**DEPARTMENT OF VETERANS AFFAIRS** **Research Service Policy Memorandum 22-52**
**South Texas Veterans Health Care System**
**San Antonio, Texas 78229-4404** **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

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 (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 orkspace 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 orkspace 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 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

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

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

staff for completeness, who will
on any of the forms.

3. Human Protocol Managers are responsible for sending IRBNet R&D Administration
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
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.
review and approval at the SRS meeting) these will be assigned by the Human Protocol Mangers to the
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
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

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

In addition, changes that have the potential to affe9tmsafety 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.
packages as needed to communicate and resolve any deficiencies for submitted documents with the PI and/or study coordinator.

3.
to R&D Committee approval (e.g., Information Security or Privacy Officer, Service Chiefs for Evaluation of Resources). Reviewers will indicate their approvals

documents/signed forms (e.g., ERDSP, Privacy Checklists).

4. Once amendment , these will be assigned
Amendment
will then be acknowledged in STVHCS R&D Administration or will b

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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 n
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 signed

c. **Human Subje9tmProtocol 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 wv r92 reW*nQq0.0qr()5(ia0.98 Tf1/F-4( VreW*nic)-4(er, S] TJETQq0.00000912 0 612 792 reW

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