

## VAMHCS RESEARCH SERVICE HOT TOPIC

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### COMPLAINTS, COMMENTS & SUGGESTIONS

- ▣ You may receive comments, complaints or suggestions from participants, their families, their advocates, your staff, coworkers or collaborators, hospital staff or other institutional personnel, anonymous sources and whistleblowers, the media, community leaders, the public, and others. You may even have your own comments, complaints or suggestions you'd like to pass along. What can you do? What should you do?
- ▣ The Research Service SOP "[Addressing and Responding to Comments, Complaints and Suggestions Related to the Human Research Protection Program](#)" (HRP 01.07) can help.
- ▣ The main points of the SOP are:
  - ▣ Create an environment in which research participants and staff can express concerns, complaints or suggestions without fear of threat, restraint, discrimination or reprisal.
  - ▣ Take the complaint, comment or suggestions seriously.
  - ▣ Be open to the possibility that it can point you to ways to improve your program (see [Hot Topic Vol. 2 No. 3](#)).
  - ▣ When possible, resolve concerns or complaints internally by handling them in a fair and open

way. Consider yourself as a patient advocate and try to find ways to solve patient issues at the lowest possible level of organizational hierarchy (within your group, directly with the person(s) involved, directly with the person(s) who can resolve the issue). Refer them to the Office of Research Compliance, the IRB or other hospital Offices as appropriate (MAS, Pastoral Care, Security, etc.). VAMHCS Policy Memorandum 512-001/OPS-010 [“Consumer Relations Program”](#) describes this in detail.

- The goal of the process is to promote goodwill with the veteran community and with staff and colleagues by responding quickly and thoughtfully to complaints and suggestions from research participants, their families, and the research staff.
- If the complaint or comment points towards an actual or potential “unanticipated problem involving risks to participants or others” or allegation of noncompliance, you MUST report it to the Office of Research Compliance and the IRB.
- For unresolved or complicated research issues or participants’ rights issues, refer the person to the ORC or IRB.
- Report minor problems to the IRB and ORC through the Continuing Review process.
- When a complaint, comment, suggestion, or allegation of noncompliance is reported to the Research Service, the Office of Research

Compliance (Melody Higgins, Research Compliance Officer) proceeds according to HRP 01.07.

- The Office of Research Compliance would like your comments as well and looks at them as potential triggers for improvements in the VAMHCS Human Research Protection Program.
- The "Contact Us" webpage is available to patients and staff to assist them in contacting appropriate persons within the Research Service. When in doubt...contact us.

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

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