

Closing/Terminating a Protocol

I Have Completed My Study – Can I Close The HAC Approval?

A study may not be terminated if research subjects are in follow-up or if data are still being analyzed. However, if all research subjects have completed study participation and all data has been analyzed, the study may be closed.

Can I Just Call Or Email To Terminate My Study?

No. A phone call or e-mail message is inadequate to terminate a study. An [HAC Form 111](#), Final Study Report, must be utilized to terminate the study. The [HAC Form 107](#), Clinical Study Status Report, may be used if the termination coincides with the approval expiration date.

Who Is Responsible For Notifying Other Departments Such As MCGHI Patient Accounting, Division Of Sponsored Programs Administration, Augusta Veterans Affairs Medical Center, Etc. the Study is Terminated?

The PI is responsible for notifying all other departments.

I Am Leaving MCG/MCGHI/Augusta VAMC. Do I Close My Protocol Here?

Yes.

The PI Left MCG/MCGHI/Augusta VAMC Without Naming A New PI. What Do We Do?

The department chairperson assumes responsibility for naming a new principal investigator. If a new PI is named, submit a completed HAC Form 113 to the HAC Administrative Office. Other forms and documentation such as a revised informed consent document may be required. If the protocol is externally sponsored, confirm the sponsor's approval of the new PI prior to submitting HAC paperwork. Notify DSPA and/or ABRC as appropriate. Contact the HAC Administrative Office for additional assistance.

What HAC Form Do I Complete To Terminate The Study?

An [HAC Form 111](#), Final Study Report, must be utilized. The [HAC Form 107](#), Clinical Study Status Report, may be used if the termination coincides with the approval expiration date.

What Information Should Be Included In The Final Report?

At study termination or completion, a timely final report must be submitted to the Human Assurance Committee (HAC). It must include the number of enrolled, discontinued and completed subjects, and the number of signed informed consent forms in the investigator's files for the entire project. Please be as informative as possible.

Sample Guidance Statement for the summarization report section:

HAC Policies and Procedures

"Twelve medical records were reviewed. The data were gathered and protected per the Description of Research Proposal. The poster presentation was made at the July meeting of National Principal Investigators. The study is now complete."

What Other Documents Are Required If The Study Is Industry Sponsored?

A copy of the sponsor termination letter should accompany the [HAC Form 111](#), Final Report, or HAC Form 107, Clinical Study Status Report, if utilized when the termination occurs during the approved project period.

Who Do I Contact if I Have Any Questions?

Contact the HAC Administrative Office at HAC@mcg.edu or call the following extensions:

(706) 721-8397 for PIs whose last names begin with A-G

(706) 721-3110 for PIs whose last names begin with H-P

(706) 721-1482 for PIs whose last names begin with Q-Z

Although the above listing indicates the staff's primary PI assignments, all HAC Administrative Office staff can answer your questions. There may be situations when your questions may require consultation with the HAC or OHRP leadership.