|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| ***Protocol reviewed:*** | | | | ***Review completed by:*** | ***Type of Review:*** |
| Protocol #:  PD: | | | | IRB Staff name:  Panel #:     Meeting Date: | Expedited Categories 1 - 7  Regular / Expedited 8a, 8b, 8c, 9 |
| **N/A** | **Yes** | **No** | **Check Admin Notes and incorporate into your review as necessary. Mark all Admin Notes DONE, when applicable. Comment Codes are in BLUE** | | |
| MPP or Training Grant |  |  | Check Funding & Obligations language | | |
|  |  | “(MPP)” or “(Training Grant)” grant is attached to Section 16 | | |
|  |  | Substudy list is attached *If no, send* ***MPP Cont. Review*** *comment* | | |
|  |  | All personnel have completed CITI, *if no,* *send* ***CITI*** *comment* | | |
|  |  | No Conflict of Interest (Individual)? *If yes****, NOTIFY MANAGER*** | | |
|  |  | No changes (e.g., personnel, new grant, etc.) *– else, note opposite:*  Click or tap here to enter text. | | |
| Expedited Review |  |  | **Expedited category 8a:** the research is permanently closed to the enrollment of new subjects; all subjects have completed all research-related interventions; and the research remains active only for long-term follow-up of subjects. *If so, send* ***8a/LTFU*** *(send when remaining long term follow up activities are unclear, as applicable)*  ***NOTE: If Stanford is lead site, need to confirm that all sites are in long term follow up*** | | |
|  |  |  | **Expedited category 8b:** no subjects have been enrolled and no additional risks have been identified. (keep convened date) *If so****,*** *send* ***CR 1.a none*** | | |
|  |  |  | **Expedited category 8c:** remaining research activities are limited to data analysis. *If so****,*** *send* ***Data Analysis Only*** *(not always applicable)* ***NOTE:*** ***If Stanford is lead site, confirm that all sites are in data analysis only*** | | |
|  |  |  | **Expedited category 9:** Research is not conducted under an IND or IDE, categories 2-8 do not apply, the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk to subjects (see Admin Notes), andno additional risks have been identified. | | |
|  |  |  | Federally funded chart reviews & nonmed protocols: **NOT ELIGIBLE**: extended continuing review period. ***ADD ADMIN NOTE*** | | |
|  |  |  | Number enrolled appropriate? If no, explain and add applicable comment below: Click or tap here to enter text.  ***CR 1.a slow number, CR 1a & b***, ***CR 1c***, ***CR cumulative***, ***CR Previous Year enrollment***, ***CR Participants > Target, CR Participants close to Target, Multi-site Enrollment*** | | |
|  |  |  | **STUDY PROBLEMS/COMPLICATIONS**  Have reasons been provided for all participant withdrawals? *If not****, send CR 2a*** *comment* | | |
|  |  |  | Has a narrative summary of adverse events been provided in 2c, or did the adverse events occur at the expected frequency and level of severity as anticipated? *If not, send* ***AE Clarification*** *comment* | | |
|  |  |  | Has a narrative summary of unanticipated problems involving risks to participants been provided in 2d? | | |
|  |  |  | Has the study team confirmed in 2d that all events and information that require prompt reporting have been reported? | | |
|  |  |  | Has noncompliance reported under 2g been explained? *If no,* ***SEND COMMENT***  When appropriate, is CAPA included? *If no, send* ***CAPA*** *comment* | | |
|  |  |  | STUDY STATUS  Open to Enrollment?  CTA with RRI. *If no interventions described,* *send* ***CR4*** *comment*  CTA with no RRI. If not permanently CTA, Regular must be Presented. | | |
|  |  |  | All Continuing Review questions answered completely? *If no****, SEND COMMENT(s)*** Click or tap here to enter text. | | |
| Mods |  |  | Are there modifications to the protocol? Click or tap here to enter text.  As applicable: are changes reflected in protocol, consent, assent, HIPAA, and documents attached in section 16?  Substantive changes? *If yes****, NOTIFY MANAGER***  Manufacturer added? *If yes,* ***NOTIFY MANAGER***  Adding multiple site/collaborators on federally supported study? I***f yes, gather additional information about research activities at other site and notify sIRB Manager.*** | | |
| CITI |  |  | CITI completed for all personnel? *If no, send* ***CITI*** *comment* *& if non-VA/Stanford/.edu emails listed, send* ***Non-Stanford email,***  confirm Resources Section is up to date; *if no, send* ***Personnel Update comment code****.* | | |
| Stanford lead |  |  | Is Stanford the lead site or issuing sub-awards? (***CHECK ADMIN NOTES & General Checklist***) – ask for IRB approval from sites at every renewal if current approval not already attached. *If Stanford lead site****,*** *send* ***Stanford Lead MultiSite*** *comment.* | | |
| Funding |  |  | SPO# in eP? If no, obtain through SERA or request *via* ***Funding: No SPO#*** comment | | |
|  |  | VA funding  *Send* ***Funding VA*** | | |
|  |  | If funding is no longer active, *send* ***Expired Funding*** comment to remove inactive funding. | | |
|  |  |  | Study is adding federal funding and involves outside collaborators, or is adding outside collaborators and is federally funded. If yes, send ‘Federal Funding/Collaborators- sIRB?’ comment. | | |
| Adding Funding |  |  | If **adding** funding, confirm General Checklist #11, Funding section, consent form(s) funding language, and HIPAA Authorization language (*send* ***HIPAA – New Sponsor*** *comment*) are correct and consistent w/ one another.  ***Note****: if study is in* ***data analysis*** *or* ***LTFU,*** *revising* ***consent is not necessary.***  ***\**** If adding Federally Funded with Stanford as prime and the only site, add admin note (See AID-39) | | |
|  |  | If **adding** new funding with federal agency requirements (i.e., DoD, ED, DOE, DJ, EPA), complete and attach the additional checklist. (see online guidance under “Staff Checklists”) | | |
| Remove Funding |  |  | If **removing** funding, confirm General Checklist #11, Funding section, consent form(s) funding language, and HIPAA Authorization language are correct and consistent w/ one another.  ***Note:*** *if study is in* ***data analysis*** *or* ***LTFU,*** *revising* ***consent is not necessary.*** | | |
|  |  | If **removing** NIH funding and study is still open to enrollment, send ***COC - Expired NIH Funding*** comment code. | | |
| SIR |  |  | **SPONSOR INVESTIGATOR RESEARCH (SIR)** – Is IND/IDE held by Stanford? (see section 5,6) if yes, is Annual Report to FDA attached? *If no,**send* ***SIR 2*** *comment* | | |
|  |  | SIR – Researcher must send copies of 3 ICFs to RCO. *Send* ***SIR 1*** *comment*  Note: These executed ICFs are NOT TO BE ATTACHED in eProtocol. | | |
|  |  | Non-Cancer SIR Only. SIR IND/IDE Annual Self-Assessment Checklist attached? *If no, send* ***SIR 3*** *comment.* | | |
|  |  |  | If IDE Study, was annual IDE progress report or final report provided? *If not attached, send* ***IDE Progress Report*** *comment* | | |
| Other |  |  | **IND/IDE (only):** if study involves an IND/IDE, and short form process is in section 13 **AND** **ONLY** if study team was previously told they will need to translate full consent form after use of the short form (review previous comments to determine if the PD was told of this requirement): *If so, send* ***CR – Short Form*** *comment****.*** | | |
|  |  | **DSMB report(s)** required by monitoring plan? ***CHECK CR 3c + ADMIN NOTES + 9e***  DSMB Report(s) attached? *If not attached, send* ***DSMB Report*** *comment*  ***NOTE:*** *Not necessary for studies in data analysis only or LTFU* | | |
|  |  |  | Is COVID-19 in-person visit language present in the ICF? If yes, and participants are still being consented/re-consented, send ‘COVID In Person Visits’ comment. | | |
| Children |  |  | Parent consent box on ICF or separate parental permission?  404/405 (50.51/50.52) – two signatures lines  406/407 (50.53/50.54) – two signature lines and checkboxes. | | |
|  |  | Is parent signature determination found in the signature block? (*refer to* ***AID-29 document****:**Parental Permission ICF*) | | |
|  |  | Assent: ensure assent includes an approval date. ***NOTE:*** *If assent has been revised, update approval date* | | |
|  |  | Consent and Assent: Does the study involve pregnancy testing for minors and is still enrolling? If so, send ***Pregnancy Test-Minors CR*** comment | | |
| COI |  |  | Existing Individual COI? ***NOTE****: If new or existing COI, always attach* ***TAR report*** *to protocol (found in section 16)* | | |
|  |  | New Individual COI? *If yes,* ***NOTIFY MANAGER*** *& ensure consent is updated, use* ***COI Disclosure*** *comment as guide* | | |
| Consent |  |  | Consent Forms **with correct # of signature lines** attached in eP (including translated consents)?  ***REMINDER:*** *Update consent dates prior to releasing, send* ***Print Name Lines*** *comment if incorrect # of signature lines* | | |
|  |  | Consent revisions: any new consent forms attached or consent form updates? *If* ***major*** *modifications,* ***NOTIFY MANAGER*** *If* ***minor*** *modifications (e.g. administrative), make sure it edits are* ***consistent*** | | |
|  |  |  | Are protocol changes (e.g. funding, procedures, target enrollment) reflected on EVERY consent version?  *If no,* ***SEND COMMENT****, If no tracked changes****,*** *use* ***Changing Consents*** *comment* | | |
|  |  |  | Short form consent process: is the appropriate regulation checked FDA 21 CFR 50.27(b)(2) or 45 CFR 46.117(b)(2)? | | |
| HIPAA |  |  | HIPAA– *if close to expiration, send* ***HIPAA Date Suggestion*** *comment. If passed expiration, send* ***Exipred HIPAA Auth*** *comment.*Dates changed?  Text changed? | | |
|  |  |  | **Obligations: is there language for approval letter?** ***Delete items not reviewed with this event*** | | |
|  |  |  | Have all unchecked Administrative Notes been addressed? *If no, should* ***additional******comment****(****s****) be sent?*  *\*\*If ‘SU sIRB’ is in study title, or SU sIRB admin note,* ***notify*** [***singleirb@stanford.edu***](mailto:singleirb@stanford.edu) | | |
| Notes | | | Click or tap here to enter text. | | |