VAMHCS RESEARCH SERVICE HOT TOPIC

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Closing Your Study

- All studies eventually close and for many reasons: enrollment goals are met (or not) and follow-ups are completed, funding ends, administrative issues such as closure by the IRB occurs, the sponsor ends the study, and so on. Whatever the reason, when a study ends, you do not want it to live on in administrative limbo! This causes extra work for all with unnecessary reminders for renewals, etc. Here are steps that you should take when a study closes.
- IRB Policy (3J.3) states that you must close studies within 30 days of ALL of the following:
  - data collection is complete,
  - there is no more participant contact, and
  - the only research activity being conducted is data analysis of deidentified data.

  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.

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:
  - Notify the IRB that you wish to close the study.
    - Enter BRAAN and access the study file.
    - Go to the question "What would you like to do?" and select option "request closure" from the drop-down list.
    - Follow the directions in BRAAN. If you have further questions, see IRB Policy 3J.3 available on the HRPO website (http://medschool.umaryland.edu/orags/hrpo/policies.asp).
  - Notify the Research Service that you wish to close the study. Do this by sending Mary Pope (x7131 or mpope001@umaryland.edu) a *very brief* summary of the study outcomes (2-3 sentences).
  - 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 in exchange at VAMHCSCIS2@med.va.gov or using the g.CIS mail group in VistA/DHCP.
- 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.
  - If you have been organized throughout your study, it should be easy to place your *accurately labeled* (!) binders, folders, audio/video tapes, CD-Roms, etc. into boxes.
  - If your data is stored electronically, be just as organized in how it is filed. Be sure to create

backups that are stored on protected networks behind the VA firewall. If you use disks for your backup, be sure to store them safely as in the steps below.

- 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, contact:

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