DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229

Policy Memorandum 22-26

December 9, 2022

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 towards the needs of our patients and will resolve all complaints in a positive and timely manner. The ACOS for Research or his/her designee is responsible for investigating all concerns/complaints from research subjects and any improprieties involving investigators or their staff. These issues are handled 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/complaint about a human research project may raise it by telephone, in writing, or in person to any component of the STVHCS Human Research Protection Program (HRPP). Each IRB approved informed consent document must include a telephone number for complaints, concerns, or questions regarding approved protocols. Telephone numbers for the VA R&D Office are listed on - 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 project involving human subjects may raise it 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 his/her designee 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 his/her designee 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) Project protocol title (or acronym) and the name of the principal investigator (PI);
   (3) Date(s) of the incident;
   (4) A summary of the complaint/concern or allegation.

b. The subject (or complainant) is assured that inquiries into the circumstances will be made and that the appropriate component of the STVHCS HRPP will take appropriate measures to address the issue. Furthermore, the subject (or complainant) will be informed 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 subject (complainant) will be informed of 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 HRPP (e.g., IRB, Public Affairs Office), the complainant will be contacted by the ACOS for R&D or his/her designee to gather all required information and the same procedures will be initiated.

d. The concern/complaint or alleged research impropriety is handled 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 information regarding the concern/complaint or alleged research impropriety is conveyed to the PI of the project in a timely manner, unless it is prohibitive (e.g., misconduct is suspected, or security of records is an issue).

f. All concerns/complaints or alleged improprieties are evaluated on a case-by-case basis, and every effort is made to correct the issue(s) at the administrative level.

g. If the alleged impropriety involves potential harm to subjects or others, the R&D Chairman and the IRB Director are notified for immediate action pending formal inquiry. Concerns/complaints or alleged research impropriety involving serious issues are reported immediately, if appropriate, to the Research Compliance Office, General Counsel, STVHCS Chief of Staff, STVHCS Information Security Officer, STVHCS Privacy 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 his/her designee, 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.
   (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 his/her designee 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.

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 his/her designee, 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., 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 Directive 1058.2. Refer to the STVHCS Research Misconduct Policy Memorandum 151-22-06 for additional information.

m. If an allegation of research noncompliance is identified, it is handled in accordance with Research Service Policy Memorandum 49.

n. 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 Directors Office as appropriate

o. Any written responses to concerns/complaints or alleged improprieties will be forwarded to the Director's Office. Established guidelines of the Patient Advocate Program Service Recovery Program.pdf (sharepoint.com)and all related VHA regulations will be followed when completing written replies for the Director's signature.

4. **REFERENCES:** VHA Directive 1058.2 ; 45 CFR 50 and 93 (Public Health Service Policies on Research Misconduct) ; 21 CFR 50.25(a); Service Recovery Program.pdf (sharepoint.com); STVHCS Research Misconduct Policy Memorandum 151-22-06; STVHCS Human Research Protection Program Policy Memorandum 151-23-03

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

6. **RECESSION:** Research Service Policy Memorandum 18-26 dated April 2, 2018

7. **RECERTIFICATION:** December 9, 2027

[Signature on File]

AMRITA KAMAT, PhD.
ACOS for Research and Development

POLICY MEMORANDUM 22-26

ATTACHMENT (1)