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

| **Yes** | | **No** | | **N/A** | **Protocol/Consent Checklist** |
| --- | --- | --- | --- | --- | --- |
|  | |  | |  | Sent out SMART PD obligations, PD must respond back in agreement |
|  | |  | |  | Protocol has undergone Scientific and Scholarly Validity review by sponsor or other source |
|  | |  | Personnel Info: All required personnel have completed CITI training |
|  | |  | Personnel Info: Protocol Director appropriate for the study |
|  | |  | If Academic Sponsor is included, check if appropriate and that AS form is completed. |
|  | |  | Single IRB Information: Contact information is for Reviewing IRB, not lead study site |
|  | |  | |  | Study Location: Stanford University selected |
|  | |  | |  | General Checklist: Human Embryos or Stem Cells. *If SCRO protocol , check with Senior Manager* |
|  | |  | General Checklist: VA protocol. *If marked yes to Veterans Affairs (VA), ), tell study team to remove VA site and let them know they will need to reach out to the VA R&D Office for a separate reliance, outside of eProtocol* |
|  | |  | General Checklist: Cancer-Related Study. *if yes request SRC review date or approval* (unless chart review only) |
|  | |  | |  | General Checklist: If Stanford is responsible for registering the study on clinicaltrials.gov, ask for NCT # |
|  | |  | |  | General Checklist: If protocol is targeting Stanford students as participants (okay if they are not the targeted population or if participants are from the Psych/GSB Behavioral Lab pools) and the study is assessing their role as a student at Stanford, check with Senior Manager to determine whether SDOC/Title IX /Athletic Department review required. If athletes, have them confirm they will contact SAROC. <https://med.stanford.edu/saroc/For-Researchers/Information%20for%20Researchers.html>  *If the study is not targeting students for the reasons above, SDOC is not needed.* |
|  | |  | |  | General Checklist: If bringing in/sending out identifiable data or specimens AND if there is no contract with sponsor*, send* ***Agreements*** *comment* |
|  | |  | |  | General Checklist: APB Protocol. If marked yes to gene transfer, check with Senior Manager |
|  | |  | |  | General Checklist: Radioisotopes/radiation procedures. *If marked yes to Radioisotopes/radiation-producing machines, assign to radiation safety reviewers* |
|  | |  | |  | General Checklist and Funding section are consistent regarding funding. |
|  | |  | |  | If using Lucas Center and/or CNI, Jordan Hall Psychology MRI, the appropriate language has been included in consent and the coils are listed in section 3 as investigational. Add a comment that the Reviewing IRB will have to make NSR determination. |
|  | |  | |  | General Checklist: if high risk protocol, notify Senior Manager to confirm if appropriate to rely or if expert review is needed. (Check if “high” risk is notated, or if first in human, first in children, or human gene transfer). |
|  | |  | |  | Funding: If ‘Other’ is checked as Administrator of grant, rather than Stanford, ask for clarification. |
|  | |  | |  | Funding: All Stanford Grants/Contracts & Fellowships (with rare exceptions) should have a SPO#. If no SPO is available in SeRA, leave admin note. |
|  | |  | |  | Funding: If ‘none’ is selected, confirm with study team about DUA/MTA |
|  | |  | |  | Funding/Protocol: If Institutional Conflict of Interest (Check AID-127 - [Institutional COI list](https://stanfordmedicine.box.com/shared/static/est2w4rib9i9tkjqp5ccgnqatkrfze99.docx)), add “ICOI” Admin noteand send both ICOI comment codes. Make sure appropriate language is included in ICF and the reliance letter. Notify Sr. HRPP Manager once study is approved. |
|  | |  | |  | Funding: If Stanford is the prime awardee of a Federal grant, request sub-site(s) IRB approval letters. If not yet available, ask for confirmation that these will be provided before research activities begin at the site(s). |
|  | |  | |  | eP section 1a: includes description for Stanford research activities |
|  | |  | |  | eP section 1b: includes both health information and identifiers and is consistent with eP section 6 (if applicable) and the HIPAA Authorization section in the consent form. **HIPAA-11(b)** |
|  | |  | |  | eP section 1b: If study team is using STARR, click on the DPA link and ensure it is populated into section 1b |
|  | |  | |  | eP section 1c non-medical: If “yes” to ‘Will you be working with any Political Action Committees or other political organizations that are involved in partisan activities’, consult with non-medical senior manager for further instruction. |
|  | |  | |  | eP section 1d: If the study team is using RPS’s honest broker services, ensure the recruitment materials are uploaded in section 7 and the STARR DPA is completed and populated into section 1b. If the Reviewing IRB is privacy board, add a note in 1d so that RPS knows Reviewing IRB will issue waiver |
|  | |  | |  | eP section 2: Includes all standard of care and research procedures using ionizing radiation |
|  | |  | |  | eP section 3 and 4: if IDE or IND held by Stanford Investigator, add SIR admin note and confirm with Senior Compliance Analyst if PD has completed SIR training. Check for IND FDA letter in section 7. If applicable, ensure that IND # is listed in section 4a. |
|  |  | |  | | eP section 3 or described in non-medical app: If a device collects and shares PHI or high-risk data with 3rd parties, send PD comment code to contact DRA for approval (unless it’s clear the 3rd party has a contract with the study Sponsor or CRO to provide the service; i.e. electronic diaries in clinical trials) |
|  |  | |  | | eP section 4: If the Investigational drug will not be controlled by a pharmacy, have study team reach out to SADR Office for next steps. Ensure approval letter is attached prior to issuing reliance letter. |
|  |  | |  | | eP section 5: OPACS completed for all listed Investigators |
|  |  | |  | | eP section 5: If COI indicated, action report has been received and attached to section 7 and appropriate language added to consent form. |
|  |  | |  | | eP section 6: Confirm reviewing IRB will serve as Privacy Board **Comment: sIRB\_HIPAA waiver of auth for recruit**. If reviewing IRB will not serve as Privacy board, request Waiver of HIPAA Authorization for Recruitment in section 6 and send for privacy board review.  \*Check if self-reported health information is collected. This is considered PHI and will need waiver and/or alteration of authorization |
|  |  | |  | | eP section 7: Reliance document attached in section 7 (Unless NCI CIRB study) |
|  |  | |  | | eP section 7: Protocol Document attached in section 7 |
|  |  | |  | | eP section 7: (If applicable) Local Context Document to be completed by study team, cross check the answers and work with study team if updates are required. |
|  |  | |  | | **Consent Checklist** |
|  |  | |  | | eP section 7: Consent Form includes Stanford required HIPAA Authorization language, in 14 point font and with HIPAA expiration date (unless repository which allows ‘end of study’ as expiration). If embedded, ensure the authorization begins and ends on its own page within ICF |
|  | |  | | **HIPAA – 1(b):** Describes PHI “Obtained, Used or Disclosed” and is consistent with eProtocol Confidentiality section |
|  | |  | | Lists the sponsor, collaborators, FDA, etc., under “who may receive…?” |
|  | |  | | **HIPAA Date Suggestion:** HIPAA expiration date appropriate for study duration? |
|  |  | |  | | If consultative/financial relationship exists: COIC/IRB-approved disclosure language included |
|  |  | |  | | **Injury Language:** Correct option depending on funding for research that is more than minimal risk. If it’s a COVID study, ensure that extra paragraph is added |
|  |  | |  | | **Bill** of Rights: Required for all medical experimentation studies |
|  |  | |  | | **POC:** Includes signature and date lines for the Person Obtaining Consent (if Bill of Rights included) |
|  |  | |  | | NCI CIRB studies: Make sure an alteration of authorization and a waiver of authorization for recruitment is requested in section 6 and send for privacy board review |
|  |  | |  | | Short form consent process: If this is mentioned as a consenting option and/or a witness signature line is included in the ICF, remind the study team that they will need to present the CA Bill of Rights to the subject in their native language, along with whichever version of the short form consent is being used (okay to use Stanford’s version or the Reviewing IRB’s version) |
|  |  | |  | | Check that assent is attached if enrolling subjects over 7 (assent signature line is recommended if study is an FDA regulated drug study) |
|  |  | |  | | Pregnancy testing language: If minors will be pregnancy tested, ensure appropriate language is included in the ICF and the assent documents |
| Notes | | | | | Click or tap here to enter text. |