

VAMHCS HUMAN RESEARCH PROTECTION  
STANDARD OPERATING PROCEDURE

SOP# HRP 01.07

Initial Approval Date: 11/8/07

**ADDRESSING AND RESPONDING TO COMMENTS, COMPLAINTS AND  
SUGGESTIONS RELATED TO THE HUMAN RESEARCH PROTECTION PROGRAM**

This SOP, originally approved on 11/8/07, was revised on 4/16/08 and has now undergone changes as summarized below:

|                         |  |                                |                 |
|-------------------------|--|--------------------------------|-----------------|
| Version                 | 2.2  | Origin                         | Version 2.1     |
| Author                  | Jessica Mendoza  |                                |                 |
| Reviewed/<br>Revised by | Jessica Mendoza  | Dates Reviewed /<br>Revised    | 10/14/08        |
| Changes                 | <ul style="list-style-type: none"> <li>• added content regarding when a complaint is a UPR or other reportable event</li> <li>• new item 4.5</li> <li>• Deleted references to “allegations”</li> </ul> | New Version #                  | 2.2             |
| Approved                | Leslie Katzel, R&D Chair<br>10/23/08   | Approved<br>R&D / Dennis Smith | <b>10/23/08</b> |
| File Name               | Complaints (HRP 01.07) 2007.2.2  |                                |                 |

This amended version (2.1) will be submitted to the HRPOC Subcommittee and the R&D Committee at their next scheduled meetings.

\_\_\_\_\_  
Leslie Katzel, MD, PhD  
Chair, R&D Committee

\_\_\_\_\_  
Date

Complaints (HRP 01.07) 2007.2.2  
Prior versions: 10/04, 11/07, 4/08

Version 2.2

Review due: 11/10

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ADDRESSING AND RESPONDING TO COMMENTS, COMPLAINTS AND  
SUGGESTIONS RELATED TO THE HUMAN RESEARCH PROTECTION PROGRAM

## OBJECTIVE:

To establish a documented process for responding to comments, complaints and suggestions as they are related to the Human Research Protection Program (HRPP).

To promote goodwill with the veteran's community by responding quickly and thoughtfully to complaints and suggestions from research participants, their families, and the research staff.

## SCOPE &amp; POLICY:

The VA Research Service welcomes comments, complaints and suggestions and looks at them as potential triggers for improvements in the VAMHCS HRPP. It also understands that prompt and thoughtful responses to comments, complaints and suggestions promote goodwill with the community at large.

Comments, complaints or suggestions may be either verbal or written and may come from participants, participants' families or advocates, research staff and investigators, hospital staff or other institutional personnel anonymous sources and whistleblowers, committee or subcommittee members, the media, community leaders, the public, and others.

Every UMB and VAMHCS informed consent document includes the principal investigator's contact information as well as contact information for the UMB. This enables research participants or their families to contact personnel who can follow-up on complaints about the research program, suggestions, and even allegations of noncompliance. If applicable, comments, complaints and suggestions will be investigated and handled in a confidential manner to the extent possible.

In accordance with VAMHCS policy, the Research Service Office of Research Compliance (ORC) expects that investigators and their staff consider themselves as patient advocates, and, as such, find ways to solve patient issues at the lowest possible level of organizational hierarchy.

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The VAMHCS also takes seriously any allegation of noncompliance of research staff with regard to human subject protections and research integrity. If, after follow-up on the comment, complaint or suggestion, it is found that an incidence of noncompliance has possibly occurred, the Research Service will proceed according to SOP 01.08 and IRB policies and procedures.

If a complaint appears to be an unanticipated problem involving risk to participants or others, or another reportable event, the VAMHCS ensures that the investigator reports this to the IRB.

The goals of follow-up on comments, complaints and suggestions are:

- to find a suitable explanation, resolution or corrective action plan, and
- to respond to the complainant in a timely manner.

#### RESPONSIBILITIES:

The VAMHCS Research & Development Service and the VAMHCS Research Compliance Officer are responsible for the implementation of this policy.

The Research Compliance Officer (RCO) is responsible for:

- Intake of the comments, complaints and suggestions;
- Conducting or supervising the follow-up on the comments, complaints and suggestions;
- Determining whether the IRB or VAMHCS entities (such as Risk Management or the Office of Consumer Relations) need to be notified;
- Evaluating whether a complaint indicates possible noncompliance, or an unanticipated problem involving risk to participants or others, or other reportable events;
- Developing or approving the corrective action plan (CAP), if applicable;
- Reporting comments, complaints and suggestions and follow-ups to the MCD and/or ACOS/R&D, the R&D Committee and the IRB (if applicable).

The R&D Committee is responsible for:

- Reviewing reports of comments, complaints and suggestions and supporting approved corrective action plans.

The Principal Investigator is responsible for:

- Ensuring that research participants can express concerns, complaints or suggestions without fear of threat, restraint, discrimination or reprisal;
- When possible, resolving research participants' concerns or complaints internally by handling them in a fair and open way;

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- When necessary, referring research participants' concerns or complaints to the Research Service Office of Research Compliance;
- When the complaint involves an unanticipated problem involving risk to participants or others, reporting the complaint to the IRB;
- Informing study participants and their families/advocates during the informed consent process that complaints can be lodged with the RCO and the IRB;
- Cooperating with the ORC's or IRB's investigations of comments, complaints and suggestions.

## SEE ALSO

|  |   |
|--|---|
| VAMHCS Research Service SOP              | HRP 01.08: Addressing and Responding to Allegations of Noncompliance with Institutional Policies Related to the Human Research Protection Program |
| VAMHCS Research Service SOP              | HRP 02.01: Overview of Quality Assurance Activities   |
| VAMHCS Research Service SOP              | HRP 02.02: Audit Triggers   |
| VAMHCS Policy Memorandum 512-001/OPS-010 | Consumer Relations Program  |
| UMB Policy and Procedure                 | I.3.M: Concerns or Suggestions Regarding the Human Research Protection Program (HRPP)   |

## PROCEDURES:

1. All comments, complaints and suggestions, involving the VAMHCS research program are directed the Research Compliance Officer (or designee) in the VAMHCS Research Service. This is done
  - verbally by calling 410-605-7000 x6512 or 410-605-7130,
  - in writing (10 North Greene Street, Baltimore, Maryland, 21201, Mail Stop 151), by email to : [melody.higgins2@va.gov](mailto:melody.higgins2@va.gov), or
  - in person to the RCO at the address above in room 3-A-125.

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- 1.1. Research participants and family members are provided contact information in the VAMHCS informed consent document (10-1086 version).
- 1.2. The UMB HRPO notifies the RCO of any complaint or compliance issues involving VAMHCS research projects or the VAMHCS HRPP.
2. Complaints may be made anonymously. Research compliance staff will:
  - inform anonymous callers that the matter will be investigated to the extent possible, given the information provided;
  - encourage anonymous callers to call the RCO within 2 business days and periodically thereafter in order to provide new information and follow-up information and to receive updates on the issue
  - inform the caller that anonymity cannot be guaranteed;
  - not pressure callers to leave personal information if they have expressed a desire to remain anonymous.
3. Intake of complaints, comments, or suggestions:
  - 3.1. Research Service staff will send all phone calls, letters, or in-person complainants directly to the RCO or a Research Compliance Specialist (RCS).
  - 3.2. The VA RCO/RCS gathers information to include, as applicable:
    - the contactor's name and phone number for follow-up calls (if they are willing to do so),
    - the subject's name and phone number,
    - study protocol title and Principal Investigator's name,
    - the identity of the person at whom the complaint is directed,
    - a description of the comments, complaints and suggestions, including details such as date of consent, date(s) of incident(s), names of involved persons, and any other information that could facilitate the investigation,
    - any evidence that the contactor is willing to provide,
    - any other descriptions or information as applicable; for example, if the complaint or suggestion is in regard to an institutional matter rather than directed to a specific investigator or study, then the intake of information should capture the context in which the complaint/suggestion is made as well as the complaint/suggestion itself.
  - 3.3. The RCO/designee will reassure the complainant that the comments, complaints and suggestions will be followed up and that appropriate measures will be taken to address the issue. S/he will inform the complainant that periodic updates will be forthcoming (providing that contact information is given).
  - 3.4. Particularly sensitive complaints (for example, whistleblowers, or staff lodging complaints against supervisors) may be handled privately by the RCO to the extent possible. However, anonymity of a complainant or whistleblower for the entire process cannot be guaranteed.
  - 3.5. The RCO will immediately notify the MCD, the ACOS/R&D the VAMHCS Office of Public and Community Relations and the HRPO of any complaints that originate from media reports or contacts.

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#### 4. Investigating comments, complaints and suggestions

- 4.1. All comments, complaints and suggestions are potential triggers for improvements in the HRPP. For example a complaint or suggestion may actually point out inefficiency in VAMHCS systems. This inefficiency should be corrected if possible. Or, some comments, complaints or suggestions may actually point toward possible incidents of noncompliance.
- 4.2. The Research Compliance Officer will try to resolve all issues that are brought to her attention at the lowest level of bureaucracy as possible. Ideally, issues can be handled within the Research Service (including the ACOS/R&D) as QA or QI matters, and reported out to the R&D Committee and institutional officials as necessary.
- 4.3. Many comments, complaints or suggestions may be handled at the time of contact or quickly resolved. For example, the RCO may be able to resolve issues by simply answering questions or clearing up misunderstandings. However, if further inquiry is necessary, the RCO Officer will conduct an initial inquiry through interviews and reviews of pertinent documents. If all issues are resolved through this process and the RCO concludes that
- (a) there was no basis in fact for the complaint, or
  - (b) the issue can be resolved through a corrective action plan,
- then the RCO or designee will follow up with the complainant or other involved persons as appropriate. In addition the RCO may perform any of the following actions or others as appropriate:
- involve the VAMHCS Office of Consumer Relations,
  - involve the VAMHCS Information Security Officer if the complaint or inquiry reveal issues with VA information security requirements,
  - involve the VAMHCS Privacy Officer if the complaint or inquiry reveal issues with unauthorized use, loss, or disclosure of individually identifiable patient information,
  - develop (or instruct the investigator to develop) a corrective action plan with the study or research unit to be carried out as a QA function,
  - develop a corrective action plan to be carried out as a Research Service QI function, such as revision of Research Service policies and procedures,
  - prepare a written report to the MCD, the ACOSD/R&D, the R&D Committee (at the next scheduled meeting), the HRPO Executive Director or Director of Quality Improvement (DQI), and quarterly reports to the Executive Performance Improvement Committee (EPIC) reports.
- 4.4. If the nature of the comment, complaint or suggestion points toward possible noncompliance or substantive QA problems, then the RCO initiates a for-cause audit of the study; or a systems audit of institutional procedures may be initiated (Research Service SOP 01.08).
- 4.5. If the nature of the comment, complaint or suggestion appears to involve an unanticipated event involving risk to participants or others, or another event that

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is reportable to the IRB, the RCO instructs the investigator to report the event to the IRB through BRAAN/CICERO (IRB P&P I.3.J).

5. Reporting:

- 5.1. The RCO will resolve all complaints within 60-90 days of becoming aware of the issues, unless circumstances prolong this period.
- 5.2. The RCO makes brief, summary reports at regularly scheduled R&D Committee meetings. If applicable, a CAP is also presented and approved by the R&D Committee.
- 5.3. The RCO (or designate) makes brief, summary reports at regularly scheduled EPIC quarterly reports.
- 5.4. As applicable the RCO also reports to the MCD, the ACOSD/R&D, the HRPO Executive Director or DC, and other institutional officials or offices.

REFERENCES:

|   |   |
|---|---|
| VAMHCS Policy Memorandum<br>512-001/OPS-010 | Consumer Relations Program  |
| Research Service SOP                        | HRP 01.08: Addressing and Responding to Allegations of Noncompliance with Institutional Policies Related to the Human Research Protection Program |
| UMB Policy and Procedure                    | I.3.M: Concerns or Suggestions Regarding the Human Research Protection Program  |

APPROVAL

This SOP entitled “Addressing and Responding to Comments, Complaints and Suggestions Related to the Human Research Protection Program” has been approved by the Medical Center Director, effective 11/8/07.

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**VA Maryland Health Care System  
Human Research Protection  
COMPLAINT INFORMATION FORM**

Date: \_\_\_\_\_ Time: \_\_\_\_\_

Contactors Name: \_\_\_\_\_ Contactor's Phone #: \_\_\_\_\_  
(Obtain only if contact is willing for f/u phone calls)

Keep contact person confidential: \_\_\_\_\_No \_\_\_\_\_Yes

Regarding whom: \_\_\_\_\_

Study Title/Number: \_\_\_\_\_

Principal investigator: \_\_\_\_\_

Issue: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Date and time IRB and ACOS (or other required notifications) \_\_\_\_\_

Dates of follow-up: \_\_\_\_\_

Comments: \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Complaint initially received by: \_\_\_\_\_