IRB Number -



VAMHCS Research Service R&D COMMITTEE

Worksheet for "closing/completing" a Human Subjects Research Project

Transaction Type

Project closed at IRB, but analysis of de-identified data continues. (VA requires these studies to remain open with the VA R&D Committee, Annual Updates are required and team members that are analyzing the data must remain current on VA required trainings.)

Project Closed at IRB, but samples/specimens are still being worked on in my lab. (Project will remain open with R&D Committee as "bench only" study. Annual Updates are required for SRS and team members that are working in the lab must remain current on VA required trainings)

Project Closed at IRB and all data analysis and laboratory work is complete. (Project will be closed at SRS and R&D Committee. Study may be scheduled for an audit by VA Compliance.)

] IRB Exempt or Non Human Subjects Research Project is complete.

(All data analysis has been completed. Project will be closed at R&D Committee. Study may be scheduled for an audit by VA Compliance.)

Principal Investigator	
PI's Phone & E-mail Address	
Study Coordinator(s)/Team	
Member(s)	
Study Coordinator's	
Phone & E-mail Address	
IRB Protocol Number	
Study Title	
Date study closed by IRB or date	
all work <u>was completed</u>	
Location (Bldg.Room) and	
person responsible for study files	
(electronic & hard copy)	

GENERAL INFORMATION

	Required for IRB Closure	Submitted
Module	submissions:	(Office use only)
Name of Form	(check materials provided)	

	IRB Number -			
Module Name of Form	Required for IRB Closure submissions: (check materials provided)	Submitted (Office use only)		
Printed copy of CICERO closure submission				
IRB Closure letter				

For studies that will be continuing and will be analyzing de-identified data or working in the lab with samples please list below the study team members that will be working with the data or samples.

(If this study is no longer analyzing data or working with samples this section does not need to be completed)

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

<u>Status of Team Member</u>		<u>VA Privacy and</u> <u>HIPAA Policy</u> <u>Training</u> (required annually)	<u>VA Privacy and</u> <u>Information</u> <u>Security Awareness</u> <u>and Rules of</u> <u>Behavior</u> (required annually)	<u>CITI Training</u> (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 PI signed or date ACOS signed
]	VA Paid	VA (List expiration Paid date on most recent WOC appointment	VA (List expiration date on most Non recent WOC VA appointment (only)	Status of Team Member HIPAA Policy Training Status of Team Member (required annually) VA Paid Staff WOC (List expiration date on most recent WOC appointment ** VA VA (only)	Status of Team Member HIPAA Policy Training Information Security Awareness and Rules of Behavior Status of Team Member (required annually) Information Security Awareness and Rules of Behavior VA Paid Staff WOC ** VA Paid Staff WOC ** VA pointment VA (List expiration date on most recent WOC VA VA Completed Completed Completed Completed	Status of Team MemberHIPAA Policy TrainingInformation Security Awareness and Rules of Behavior(required every 3 years)Status of Team Member(required annually)(required annually)(required annually)VA Paid GstaffWOC recent WOC appointment** VA VA (List expiration VA (conby)Date CompletedDate Completed

I confirm that this is a list of staff who will be working on <u>data analysis or samples</u> for this study and that all required trainings are current and Scopes of Practice are on file.

Principal Investigator _____

Date _____