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

| **If any apply to this study: Specimens** [ ]  **Data Registry** [ ]  **FDA regulated** [ ] **convert to Expedited and return protocol for additional issues** |
| --- |
| **Yes** | **No** | **N/A** | **Protocol Checklist***check for adequacy or appropriateness*  | **Comment Code**or **‘***write comment***’** |
|[ ] [ ]   | CITI training | CITI |
|[ ] [ ]   | Protocol Director (their title is appropriate to be a PD) | *write comment* |
|[ ] [ ] [ ]  **If PD is a student**: Is Academic Sponsor appropriate ***and*** APP-9 attached (*Review of Scientific and Scholarly Validity, and Oversight (by Academic Sponsor)*?  | Academic Sponsor – for student |
|[ ] [ ]   | Participant Population: At least one choice is marked | *write comment* |
|[ ] [ ] [ ]  Study Location: Stanford University should be selected (except for “VA only” studies) | *write comment* |
|[ ] [ ] [ ]  General Checklist: Collaborators: Need IRB approval letters from all collaborators | IRB APPROVAL |
|[ ] [ ] [ ]  General Checklist and Funding sections: Consistent | *write comment* |
|[ ] [ ]   | Eligible for Extended Approval? See AID-38 |  |
|[ ] [ ] [ ]  eProtocol 1c: Obtaining Stanford data from STRIDE | STRIDE |
|[ ] [ ] [ ]  eProtocol 2: Complete (age range in 2b) and consistent with Participant Population | Chart Review - age range |
|[ ] [ ] [ ]  eProtocol 2c: Rationale for excluding children | Chart Review - age range |
|[ ] [ ] [ ]  eProtocol 3c: Encryption | *write comment* |
|[ ] [ ]   | eProtocol 3e: Should be no HIPAA identifiers | Chart Review - no identifiers |
|[ ] [ ]   | eProtocol 5: Waiver of Consent (all boxes should be “True”) | *write comment* |
|[ ] [ ]   | eProtocol 5: Waiver of HIPAA Authorization, (all boxes should be “True” and information consistent with eProtocol 3a) | *write comment* |
|[ ] [ ] [ ]  eProtocol 5: Waiver of Assent if study involves children (all boxes should be “True”)  | *write comment* |
| Notes | Click or tap here to enter text. |  |