**Sample Checklist**

**Research & Development Committee**

**Initial Review**

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

|  |  |
| --- | --- |
| **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**