



**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. No further data analysis, publication or access to data. (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.)

GENERAL INFORMATION

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 <u>study closed by IRB</u> or date <u>all work was completed</u>	
Location (Bldg.Room) and person responsible for study files (electronic & hard copy)	

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		
Research records Storage/Destruction form		
Is there a data or tissue repository for future research associated with this study?		

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 the section below does not need to be completed)

Status, Required Trainings and Scope of Practice

Principal Investigator, Sub-investigators, and Research Team Members (only include team members who will work on analyzing the data or samples)	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 PI signed or date ACOS signed

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

Principal Investigator _____ Date _____

For projects that checked box 3 or 4 on first page

I understand that:

- If I no longer hold an appointment as an employee (compensated or uncompensated (WOC)), all research records, data, and data in repositories must remain at VA and under VA control.
- All data and records are the property of the VA. The data may not be copied or removed unless all requirements for use of VA data by non-VA investigators are met.
- I can no longer access or use the data or specimens obtained from this study for any reason.
- I must retain the study records until the requirements of RCS 10-1 have been met (per the information provided on the attached Records/Destruction form).
- I must notify the VAMHCS Research & Development Service if the location of VA research records or electronic data changes.
- If I leave the University of Maryland or VAMHCS I may not remove the VA data or VA records without special written permission (Contact the ACOS/R&D), and I must inform the R&D Service of the individual who has assumed custody of my research records/data/specimens.

Principal Investigator _____ Date _____