Approve with minor modifications <input type="checkbox"/> Table (Requires Substantive Changes) <input type="checkbox"/> Disapprove	COMMENTS:
<hr style="border: 0; border-top: 1px solid black; margin: 5px 0;"/> R&DC Committee Member Signature Date	