

 <p><b>VA MARYLAND</b> HEALTH CARE SYSTEM</p>	<p><b>VAMHCS Research Service R&amp;D COMMITTEE</b></p> <p>Worksheet for Submitting a Modification or Annual Update for a Research Project</p>
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- Project transferred to new PI      IRB Modification # \_\_\_\_\_
- Annual Update (for IRB Exempt, NHSR or “Data Analysis Only” Projects)

**GENERAL INFORMATION**

<b>Principal Investigator</b>	
<b>PI’s phone &amp; E-Mail Address</b>	
<b>Study Coordinator (s) or Point of Contact</b>	
<b>Study Coordinator (s) or Point of Contact’s Phone &amp; E-mail</b>	
<b>IRB Protocol Number</b> CICERO # or C-IRB #	
<b>Study Title</b>	
<b>If modification to change PI, provide previous PI name:</b>	
<b>If Annual Update for Exempt, NHSR or “Data Analysis Only” provide a current abstract</b>	

Module Name of Form (Gray shaded areas are no submission needed)	Required for: (PI/Coordinator check materials provided)		Office Use Only
	Modification	Annual Update for Exempt, NHSR or “Data Analysis Only”	
Printed copy of modification request (from CICERO or C-IRB)			
IRB Approval letter for Modification			
If new PI is a licensed professional is he/she credentialed at the VAMHCS	Yes <input type="checkbox"/> No <input type="checkbox"/>		
New PI VA status	VA Employee <input type="checkbox"/> WOC <input type="checkbox"/>		
VA Conflict of Interest: new PI must submit			

Module Name of Form (Gray shaded areas are no submission needed)	Required for: (PI/Coordinator check materials provided)		Office Use Only
	Modification	Annual Update for Exempt, NHSR or "Data Analysis Only"	
Have there been any changes to privacy or information security? If yes submit "ISO/PO Checklist for CRs and Mods".	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Has there been any change in location of electronic or hard copy data? If yes submit updated "VAMHCS Research Data Inventory Tool"	Yes <input type="checkbox"/> No <input type="checkbox"/>		
Has there been any change in location of tissue repository or data repository?	Yes <input type="checkbox"/> No <input type="checkbox"/>		

**The table below must be completed for all team members**

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:  
VA Status, Required Trainings and Scope of Practice**

Principal Investigator, Sub-investigators, and <u>ALL</u> Research Team Members	<u>Status of Team Member</u>			<u>VA Privacy and HIPAA Policy Training</u>  (required annually)	<u>VA Privacy and Information Security Awareness and Rules of behavior</u>  (required annually)	<u>CITI Training</u>  (required every 3 years)	<u>Scope of Practice</u>  (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.