**Sample Checklist**

**Research & Development Committee**

**Initial Review**

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

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| **Project Number** |  |
| **Facility** |  |
| **Title of Project** |  |
| **Principal/**  **Local Site Investigator** |  |
| **Type of Review** | Convened Board  Designated Review |
| **Assigned Reviewer** |  |
| **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. **Type of Study/Review**   (select all that apply) | Non-Human Subjects Data  Human Subjects Research  Animal  Exempt from IRB Review  Safety/Science/Laboratory  Other (explain): | | |
| 1. **Approval/**   **Determination Dates** | SRS Initial Approval Date: |  | n/a |
| IRB Initial Approval Date: |  | n/a |
| IACUC Approval Date: |  | n/a |
| Radiation Safety Approval Date: |  | n/a |
| Exempt Determination Date: |  | n/a |
| Other Committee Approval Date (specify): |  | n/a |

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| 1. **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. Are there 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. **For Research & Development Committee Use:**

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| 1. **Merit / Relevance** | 1. Does this study support the VA mission and is it relevant to the care of Veterans? | Yes  No |
|  | 1. Does the protocol have scientific merit?   NOTE: If the protocol has been reviewed by a VA merit review committee, an NIH study section or other Federal peer review committee, the R&DC may rely on that peer review if the findings are submitted with the protocol. | Yes  No |
|  | 1. If the study has been peer-reviewed, has documentation of the peer-review been received? | Yes  No  n/a |
|  | 1. Is the objective/hypothesis of the proposed project clearly stated? | Yes  No |
|  | 1. Are the research procedures consistent with a sound research design? | Yes  No |
|  | 1. If no to any of the above questions, please explain: | |
| 1. **Resources** | 1. Are the investigator(s) and research team members qualified to conduct the study? | Yes  No |
|  | 1. Is the budget for the study adequate? | Yes  No  n/a |
|  | * 1. Does the budget provide for reimbursement of medical center costs, if applicable? | Yes  No  n/a |
|  | 1. Are resources (personnel, time space, equipment, and 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: | |
| 1. **Privacy & Data Security** | 1. Was a data security review conducted by the ISSO? | Yes  No  n/a |
|  | 1. Was a Privacy Review conducted by the PO? | Yes  No  n/a |
|  | 1. Do all disclosures and data transmissions meet privacy and security requirements contained in VHA Directive 1605.01 and VA Handbook 6500? | Yes  No  n/a |
|  | Comments: | |
| 1. **Non-Veterans** | *If not applicable, skip to section E.* n/a | |
|  | 1. Does the investigator wish to enroll non-Veterans in the study? | Yes  No |
|  | * 1. If yes, is the inclusion of the non-Veterans justified? | Yes  No |
|  | Comments: | |
|  | 1. Does the study 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. Have funds to cover reimbursement of research related injuries been identified? | Yes  No |
| 1. **Collaborative Research** | *The VA R&DC must ensure it only approves VA activities in a collaborative study. If not applicable, skip to section F.* n/a | |
|  | 1. Are VA research activities clearly separated from non-VA research activities in the protocol and all accompanying documents? | Yes  No |
|  | 1. Does the study describe the data to be disclosed and to which entity(ies)/collaborator(s) it will be disclosed? | Yes  No |
|  | 1. Does the study adequately describe the collection, use, transfer, and disposition of the data obtained and/or collected? | Yes  No |
|  | 1. Is it clear who will own or have responsibility for the disclosed copies of the data? *This includes data developed directly from the research including the analytic data and the aggregate data.* | Yes  No |
|  | 1. Will the VA retain a complete record of all the data obtained during the VA portion of the research? | Yes  No |
|  | 1. Does the study involve biospecimens? If no, skip to section F. | Yes  No |
|  | * 1. Does the study adequately describe the collection, use, transfer, and disposition of biospecimens obtained or collected? | Yes  No |
|  | * 1. If the study involves transferring biospecimens outside the VA, will a Material Transfer Agreement (MTA), or other agreement such as a CRADA, subaward or MOU be executed by all appropriate parties?   *NOTE: If a CRADA is executed for a research study where the scope of work specifically describes analysis, retention, and disposal of biospecimens by a central laboratory, then an MTA is not required.* | Yes  No  n/a |
|  | Comments: | |
| 1. **Exempt Human Subjects Research** | *If not applicable, skip to section G.* n/a | |
|  | 1. Is the study exempt from IRB review? | Yes  No |
|  | 1. If yes, does the study meet exempt categories 2(iii); 3(i)(c); 7; or 8 requiring limited IRB review? | Yes  No |
|  | 1. For studies requiring limited IRB review, has the investigator provided documentation that the IRB conducted limited IRB review of the study? | Yes  No |
|  | 1. Does the study involve the Investigator interacting with human subjects or obtaining information by educational tests, survey or interview procedures, or behavioral interventions? | Yes  No |
|  | 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. Are recruitment procedures acceptable? | Yes  No |
|  | 1. Is a waiver of HIPAA authorization required for access to or use of Protected Health Information for research purposes? | Yes  No |
|  | 1. If yes, was a waiver of HIPAA authorization approved by the IRB or privacy board? | Yes  No |
|  | Comments: | |
| 1. **Medical Center Director Approval and Certifications** | *Medical Center Director approval or certification is required for research involving certain groups of subjects. If not applicable, skip to section H.* n/a | |
|  | 1. Does the study involve interventional studies or invasive monitoring of pregnant women? | Yes  No |
|  | 1. If yes, has the Medical Center Director certified that the facility has sufficient expertise in women’s or reproductive health to conduct the proposed research? | Yes  No |
|  | 1. Does the research involve noninvasive monitoring of neonates or prospective observational or retrospective record review of neonates or their data? | Yes  No |
|  | 1. If yes, has the Medical Center Director certified that the facility has sufficient expertise in neonatal health to conduct the proposed research? | Yes  No |
|  | 1. Does the research involve children? | Yes  No |
|  | 1. If yes, is the research not greater than minimal risk and has the Medical Center Director approved participation in the proposed research? | Yes  No |
|  | 1. Does the study involve prisoners? | Yes  No |
|  | 1. If yes, has a waiver been granted by the CRADO? | Yes  No |
|  | 1. Does the study include international research? | Yes  No |
|  | 1. If yes, has approval from the Medical Center Director been obtained? | Yes  No |
|  | Comments: | |
| 1. **Ethical Concerns** | 1. Are there any ethical concerns that have not been sufficiently addressed? | Yes  No  n/a |
|  | Comments: |  |
|  | Comments: | |

1. **Reviewer Recommendation:** *(For studies to be reviewed at a convened meeting)*

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| Approve as submitted  Approve pending minor modifications *(Final approval will be granted by designated review once the designated reviewer has confirmed that all required modifications have been made)*  Deferred: Major modifications are required to obtain approval and the study must be re-reviewed at a convened meeting of the R&D Committee. *(Study may require re-review by appropriate subcommittee)*  Disapprove |

1. **Designated Reviewer Determination: (***For studies eligible for initial approval by designated member review.)*

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| Approve as submitted  Modifications needed to secure approval  Defer for review by the convened R&D Committee (include rationale in section 5) |

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

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1. **Approval Period:** *(For studies that are not followed by a subcommittee/committee or external IRB and are therefore under the sole oversight of the R&D Committee, select the appropriate/recommended approval period. If study is followed/approved by a subcommittee of the R&D Committee or external IRB check NA below.*

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| n/a  3 months  6 months  12 months |

**Signature of Reviewer Date**