

STVHCS Research and Development Committee Continuing Review Application

Instructions: Use this Continuing Review form only for studies that are FUNDED Nonregulated Research (QI, Program Evaluation, Implementation Research), Center infrastructure funding, and NonHuman Subject Determinations (de-identified data or specimen studies).

Submit this form through IRBNet. You must receive an R&D Committee re-approval letter to continue your research.

This form should only be used to submit continuing reviews. Please complete and submit an amendment/modification request form to submit proposed changes to the research or an inactivation form to close the study.

1. Project and Investigator Information

VA Project Number	Click or tap here to enter text.
IRB Project Number	Click or tap here to enter text.
VA Facility	Click or tap here to enter text.
Title of Project	Click or tap here to enter text.
Principal Investigator	Click or tap here to enter text.
PI Email	Click or tap here to enter text.
PI Telephone	Click or tap here to enter text.
Name of Point of Contact other than PI:	Click or tap here to enter text.
POC Email	Click or tap here to enter text.
POC Telephone	Click or tap here to enter text.

2. Project Status

Check one of the following to indicate the overall status of the study:	
<input type="checkbox"/>	1. Study not yet open to enrollment
<input type="checkbox"/>	2. Open to enrollment; no research subjects enrolled.
<input type="checkbox"/>	3. Active and open to enrollment; research subjects are undergoing research procedures per approved project. <i>Indicate # of subjects approved for enrollment:</i> <i>Indicate # of subjects enrolled:</i>
<input type="checkbox"/>	4. No longer enrolling subjects; subjects continue to undergo research procedures per protocol. <i>Date Enrollment Ended:</i>
<input type="checkbox"/>	5. Research procedures are complete. Only data analysis ongoing. <i>Date Research Procedures Ended:</i>

STVHCS Research and Development Committee Continuing Review Application

<input type="checkbox"/>	6. Study is a data collection and analysis only study; research subjects did not undergo research interventions or interactions, to include interviews and surveys. Data analysis is ongoing.
<input type="checkbox"/>	7. Other:

3. Project Team Members

Have there been changes to study personnel?

- ☐ No, Personnel on VA-Project Cover Sheet are current
- ☐ Yes, Submit a revised VA-Project Cover Sheet with this package

Each PI and any investigator(s) must create an Annual Disclosure in IRBNet under the “My COI” page.

Note: Personnel on VA-Project Cover Sheet will be used to verify VA Research Privileges.

4. Scientific Progress Since Last Continuing Review

Please submit project abstract and describe the scientific progress made on this project in the past year. Include information on the following:

- **Progress:** briefly describe the progress of the research and highlight progress, if any, that has been made since the last continuing review.
- **Observations/Interim Findings:** briefly describe any significant preliminary observations/interim findings since initial approval or the last report.
- **Recent Literature:** summarize any recent (within the last year) literature from peer reviewed publications relevant to your research project.
- **Publications and Presentations:** provide a list of any journal articles that have been published or accepted for publication and any conference papers that have been presented or accepted.
- **Additional Information (Optional):** provide any additional information specific to this project not addressed in the Continuing Review application (e.g., presentations or publications).

5. Updates Since Last Continuing Review

Please provide responses to the following questions.

1. Is/was this project funded by any source?

- ☐ No.
- ☐ Yes.

STVHCS Research and Development Committee Continuing Review Application

If yes, please provide funding source & grant or funding #:

☐ Check if no cost extension.

2. Since the last review, have there been any budget changes or changes in requirements for space, personnel, equipment, or supplies that may impact the STVHCS?

☐ No.

☐ Yes.

If yes, please explain:

3. Provide a summary of any unanticipated problems that have occurred since the last continuing review and indicate what impact, if any, they have had on the research study.

4. Since the last continuing review, have all unanticipated, serious, and related adverse events and any unanticipated problems involving risks to subjects or others been reported to the R&D Committee?

☐ No. If no, a report must be submitted to the R&D Committee for review.

☐ Yes.

☐ N/A There have been NO events or problems since last Continuing Review.

5. Provide a summary of any issues of serious non-compliance with applicable policies, including privacy and security that have occurred since the last continuing review and indicate what impact, if any, they have had on the research study.

6. Since the last continuing review, have all incidents of serious non-compliance been reported to the R&D Committee?

☐ No. If no, a report must be submitted to the R&D Committee for review.

☐ Yes.

☐ N/A There have been NO events or problems since last Continuing Review.

☐ I attest that the project continues to be scientifically and ethically sound. My study team and I have the competencies and resources to continue to conduct the research described in this Continuing Review application. My study team and I will continue to meet the ethical standards for research and will comply with all VA research requirements.