1. **Project and Reviewer Identification (to be completed by the Research Office)**

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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:  |
| **R&D Committee** **Initial Approval Date** | Click or tap here to enter text. |
| **R&D Committee Approval Expiration Date** | Click or tap here to enter text. |
| **Type of Review** | [ ]  Convened Board [ ]  Designated Review\**\*If the VA research activity was eligible for initial review by designated review, continuing review of the study can be conducted 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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| **Training and COIs** | 1. Have all members of the research team completed all required training?
 | [ ]  Yes [ ]  No |
|  | 1. Have all members of the research team that require credentialing completed all credentialing requirements (VA appointment, IPA, WOC?)
 | [ ]  Yes [ ]  No |
|  | 1. Do any 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 |
|  | Comments:  |

1. **Continuing Review (To be completed by the Reviewer)**

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| 1. **Study Personnel and Resources**
 | 1. Have there been any changes in the status of the Principal Investigator, Investigators, or study team members (e.g. additions or removal) since the most recent approval of the study?
 | [ ]  Yes [ ]  No  |
|  | 1. If yes, have all changes been reported in accordance with local SOPs?
 | [ ]  Yes [ ]  No |
|  | 1. Does the study team continue to have the expertise and qualifications needed to conduct the study?
 | [ ]  Yes [ ]  No |
|  | 1. Do the proposed resources (personnel, budget, time, space, equipment, and supplies) continue to be sufficient to perform the study and to assure the safety of subjects and others?
 | [ ]  Yes [ ]  No |
|  | 1. Comments:

Click or tap here to enter text. |
| 1. **Scientific Progress**
 | 1. Has the number of subjects entered into the study exceeded the number of subjects approved for this project?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. If yes, was an amendment submitted revising the enrollment number?
 | [ ]  Yes [ ]  No |
|  | 1. Have any subject recruitment issues been identified by the PI that require additional action by the R&D Committee?
 | ☐ Yes ☐ No [ ]  N/A |
|  | 1. Is the timeline to complete the research still appropriate?
 | [ ]  Yes [ ]  No  |
|  | 1. Did the PI report any preliminary observations, interim findings not included in a report, literature, or other information about presentations or publications that require action by the R&D Committee?
 | [ ]  Yes [ ]  No  |
|  | Comments:Click or tap here to enter text. |
| 1. **Reportable Events**
 | 1. Have there been any Serious Adverse Events (SAEs), Serious Problems, or Unanticipated Problems (UAPs) since the last approval?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. If yes, were they reported in a timely manner and reviewed by the R&D Committee?
 | [ ]  Yes [ ]  No  |
|  | 1. Are there any significant impacts to the research from serious unanticipated events or problems that have occurred to-date?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. Have there been any issues of serious non-compliance, including privacy and security incidents, since the last approval?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. If yes, were they reported in a timely manner and reviewed by the R&D Committee?
 | [ ]  Yes [ ]  No  |
|  | 1. Are there any significant impacts to the research from any serious non-compliance that have occurred to-date?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | 1. Have there been any complaints associated with the research that require additional action by the R&D Committee?
 | [ ]  Yes [ ]  No [ ]  N/A |
|  | Comments:Click or tap here to enter text. |
| 1. **Additional Information**
 | 1. Is there any new information reported in the continuing review application (e.g. RCO audit, external audits) that requires additional review by the R&D Committee?

*If yes, include recommendation in comments.* | [ ]  Yes [ ]  No  |
|  | 1. Do you recommend independent verification (e.g. an audit) of this project to ensure that no changes have occurred prior to review and approval by the R&D Committee? If yes, include recommendation in comments section.
 | [ ]  Yes [ ]  No  |
|  | 1. Has all required information been included in the continuing review submission? If no, indicate in the comments section what remains outstanding.
 | [ ]  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 project requires continuing review at a convened meeting)***

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

1. **Designated Reviewer Determination:**

***(Only complete if project is eligible for designated review.)***

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

1. **Continuing Review Approval Period:**

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| --- |
| [ ]  12 months [ ]  6 months[ ]  Other, specify: Click or tap here to enter text. |

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

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

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