

## VAMHCS RESEARCH SERVICE HOT TOPIC

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### INVESTIGATOR RESPONSIBILITIES TO MANAGE THE QUALITY OF THEIR RESEARCH PROGRAMS

- Investigators are responsible for the conduct of their research studies. This includes:
  - the quality of the informed consent process and the documentation of it,
  - the quality of the recruitment and enrollment processes,
  - the quality of the measurements and data collected for the study,
  - the completeness and organization of regulatory documents,
  - the accuracy and timeliness of reports of unanticipated problems involving risks to participants and others (UPRs)
  - the quality of the management of UPRs,
  - the management of complaints, comments and concerns from study participants, families, and staff.
- The Research Service has recently published a new SOP entitled “Investigator Responsibilities to Manage the Quality of Their Research Programs” (HRP 02.04), available at the website: [http://www.maryland.research.va.gov/research/human/human\\_subject\\_sops.asp](http://www.maryland.research.va.gov/research/human/human_subject_sops.asp). As with all applicable

Research Service SOPs, investigators and research staff must comply with the requirements in this SOP.

- The SOP outlines procedures for you to develop and manage a research program that fits with Good Clinical Practices and VA expectations. It also lists tools and policies that can help you.

- The PI responsibilities listed in the SOP are:

- Becoming knowledgeable about institutional and regulatory policies and procedures regarding conduct of research involving human subject participants;

- Establishing internal policies and procedures to ensure compliance with VAMHCS SOPs, IRB policies and procedures, study protocols, GCPs, and other human subject protection regulations;

- Establishing internal policies to respond to comments, complaints, suggestions or allegations of noncompliance that may come from study participants, their families, research staff, or others

- Ensuring that his/her staff complies with these internal policies and procedures and facilitating their efforts in this area

- Using the Research Service staff, and other sources such as trainings and conferences as resources

- Using this process as a learning tool to improve “good clinical practices”.

- A necessary part of your quality management program is a plan for evaluating the effectiveness of your procedures and for making changes when necessary. This involves some level of auditing of your processes. This can be a program of your own, a program in collaboration with other investigators, or in collaboration with the Office of Research Compliance. When your internal audits uncover problem areas, you must make plans to correct them, follow through with the corrections

and then re-evaluate to make sure the problem has been fixed.

- ▣ Recognize that complaints, comments or suggestions from participants, family members or staff might be a sign that there's need for improvement in a part of your program.
- ▣ Recognize that whenever you find a protocol exception or deviation, it could indicate a problem with how your program is set up.
- ▣ Recognize that how you conduct your research program is part of an overall human research protections program. It includes what you do to comply with VAMHCS and IRB requirements (such as scanning of informed consents, RSCWs, reporting of UPRs to the IRB, etc.).
- ▣ Recognize that whenever you tell the IRB, the Office of Research Compliance, a study monitor, etc that you will do "xxx" to fix "yyy" in the future, you have just performed a quality management activity.
- ▣ Put it in writing (even a simple memo is acceptable), disseminate it to staff, and file it in your procedures manual.
- ▣ Check back in a period of time to see how well the plan worked, document the results, and make a new plan if the first one didn't work.
- ▣ **NONE OF THIS NEEDS TO TAKE HUGE AMOUNTS OF TIME, RESOURCES OR STAFF TIME!** You do not have to write long, formal policies, procedures, tools or reports!!! Instead:

- ▣ adapt the ones available on the Research Service website. (You can even use them *in toto* as long as you state in writing that your site follows “XXX” SOP for [activity] or at least change the headers and footers), OR
- ▣ share/collaborate with other investigators, OR
- ▣ jot down how to do XXX activity into simple memos or step-by-step instructions.
- ▣ Collect the policies, procedures, memos, instructions, reports, staff communications, etc. into a central file where staff knows to go to find guidance. Organize it (!) so that staff can find things quickly when they need something!
- ▣ Re-evaluate your processes periodically and communicate to staff (!) when you change a procedure.
- ▣ Keep the binder current. Discard outdated materials.
- ▣ Make sure staff knows that they’re expected to know and follow the procedures you’ve organized and publicized. Give them feedback when they don’t. Find out why they don’t..the reason could be another trigger for improving your processes or write-ups.
- ▣ Now you have internal policies and procedures and a quality management program to go with it.

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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