

 <p>VA MARYLAND HEALTH CARE SYSTEM</p>	<p>VAMHCS Research Service R&D COMMITTEE</p>
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**Worksheet for Submitting a Human Subjects Research Project to
the VA Research & Development Committee**

Transaction Type

- New Protocol
 Continuing Review
 Modification # _____
 Closeout

 Annual Update (for Exempt or NHR)

IRB Determination

- Exempt
 Expedited
 NHR
 VA Central-IRB Reviewed

Funding

- VA Funded
 BREF Funded
 No Funding
 University/Other

GENERAL INFORMATION

Principal Investigator	
PI's Phone & E-mail Address	
Study Coordinator (s)	
Study Coordinator (s) Phone & E-mail Address(s)	
IRB Protocol Number <i>CICERO # or C-IRB #</i>	
Study Title	
Date this action was approved by IRB	
If modification, provide a short description:	

Module Name of Form	Required for: (PI/Coordinator check materials provided)				Submitted (Office use only)
	New Submis- sions	Modific- ation	Continu- ing Review	Close- Out	
Printed copy of CICERO protocol <i>(Please print double sided & check that right margin is not cut off)</i>					
Printed copy of Modification Request <i>(from CICERO)</i>					
Printed copy of Continuing Review <i>(from CICERO) Note: Print so the right margin is not cut off)</i>					
HIPAA authorization form		[if applicable]			
IRB Approval letter					
IRB Approved VA Form 10-1086 consent form Provide unstamped draft consent that was approved by the IRB. (VA Consent will be stamped after VA R&D approval for new submissions after IRB approval for Modifications and CRs)		[if modification changed VA consent]			
Required Trainings for PI Y <input type="checkbox"/> N <input type="checkbox"/> CITI and GCP (UM or VA)(biannually) Y <input type="checkbox"/> N <input type="checkbox"/> VHA Privacy & HIPAA (annually) Y <input type="checkbox"/> N <input type="checkbox"/> VA Privacy & Information Security Awareness and Rules of Behavior (annually) Once only Y <input type="checkbox"/> N <input type="checkbox"/> Information Security 201 <i>(PI is responsible for research staff adherence to required research training. Training adherence will be audited. Questions: Holly Bowen ext. 5063)</i>		[[for changing PI only]			
Scope of Practice: Current Scope of practice must be on file in Research Admin Office. <i>(PI is responsible for their research staff adherence to this requirement .Questions: Holly Bowen ext. 5063)</i>					
If PI is a licensed professional, is (s)he credentialed at the VAMHCS? In what department? Dept <input type="checkbox"/> VA Employee <input type="checkbox"/> WOC <i>(PI is responsible for research staff adherence to WOC or VA employee status requirements. Questions: ext 7130)</i>					
Is PI new to research at the Baltimore VA? N <input type="checkbox"/> Y <input type="checkbox"/> eCommons ID # _____ <i>If yes, complete ePromise page 18 (Obtain from R&D coordinator) and provide eCommons ID #</i>					

IRB Number - _____

Module Name of Form	Required for: (PI/Coordinator check materials provided)				Submitted (Office use only)
	New Submis- sions	Modifi- cation	Continu- ing Review	Close- Out	
<p>Will ANY drug (investigational or not be used for the purpose of this study)? Y <input type="checkbox"/> N <input type="checkbox"/> If "Y", VA Form 10-9012 is required for each study-related drug.</p>		[if applicable]			
<p>Investigator must meet with the VA Investigational Drug Pharmacist (IDP) (Hai Yan Jiang, RPh. x7113) and must provide a hard copy of the research protocol to the IDP Provide copy of IDP approval letter. (Discussions on the agreement occur during the meeting above.)</p>					
<p>VA Form 10-0398 "Research Protocol Safety Survey" (RPSS) (questions about this form can be sent to peggy.wess@va.gov) (Annual updates of RPSS are required and you will be reminded of the due date by Peggy Wess)</p>		[if applicable] Only submit new RPSS if "Safety" procedures have changed			
<p>Did you complete an IBC application in CICERO? N <input type="checkbox"/> Y <input type="checkbox"/> If yes, provide a copy of application and IBC letter.</p>		[if applicable]			
<p>Did you complete a Radiation use application in CICERO? N <input type="checkbox"/> Y <input type="checkbox"/> If yes, provide a copy of application and letter from VA Radiation Safety Officer.</p>					
<p>Does your study involve: a. International Research b. Children c. Women of childbearing capacity & FDA Class D or X drugs d. Prisoners N <input type="checkbox"/> Y <input type="checkbox"/></p>					
Other:					

Research Office Use Only	
VA Funded/ JIT _____	Funding Source Code: - _____ Admin Code _____
HIPAA Waiver - None _____	For recruitment purposes _____ For Entire Study _____
IRB Approval letter documents HIPAA Waiver _____	ISO/PO Checklist - _____
R&D Contingent approval date - _____	SRS Approval Date - _____
R&D Approval Date - _____	R&D Letter Sent - _____
Date entered into ePromise - _____	ICF stamped - _____

Questions: Ann Kimball 410-605-7000 ext 6506 or Tina McGinley (Ross-Fischer) ext. 6568

10/22/1210/30/12

http://www.maryland.research.va.gov/research/human/human_subject_forms.asp

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