**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 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.

Contact your research office to coordinate the review of modifications that require review by committees other than the R&D Committee.

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**

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| --- | --- |
| ***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** |
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1. **Changes in Personnel  N/A**

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| --- |
| ***If the requested modifications do not involve any changes in personnel check the N/A box above and proceed to Section 5.*** |
| **For changes in study team personnel, please complete the below tables and questions:**     |  |  |  |  |  | | --- | --- | --- | --- | --- | | Project Team Member | Degrees | VA Employee Status  (WOC, IPA, #8ths etc.) | Project Role | All required training is up-to-date? | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No | |  |  |  |  | Yes  No |   ***For new team members who have a role of “investigator”, include a CV with this submission. Also attach any other study materials that will need to be changed if the individual is referenced by name. COI forms should also be submitted to the research office for processing.***  ***List personnel who have departed.***   |  |  | | --- | --- | | **Name** | **Project Role** | |  |  | |  |  | |  |  | |  |  | |  |  | |

1. **Additional Reviews**

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| 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. |  |

1. **Principal Investigator/Local Site Investigator Signature**

|  |  |  |
| --- | --- | --- |
| ***The Principal Investigator or Local Site Investigator must sign/date the request below.*** | | |
| All proposed changes to be made in this project have been reported on this form and the attached documents. The project continues to be scientifically and ethically sound. | | |
|  | Signature of PI Date |  |