

Closing Your Research Study

- This Hot Topic (Vol. 6 No. 4) updates the information on procedures for closing out research protocols at the VAMHCS. In October 2007, the VAMHCS Research Service issued a Hot Topic entitled “Closing Your Study” (Vol. 1 No. 5); that Hot Topic (Vol. 1 No. 5) is now rescinded.
- IRB Policy states that the following must be true in order to close a studyⁱ:
 - data collection is complete,
 - there is no more participant contact, and
 - the only research activity being conducted is data analysis of deidentified data.
 - VAMHCS NOTE: *If you use “Individually Identifiable Information” for your data analysis, do not close your study until you have completed your analysis.* Even if you have completed all interactions with your subjects, you must keep the study open and continue to report to the IRB and Research Service for as long as you work with identifiable data. You may, however, submit a Modification Request to the IRB asking that the risk level of the study be reduced to minimal risk. This will reduce some of the administrative load associated with keeping the study open.
 - VAMHCS NOTE: *If you close the study, you may not use the data unless you reapply to the IRB!* If you decide you wish to use the data in ways different from or in addition to what has been approved by the IRB and R&D Committee, you will need to submit a Modification Request or submit a new proposal.
- Steps to close a study:
 - Close the study in CICEROⁱⁱ:
 - Complete the “Closure Report” in CICERO.
 - Attach relevant documents and submit the report.
 - A Closure Report must be submitted within 45 days of study closure. (If you fail to submit a Closure Report to close out Human Research, you will be restricted from submitting new Human Research until the completed application has been received).
 - Close the study at the VAMHCS:
 - R&D Committee (RDC)
 - Complete the Worksheet for Submissions to R&D Committee (see column for “Closure”)
 - RDC Coordinators will obtain final abstract from CICERO.
 - RDC Coordinators will send the study to the next scheduled RDC meeting for acknowledgement.
 - Contact Ann Kimball (x6506, ann.kimball@va.gov) or Tina Ross-Fischer (x6568, tina.ross-fischer@va.gov) for questions.
 - CPRS Research Subject Clinical Warnings (RSCW)

- Remove the Research Subject Clinical Warnings (RSCW) from CPRS (if you have not already done so as individual patients completed their participation in the study):
- For each participant, locate the original RSCW note.
- Write an addendum to the note indicating that the participant is no longer on the protocol (or that the protocol has been closed) and that the RSCW is to be removed.
- Send a message to the VAMHCS Clinical Informatics Service requesting that the RSCW(s) be removed from the “Postings” section. Tell them the name of the participant, their last 4, and the date of the original RSCW note. **YOU CANNOT DO THIS OVER OUTLOOK UNLESS IT IS PKI ENCRYPTED.** Use DHCP instead or personally deliver the information to CIS staff.
- Contact the Clinical Informatics staff via email at VAMHCS Clinical Informatics (in Outlook) [VAMHCSCIS2@med.va.gov].
- Investigational Drug Service
 - Notify the VAMHCS Investigational Drug Service if the study has involved the dispensing of study drugs.
- Once you are reasonably sure that the sponsor has completed their queries or that you will no longer need your study documents, pack up your regulatory binder(s), source documents, and other documents in an ORGANIZED fashion. You may need to locate a document in the future and you will be happy to find it in a precise place rather than having to sort through boxes and binders.
- Discard **duplicate** documents but otherwise keep ALL documents.
(Remember that research documents may not be destroyed at this time.)
- If you have been organized throughout your study, it should be easy to place your accurately labeled binders, folders, audio/video tapes, etc. into boxes.
- If your data is stored electronically, be just as organized in how it is filed. Be sure that data is stored on protected networks behind the VA firewall.
- Catalogue the contents of the boxes into a log book or other central, reliable file so that you will be able to easily locate boxes and contents in the future.
- Label the boxes. Be sure to include a count (“Box _ of _”, for example) as well as a description of the contents (“Study _, Subjects #001-010”, for example). Include the box labeling on your catalogue.
- Place the boxes into long-term storage at an approved location. Be sure to take note of the location of the boxes. Write the information on your catalogue: building name, room number, shelf number, etc.

For questions concerning this or other Research Service Hot Topics OR for adding staff or colleagues to the Hot Topics mailing list, contact:

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Can't put your finger on a past Hot Topic you know would solve your problem? No problem. Check the Hot Topics archive on the Research Service website:
http://www.maryland.research.va.gov/hot_topics.asp

For comments, complaints or suggestions regarding the Research Service or Office of Research Compliance, contact:

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ⁱ See UMB Investigator Manual