# Record Retention and Required Periodic Submissions for Sponsor/Investigator IND

| Submission | Timing |
|---|---|
| Amendment – New Protocol | After IRB approval |
| Amendment – Changed Protocol | At time of change |
| Amendment – New Investigator | Within 30 days of being added |
| Amendment – Information | At time of occurrence |
| IND safety report (disability, serious, life-threatening or unexpected) | Within 15 calendar days of receiving notification |
| IND safety report (death) | Within 7 calendar days of receiving notification |
| Annual report | Within 60 days of anniversary of IND |
| Withdrawal of IND | At time of withdrawal |
| Discontinuation of investigation | Within 5 working days of discontinuance |
| Financial disclosure report | At time of change |
| Final Report | Within 6 months of study completion |

New Protocol 21 CFR 312.30(a) – Whenever a sponsor intends to conduct a study that is not covered by a protocol already contained in the IND, the sponsor is required to submit to a protocol amendment. The new study may begin once the following conditions are met: (1) The sponsor has submitted the protocol to the FDA for review; and (2) the protocol has been approved by the IRB.

Changes in a protocol 21 CFR 312.30(b) - A sponsor is required to submit a protocol amendment describing any change in a Phase 1 protocol that significantly affects the safety of subjects or any change in a Phase 2 or 3 protocol that significantly affects the safety of subjects, the scope of the investigation, or the scientific quality of the study.

New Investigator 21 CFR 312.30(c) – A sponsor is required to submit a protocol amendment when a new investigator is added. Once added the Investigational drug or device can be shipped to the new Investigator. The sponsor is required to notify the FDA within 30 days of the investigator being added

Information Amendments 21 CFR 312.31(a) – A sponsor is required to report essential information on the IND that is not within the scope of a protocol amendment, IND safety report, or annual report. Examples of information requiring an information amendment include: (1) New toxicology, chemistry, or other technical information; or (2) A report regarding the discontinuance of a clinical investigation.

IND Safety Reports 21 CFR 312.32 – Any disability, life-threatening, serious, or unexpected adverse drug experience associated with the use of the investigational drug shall be submitted to the FDA in writing ASAP and in no event later than 15 calendar days after the sponsor initial receipt of the information. Any unexpected fatal or life-threatening experience associated with

the use of the drug must be reported to the FDA by telephone or fax as soon as possible but in no event later than 7 calendar days after the sponsor initial receipt of the information.

Annual Report 21 CFR 312.33 – A sponsor is required within 60 days of the anniversary date that the IND went to effect; submit a brief report of the progress of the investigation.

Withdrawal of an IND 21 CFR 312.38 – At any time a sponsor may withdraw an effective IND without prejudice.

Discontinuation of Investigation 21 CFR 312.56(d) – Sponsor is required to notify the FDA and discontinue the investigation as soon as possible, and in no event later than 5 working days after making the determination that the investigation should be discontinued.

IND Record Retention 21 CFR 312.57(c), 21 CFR 312.62(c) - Sponsor and investigator shall retain the IND records and reports for 2 years after a marketing application is approved for the drug; or, if an application is not approved for the drug, until 2 years after shipment and delivery of the drug for investigational use is discontinued and the FDA has been notified.

Financial Disclosure Reports 21 CFR 312.64(d) – Investigator is required to update the financial disclosure information if any relevant changes occur during the course of the investigation and for 1 year following the completion of the study.