

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

SOP# HRP 01.07/PM #046

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**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 and research community by responding quickly and thoughtfully to complaints and suggestions from research participants, their families, and the research staff.

SCOPE & POLICY:

The VAMHCS Research & Development (R&D) 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 VAMHCS Human and Animal Research Protections Officer (H&ARPO) and the UMB Human Research Protections Office (HRPO). This enables research participants or their

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

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 R&D Service expects that investigators and their staff consider themselves as patient advocates, and, as such, find ways to solve patient issues at the most immediate level of organizational hierarchy possible.

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 incident of noncompliance has possibly occurred, the R&D 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 (R&D) Service and the VAMHCS Human and Animal Research Protections Officer (H&ARPO) are responsible for the implementation of this policy.

The Human and Animal Research Protections Officer (H&ARPO) is responsible for:

- Intake of the comments, complaints and suggestions;
- Conducting or supervising the follow-up on the comments, complaints and suggestions;
- Notifying the ACOS/R&D and determining whether the IRB or VAMHCS entities (such as the Research Compliance Officer, Privacy Officer, Information Security Officer, Risk Management or the Office of Public & Community Relations) should 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 ACOS/R&D, the R&D Committee and the IRB (if applicable).

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

The R&D Committee (RDC) is responsible for:

- Reviewing reports of complaints that involve deficiencies of the R&D program, and approving 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;
- When necessary, referring research participants' concerns or complaints to the VAMHCS Human and Animal Research Protections Officer (H&ARPO);
- 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 VAMHCS HARPO a and the IRB;
- Cooperating with the H&ARPO's or IRB's investigations of comments, complaints and suggestions.

SEE ALSO

VAMHCS Policy Memorandum 512-001/CRS-001, "Consumer Relations Program"

PROCEDURES:

1. All comments, complaints and suggestions, involving the VAMHCS research program are directed the VAMHCS Human and Animal Research Protections Officer (H&ARPO). 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 : jessica.mendoza@va.gov, or
 - in person to the HARPO at the address above in room 6B-135.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- 1.1. Research participants and family members are provided contact information in the VAMHCS informed consent document.
- 1.2. The UMB HRPO notifies the VAMHCS HARPO or RCO of any complaint or compliance issues involving VAMHCS research projects or the VAMHCS HRPP.
2. Complaints may be made anonymously. The HARPO will:
 - inform anonymous callers that the matter will be investigated to the extent possible, given the information provided;
 - encourage anonymous callers to call the within 2 business days and periodically thereafter in order to be provided with new information and 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. R&D Service staff will send all phone calls, letters, or in-person complainants directly to the H&ARPO.
 - 3.2. The VAMHCS HARPO gathers information, 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 HARPO 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 may be handled privately by the HARPO to the extent possible. However, anonymity of a complainant or whistleblower for the entire process cannot be guaranteed.
 - 3.5. The HARPO will immediately notify the ACOS/R&D, the VAMHCS Office of Public and Community Relations and the UMB HRPO of any complaints that originate from media reports or contacts.
4. Investigating comments, complaints and suggestions

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

- 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. Many comments, complaints or suggestions may be handled at the time of contact or quickly resolved. For example, the HARPO may be able to resolve issues by simply answering questions or clearing up misunderstandings. However, if further inquiry is necessary, the HARPO will conduct an initial inquiry through interviews and reviews of pertinent documents. If all issues are resolved through this process and the HARPO 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 HARPO will follow up with the complainant or other involved persons as appropriate. In addition the HARPO may perform any of the following actions or others as appropriate:
- involve the VAMHCS Office of Research Compliance,
 - involve the VAMHCS Privacy Officer if the complaint or inquiry reveal issues with unauthorized use, loss, or disclosure of individually identifiable patient information,
 - involve the VAMHCS Information Security Officer if the complaint or inquiry reveal issues with VA information security requirements
 - involve the VAMHCS Office of Consumer Relations,
 - 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 R&D Service QI function, such as revision of R&D Service policies and procedures,
 - prepare a written report to the ACOSD/R&D, the RDC (at the next scheduled meeting), or other VAMHCS or UMB entities.
- 4.3. If the comment or suggestion involves ideas from participants or the research community for program innovations, the HARPO will engage the individual(s) in further conversation, feedback and potential collaboration in program improvements.
- 4.4. If the nature of the comment, complaint or suggestion points toward possible investigator or research noncompliance, then the HARPO notifies the ACOS/R&D.
- 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 is reportable to the IRB, the HARPO instructs the investigator to report the event to the IRB through CICERO.
- 4.6. If the nature of the comment, complaint or suggestion appears to involve substantive quality management issues involving the conduct of research, the HARPO notifies the ACOS/R&D and initiates a systems audit of Service or institutional procedures as necessary.

VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE5. Reporting:

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

REFERENCES:

VAMHCS Policy Memorandum 512-001/CRS-001	Consumer Relations Program
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VAMHCS HUMAN RESEARCH PROTECTION
STANDARD OPERATING PROCEDURE

**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: _____