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

Research Service Policy Memorandum 10-52

February 8, 2010

RESEARCH STANDING OPERATING PROCEDURES (SOP)
Protocol Management for VA Approved Human Subject Research Projects

1. **PURPOSE:** The purpose of this SOP is to outline the administrative procedures for protocol management of R&D Committee approved human subject research projects.

2. **POLICY:** Protocol management of research protocols is a key component of the function of the R&D office staff and the R&D committee. Protocol management includes a continuing review process, assessment of amendments, project inactivation, and maintenance of records storage. In addition to the local protocol management, annual progress updates and inactivations in the VA Research and Development Information System (VARDIS) is a requirement by VA Central Office.

3. **ACTION:**

a. **Human Subject Protocol Management – Continuing Review:**

(1) All research with a human subject focus (i.e. IRB approved protocols, exempt patient chart reviews, patient data extractions with or without identifiable information, lab studies of human specimens with or without identifiable information) will have continuing review conducted by the R&D Human Protocol Management Staff Assistant.

(a) Expiration dates for the continuing review process are based on the IRB approval and expiration dates with the exception of IRB exempt protocols and protocols determined by the IRB to not be human subjects research (i.e., lab studies of human specimens without identifiable information) which are based on the R&D approval and expiration dates. The R&D Human Protocol Management Staff Assistant will:

1. Send a continuing review notification to the principal investigator (PI) and/or study coordinator at least 6 weeks prior to the R&D Committee meeting scheduled prior to expiration. (Appendix A: Notification Template)

2. Send a follow up notification to the PI and/or study coordinator at least 4 weeks prior to the R&D Committee meeting scheduled prior to expiration if response is still pending.

3. If a response from the PI and/or study coordinator is still pending 2 weeks prior to the R&D Committee meeting, send a follow up notification to the PI and study coordinator, if applicable, copied to ACOS for R&D or designee, with notification of possible administrative hold on project if response is not received. An administrative hold is defined as a voluntary interruption of research enrollments and/or ongoing research activities. (Appendix B: Possible Administrative Hold Template)

4. If no response is received by the time of the R&D Committee meeting, notify the ACOS for Research or designee who will notify the PI of the administrative hold on the protocol pending a response.

5. When the continuing review is received in the R&D office, conduct an administrative review of the VA Continuing Review of Research Protocols form, IRB Progress Report form and associated informed consent document if applicable.

6. Submit the Research Safety Review form to the Subcommittee for Research Safety (SRS) administrator for review at the next scheduled SRS meeting.

7. Provide the Personnel Administrative Assistant with the active personnel list to verify required training is current for all study personnel. Following verification, the R&D Human Protocol Management Staff Assistant will communicate with the PI and/or study coordinator the status of study personnel. Study personnel who are delinquent on their training required for human subject research will be notified that they cannot participate in project related activities until personnel have met the training requirements. If the PI is not current on his/her training, the project will be placed on administrative hold and the project approval will expire. If research personnel, who are listed as contact persons on an Informed Consent document, are not current on their required annual training at the time of Continuing Review, then that Informed Consent document cannot be used to enroll subjects until the personnel have met the training requirements, or the Informed Consent document has been revised to remove the personnel as contact persons.

8. Provide the Designated Scientific Reviewer with the projects identified for continuing review at least 2 weeks prior to the next scheduled R&D Committee meeting.

(b) The Designated Scientific Reviewer will present the projects identified for continuing review at the R&D Committee in a summary format with R&D Committee discussion of relevant or pertinent issues.

1. If substantive administrative issues remain or the R&D Committee imposes stipulations for project continuation, the R&D Protocol Management Staff Assistant will provide the PI with an email notification on behalf of the ACOS for Research copied to the ACOS for Research and/or designee following the R&D Committee. (Appendix C R&D Stipulation Notification)

2. Once all administrative issues and R&D Committee stipulations have been addressed the R&D Protocol Management Staff Assistant will generate a R&D Committee project review notice, acknowledging the continuation of the project until the next established expiration date to PI and/or study coordinator by email correspondence on behalf of the ACOS for Research. (Appendix D R&D Project Continuation Notification)

3. The R&D Management Staff Assistant will update the electronic and hard copy protocol file maintained in the R&D office.

4. The R&D Management Staff Assistant will update the VA RDIS system.

b. **Human Subject Protocol Management – Assessment of Modifications and Amendments:**

(1) All modifications and amendments submitted to the UTHSCSA IRB for active VA approved research with a human subject focus (i.e. IRB approved protocols, exempt patient chart reviews, patient data extractions with or without identifiable information, lab studies of human specimens with or without identifiable information) will be reviewed by the R&D Human Protocol Management Staff Assistant.

(a) The R&D Human Protocol Management Staff Assistant will:

1. Access amendments and modifications submitted to the UTHSCSA IRB through the UTHSCSA IRB Share Point.

2. Documents will be reviewed for VA specific elements as outlined in the Guidance for R&D Office Administrative Review of IRB Documents (\\Vhastxsan2\ServiceLines\Research\DATABASES).

3. Communicate and resolve any changes or clarifications for submitted documents with the PI and/or study coordinator. Changes related to already approved template wording on the informed consent documents may be done without clarification or discussion with the PI and/or study coordinator.

4. Items identified beyond the scope of an administrative review will be provided to the Designated Scientific Reviewer for resolution.

5. Once all administrative and/or scientific issues have been addressed, stamp the IRB approved amendment as R&D Office Acknowledged with the appropriate date when R&D documentation is requested by the PI and/or study coordinator.

6. Update the electronic and hard copy protocol file maintained in the R&D office.

c. **Human Subject Protocol Management – Inactivations:**

(1) All inactivation requests submitted to the UTHSCSA IRB and/or R&D Office for active VA approved research with a human subject focus (i.e. IRB approved protocols, exempt patient chart reviews, patient data extractions with or without identifiable information, lab studies of human specimens with or without identifiable information) will be reviewed by the R&D Human Protocol Management Staff Assistant.

(a) The R&D Human Protocol Management Staff Assistant will:

1. Ensure the Request for Inactivation of a Research Protocol is completed and signed by the PI.

2. Ensure that the project has been inactivated at the UTHSCSA IRB or that the STVHCS has been removed as an engaged site at the IRB.

3. Update the electronic and hard copy protocol file maintained in the R&D office.

4. Update the VA RDIS system.

d. **Human Subject Protocol Management – Maintenance of Records Storage:**

(1) All requests for the long term storage of records for VA approved research with a human subject focus (i.e. IRB approved protocols, exempt patient chart reviews, patient data extractions with or without identifiable information, lab studies of human specimens with or without identifiable information) will be handled by the R&D Human Protocol Management Staff Assistant according to the Research Service SOP "Long Term Storage of Records Associated with VA Approved Research Projects".

e. **Principal Investigator Responsibilities:**

(1) Obtaining continuing review and approval from all appropriate subcommittees and the R&D Committee and completing of required documentation (http://www.southtexas.va.gov/Research/Documents/ContinuingReviewFormHumanStudies.pdf). The investigator is expected to know the date of the continuing review and to be aware that the project approval will expire when the continuing review does not occur on schedule.

(2) Completing the required continuing protocol review forms and returning them to the R&D office in a timely fashion to meet all subcommittee or R&D Committee deadlines for review.

(3) Complying with all applicable personnel and training requirements to maintain credentialing and privileging to conduct research at the STVHCS.

(4) Reviewing the current and approved Research Scope of Practice for all applicable personnel and verifying that it includes all required duties and procedures for conducting assigned activities for a specific protocol at the time of continuing review and when personnel modifications are requested.

(5) Disclosing any potential, actual, or perceived conflict of interest of a financial, professional, or personal nature that may affect any aspect of a research project for themselves and any listed research personnel for the project.

(6) Obtaining IRB approval and R&D acknowledgement for all changes to the research project (i.e. amendments or modifications), including changes to the informed consent form, prior to implementing the changes. The only exception is when it is necessary to change the protocol to eliminate apparent immediate hazards to the subject. The investigator must promptly report these changes to the IRB.

(7) Notifying the R&D office at the completion of a research project, completing all required documentation (http://www.southtexas.va.gov/Research/Documents/RequestInactivationResearchProtocol.doc) and storing records according to VA requirements.

(8) Contacting the R&D office if assistance with long term storage of research records is required.

4. **REFERENCES:** VHA Handbook 1200.05; VHA Handbook 1200.01

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

6. **RECISSION:** None

7. **RECERTIFICATION:** This policy will expire on February 2015

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

Attachments: (4)

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APPENDIX A: Notification Template

E-mail Header: VA Continuing Review (<PI>, VA Project #<#>) DUE: <date>

Project Title	PI Name	Project #	IRB #	IRB and R&D Expiration

The above study is due for R&D continuing review. Please complete the VA form titled: Continuing Review of Research Protocols for Human Studies and return no later than <Due date> to Research Service (151), Q201. If the study requires inactivation, please submit the VA form titled: Request for Inactivation of a Research Protocol.

Note: the VA Continuing Review form is a supplement to the UTHSCA IRB form that you have already turned in or in the process of turning in. The VA Continuing Review form captures VA specific continuing review requirements.

If you have questions or need assistance, please do not hesitate to call.

Thank you!

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APPENDIX B: Notification of Possible Administrative Hold of Project

E-mail Header: VA Continuing Review (<PI>, VA Project #<#>) DUE: <date>

Sent on behalf of the Associate Chief (ACOS) for Staff for Research.

As of today, the R&D Office has not received your Continuing Review of Research Protocols for Human Studies form for the below listed project. If the form is not received within the R&D Office by <Date> the R&D Committee will understand this as your voluntary interruption of research enrollments and/or ongoing research activities at the STVHCS and the protocol will be placed on administrative hold.

Project Title	PI Name	Project #	IRB #	IRB and R&D Expiration

The above study is due for R&D continuing review. Please complete the VA form titled: Continuing Review of Research Protocols for Human Studies and return no later than <Due date> to Research Service (151), Q201. If the study requires inactivation, please submit the VA form titled: Request for Inactivation of a Research Protocol

If you have questions or need assistance, please do not hesitate to call.

Thank you!

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APPENDIX C: R&D Stipulation Notification

Email header: R&D Stipulations for Project Continuation - <Principal Investigator> VA Project #<#> /IRB < #>

Sent on behalf of the Associate Chief for Staff ("ACOS) for Research.

Project Title: <title>

1. The above project was reviewed at the Research and Development (R&D) Committee on <date>. The following items must be addressed before final approval can be given for project continuation:

    a.

    b.

    c.

2. If you have questions or need assistance, please do not hesitate to call.

Thank you!

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APPENDIX D: R&D Project Continuation

FILE COPY: R&D Project Review and Continuation Acknowledgement - <Principal Investigator> VA Project #<#> /IRB <HSC#>

Sent on behalf of the Associate Chief of Staff (ACOS) for Research.

Project Title: <title>

3. The above project was reviewed at the Research and Development (R&D) Committee on <date>. All administrative stipulations for continued research activities on this project have been met.

   Project Expiration Date: <date>

   Next R&D Continuing Review Submission Date: <6 weeks prior to the next R&D meeting >

4. ***(Use if applicable)*** The most current VA informed consent document(s) *stamped* **<date>** must be used for this project. Any changes to this VA informed consent document must be submitted for review by the IRB and R&D committees.

5. Personnel approved to work on this project are:

   <personnel list>

6. ***(Use if applicable)*** **<Name of exempt personnel> is approved to work on this project in an EXEMPT status.** Exempt personnel consists of persons who are not utilizing VA resources (e.g. salary, space, equipment) as part of the research project AND only analyze coded data or specimens, or consult on projects without intervention/interacting with subjects or obtaining subject's identifiable private information for research purposes (*Note: exempt personnel must check-in as a visitor with the Research Service when on VA property if they do not have a current VA affiliation*).

7. ***(Use if applicable)*** **PLEASE NOTE: Non-licensed MD's cannot perform physical examinations at this facility.**

8. **Any changes to your project and/or study personnel must be reported to and reviewed by the VA Research office prior to implementation.**

9. ***(Use if applicable)*** Every reasonable effort should be made to make available the informational brochure "Volunteering in Research –Here are some things you need to know" (http://www.research.va.gov/programs/pride/veterns/tri-fold.pdf or in hard copy in the R&D office) to potential research subjects and their surrogate where applicable when an individual is approached to take part in this project.

If you have questions or need assistance, please do not hesitate to call.

Thank you!