|  |  |
| --- | --- |
| ***Protocol reviewed:*** | ***Review completed by:*** |
| Protocol # and PD:       | Name:       Date:       | IRB#:     |

|  | **Yes** | **No** | **N/A** | **Protocol Checklist**  |
| --- | --- | --- | --- | --- |
| Expedited Review[ ]  Met |[ ] [ ] [ ]  The research presents no more than minimal risk to participants |
|  |[ ] [ ] [ ]  The identification of subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal |
|  |[ ] [ ] [ ]  The research is not classified |
|  |[ ] [ ] [ ]  Correct expedited review category/categories selected in eProtocol |
|  |[ ] [ ] [ ]  Eligible for Extended Approval per 1/21/19 revised Common Rule |
| Personnel Info[ ]  Met |[ ] [ ] [ ]  **PD:** Protocol Director appropriate for the study (see AID-25) |
|  |[ ] [ ] [ ]  **Chair Approval, Academic Sponsor:** Scientific and Scholarly Validity (SSV) completed by Dept. Chair, Academic Sponsor, or other source (see AID-107) |
|  |[ ] [ ] [ ]  **CITI:** All required personnel have completed CITI training |
|  |[ ] [ ] [ ]  **Non-Stanford:** Only Stanford/secure email addresses listed in Personnel Info section |
| Participant PopulationChecklist[ ]  N/A |[ ] [ ] [ ]  **Decisionally Challenged:** if targeting participants with impaired decision making capacity |
|  |[ ] [ ]  [ ]  | If children/pregnant women/healthy volunteers selected, confirm consistent with sections 8f and 9f  |
|  |[ ] [ ] [ ]  **Student Data Oversight Committee**: If Stanford students selected, confirm SDOC review completed or confirm with Sr. Manager SDOC review needed |
| Study Location[ ]  Met |[ ] [ ] [ ]  Stanford University selected unless VA-only study  |
|  |[ ] [ ] [ ]  If study takes place at VAPAHCS, Karamjeet Kaur has been added as a Reviewer and VA Research Required Questions have been completed/attached to section 16  |
| International[ ]  N/A |[ ] [ ] [ ]  **International Research**: section 9b completed and International Research Supplemental Questions have been attached to section 16 |
|  |[ ] [ ] [ ]  **GDPR:** Participants residing in the EU while their study data is being collected |
|  |[ ] [ ] [ ]  **Data – China PIPL, Samples – China:** Appropriate requirements met forresearch conducted in China |
|  |[ ] [ ] [ ]  **Int’l biological materials to US, Int’l India clinical trial, Int’l DHHS funds to India, Int’l India HSMC Review:** Appropriate requirements met forresearch conducted in India |
| General Checklist collaborators[ ]  N/A |[ ] [ ] [ ]  **Multi-site/Collaboration:** If study is listed as both multi-site study and collaboration |
|  |[ ] [ ] [ ]  **IRB Approval:** If Stanford is the lead/coordinating site, IRB approval letters from other sites have been received or appropriate approval note will be added  |
|  |[ ] [ ] [ ]  **Federal Funding/Collaborators- sIRB?:** Study has federal funding and involves outside collaborators, confirm if the other site(s) are engaged in HSR and notify sIRB Manager. |
|  |[ ] [ ] [ ]  **DUA , MTA OTL:** no funding listed AND data or tissues will be sent out of Stanford  |
| General Checklist [ ]  N/A |[ ] [ ] [ ]  **CTgov-General Checklist, CTgov- confirm, CTgov- SU Responsible Confirm, CTgov – NCT#:** Send applicable comment code(s) if clinical trial requiring CTgov registration |
|  |[ ] [ ] [ ]  **Common Rule- Consent Posting Required:** For clinical trials conducted or supported by a federal agency and/or VA, Stanford prime awardee of the federal grant/support and responsible for posting consent form on a federal website. (Add Admin note “Consent Posting”.) |
|  |[ ] [ ] [ ]  General Checklist and section 8k are consistent regarding payment |
|  |[ ] [ ] [ ]  General Checklist and Funding section are consistent regarding funding |
| Funding[ ]  N/A  |[ ] [ ] [ ]  **SPO:** SPO number listed as pending |
|  |[ ] [ ] [ ]  If federally funded with Stanford as Prime and the only site, add admin note (See AID-39) |
| Protocol InfoSections 1-7[ ]  N/A  |[ ] [ ] [ ]  Section 2c: If deception will be used, rationale for use of deception has been provided and debriefing attached to section 16 |
|  |[ ] [ ] [ ]  Section 5 and 6: Study includes the use of an IDE Exempt Device and/or Drug which is being studied Manufacturer added to section 5 or 6 during review, email a pdf of protocol to OTL and update admin note  |
| Protocol InfoSections 8-10[ ]  Met  |[ ] [ ] [ ]  Section 8a: Number of participants to be enrolled consistent with consent form and all other documents |
|  |[ ] [ ] [ ]  Section 8g: **Recruitment 1, Cold Calling, Facebook/Public Forums:** Recruitment method acceptable |
|  |[ ] [ ] [ ]  Section 9c: Methods to ensure proper protections are in place maintain confidentiality (e.g. encryption, password protected, etc.) are consistent with section 11 |
|  |[ ] [ ] [ ]  Section 9e: The appropriate child risk determination has been made (OHRP vs. FDA) and justification provided**check that both OHRP and FDA findings are selected for FDA studies with HHS support** |
|  |[ ] [ ] [ ]  Section 9e: For research including pregnant women or fetus, the required conditions have been met |
|  |[ ] [ ] [ ]  Section 10a: **Benefits:** Possible benefit to the participant or the acquisition of important knowledge explained |
| Section 11[ ]  Met  |[ ] [ ] [ ]  **Privacy:** Physical setting of interactions described, not confidentiality of data |
|  |[ ] [ ] [ ]  **HIPAA-11(b):** PHI consistent with section 15 and HIPAA Authorization in the consent form |
|  |[ ] [ ] [ ]  **SSN Justification:** If SSN’s are collected, there is a clear rationale |
|  |[ ] [ ] [ ]  **Encryption:** All electronic devices are encrypted |
|  |[ ] [ ] [ ]  **De-identified, Anonymous v. Coded**: Terms de-identified, anonymous and coded are appropriately used |
| Section 12 [ ]  N/A |[ ] [ ] [ ]  **COI-OPACS**: OPACS completed for all listed Investigators |
|  |[ ] [ ] [ ]  **COI Disclosure:** If COI indicated, TAR has been received and attached to section 16 and appropriate COI language added to the consent |
| Section 13 [ ]  N/A |[ ] [ ] [ ]  **Phone Script, Phone Screen-sensitive questions:** Screening by phone or online |
|  |[x] [ ] [ ]  **Waiver of Doc-** **Minimal Risk, Waiver of Doc- Only Link:** Check funding and support for waiver or alteration or waiver of documentation and cite both findings if study is HHS supported and FDA regulated (Studies/procedures no more than minimal risk--only FDA option for waiver of documentation of consent) |
|  |[ ] [ ] [ ]  **Short Form- Translated ICF:** Short form process requested or fully translated consent will be submitted as a modification once consent is approved |
| Section 14 [ ]  N/A |[ ] [ ] [ ]  Section correctly completed with assent form, waiver of assent , and/or assent N/A *(***Assent- Tell Parents**, if applicable) |
|  |[ ] [ ] [ ]  **Re-consenting Minors:** For children who become adults during active participation, details regarding the plan to re-consent the child as an adult has been provided |
| Section 15 [ ]  N/A |[ ] [ ] [ ]  **HIPAA waiver of auth for recruit:** PHI will be obtained prior to obtaining HIPAA Authorization, minimum PHI necessary for recruitment listed in waiver |
|  |[ ] [ ] [ ]  **Alteration of HIPAA Authorization, Short Form- HIPAA:** requested if using short form or consent process requesting a Waiver of Documentation and obtaining PHI |
| Section 16 [ ]  N/A |[ ] [ ] [ ]  **Questionnaires:** Questionnaires attached to section 16 |
|  |[ ] [ ] [ ]  **Questionnaires – Suicide:** Plan to review responses to questionnaires asking about suicidal ideation provided  |
|  |[ ] [ ] [ ]  **Recruitment 2, Flyer Contact:** Recruitment materials provided and include IRB contact info |
|  |[ ] [ ] [ ]  All additional checklists (i.e. VA, **42-DOE, 42-DOE-PII, 42-DOJ, 42-DOJ-NIJ, DOJ-waiver, 42-DoD-42-ED, 42-NSF-disclosure**) have been completed |
| Notes | Click or tap here to enter text. |