VAIRRS	Research and Development Committee Request to Amend or Modify an Approved Project

Instructions

This form should be used to request modifications to approved research studies that meet at least one of the following criteria:

1) The R&D Committee is the sole oversight committee for the study (e.g. research that is exempt from the common rule determined by a non-UTHSA IRB and/or research involving only non-human subjects data* or only animal data);
2) Inclusion of non-Veterans that was not previously approved is being requested;
3) The change involves institutional issues that require R&D Committee review, in accordance with your local SOP.

*Non-human subjects data includes de-identified data or data on decedents.

Submit this form, modified IRB approved documents, and applicable forms indicated below through IRBNet. You must receive an R&D Committee approval letter prior to initiating the change.

If your amendment does not meet criteria indicated above, submit a summary of the changes and modified documents in IRBNet. An acknowledgement will be received through IRBNet after administrative review.

1. Project and Investigator Information

Project Number	
VA Facility	
Title of Project	
Principal Investigator	
PI Email	
PI Telephone	
Name of Point of Contact other than PI:	
POC Email	
POC Telephone	

2. Type of Amendment or Modification Request

Please check all applicable boxes.	
Change Requested	**Documents Required**
☐ **Revised research plan/study protocol**	**Submit revised protocol (both clean and track changes version), updating current version number. If the change involves Biosafety or Radiation Safety, a copy of the approval letter from the respective committee must be included.**

☐ Information Sheet or Recruitment Materials	Submit revised information sheet or recruitment materials with updated version dates. If there is a change in the recruitment process, submit revised protocol. If there is a change in participant payment, submit revised protocol and information sheet if applicable.
☐ Questionnaires, interviews, and/or surveys	Submit revised questionnaires and/or surveys reflecting updated version dates. Submit a revised protocol if there is a change in how these are administered or if there is a new procedure.
☐ Inclusion of Non-Veterans	Complete non-Veteran application and submit a revised protocol.
☐ Enrollment goals and/or change in inclusion/exclusion criteria	Submit revised protocol.
☐ Change in study team members who serve in the role of "investigator" and/or are named in study documents provided to participants	Submit revised protocol and affected documents. Conflict of Interest Forms for each new investigator must be submitted in IRBNet under the "My COI" page.
☐ Change in source of data	Submit revised protocol and revised waiver of HIPAA authorization form, if applicable.
☐ Other *Specify:*	Specify forms or documents being submitted if not checked above:

3. Description of Changes and Rationale

Please provide a brief description and rationale for <u>each</u> type of change requested. Additional rows may be added as necessary.	
Description of Change or Modification	**Rationale for Change or Modification**

4. Changes in 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.

5. Additional Reviews

A. Might the change impact the exempt status of the project?	☐ Yes ☐ No ☐ N/A
i. If yes, this modification request must also be submitted to the Exempt Determination Official or IRB for review	
B. Does the change impact Information Security Requirements?	☐ Yes ☐ No
i. If yes, complete the Enterprise Research Data Security Plan (ERDSP). ISSO review may be required.	
C. Does the change impact Privacy Requirements?	☐ Yes ☐ No
i. If yes, does the study involve human subjects research?	☐ Yes ☐ No
ii. If yes, complete VA Form 10-250. Privacy Officer review is required.	