**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** |  |

1. **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 to the research office for processing.** |
| **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:** |

1. **Description of Changes and Rationale**

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

1. **Changes in Personnel**

No, Personnel on VA-Project Cover Sheet are current

Yes, Submit a revised VA-Project Cover Sheet with this package

***Submit a new Financial Conflict of Interest Form for all research investigators. This includes all PIs, Co-PIs, and Sub-Investigators. Please submit in electronic format only and do not lock document.***

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

1. **Additional Reviews**

|  |  |
| --- | --- |
| 1. Might the change impact the exempt status of the project? | Yes  No  N/A |
| 1. If yes, this modification request must also be submitted to the Exempt Determination Official or IRB for review |  |
| 1. Does the change impact Information Security Requirements? | Yes  No |
| 1. If yes, complete the Enterprise Research Data Security Plan (ERDSP). ISSO review may be required. |  |
| 1. Does the change impact Privacy Requirements? | Yes  No |
| 1. If yes, does the study involve human subjects research? | Yes  No |
| 1. If yes, complete VA Form 10-250. Privacy Officer review is required. |  |