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

| **Yes** | **No** | **N/A** | **Protocol Checklist** | | | | | |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  | **PD:** Protocol Director is eligible to serve as PD (See AID-25). | | | | | |
| Scientific Review  (select one) | | |  | Scientific and Scholarly Validity (SSV) completed by FDA, funder or other source **(See AID-107)** | | | | |
|  | **Academic Sponsor:** Academic Sponsor form completed if PD is student, resident, or fellow | | | | |
|  | **Chair Approval:** SSVcompleted by Dept. Chair, Division Chief, or their designee. See Sr. Manager is Chair/Chief has a conflict | | | | |
|  |  |  | **CITI:** All personnel have completed required CITI/GCP training | | | | | |
|  |  |  | **Non-Stanford:** Only Stanford/secure email addresses listed in Personnel Info section | | | | | |
|  |  |  | **Federal Funding/Collaborators- sIRB?** Study has federal funding and involves outside collaborators. | | | | | |
| Participant Population  Checklist  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 and **for children, check that both OHRP and FDA findings are selected for FDA studies with HHS support** |
|  |  | |  | | **Student Data Oversight Committee**: If Stanford students selected, confirm SDOC review completed or confirm with Sr. Manager SDOC review needed |
|  |  | |  | | If Prisoners selected, confirm seven findings are met as applicable to the study (See GUI-10) |
|  |  |  | Study Location: Stanford University selected unless VA only study  *\*If applicable,* International participants will be recruited from or traveling to the EU while their study data is being collected, send **GDPR** | | | | | |
|  |  |  | **External Stanford Hospital and Clinics Sites:** Sites referenced that are not part of Stanford Hospital and Clinics, send comment code and follow up with manager. | | | | | |
| Funding    N/A | | |  |  | |  | | If federally funded, Stanford prime awardee of grant, and only site, add admin note (See AID-39) |
|  |  | |  | | **SPO:** SPO number listed as pending. |
| General Checklist (GC)  Sites:  N/A | | |  |  | |  | | **Multi-site/Collaboration:** If study is listed as both multi-site study and collaboration. |
|  |  | |  | | If federally funded/supported and multi-site or collaborative study, gather additional information about research activities at other site(s) and notify sIRB Manager. |
|  |  | |  | | **IRB Approval:** If Stanford lead/coordinating site, collaborators listed, or Stanford is issuing funding to other sites (sub-awardees), ask for IRB approval letters, add approval note, and/or admin notes as applicable. (See AID-39) |
|  |  |  | **DUA , MTA OTL:** no funding listed AND data or tissues will be sent out of Stanford | | | | | |
|  |  |  | General Checklist and Funding are consistent regarding funding. | | | | | |
| GC, 4. Clinical Trials  N/A | | |  |  | |  | | **CTgov-General Checklist, CTgov- confirm, CTgov- SU Responsible Confirm, CTgov – NCT#:**  Send applicable comment code(s) if clinical trial requiring CTgov registration. |
|  |  | |  | | CTgov - Revise NCT#: For non-Cancer Stanford investigator-initiated studies, the NCT# in the General Checklist is consistent with the NCT# registered with ClinicalTrials.gov. (To check, search clinicaltrials.gov using the Study IDs filter.) |
|  |  | |  | | **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”.) |
|  |  |  | Section 4: Standard of care and research procedures using radiation listed. Add Radiation Safety reviewers. | | | | | |
|  |  |  | **Radiation SOC:** If all radiation scans in 4a are listed as standard of care. Ensure this comment is the first in order for radiation safety to be able to easily identify once assigned. | | | | | |
| Section 5  N/A | | |  |  | |  | | Study includes the use of a non-significant risk device and the justification for the NSR determination has been provided.  *\*MRI’s taking place at the Lucas Center and CNI may need to be listed as an NSR device.* |
|  |  | |  | | **Mobile Medical App:** Ifapp may be used for diagnosis, treatment or mitigation of disease. |
|  |  | |  | | **SIR/NSR:** If Stanford investigator is the sponsor of the NSR device |
|  |  | |  | | **DRA:** Study involves a product/application that sends, receives, or stores research information. May not be needed for industry-sponsored clinical trial |
|  |  | |  | | **Website Terms, EULA/ToS/PP:** If participants must agree to End User License Agreement/Terms of Service/Privacy P as a condition of the research. |
|  |  | |  | | Study includes a companion diagnostic device or combination device and listed correctly as IVD, IDE or NSR (See AID-117). |
| Drug/Device  N/A | | |  |  | |  | | Drug/device procedures described under Protocol Information, section 2. |
|  |  | |  | | **IND/IDE Documentation**: FDA or Sponsor documentation of IND/IDE number |
|  |  | |  | | Investigator’s Brochure(s) provided for investigational drug(s) or package insert for any commercial drugs being studied. |
|  |  | |  | | For IDE studies, admin note requesting FDA annual report at renewal added. |
|  |  | |  | | Stanford Investigator sponsor of IND/IDE, confirm with [cqi-support@stanford.edu](mailto:cqi-support@stanford.edu) that PD has completed SIR training(**SIR Multi-Site,** if multi-site study). |
|  |  | |  | | **IND Exempt**: use of commercial drugs is consistent with indications/labeling in package insert or all IND Exempt criteria are met. |
|  |  | |  | | **Pharmacy-security and controlled access plan**, **IND Exempt Pharmacy:** If the Investigational drug will not be controlled by a pharmacy, the PD has provided a Security and Controlled Access Plan. (**External Pharmacy,** if applicable). |
|  |  | |  | | **Dietary Supplement:** Use of dietary supplement or food listed correctly as IND, IND Exempt or does not need to be listed. |
|  |  | |  | | Manufacturer added to section 5 or 6 during review, email a pdf of protocol to OTL and update admin note |
|  |  | |  | | **Medical device studies:** Device brochure/manual and/or screenshots of device interface, if applicable. |
|  |  |  | section 8a: Number of participants to be enrolled consistent with consent form, clinical protocol, IND/IDE documentation, etc. | | | | | |
| section 8  N/A | | |  |  | |  | | **Recruitment 1, Recruitment 3:** Recruitment method acceptable. |
|  |  | |  | | **Recruitment 2, Flyer Contact:** Recruitment materials provided and include IRB contact info. |
|  |  | |  | | **Online Study Advertisements:** Recruitment materials posted on Facebook/public forums |
|  |  | |  | | Payment consistent in section 8k and General Checklist. (**Pay Justification, Drawing/Sweepstakes** as applicable) |
|  |  |  | section 9a, notify Sr. Management of high risk protocol and if an expert reviewer is required. | | | | | |
|  |  |  | section 9e, Data Safety Monitoring Plan included for all medium or high risk protocols. Add admin note regarding frequency of DSMB/DMC reports if specified. (Guidance: GUI-P20, AID-59, GUI P46) | | | | | |
| Children and Pregnant Women    N/A | | |  | |  | |  | Appropriate child risk determination indicated (FDA vs. OHRP) and justification provided. |
|  | |  | |  | **Component Analysis-Children:** separate children’s finding for each cohort or group of participants (ex. placebo study with no crossover, invasive screening, food challenge). |
|  |  |  | **Benefits:** Possible benefit to the participant or the acquisition of important knowledge explained | | | | | |
| eP section 11    Confirm | | |  |  | |  | | **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 |
| eP section 12  N/A | | |  |  | |  | | **COI-OPACS**: If investigators have NOT completed OPACS disclosure |
|  |  | |  | | **COI Disclosure:** If COI review not complete, appropriate COI language added to the consent form PRIOR to the meeting.Management plan - add protocol to Early Agenda. |
|  |  | |  | | **ICOI enroll:** If ICOI exists, IRB will be notified when first participant enrolled. Add protocol to Early Agenda. |
| Non-English  N/A\* | | |  |  | |  | | **\*Non-English Speaking:** If Non-English speaking are excluded, a justification is included in section 8d |
|  |  | |  | | **Short Form- Translated ICF:** Short form process requested or fully translated consent will be submitted as a modification once consent is approved |
|  |  | |  | | **Short Form - Full Translation:** entire consent will be translated for studies involving an IND/IDE |
|  |  | |  | | **Short Form – HIPAA:** Alteration of HIPAA requested |
| Section 13: Waiver of Doc  N/A | | |  |  | |  | | **Phone Script:** Screening by phone or online |
|  |  | |  | | **Phone Screen-sensitive questions**: Phone screen includes sensitive information (e.g. psychiatric diagnoses, symptoms of depression, illegal drug use) |
|  |  | |  | | **Waiver of Doc-** **Minimal Risk** (Studies/procedures no more than minimal risk--only FDA option): mark both OHRP and FDA findings for FDA studies with HHS support |
|  |  | |  | | **Waiver of Doc- Only Link:** Only link to participant would be their signature (cannot be used if FDA regulated, must use minimal risk option) |
| Section 14: Assent    N/A | | |  |  | |  | | Assent form provided or waiver of assent or N/A indicated *(***Assent- Tell Parents**, if applicable). |
|  |  | |  | | **Re-consenting Minors:** plan to re-consent children who become adults during active participation provided |
|  |  |  | **HIPAA waiver of auth for recruit:** PHI will be obtained prior to obtaining HIPAA Authorization. **HIPAA waiver for recruit PHI**: Minimum PHI necessary for recruitment listed in waiver and consistent with section 11b. | | | | | |
| eP section 16 N/A | | |  |  | |  | | **Questionnaires:** Questionnaires are not attached |
|  |  | |  | | **Questionnaires – Suicide:** Plan to review responses to questionnaires asking about suicidal ideation provided |
|  |  | |  | | eP section 16: 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 |
| International  N/A | | |  |  | |  | | **Samples – China**: Specimens and/or genetic information will be shared with a site 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 |
|  |  | |  | | Local IRB/Ethics approvals received. |
|  |  | |  | | **International Research:** Investigator to complete International Research Form |
| Other  N/A | | |  |  | |  | | **Marijuana:** Stanford Policy if applicable |
| Notes | | | Click or tap here to enter text. | | | | | |