

DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
7400 Merton Minter Boulevard
San Antonio, Texas 78284

RESEARCH SERVICE
MEMORANDUM 05- 26

April 26, 2005

Standard Operational Procedures

Research-related Complaints/Allegations of Noncompliance

1. PURPOSE: To outline the Research and Development (R&D) process for responding to research-related complaints and allegations of noncompliance with institutional research policies.
2. POLICY: All complaints or concerns about the conduct of a research project shall be addressed promptly. Complaints may be in the form of a verbal or written complaint from the subject of a study, staff observing a possible failure to follow the protocol as approved by the Institutional Review Board (IRB) or the Institutional Animal Care and Use Committee (IACUC), a whistleblower, or others. All Office of R&D staff receiving information on complaints or allegations will respond as indicated in this policy. Allegations of misconduct (e.g., fabrication, falsification, plagiarism) are handled separately in accordance with VHA Handbook 1058.2.
3. RESPONSIBILITY: The Associate Chief of Staff for Research and Development has been delegated the responsibility of administering the South Texas Veterans Health Care System's Research and Development Program by the STVHCS Director through the Chief of Staff. The ACOS for R&D is responsible for insuring that complaints are reviewed and appropriate actions have been taken.
4. PROCEDURES:
 - a. Receipt of Complaint/Allegation. The complaint process is initiated when an individual receives information regarding a complaint, concern, or allegation.
 - (1) This individual will gather as much information as possible from the person making the complaint, recording all pertinent information about the complaint incident to include:
 - Caller's name, address, and phone number. This is not mandatory and is obtained only if the caller is willing to provide this information. A caller can report an incident anonymously. However, if the caller wants to be advised of the results (e.g., subject in a human study) he will be advised that without this information, follow-up responses to the individual would not be possible.
 - Study protocol title and principal investigators name
 - Date of the incident
 - Summary of the complaint or concern

(2) The caller will be reassured that all means will be taken to inquire into the circumstances and that appropriate measures will be taken to address the issue. If the caller requests he be informed of the inquiry results, he will be advised a response will be forthcoming (providing that contact information is given).

(3) In some cases, there may be a misunderstanding about the study that can be resolved immediately. If so, the complaint and the information provided to resolve the complaint should be documented.

(4) If notice is received that a complaint has been received through UTHSCSA regarding a VA study, a report of that information will be prepared in the same manner.

b. Processing the Complaint/Allegation. A report of the information received will be provided to the ACOS for R&D.

(1) A review will be conducted as appropriate to the nature of the complaint/non-compliance/impropriety to include evaluating information provided and gathering additional information. The ACOS for R&D will promptly notify the principal investigator of the complaint and the ongoing review, providing information as appropriate without affecting the review. Referral to the IRB or IACUC and their subsequent actions may resolve the concerns, requiring no additional inquiries. If the seriousness of the complaint indicates that immediate project suspension may be required, the ACOS will immediately contact the IRB/IACUC for possible action prior to completing an investigation.

(1) Human Studies. If the complaint identifies a human study, the ACOS for R&D will review any prior STVHCS Compliance Office evaluations/audits of the study. If information warrants, ACOS for R&D may request that an immediate audit be initiated by the Compliance Office. Findings and actions taken by the ACOS will be provided to the UTHSCSA IRB to determine if any further action is necessary. The ACOS for R&D will follow up with the IRB Office to determine if any additional action was required.

(3) Animal Studies. If the complaint involves a particular animal study, the information will be provided to the VA IACUC administrator for investigation of the concern. Information will be gathered as necessary. The IACUC, including the veterinarian, will take appropriate action to resolve the concern. All actions taken will be in accordance with animal welfare regulations and guidelines and local IACUC procedures. The IACUC administrator will inform the ACOS for R&D of the findings of any complaint referred by the ACOS.

c. Resolution. Upon completion of the investigation, the ACOS for R&D will:

- (1) Advise the IRB or IACUC of the findings
- (2) Advise the principal investigator of the findings.
- (3) Advise the informant if a response was requested and contact information was provided
- (4) Advise the R&D Committee's QA Subcommittee, Chief of Staff, and Medical Center Director
- (5) Dependent on the nature of the circumstances, administrative action may be taken, with recommendations forwarded to the Chief of Staff and/or Medical Center Director, as deemed appropriate. The final course of action is dependent upon the nature and severity of the findings. All actions taken will be at the institutional level most appropriate for the circumstances.

d. Documentation. The Office of R&D will maintain a database of complaints/allegations of noncompliance. This information on previous complaints will be available to the ACOS for R&D when determining actions to be taken.

5. RECISSION: None.

6. REVIEW DATE: April 2008

A handwritten signature in black ink, appearing to read "Peter Melby", with a long, sweeping horizontal stroke at the end.

PETER MELBY, M.D.
ACOS for Research and Development