1. **Project and Reviewer Identification**

|  |  |
| --- | --- |
| **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. |
| **Type of Study** | [ ]  Non-Human Subjects Data Only [ ]  Animal Data Only [ ]  Exempt from Common Rule requirements[ ]  Other (explain):        |
| **Type of Review** | [ ]  Convened Board [ ]  Designated Review\**\*If the VA research activity was eligible for initial review by designated review, modifications to the research activity are also eligible for review and approval by designated review.* |
| **Assigned Reviewer** | Click or tap here to enter text.  |
| **Reviewer COI** | If the assigned reviewer has a conflict of interest (COI), check the box below and return to the Research Office[ ]  I have a conflict of interest and am returning this form without action. |

|  |  |  |
| --- | --- | --- |
| 1. **Recruitment and Enrollment**
 | 1. Does the modification involve changes to recruitment procedures?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | * 1. If yes, are the proposed changes ethical and in compliance with VA research policies?
 | [ ]  Yes [ ]  No |
|  | 1. Does the modification involve a change in the enrollment criteria or enrollment goals?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. If yes, are the requested changes acceptable?
 | [ ]  Yes [ ]  No |
|  | Comment:Click or tap here to enter text. |
| 1. **Study Personnel and Resources**
 | 1. Does the modification involve changes in investigators?
 | [ ]  Yes [ ]  No (skip to B2) |
|  | * 1. If yes, are the new investigator(s) qualified to conduct the study?
 | ☐ Yes ☐ No |
|  | * 1. Do any new investigators have any potential, actual or perceived conflicts of interest related to any aspect of the research, including financial interests, clinical roles (i.e., investigator-patient relationships), and other professional or personal roles?
 | [ ]  Yes [ ]  No  |
|  | * 1. If yes, have they been appropriately managed?
 | [ ]  Yes [ ]  No |
|  | 1. Does the modification involve changes in resources?
 | [ ]  Yes [ ]  No (skip to C1) |
|  | * 1. If yes, are the proposed resources (personnel, time space, equipment, and/or supplies) sufficient to perform the study and to assure the safety of subjects and others?
 | [ ]  Yes [ ]  No |
|  | * 1. Have the appropriate departments approved use of the proposed space? *(i.e., Laboratory, Pharmacy, Surgery, etc.)*
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | * 1. If new space has been requested, has use of the new space been approved by the relevant entities?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | Comments:Click or tap here to enter text. |
| 1. **Questionnaires, Surveys, Forms**
 | 1. Does the modification impact any data collection instrument used in the study?
 | [ ]  Yes [ ]  No (skip to D1) |
|  | 1. If yes, are the modified or additional tools acceptable?
 | [ ]  Yes [ ]  No  |
|  | Comments:Click or tap here to enter text. |
| 1. **Privacy & Data Security**
 | 1. Do the requested changes impact data security?
 | [ ]  Yes [ ]  No (skip to D2) |
|  | 1. If yes, is submission of the Enterprise Research Data Security Plan (ERDSP) required?
 | [ ]  Yes [ ]  No  |
|  | 1. Do the requested changes impact Human Subjects Privacy Requirements?
 | [ ]  Yes [ ]  No (skip to E1) |
|  | 1. If yes, has a review by the PO been conducted?
 | [ ]  Yes [ ]  No  |
|  | Comments:Click or tap here to enter text. |
| 1. **Non-Veterans**
 | 1. Does the modification include the enrollment of non-Veterans?
 | [ ]  Yes [ ]  No (skip to F1) |
|  | * 1. If yes, has the non-Veteran supplement form been completed and is the inclusion of non-Veterans justified?
 | [ ]  Yes [ ]  No |
|  | Comments: Click or tap here to enter text. |
|  | 1. Does the modification involve outpatient or inpatient treatment of non-Veterans?
 | [ ]  Yes [ ]  No  |
|  | * 1. If yes, has the PI demonstrated that there are insufficient Veteran patients suitable for the study?
 | [ ]  Yes [ ]  No  |
|  | 1. Is there a high likelihood of research-related injuries?
 | [ ]  Yes [ ]  No |
|  | * 1. Have funds to cover reimbursement of research related injuries been identified?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | Comments:Click or tap here to enter text. |
| 1. **Exempt Human Subjects Research**
 | 1. Was the study originally determined to be exempt from the Common Rule?
 | [ ]  Yes [ ]  No (skip to G1) |
|  | 1. Does the amendment involve changes that affect the exempt categories?
 | [ ]  Yes [ ]  No (skip to F4) |
|  | 1. If yes, does the study meet exempt categories 2(iii); 3(i)(c); or 8 requiring limited IRB review?
 | [ ]  Yes [ ]  No |
|  | 1. If yes, has the investigator provided documentation that an IRB conducted limited IRB review of the study?
 | [ ]  Yes [ ]  No |
|  | 1. Indicate which exempt categories apply.
 | Click or tap here to enter text. |
|  | 1. Does the study still qualify as exempt?
 | [ ]  Yes [ ]  No (IRB Review Required) |
|  | 1. Does the amendment involve the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions?
 | [ ]  Yes [ ]  No (skip to F5) |
|  | 1. If yes, has the Investigator described how he/she will provide prospective subjects with the following information required by VHA Directive 1200.05 paragraph 10c:
2. The activity is research;
3. Participation is voluntary;
4. Permission to participate can be withdrawn;
5. Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data; and
6. Contact information for the VA Investigator.
 | [ ]  Yes [ ]  No |
|  | 1. Does the amendment result in the need for a waiver of HIPAA authorization (or updated waiver of HIPAA authorization) required for access to or use of Protected Health Information for research purposes?
 | [ ]  Yes[ ]  No (skip to G1) |
|  | 1. If yes, has the waiver of HIPAA authorization been approved by the IRB or Privacy Board?
 | [ ]  Yes [ ]  No |
|  | Comments:Click or tap here to enter text.  |
| 1. **Ethical Concerns**
 | 1. Are there any ethical concerns that have not been sufficiently addressed?
 | [ ]  Yes [ ]  No  |
|  | Comments:Click or tap here to enter text. |

1. **Reviewer Recommendation:**

***(Only complete if amendment requires review at a convened meeting)***

|  |
| --- |
| [ ]  Recommend approval [ ]  Require modifications to secure approval (include comments in section 6)[ ]  Recommend disapproval (include comments in section 6) |

1. **Designated Reviewer Determination:**

***(Only complete if amendment is eligible for approval by designated review.)***

|  |
| --- |
| [ ]  Approve as submitted[ ]  Require modifications to secure approval (include comments in section 6)[ ]  Defer for review by the convened R&D Committee (include comments in section 6) |

1. **Additional Comments or Requested Modifications:**

|  |
| --- |
| Click or tap here to enter text. |

**Signature of R&D Committee Reviewer Date**