IRB Number - _____

VAMHCS Research Service
R&D COMMITTEE

Worksheet for Submitting a Transaction for a Human Subjects Research Project

Transaction Type

☐ **New Protocol** ☐ **Continuing Review** ☐ **Modification #** _____

☐ **Annual Update (for IRB Exempt or NHSR)** **(Study Closure should use Closure Worksheet)**

IRB Determination

☐ **Full Board** ☐ **Exempt** ☐ **Expedited** ☐ **NHSR** ☐ **VA Central-IRB**

Funding

☐ **VA Grant Funded** ☐ **BREF Funded** ☐ **No Funding** ☐ **University/Other**

GENERAL INFORMATION

Principal Investigator	
PI's Phone & E-mail Address	
Study Coordinator(s) or Point of Contact	
Study Coordinator or Point of Contact's Phone & E-mail	
IRB Protocol Number *CICERO # or C-IRB #*	
Study Title	
Date this action was approved by IRB	
If modification, provide a short description of changes: If Annual Update for Exempt or NHSR provide an abstract.	

Module Name of Form **Gray shaded areas no submission needed**	**Required for: (PI/Coordinator check materials provided)**				**Submitted (Office use only)**
	New Submission	**Modification**	**Continuing Review**	**Annual Update for Exempt or NHSR**	
Printed copy of **CICERO protocol**					
Printed copy of **Modification Request** *(from CICERO)*					
Printed copy of **Continuing Review** *(from CICERO)*					
HIPAA authorization form 10-0493		[if modification changed form]	{if Continuing Review changed form}		

IRB Number - _____

Module Name of Form Gray shaded areas no submission needed	Required for: (PI/Coordinator check materials provided)				Submitted (Office use only)
	New Submission	Modification	Continuing Review	Annual Update for Exempt or NHSR	
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 and after IRB approval for Modifications and CRs. (*Questions Tina McGinley x6568*)		[if modification changed VA consent]			
Checklist for Reviewing Privacy, Confidentiality and Information Security in Research-New Submission Form. Please submit final version of checklist from CICERO Public Comments w/ISO and PO signatures (referred to as ISO/PO Checklist)					
Collaborative Studies Template (if applicable)					
Will ANY drug (investigational or not be used for the purpose of this study? Y ☐ N ☐ **Investigator must meet with the VA Investigational Drug Pharmacist** (IDP) (Hai Yan Jiang, RPh. x7113)		[if applicable]			
Provide copy of IDP approval letter.		[if applicable]			
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) http://www.maryland.va.gov/research/human/forms/research_protocol_safety_survey_form_instructions.pdf		[if applicable] Do not submit new RPSS unless safety procedures have changed	SRS will notify you when annual update is due. Do not submit here		
Did you complete an IBC application in CICERO? N ☐ Y ☐ **If yes, provide a copy of application and IBC letter.**		[if applicable]			
Did you complete a Radiation use application in CICERO? N ☐ Y ☐ **If yes, provide a copy of application and letter from VA Radiation Safety Officer.**					
Will tissue samples be banked? N ☐ Y ☐					
Does your study involve?: **a. International Research b. Children c. Prisoners** N ☐ Y ☐ If yes is checked, Facility Director or CRADO approval is required before study may start.					
If PI is a licensed professional, is (s)he credentialed at the VAMHCS? Y ☐ N ☐ **VA Status:** ☐ VA Employee ☐ WOC					
Is PI new to research at the Baltimore VA? N ☐ Y ☐ eCommons ID # _____ *If yes, complete ePromise page 18 (Obtain from R&D coordinator) and provide eCommons ID #*					
VA Conflict of Interest: form must be on file in					

IRB Number - _____

Module Name of Form Gray shaded areas no submission needed	Required for: (PI/Coordinator check materials provided)				Submitted (Office use only)
	New Submission	Modification	Continuing Review	Annual Update for Exempt or NHSR	
Research Office for **each study**					
Data Inventory- form must be on file in Research Office for each study					
Plan for Accounting of Disclosures for this study: ☐ Scenario A ☐ Scenario B-1 ☐ Scenario B-2 ☐ Scenario C ☐ Scenario D For detailed information/instructions see: http://www.maryland.va.gov/research/human/forms/scenarios_of_accounting_of_disclosures.pdf					

This section below must be completed for all **New**, **Continuing Reviews, or Modifications that add team members** and for **Annual Updates(Exempt/NHSR)**

If the team member interacts with VAMHCS patients, performs procedures at the VAMHCS, or has access to VA data then all information for the person must be listed here.

Confirmation of required items for study team members:
Status, **Required Trainings** and **Scope of Practice**

Principal Investigator, Sub-investigators, and ALL Research Team Members (include everyone listed in your CICERO submission)	Status of Team Member			VA Privacy and HIPAA Policy Training (required annually)	VA Privacy and Information Security Awareness and Rules of behavior (required annually)	CITI Training (required every 3 years)	Scope of Practice (copy should be on file in Research Office and also in study binder)
	VA Paid Staff	WOC (List expiration date on most recent WOC appointment letter)	** UM/ Non VA (only)	Date Completed	Date Completed	Date Completed	Date ACOS signed

If this study is a collaborative project and there are team members who do not participate on the VA portion of the study **they should be listed here as UM/Non VA only and no other info on status, trainings or Scope of Practice is required.

I confirm that this is a complete list of all staff for this human research project and that all required trainings are current and Scopes of Practice are on file.

Principal Investigator _____ Date _____