Study Closure Checklist

This is an informational checklist to ensure that Principal Investigators are aware of VA policies and regulations pertaining to study closure. Some items on this checklist do not apply to every study. Please contact the Administrative Officer for Research Service for questions or assistance.

☐ By closing the study you acknowledge that no participants are receiving any research-related project interventions or interactions, including interactions or interventions related to collection of long-term follow-up data, at any of the local participating sites and the project will not enroll any more participants.

☐ If you anticipate the possibility of additional data analysis and/or manuscript preparation on a closed study, the data must be de-identified (according to Common Rule and HIPAA requirements). Enrollment logs or other documents linking participants' identity to their data must be destroyed or modified to ensure de-identification. If you are still conducting analysis of identifiable data, or do not want to de-identify your data for any other reason, do not close the study.

☐ Federal regulations require that VA records should be stored for a minimum of 6 years. In some cases, sponsors may require a longer period for records retention. There is no off-site storage option for paper records, and limited on-site storage. Therefore, paper records should generally be scanned to electronic files and saved on the VA "S" drive, and the original paper should be discarded (shredded if it contains private information). Please contact the Records Liaison in the Research Office for guidance on records retention and storage.

☐ When working with external collaborators (e.g., University of Florida), the VA must retain either the original data or a copy of the data. Which of these applies depends on the terms of any study agreements, such as a Data Use Agreement or a Memorandum of Understanding.

☐ In some cases, study closure is accompanied by separation of staff from the VA (including "without compensation" employees). Please contact the Research Service Administrative Officer to ensure that proper separation procedures are followed.

☐ For clinical trials, the informed consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when the entire study has closed to subject recruitment. Consent forms must be posted on either https://clinicaltrials.gov or a docket folder on http://Regulations.gov (Docket ID: HHSOPHS-2018-0021). Studies registered with ClinicalTrials.gov may have additional requirements at or around the time of study closure, such as entering study results into the website.

☐ For VA funded awards, the VA Office of Research and Development has an award closeout policy requiring the submission of a final report no later than 120 calendar days after termination of the award. A Final Research Performance Progress Report (FRPPR) is required to be submitted via the eRA Commons.

☐ Clinicians (whether PI, Co-I, or study staff) should notify their Service Chief if involvement with the study provided justification for protected research time.

☐ If the study provided justification for assignment of research space, notify the Research Service Administrative Officer to consider whether space assignments should be modified.

☐ If the study involved intellectual property (e.g., invention or patent), you must communicate with the VA Technology Transfer Program to ensure that all laws and regulations are followed.

☐ In some sponsored trials, sponsor permission is required for study closure.

☐ If the lab is also closing, the PI must complete the Laboratory Close-Out Checklist. The checklist is posted on the Research Service website.

☐ If the Principal Investigator is separating from NF/SGVHS, the PI must complete the "Investigator Departure Checklist". The checklist is posted on the Research Service website.