

RESEARCH SERVICE

April 1, 2008

## RESEARCH STANDARD OPERATING PROCEDURES

### Human Subject Concerns / Complaints / Allegations of Research Improprieties

**1. PURPOSE:** The purpose of this memorandum is to describe the Research Service standard operating procedure for addressing all complaints, concerns, and allegations of research improprieties expressed orally or in writing regarding research involving human subjects.

**2. POLICY:** In accordance with VA policy, STVHCS employees will be responsive and sensitive toward the needs of our patients and will resolve all complaints in a positive and timely manner. The ACOS for Research or the Assistant Director for Clinical Research is responsible for investigating all concerns/complaints from research subjects and any improprieties involving investigators or their staff. The ACOS for Research or the Assistant Director for Clinical Research handles these issues in a timely manner, assuring protection of human subjects and holding any violators accountable to the applicable regulation. A research subject (past, current or prospective), a designated spokesperson, family member or anyone with a concern about a human research study may raise concerns/complaints about a research project by telephone, in writing, or in person to any component of the STVHCS Human Research Protection Program (HRPP). Each IRB approved informed consent document includes a telephone number for complaints, concerns, or questions regarding approved protocols. Telephone numbers for the VA R&D Office are listed on the STVHCS Research website and all Community Outreach posters and pamphlets.

### **3. ACTION:**

- a. A research subject or anyone with a concern/complaint or alleged research impropriety regarding a research study involving human subjects may raise the concern/complaint with the R&D Office or any component of the STVHCS HRPP. Upon receipt of a concern/complaint or allegation, the ACOS for R&D or the Assistant Director for Clinical Research gathers the following information from the complainant:
  - (1) Subject's (or complainant's) name, address, and phone number (This information is NOT MANDATORY, and a caller may report an incident anonymously; however, the ACOS for R&D or the Assistant Director for Clinical Research advises the caller that a thorough review may not be possible, and that, without this information, follow-up responses to the subject are not feasible.);
  - (2) Study protocol title (or acronym) and the name of the PI;
  - (3) Date(s) of the incident;
  - (4) A summary of the complaint or concern.

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- b. The ACOS for R&D or the Assistant Director for Clinical Research assures the subject (or complainant) that he/she will inquire into the circumstances and that the appropriate component of the STVHCS HRRP will take appropriate measures to address the issue. Furthermore, the ACOS for R&D or the Assistant Director for Clinical Research informs the subject that a response to him or her will be forthcoming as rapidly as possible provided that contact information is given (e.g., if possible, within 2 to 3 weeks of the complaint). The ACOS for R&D or the Assistant Director for Clinical Research also explains to the subject the limits to confidentiality.
- c. If notice is received that a concern/complaint or alleged research impropriety has been received by another component of the STVHCS HRRP (e.g. IRB, Public Affairs Office), the complainant will be contacted by the ACOS for R&D or the Assistant Director for Clinical Research to gather all required information and the same procedures will be initiated.
- d. The ACOS for R&D or the Assistant Director for Clinical Research handles the concern/complaint or alleged research impropriety in a confidential manner to the extent allowed by law. The R&D Office limits access to information concerning the complaint to employees with responsibilities that require knowledge of the concern/complaint or alleged research impropriety.
- e. The ACOS for R&D or the Assistant Director for Clinical Research conveys the information regarding the concern/complaint or alleged research impropriety to the PI of the study in a timely manner, unless it is prohibitive (e.g. misconduct is suspected or security of records is an issue).
- f. The ACOS for R&D or the Assistant Director for Clinical Research promptly investigates the concern/complaint, evaluates the alleged impropriety on a case-by-case basis, and makes every effort to correct the issue(s) at the administrative level.
- g. If the alleged impropriety involves potential harm to subjects or others, the ACOS for R&D or the Assistant Director for Clinical Research notifies the R&D Chairman and the IRB Director for immediate action pending formal inquiry. The ACOS for R&D or the Assistant Director for Clinical Research reports concerns/complaints or alleged research impropriety involving serious issues immediately, if appropriate, to the Compliance Office, General Counsel, STVHCS Chief of Staff, STVHCS Information Security Officer, and STVHCS Director for solicitation of additional input.
- h. The IRB Director and R&D Chairman or his/her designees, in collaboration with the ACOS for R&D and the Assistant Director for Clinical Research, ensures appropriate response to each alleged impropriety and reports the action(s) taken to the IRB and R&D Committees.
  - (1) If the complaint or concern is of a minor nature (e.g. misunderstanding, clerical or administrative issue such as a payment) the issue may be resolved without bringing it forth for an IRB or R&D committee vote.

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- (2) Major issues such as failure to acquire signed informed consent from potential subjects (if required), are presented to the IRB and R&D Committee and any actions are voted on.
  - (3) All actions taken are at the institutional level and appropriate for the circumstances, and the final course of action is entirely dependent on the nature, severity, and degree of seriousness of the findings.
- i. The ACOS for R&D or the Assistant Director for Clinical Research manages the inquiry, preparing related correspondence, and maintaining documentation of the review for up to six years from completion of the inquiry or close out of the STVHCS R&D file, whichever is longer. In addition, the R&D Office will maintain a database of complaints/concerns and allegations of research improprieties. Information from previous complaints/concerns or improprieties will be available to the ACOS for R&D and the Assistant Chief for Clinical Research when determining actions to be taken with current inquiries.
- j. Depending on the nature of the event or circumstances, actions that may be taken include but are not limited to:
  - (1) Further inquiry;
  - (2) Administrative action;
  - (3) Details and recommendations forwarded to the appropriate committee Chairs (e.g., IRB, Radiation and/or Safety Committees) for consideration in their committees;
  - (4) Details and recommendations forwarded to the appropriate department Chair for action as appropriate;
  - (5) Details and recommendations forwarded to the STVHCS Director and/or Legal Counsel for action;
  - (6) Other actions as deemed appropriate.
- k. The IRB Director, or ACOS for R&D through the Medical Center Director as the Institutional Official for the STVHCS HRPP, will report all actions requiring reporting to regulatory bodies outside the medical center (e.g. Regional Office of Research Oversight (ORO), Office for Human Research Protections (OHRP), the Food and Drug Administration (FDA), VHA Information Security Officer and/or any other federal agencies overseeing research who require separate reports from OHRP).
  - (1) Reports shall be made as soon as possible after recognition of a reportable event and within the maximum allowable time required by the applicable regulatory body.
- l. If an allegation of research misconduct is identified, it is handled in accordance with VHA Handbook 1058.2. Refer to the STVHCS Research Misconduct Policy Memorandum 151-07-06 for additional information.

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- m. Concerns/complaints or alleged improprieties that cannot be resolved within the R&D Service will be referred to either the STVHCS Patient Advocate or the Director staff as appropriate
- n. Any written responses to concerns/complaints will be forwarded to the Director's Office. Established guidelines of the Patient Advocate Program Policy Memorandum 003-04-02 and all related VHA regulations will be followed when completing written replies for the Director's signature.

**4. REFERENCES:** 45 CFR 46.116(a); 21 CFR 50.25(a); STVHCS Patient Advocate Program Policy Memorandum 003-04-02; STVHCS Research Misconduct Policy Memorandum 151-07-06; STVHCS Human Research Protection Program Policy Memorandum 151-08-03

**5. RESPONSIBILITY:** ACOS for Research and Development (151)

**6. RECESSION:** Research Service Policy Memorandum 05-26 dated April 26, 2005

**7. RECERTIFICATION:** March 2010

//signed//

PETER MELBY, M.D.

ACOS for Research and Development

ATTACHMENT (1)

**POLICY MEMORANDUM 151-08-26**

