1. **Project and Reviewer Identification**

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| **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. |

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| 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)***

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| 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.)***

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| 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:**

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| Click or tap here to enter text. |

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