DEPARTMENT OF VETERANS AFFAIRS
South Texas Veterans Health Care System
San Antonio, Texas 78229-4404

Research Service Policy Memorandum 12-37

January 31, 2012

RESEARCH STANDING OPERATING PROCEDURES (SOP)
Correspondence and Communication between the Research and Development (R&D) Office and Components of the Human Research Protection Program and Regulatory Agencies

1. **PURPOSE:** To outline the policy and procedures related to the lines of correspondence and communication between the various entities that are involved in the South Texas Veterans Health Care System (STVHCS) Human Research Protection Program (HRPP).

2. **POLICY:** Effective communication between the various components of the STVHCS HRPP is essential to the function of the HRPP and protection of human research subjects. The ACOS for Research and Development (ACOS for R&D), or designee, is the point of contact (POC) for all communications from the various components of the STVHCS HRPP, including the UTHSCSA Institutional Review Board (IRB). The POC at the STVHCS is responsible to communicate with the appropriate STVHCS officials.

3. **ACTION:**

a. **Communication with the IRB.** The IRB of the University of Texas Health Science Center at San Antonio (UTHSCSA; university affiliate) is the IRB of record for the STVHCS, as established by a Memorandum of Understanding. There are a number of instances when the IRB and the STVHCS must communicate, either under routine or urgent circumstances. In addition, as a general rule, the Office of the IRB (OIRB) and R&D Office will communicate any information to the reciprocal office as needed to ensure the protection of human subjects in research.

(1) **Initial Protocol review**

(a) Administrative pre-review. The UTHCSA IRB will notify the R&D Office when a VA research protocol is submitted to the IRB. The administrative staff responsible for human subjects protocol reviews at the R&D Office will be given access to OIRB documents and will conduct an administrative pre-review to ensure that the submitted documents (Consent form, VA 10-9012 form, etc.) are compliant with VA regulations. The administrative staff will communicate with the investigators and/or study staff and the OIRB to incorporate any required modifications prior to final IRB approval.

(b) IRB minutes. The OIRB staff will provide minutes of IRB Committee meetings to STVHCS R&D Office staff. The minutes are provided to the R&D Committee members for review at the next R & D Committee meeting.

(c) The OIRB will forward to the R&D Office documentation of IRB actions and approvals.

(d) If a concern or disagreement with the IRBs review and determination related to the research protocol is raised in the R&D Committee review, or information is discovered that the IRB should know about (e.g. issues related to human subject safety, protection of privacy, etc.) the Chair of the R&D Committee, or his/her designee, will promptly (within 2 working days) notify by phone or email, followed by paper copy, the Director of the IRB and provide the information necessary for the IRB to evaluate and take appropriate action.

(e) If the R&D Committee withholds approval because of stipulations that must be met in addition to the requirements of the IRB, the R&D Committee will inform the IRB (and PI) in writing of its additional stipulations.

(2) **Continuing review**

(a) Continuing review by the R&D Committee will be coordinated with the Continuing Review by the IRB. If approval of a human subject research protocol expires at the IRB, its approval by the R&D Committee will expire simultaneously.

(b) In addition to the STVHCS Continuing Review form, Continuing Review documents that are submitted by the PI to the relevant Subcommittees will be reviewed by the STVHCS R&D Office staff and the ACOS for R&D, or designee, and reported to the R&D Committee.

(c) A copy of the IRB continuing approvals will be made available to the STVHCS R&D Office staff.

(d) The findings of STVHCS Continuing Review will be communicated to the PI in writing by the ACOS for R&D or designee.

(3) **Human subject research-related events.** The STVHCS follows the UTHSCSA IRB "Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO) Policy and Procedure", "Non-compliance Policy and Procedure", and "IRB/OIRB Reporting Policy and Procedure" in addressing research-related events.

(a) Unanticipated Problems Involving Risk to Subjects or Others (UPIRSO). VA Research investigators must report possible UPIRSOs as defined by and in compliance with the IRB UPIRSO policy. The procedures and timeline for the IRB to report UPIRSOs to the R&D Office and subsequent reporting by the R&D Office to the appropriate entities is outlined in Research Service Policy Memorandum 048.

(b) Research non-compliance. The STVHCS uses the UTHSCSA IRB definition of non-compliance (including continuing non-compliance and serious non-compliance) as found in the IRB glossary (http://research.uthscsa.edu/irb/GLOSSARY OF OIRB TERMS.doc). The procedures for reporting research non-compliance are detailed in the Research Service Policy Memorandum 049.

(c) Research Misconduct. Any allegation, suspicion, or evidence of research misconduct received by the IRB or STVHCS will be promptly reported to the reciprocal office. The ACOS for R&D is the STVHCS Research Integrity Officer, who handles allegations of research misconduct according to VHA Handbook 1058.2.

(4) **Federalwide Assurance.** The UTHSCSA Office of the IRB and STVHCS R&D Office will promptly inform the reciprocal office of changes in the institutions FWA status.

(5) **IRB membership.** The IRB will inform the STVHCS Research Office when any issues related to VA membership on the IRB arise (e.g. need for new members, absence of VA representation for a committee meeting, etc.). The STVHCS R&D Office will work with the IRB to ensure that adequate VA representation is maintained on the IRB.

b. **Communication with the Subcommittee for Research Safety (SRS)**

(1) The SRS will notify the R&D Committee of the results of subcommittee protocol including the Research Safety Survey reviews and committee actions through submission of written, signed minutes from its convened subcommittee meetings.

(2) The SRS will notify the Principal Investigator or his/her research staff of the results of subcommittee protocol including the Research Safety Survey reviews and committee actions in writing, either via paper copy or email.

(3) Any urgent research personnel safety issue that come to the attention of the SRS will be promptly reported verbally (with written follow-up communication) to the ACOS for R&D, the STVHCS Safety Officer, and R&D Committee Chair. If the research personnel safety issue involves a human subject study, the IRB Director will also be notified.

c. **Communication with Investigators and research staff**

(1) The items that must be submitted to the R&D Office for administrative review and R&D Committee for review and approval of a new research protocol are identified in the Research Service SOP for Submission and Review of Protocols. The required forms for submission to the R&D Committee or its subcommittees are found on the R&D Office website (http://www.vasthcs.med.va.gov/research/default.htm) or can be obtained as paper copy through the R&D Office. Any questions related to submission of documents to the R&D Committee or one of its subcommittees should be addressed to the contact person listed at the end of this document.

(2) All official communication from the Principal Investigator or his/her research staff should be in writing, either via paper copy or email.

(3) All correspondence from the R&D Office to the Principal Investigator or his/her research staff will be in writing, either via paper copy or email. Phone communication, while helpful and efficient, should not be considered as official communication from the R&D Office.

(4) The R&D Committee or one of its subcommittees (via the Research Office) will notify Investigators of any decision(s) rendered by the R&D Committee or the subcommittee in writing, either via paper copy or email.

(5) The Research Office will, by email (and phone if necessary), notify Investigators of upcoming deadlines, including deadlines for submission for Continuing Review, expiration of STVHCS appointments, and the required annual training.

(6) Anyone involved in STVHCS research is encouraged to contact the UTHSCSA IRB Office or the STVHCS R&D Office at anytime with any comments, suggestions, concerns, or questions regarding research.

(7) Within one hour of becoming aware of any unauthorized use, disclosure, transmission, removal, theft, loss, or destruction of VA research-related protected health information (PHI), individually identifiable private information, or confidential information, investigators or study staff are required to ensure that the situation has been reported to the ACOS for Research, the facility ISO, and the facility PO.

d. **Communication with Research Participants**

(1) The STVHCS HRPP maintains an open door policy. Any individual, including a past, current, or prospective research participant is welcome to contact the research office or any other component of

the HRPP with a question, concern, complaint, comment, or suggestion. Contact information for the UTHSCSA IRB is provided in the Informed Consent document, and contact information for the R&D Office is listed on posted pamphlets and posters and the R&D Office website.

(2) The STVHCS R&D Office proactively reaches out to past, current, or prospective participants in research through the inclusion of contact information on posters and pamphlets displayed in public areas of the STVHCS and the R&D Office website.

(3) The ACOS for R&D is responsible for ensuring that complaints, concerns, allegations, questions, or requests for information related to research are reviewed and appropriate actions are taken.

e. **Communication with the STVHCS Research Compliance Officer (RCO)**

(1) The STVHCS RCO's primary responsibility is oversight of research projects for compliance to applicable Federal, VHA, and local regulations/policies. The RCO coordinates auditing activities with, but works independently of, the R&D Office. The RCO reports directly to the Medical Center Director and reports results of auditing activities to the R&D Committee and UTHSCSA IRB.

(2) The RCO will notify Principal Investigators in writing of the intent to audit. The investigator will be informed of the steps of the audit process and the documentation required by the RCO. The Principal Investigator must respond to the request for information and to schedule a date to conduct the audit within the timeline specified by the RCO, or must provide a reasonable justification for why the timeline cannot be met. Failure of the Investigator to comply with the request will result in the request being routed through the Medical Center Director, and non-compliance being reported to the Director of the IRB and ACOS for R&D. The RCO has the right to conduct audits without prior notification if circumstances warrant.

(3) If the ACOS for R&D becomes aware, either directly or through communication with any other component of the HRPP, of any real or suspected non-compliance, or has concerns over the conduct of a study, the RCO will be requested to conduct an audit as appropriate.

(4) **Audit Reports.** Findings of audits will be reported as follows:

(a) Non-significant findings. The findings will be compiled into an audit report that will be sent to the Study Coordinator and/or PI with a timeline for resolution of the findings, and a deadline for providing written documentation of completion to the RCO. Audit findings will be compiled monthly into a summary report that will be presented to the Medical Center Director, R&D Committee, and appropriate subcommittees for review, discussion, and determination of the need for any actions. A copy of the completed report and all documentation will be kept in a study specific file in the Research Compliance Office.

(b) Significant findings. Audit findings that constitute apparent serious or continuing non-compliance, including but not limited to human subject protection violations, will be reported as outlined in VHA Handbook 1058.1. The PI will be promptly notified of significant findings and will be given instructions on the next step(s) in the reporting process. The audit report will be communicated promptly by the Research Compliance Officer via phone and/or in writing through paper copy or encrypted email to the Medical Center Director, ACOS for R&D, R&D Committee Chair, and Director of the IRB. Where applicable, noncompliance may be reported to the Office of Research Oversight, Office of Research and Development, Office of Human Research Protections, and

FDA. The Research Compliance Office will be copied on any communications related to any noncompliance-related evaluation and action of the IRB or R&D Committee.

f. **Communication with the Information Security Officer (ISO)**

(1) **Protocol review.** The ISO or Alternate ISO will review the protocol and "Collection, Storage, and Use of VA-Sensitive Research Data" worksheet and provide comments to the Research Data Security and Privacy Subcommittee. The ISO or a designated representative will attend the convened R&D Committee meetings to participate in discussion and offer expert advice in matters pertaining to research information security. A research protocol will not be approved by the R&D Committee without review by the ISO or Alternate ISO.

(2) Any real or suspected violation or compromise of VA Information Security related to a VA research protocol reported by an investigator or research staff to the ACOS/Research will be reported to the facility director, R&D committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report. The ACOS/Research will also ensure the facility ISO has been notified. Communication in writing will follow as appropriate.

g. **Communication with the Privacy Officer**

(1) **Protocol review.** The Privacy Officer, or Alternate Privacy Officer will review the protocol and "Collection, Storage, and Use of VA-Sensitive Research Data" worksheet and provide comments to the Research Data Security and Privacy Subcommittee. The Privacy Officer, or Alternate Privacy Officer will attend the convened R&D Committee meetings to participate in discussion and offer expert advice in matters pertaining to human subject privacy. No approval will be given by the R&D Committee until the protocol is reviewed by the Privacy Officer.

(2) Upon receipt of a report of any real or suspected unauthorized use, loss, or disclosure of individually-identifiable information related to a VA research protocol reported by an investigator or research staff to the ACOS/Research will be reported to the facility director, R&D committee, and any relevant research review committee upon discovering, receiving, or otherwise becoming aware of a credible report. The ACOS/Research will also ensure the facility Privacy Officer has been notified. Communication in writing will follow as appropriate.

h. **Communication with the Research Pharmacy**

(1) **Protocol review.** Prior to R&D Committee review and approval of a research protocol that involves medications and/or investigational test agents, the Research Pharmacist will review the protocol, focusing on safety of the medication/test agent and adequacy of pharmacy resources needed to support the research. The Research Pharmacist will attend the convened R&D Committee meetings to participate in discussion and offer expert advice in matters pertaining to medications and/or investigational test agents. The R&D Committee will consider the input from the Research Pharmacist in its review of the protocol. The R&D Committee cannot approve a proposal involving investigational drugs unless the research pharmacist documents that resources are adequate for the conduct of the study.

(2) Following approval of a research protocol that involves medications and/or investigational test agents, the R&D Office will ensure the Research Pharmacist has access to the following:

(a) The signed VA 10-9012 form(s).

(b) An IRB approval letter signed by the IRB Chair or designated reviewer.

(c) The R&D Committee approval letter.

(3) If the Research Pharmacist becomes aware of any real or suspected violation or compromise of local or federal regulations related to research involving investigational test agents, he/she will notify the ACOS for R&D and/or the IRB.

i. **Communication with Non-Research Units**

(1) **Protocol review.** Prior to R&D Committee review and approval of a research protocol that involves services provided by a non-research unit (e.g. Nursing Service, Radiology, Pathology and Laboratory, Nuclear Medicine), the relevant service will review the protocol and the *Evaluation of STVHCS Resources for Clinical Research*, focusing on the service's adequacy of resources needed to support the research.

(2) The non-research unit designated reviewer will determine if the service can or cannot provide the resources necessary to effectively and safely conduct the research. The R&D Committee will consider the input from the *Evaluation of STVHCS Resources for Clinical Research* in its review of the protocol. The R&D Committee cannot approve a proposal involving a non-research unit if resources are determined to be inadequate for the conduct of the study.

(3) Following approval of a research protocol that involves a non-research unit, the R&D Office will provide to the non-research unit a copy of the R&D Committee approval letter.

(4) Protocol amendments that would alter the original approval and have the potential to significantly increase the requirement for resources of the non-research unit will be submitted with a modified *Evaluation of STVHCS Resources for Clinical Research* to the non-research unit for review and approval.

j. **Communication with STVHCS study sites outside the Audie Murphy Hospital**

(1) Following approval of a research protocol that involves a non-Audie Murphy Hospital site (e.g. Kerrville Division, Frank Tejeda Outpatient Clinic, South Bexar County VA Outpatient Clinic, Corpus Christi VA Outpatient Clinic, Laredo VA Outpatient Clinic, McAllen VA Outpatient Clinic, Victoria VA Outpatient Clinic), the R&D Office will provide to the site Director or designee a copy of the R&D Committee approval letter.

k. **Communication with Regulatory and Oversight agencies**

(1) Findings of serious or continuing noncompliance, and suspensions or terminations of research will be reported as outlined in Research Service Policy Memorandum 49.

(2) Unanticipated problems involving risks to subjects or others (UPIRSOs) and Unanticipated Adverse Device Effects (UADEs) will be reported as outlined in Research Service Policy Memorandum 48.

(3) The following are reported to ORO Central Office, with a simultaneous copy to the Western Regional ORO Office

(a) Changes in the number of IRBs and significant changes in the makeup of the membership rosters of the IRBs.
(b) Substantive changes to an IRB MOU will be reported to ORO within 5 business days
(c) Research accreditation problems will be reported to ORO within 5 business days

1. **STVHCS R&D Office Contact Information**

R&D Administrative Office: (210) 617-5123

ACOS for R&D: (210) 617-5300, ext 15542

Deputy ACOS for Clinical Research: (210) 617-5300, ext 15969

R&D website: http://www.southtexas.va.gov/Research/Index.asp

4. **REFERENCES:** MOU between STVHCS and UTHSCSA regarding IRB; VHA Handbook 1200.05; What to Report to ORO

5. **RESPONSIBILITY:** Associate Chief of Staff for Research (151)

6. **RECISSION:** STVHCS Research Service Policy Memorandum 10-37, dated November 1, 2010

7. **RECERTIFICATION:** January 2017

KIMBERLY K. SUMMERS, PHARM.D.
Acting ACOS for Research and Development