

April 4, 2018

**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's (VA RDIS) ePROMISE database 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. Notification should include Human Continuing Review of Research Protocols form, Research Financial Conflict of Interest form, and Data Inventory Human Studies form. (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 required interruption of research enrollments and/or ongoing research activities until administrative issues are resolved. (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 Human Continuing Review of Research Protocols form, Research Financial Conflict of Interest

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form, and Data Inventory Human Studies form, IRB Progress Report form (if applicable) and associated informed consent document (if applicable).

6. If the initial submission safety form was previously approved by the Subcommittee for Research Safety (SRS) with safety risks, R&D Human Protocol Management Staff Assistant will complete page 5 on Human Continuing Review of Research Protocols and submit page to the Subcommittee via the Research Safety (SRS) administrator for review at the next scheduled SRS meeting. If initial safety form was previously approved as No Safety Risk (NSR), R&D Human Protocol Management Staff Assistant will sign and date page 5 "Reviewed and Verified by R&D Office Staff" and annotate "NSR."

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 Associate Chief of Staff for Research (ACOS) or designated alternate with the projects identified for continuing review at least 2 weeks prior to the next scheduled R&D Committee meeting.

(b) The ACOS or designated alternate 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 Human Protocol Management Staff Assistant will update the electronic and hard copy protocol file maintained in the R&D office.

4. The R&D Human Protocol Management Staff Assistant will update the VA RDIS (ePromise) 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

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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.
3. Communicate and resolve any changes or clarifications for submitted documents with the PI and/or study coordinator. When an amendment requesting a change in PI is received, if the PI is new to the STVHCS, an administrative review meeting will be scheduled with the project PI and/or study coordinator to address and finalize administrative issues.
4. Items identified beyond the scope of an administrative review will be provided to the ACOS or designated alternate for resolution.
5. 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 including a final data inventory update.
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. Present inactivation request at the R&D monthly meeting and obtain signature of R&D Chairperson on VA Request for Inactivation. Letter of approval from ACOS or designated alternate, Closed Protocol Record Storage Instructions, and signed Request for Inactivation will be emailed to the PI upon approval.
4. Update the electronic and hard copy protocol file maintained in the R&D office.
5. Update the VA RDIS (ePromise) system.

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

- (1) Currently all records (electronic and paper) must be stored for 6 years after the inactivation of the study. At the time of request for inactivation, the data inventory must be updated a final time.
- (2) At the end of the 6 years of storage, the STVHCS Records Manager should be contacted for directions regarding destruction of any paper records containing VA Sensitive Data.

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- (3) If the PI runs out of storage space OR the PI leaves the institution, the Research Office must be contacted for alternative storage options.

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/forms\\_STVHCS\\_Research.asp](http://www.southtexas.va.gov/research/forms_STVHCS_Research.asp) ). 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 and any listed research personnel for the project.

(6) Obtaining IRB approval 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 (including a data inventory final update) ([http://www.southtexas.va.gov/research/forms\\_STVHCS\\_Research.asp](http://www.southtexas.va.gov/research/forms_STVHCS_Research.asp) ) and storing records according to VA requirements.

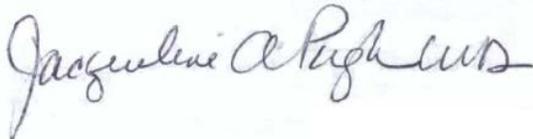
(8) Contacting the R&D office if assistance with long term storage of research records is required.

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

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

6. **RECISSION:** Research Service Policy Memorandum 16-52, dated January 7, 2016

7. **RECERTIFICATION:** April 5, 2023



JACQUELINE A. PUGH, 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>

Good morning/afternoon,

The above study is due for R&D continuing review. Please complete the VA forms titled: Continuing Review, Research Financial Conflict of Interest (for all PIs, Co-Investigators and Sub-Investigators) and - **updated** Data Inventory worksheet and **return no later than <Due date>**.

All PIs, Co-PIs, Co-Investigators and Sub-PIs must submit a **Financial Conflict of Interest** with their VA Continuing review submission to the R&D Administrative office.

**NOTE:** Partial continuing review packets received by the Administrative office delays R&D Committee approval, causing an Administrative Hold on the study. An administrative hold suspends any VA activity and avoids a reportable non-compliance on the study until the R&D Committee grants continued approval.

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

\*\* 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. In order for project to remain active at STVHCS, the protocol must be submitted for continuing review at least annually.**

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.**

<b>Project Title</b>	<b>PI Name</b>	<b>Project #</b>	<b>IRB #</b>	<b>R&amp;D Expiration</b>

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 OR Approval - <Principal Investigator> VA Project #<#> /IRB <HSC#>

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

**Primary Investigator:**

**Project Title:**

**VA Project #/HSC**

1. 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.

IRB Expiration Date: <date>

Next R&D Continuing Review Submission Due: <date>

2. The most current VA informed consent document(s) *stamped* <date> must be used for this project. In addition, the most current Health Information Portability and Accountability Act (HIPAA) form dated <date> must be used in conjunction with your project approved informed consent form. Any changes to this VA informed consent document must be submitted for review by the IRB and R&D committees.
3. Personnel approved to work on this project are:  
<List from personnel query>
4. **PLEASE NOTE:** It is the responsibility of the Research Principal Investigator to ensure all personnel working under a Scope of Practice are conducting only the approved tasks assigned under their specific Scope.
5. *(Use if applicable)* **PLEASE NOTE:** <Name of Personnel> does not have current VA research privileges and cannot engage in VA research activity at this time regarding this project. For questions regarding VA research privileges, please contact Joanna “Annie” Sierra at ext. 15991. **If they are no longer part of the research team, please update personnel list and submit to IRB.**
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 physically conducting research on VA property AND only analyze coded data or specimens, or 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 without the Delineation of Physical Assessment Tasks Form. They are also not allowed to write orders in patient charts or perform medical procedures requiring a license.

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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. 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/veterans/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.
10. Effective October 1, 2011, all VA Investigators are required to notify VHA Research Communications of all scientific publications or presentations upon acceptance by a journal or meeting sponsor. The STVHCS research website contains further information: <http://www.southtexas.va.gov/research>.

If you have any questions or concerns, please contact the VA Human Research Protocol Office at ext.14837/18058.