|  |  |  |
| --- | --- | --- |
| ***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. |  |