

August 30, 2022

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 Research and Development (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 (CR) process, assessment of amendments, project inactivation, and maintenance of records storage as documented in the VA Innovation Research Review System (VAIRRS). Study submissions are no longer accepted by email or by hard copy and must be submitted in the VA's instance of IRBNet (gov.irbnet.org). The only exception is the Financial Conflict of Interest (FCOI) form, which must be submitted outside of IRBNet. In addition to the local protocol management, annual progress updates and inactivations should be recorded in the VA Research and Development Information System's (VA RDIS) ePROMISE database as required 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 human protocols with full board or expedited approvals, studies with exempt determinations, lab studies of human specimens with or without identifiable information and funded non-regulated research projects such as program evaluations or implementation projects) require either annual continuing reviews in accordance with Office of Research and Development (ORD) guidelines or annual institutional updates.

(a) Per VA ORD guidelines, studies that are followed by another subcommittee such as the IRB or Subcommittee of Safety Research (SRS), as well as exempt studies and human studies transitioned to the common rule, no longer require continuing review or approval by the R&D Committee. Institutional updates for human studies followed by the SRS are based on the most recent SRS approval dates and are acknowledged in the STVHCS R&D Administration "workspace" in IRBNet. Institutional updates for exempt studies or human studies that are followed by the IRB or that have been transitioned to the common rule are based on the most recent R&D approval or acknowledgement are also acknowledged in the STVHCS R&D Administration "workspace" in IRBNet with additional documentation as needed (e.g., FCOI acknowledgement memo). Protocols determined by the IRB to not be human subjects research and/or not followed by SRS, non-regulated research (e.g., funded implementation projects or program evaluations) or Center Infrastructure grants require formal R&D Committee continuing review and approval; expiration dates for these are based on the most recent R&D approval. R&D processes and management are outlined below.

1. Automated report due or expiration "alerts" generated by IRBNet are sent to the principal investigator (PI) and/or study coordinator at 45, 30, and 15 days for all human-focused studies. Alerts for human studies followed by the SRS include instructions to upload the required Safety CR forms and the Human Institutional Update form into IRBNet (based on the README SRS Safety Annual Continuing Review.docx guidance in the IRBNet STVHCS R&D Administration library). The Human Institutional Update form is used to confirm current funding, personnel, and adequacy of resources as these are not assessed on the SRS CR form. The alert also instructs PIs and study coordinators to submit FCOI forms

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outside of IRBNet per ORD guidelines by email to VHASTXSafetyIACUC@va.gov. Alerts for studies not followed by SRS but followed by the IRB instruct PIs / study coordinators to submit an Institutional Update form in IRBNet and to email the Research Financial Conflict of Interest forms (required for any investigator or sub-investigator) to STXResearchService@va.gov and VAHumanResearch@uthscsa.edu. Alerts for studies followed by the R&D Committee instruct PIs / study coordinators to submit an R&D Continuing Review Application in IRBNet and to email the Research Financial Conflict of Interest forms (required for any investigator or sub-investigator) to STXResearchService@va.gov and VAHumanResearch@uthscsa.edu. In addition, submission packages for all human-focused studies that are still followed by the IRB should also include the most recent IRB continuing review or progress report approval.

2. Failure to submit the R&D Continuing Review Application by the expiration/due date will generate an automated IRBNet notice sent to the PI / study coordinator one day after the project expiration date indicating that the study has lapsed and is on administrative hold, and that all activities, including data analyses, must cease. An administrative hold is defined as a required interruption of research enrollments and/or ongoing research activities until administrative issues are resolved. Staff responsible for Human Protocol management will send personalized follow-up emails, copied to ACOS for R&D (or designee) and PI's Service Chief, if needed.

All CR and Institutional Update forms and related documents are initially submitted in IRBNet in the STVHCS R&D Administration "workspace" for administrative review, where they appear in the "unassigned" view. These are reviewed by the SRS administrator and/or Human Protocol Management staff for completeness, who will "unlock" the package and request corrections if the deficiencies are noted on any of the forms.

3. Human Protocol Managers are responsible for sending IRBNet R&D Administration "Committee" messages requesting personnel checks by R&D WOC/Training Coordinators to verify that required training and research privileges are current for all study personnel, which must be listed on the VA-Project Cover Sheet. Following verification, the R&D WOC/Training Coordinators will note findings in IRBNet using the "review" function and email the PI and/or study coordinator deficiencies for any 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 by the R&D WOC/Training Coordinators. For studies placed on administrative hold investigators must stop all research activities including, but not limited to, enrollment of new subjects, analyses of individually identifiable data, and for studies followed by the IRB, research interventions or interactions with currently participating subjects, except where stopping such interventions or interactions could be harmful to those subjects. A list of research subjects who could be harmed by stopping specified study interventions or interactions must be submitted immediately to the IRB Chair. 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 the Informed Consent document will be revised to remove the personnel as contact persons if the study is open to enrollment.

4. Once study submission "packages" have completed administrative review (and if required, review and approval at the SRS meeting) these will be assigned by the Human Protocol Managers to the end of the month R&D Administration "agenda." Institutional updates will then be acknowledged in STVHCS R&D Administration (noting any related approvals by the SRS and/or IRB) and R&D Continuing Review Applications will be forwarded in IRBNet to the R&D Committee "Board" for review and "assign" these to the next scheduled R&D Committee meeting agenda.

5. Study abstracts, Continuing Review forms, and reviewer checklists for studies that require formal R&D review and approval will be sent to two R&D Committee Members for pre-review 7 days

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prior to the next scheduled R&D Committee meeting so that they can present their recommendations to the Committee.

6. Human Protocol Managers will: a) ensure that required FCOIs have been received from all PIs, Co-Investigators, and Sub-investigators and contact PIs / study coordinators as needed if any are missing; b) prepare the “FCOI Acknowledgement form” and bundle with the FCOIs for each study for the FCOI Administrator’s review; and c) upload the signed Acknowledgement forms as “Board” documents in the STVHCS R&D Committee or STVHCS R&D Administration “workspace”.

7. If the R&D Committee imposes stipulations for project continuation, the R&D Protocol Manager will generate a R&D Committee Modification Required letter, send to the R&D Committee Chair for signature, and “publish” signed letter as a “Board” document.

8. Once all administrative issues and R&D Committee stipulations have been addressed, the R&D Protocol Managers will note R&D Committee approval board actions in IRBNet and upload additional documentation as needed (e.g., FCOI acknowledgement memo). R&D Protocol Managers will also generate an R&D Committee Continuing Review letter of approval (LOA), send LOA to the R&D Committee Chair for signature, and “publish” signed LOA as a “Board” document. The Human Protocol Managers will also set the next “report due” and “expiration” dates in the R&D Committee “workspace”. Next report due dates for studies that will continue to be followed by IRB (but not followed by SRS) will be set by the R&D Protocol Managers in STVHCS R&D Administration. Next report due dates for studies that will continue to be followed by Safety will be set by the safety administrator in the SRS “workspace” (so as not to generate overlapping report due dates).

9. The Administrative Office or his/her designee will update the VA RDIS (ePromise) system.

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

(1) All modifications and amendments to active VA-approved research with a human subject focus, must be submitted in IRBNet for administrative review in the STVHCS R&D Administration “workspace”. Per VA ORD guidelines, the R&D Committee must approve all modifications/amendments of studies not followed by and/or approved by the IRB of record. In addition, the R&D Committee must also approve the following modifications, even if approved by the IRB of record: 1) enrollment of non-Veterans at STVHCS (not previously approved), 2) changes in data access, use, disclosure, or storage; 3) addition or expanded use of institutional resources; 4) changes in PI or addition of Co-PI. Studies not previously approved by the R&D Committee that receive IRB-approval of an amendment to add the STVHCS as a study site are treated as “New” research protocols, not amendments. Modification and amendments that meet the criteria for R&D Committee approval will be forwarded to the R&D Committee for approval. Modification and amendments that do not meet the criteria for R&D Committee approval and are approved by the UT Health San Antonio IRB will be reported to the R&D committee for information purposes only through the minutes posted for review at the R&D meetings. Modification and amendments that do not meet the criteria for R&D Committee approval and are approved by a non-UT Health San Antonio IRB will be reported to the R&D committee for informational purposes only.

(2) PIs of approved studies are responsible for submitting amendment packages with required documents in IRBNet as outlined on the website listed in the README_RDCHumanStudies guide in the STVHCS R&D Administration library and on the R&D Committee Amendment Application form. Depending on the amendment, required documents may include: 1) IRB-approved amendment forms (i.e., LOA and all associated documents stamped by IRB of record); 2) RDC Amendment Application for amendments that include changes that require R&D Committee approval; 3) Non-Veteran Application (for studies adding enrollment of non-Veteran at STVHCS); 4) applicable Evaluation of Resources for Clinical Research form (for addition or expanded use of institutional resources); 5) the Enterprise Research Data Security Plan (ERDSP) and/or Privacy Checklist for amendments that involve changes in data access, use, disclosure, or storage; and 6) CV and FCOI form (for change in PI or addition of Co-PI).

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In addition, changes that have the potential to affect safety of research personnel must be reviewed and approved by the SRS Committee. All these forms, except the FCOI forms, must be submitted in IRBNet to the STVHCS R&D Administration. FCOI forms should be submitted to STXResearchService@va.gov and VAHumanResearch@uthscsa.edu.

(a) The R&D Human Protocol Managers will:

1. Monitor submission of amendments and modifications in IRBNet and check for IRB-approved amendments and modifications that have not been submitted in IRBNet, following up with PIs as needed to remind them of their responsibility of submitting in IRBNet.

2. Review submitted packages to ensure they contain required documents and “unlock” packages as needed to communicate and resolve any deficiencies for submitted documents with the PI and/or study coordinator.

3. “Share” packages in IRBNet for additional reviews / approvals from Administrative “Committee” members that are needed prior to R&D Committee approval (e.g., Information Security or Privacy Officer, Service Chiefs for Evaluation of Resources). Reviewers will indicate their approvals using the reviewer “comments” function in the STVHCS R&D Administration and upload reviewer documents/signed forms (e.g., ERDSP, Privacy Checklists).

4. Once amendment “packages” have completed administrative review, these will be assigned by the Human Protocol Managers to the end of the month R&D Administration “agenda.” Amendment “packages” will then be acknowledged in STVHCS R&D Administration or will be “forwarded” in IRBNet to the R&D Committee “Board” in IRBNet for review or information purposes only and “assigned” to the next scheduled R&D Committee agenda.

5. Amendment forms and reviewer checklists for studies that require formal R&D review and approval will be sent to two R&D Committee Members for pre-review 7 days prior to the next scheduled R&D Committee meeting so that they can present their recommendations to the Committee.

6. Human Protocol Manager will note R&D Committee approval or “acknowledgement” R&D Committee board actions in IRBNet, noting dates of related approvals (e.g., IRB, Privacy, Information Security). R&D Protocol Managers will also generate an RDC Amendment letter of approval (LOA) for amendments that required formal approval, send to the RDC Chair for signature, and “publish” signed LOA as a “Board” document.

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

(1) PIs are responsible for submitting inactivation requests forms and related IRB approvals in IRBNet. Human Protocol Managers will monitor submission of Closure / Inactivation packages in IRBNet and check for IRB-approved inactivations that have not been submitted in IRBNet, following up with PIs as needed to remind them of their responsibility of submitting in IRBNet. Protocol Managers may submit closure packages when needed on behalf of the PI when needed (e.g., due to PI death/retirement or PI omission) by using the “Special Event Package” on the Project History page in IRBNet.

(a) The R&D Human Protocol Managers will:

1. Review closure package and ensure the Request for Inactivation of a Research Protocol is completed including a final data inventory update.

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2. Ensure that IRB-approved human and exempt protocols have been inactivated by the IRB of record or that the STVHCS has been removed as an engaged site by the IRB and that the associated IRB LOA is included in the package; if not, Human Protocol Manager will notify PI / study coordinator and the liaison of the IRB of record.

3. After completing administrative review, assigning packages to STVHCS R&D Administration end of month agendas, forwarding packages in IRBNet to the R&D Committee Board, and assigning them to the next scheduled meeting agenda.

4. Note R&D Committee Board actions in IRBNet (i.e., either acknowledgement if already closed by IRB of record or approval if not under IRB oversight); remove next report due and/or expiration dates; obtain signature of R&D Chairperson on RDC Closure Acknowledgement Letter; and publish these and the Closed Protocol Record Storage Instructions as “Board” documents in IRBNet.

5. Update the VA RDIS (ePromise) system.

d. **Human Subject Protocol Management – R&D Committee Agenda**

- (1) The Human Subject Protocol Managers will provide the Associate Chief of Staff for Research (ACOS) or his/her designee with the draft R&D Committee agenda 7 days prior to the next scheduled R&D Committee meeting.

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

- (1) Currently all records (electronic and paper) must be stored for 6 years (or longer if required by other Federal regulations (i.e., FDA) 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.
- (3) If the PI runs out of storage space OR the PI leaves the institution, the Research & Development Service Administrative Officer must be contacted for alternative storage options.

f. **Principal Investigator Responsibilities:**

(1) Obtaining continuing review and approval from all appropriate subcommittees and the R&D Committee and completing of required documentation as indicated on the website listed in the README_RDCHumanStudies guide or through automated “alerts” generated in IRBNet. The investigator is expected to know the date of the continuing review or institutional update 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 or institutional updates and related forms and submitting them in IRBNet 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.

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(5) Disclosing any changes to 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 investigator or sub-investigator for the project by submitting revised Research Financial Conflict of Interest form(s) to STXResearchService@va.gov and VAHumanResearch@uthscsa.edu.

(6) Obtaining IRB and/or R&D Committee approval as required for changes to human-focused research prior to implementing changes. Changes that affect safety of study personnel must be approved by the SRS Committee. 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. All modifications must be reported in IRBNet, even if R&D Committee approval is not required.

(7) Notifying the R&D office at the completion of a research project, completing all required documentation 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 Directive 1200.05(2); VHA Directive 1200.01

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

6. **RECISSION:** Research Service Policy Memorandum 22-52, January 14, 2022

7. **RECERTIFICATION:** August 2027

[Signature on File]

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