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| Protocol #:       | Name:       | Date:       |

| **Yes** | **No** | **N/A** | **Protocol Checklist**  |
| --- | --- | --- | --- |
| [ ]  | [ ]  |  | Add VA Human Protections Administrator and Privacy Officer, Karam Kaur as a reviewer. |
| [ ]  | [ ]  | [ ]  | Funding and General Checklist: For Unfunded VA Research confirm SIGNED VA Scientific Review Subcommittee- Initial Project Checklist attached.  |
| Participant Population Checklist: Prohibited and Conditional Research[ ]  N/A | [ ]  | [ ]  | [ ]  | See [AID-27](https://stanfordmedicine.box.com/shared/static/20xhu8go436rp3dxe5rwc051w8qrioie.pdf) regarding requirements for research with prisoners. . |
| [ ]  | [ ]  | [ ]  | See AID-27 regarding requirements for research with those who are **pregnant** |
| [ ]  | [ ]  | [ ]  | **Neonates, fetal tissue, embryos, have PD confirm**: 1. VA investigators are not conducting interventions in research that include neonates while on official VA duty, at VA facilities, or at VA-approved off-site facilities. VA investigators are only conducting research involving noninvasive monitoring of neonates and research is minimal risk;
2. Research is not using human fetal tissue or focusing on either a fetus, or human fetal tissue in-utero or ex-utero;

Research does not involve the creation of a human embryo or embryos solely for research purposes or research in which a human embryo or embryos are destroyed, discarded, or knowingly subjected to risk of injury or death greater than that allowed for research on fetuses in utero under 45 CFR 46.208(a)(2) and Section 498B of the Public Health Service Act (42 U.S.C. 289g(bAssign an IRB reviewer with the appropriate expertise to evaluate VA research involving neonates.*Note: Prospective observational and retrospective record review studies that involve neonates or neonatal outcomes are permitted.*  |
| [ ]  | [ ]  | [ ]  | If the research involves **children**, have PD confirm1. study is relevant to VA mission (R&D will also review);
2. **is minimal risk to the children**; and
3. Assign a VA IRB reviewer.

*NOTE: Research involving biological specimens or data obtained from children is considered to be research involving children even if de-identified*  |
| [ ]  | [ ]  | [ ]  | If study is conducted **internationally** (including internet research and specimens or data sent outside of the U.S.), this study received equivalent protections as participants would inside the U.S,Have PD confirm they will received required local Medical Director approval (unless exempt, note this requirement does include limited IRB review), except for Cooperative Studies Program activities which must be approved by the CRADO (R&D will check this). |
| [ ]  | [ ]  | [ ]  | Section 2(a): Joint SU/VA study: Regarding “For research involving collaborators, please specify the respective roles of Stanford and each collaborator on the protocol”, the section lists which personnel are engaged with VA research/who has access to VA data. |
| [ ]  | [ ]  | [ ]  | Section 2(a): Joint SU/VA study: Procedures section clearly delineates which procedures will occur at Stanford facilities, and which at VA. |
| [ ]  | [ ]  | [ ]  | Section 8(g): Joint SU/VA study: Recruitment section clearly delineates what recruitment processes will occur at Stanford facilities, and which at VA (and if varies for different populations such as VA subjects and non-VA subjects at the VA). |
| [ ]  | [ ]  |  | Section 8(g): During the recruitment process, PD makes initial contact with potential subjects in person or by letter (must get subject permission through treating physician or have physician forward materials to subjects and subjects contact researcher) prior to initiating any telephone contact, unless there is written documentation that the subject is willing to be contacted by telephone about the study in question or a specific kind of research as outlined in the study. (a)Any initial contact by letter or telephone must provide a telephone number or other means that the potential subject can use to verify that the study constitutes VA research; and (b) If a contractor makes the initial contact by letter, the VA investigator must sign the letter. |
| [ ]  | [ ]  | [ ]  | Section 11: If the investigator contracts with a firm (e.g., a survey research firm) to obtain consent from subjects, collect private individually identifiable information from human subjects, or be involved in activities that would institutionally engage the firm in human subjects research, the firm must have its own IRB oversight of the activity |
| [ ]  | [ ]  | [ ]  | Section 11h: Confirm the entities listed is consistent with the HIPAA Authorization or a Waiver of HIPAA Authorization in section 15. |
| [ ]  | [ ]  | [ ]  | Section 11h: If the study involves use of pre-existing VA biological specimens or data that will be reused outside of VAPAHCS, the consent or authorization gives proper authority for reuse.  |
| [ ]  | [ ]  | [ ]  | Section 13 in Consent Background: “VA” should be checked when the consent, waiver, or alteration applies to consenting procedures at the VA. |
| [ ]  | [ ]  | [ ]  | Section 13 in Consent Background: VA DocuSign, not University DocuSign, is used for electronic consent, and is used with Waiver of HIPAA Authorization.  |
| [ ]  | [ ]  | [ ]  | Section 13: For Joint SU/VA Studies:Separate consent forms must be used (SU, VA), depending on the location. VA ICF restricted to VA use only. **Refer to ICF checklist and VA ICF template for VA required language.**  |
| [ ]  | [ ]  | [ ]  | Section 13 and 15: For Joint SU/VA Studies, HIPAA waiver, ICF waiver, or alteration of consent should state to which institution it applies.\**Short Form Consent Process is not permitted at the Palo Alto VA.* |
| [ ]  | [ ]  | [ ]  | Section 15: Alteration of HIPAA Authorization is not permitted for VA only study. -For minimal risk studies with waiver of documented consent, a HIPAA Waiver of Authorization has been requested if PHI is involved. |
| [ ]  | [ ]  | [ ]  | Section 15: For Waiver of HIPAA Authorization for VA; If accessing/using includes information related to alcohol or drug use, HIV status, or sickle cell anemia, the research team confirms: 1.The information will be maintained in accordance with all VA information security policies;2. The information will not be re-disclosed, except back to the VA; and 3. The information will not identify any individual patient in any report of the research or otherwise disclose patient identifiers.  |
| [ ]  | [ ]  | [ ]  | Section 15: The HIPAA authorization is embedded in the consent form, or is separately attached. |
| [ ]  | [ ]  | [ ]  | Exempt Categories 2 and 3: Confirm that (a) The following information is given to the prospective human participant as applicable in writing or orally:(i) The activity is research.(ii) Participation is voluntary.(iii) Permission to participate can be withdrawn.(iv) Permission for use of data can be withdrawn for exempt research activities involving the collection and use of identifiable data.(v) Contact information for the VA researcher. |
| [ ]  | [ ]  | [ ]  | Exempt Category 5: Confirm with PD that the determination of exempt status for research and demonstration projects meeting the criteria for exempt category 5 has been made by the Under Secretary for Health on behalf of the Secretary of VA, (after consultation with Office of Research and Development (ORD), Office of Research Oversight (ORO), Office of General Counsel (OGC), and other experts, as appropriate). |