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| **Study Information** | | |
| eProtocol #:  PD: | Protocol Title: | |
| IND/IDE #: | IND/IDE Holder: | IND/IDE Anniversary Date: |

| **Required Documents in Regulatory Binder (and/or organized in electronic media)** | | **Yes** | **No** | **N/A** | **Comments** |
| --- | --- | --- | --- | --- | --- |
| **FDA Correspondence and Forms** | | | | | |
| **1** | Clinicaltrials.gov certification (including FDA Form [3674](https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048364.pdf), if available) |  |  |  | **First Continuing Review Only** |
| **2** | **IDE:** Current Investigational plan |  |  |  | **First Continuing Review Only** |
| **3** | Amendments to the IND/IDE submitted to the FDA |  |  |  |  |
| **4** | All FDA correspondence (i.e., IND Forms [1571](https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdfhttps:/www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083533.pdf)/1572) |  |  |  |  |
| **5** | **IDE:** Submission of Investigator List to the FDA every six (6) months |  |  |  |  |
| **6** | [Annual / Progress Reports](https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm362663.htm) |  |  |  | Date submitted or expected submission to FDA: |
| **Investigator Forms** | | | | | |
| **7** | Current delegation of authority log |  |  |  |  |
| **8** | Financial disclosure form for each investigator |  |  |  | If NO financial interests or conflicts, use FDA form [3454](http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM048304.pdf) |
| **9** | Biographic sketch or CV for each investigator |  |  |  |  |
| **10** | Current licenses for licensed investigators |  |  |  |  |
| **11** | Protocol/study specific training records for each staff member listed on the delegation of authority log |  |  |  |  |
| **Study Documentation** | | | | | |
| **12** | Records of participant case histories for all participants |  |  |  |  |
| **13** | Signed Informed Consent Forms for all participants in the subject’s binder or in a separate file. |  |  |  |  |
| **14** | Stanford protocol deviations and adverse event records (events that do not require prompt reporting to the IRB) |  |  |  |  |
| **15** | External (non-Stanford) Safety reports (events that do not require prompt reporting to the IRB) |  |  |  |  |
| **16** | Chronologic screening and/or enrollment log |  |  |  |  |
| **17** | Drug/biologic/device acquisition, dispensing, and disposition records |  |  |  |  |
| **18** | Laboratory certifications and normal values for tests included in the protocol |  |  |  |  |
| **19** | Study monitoring records |  |  |  |  |
| **20** | Plan for long term record retention |  |  |  |  |
| **21** | Other correspondence relevant to the study |  |  |  |  |
| **22** | Assurance that the most recent Investigator Brochures, Investigational Device Manuals, and Investigational plans (IND required) and/or protocols have been submitted to the IRB |  |  |  |  |