**REGULATORY DOCUMENTS CHECKLIST**

**REQUIRED FOR *ALL* CLINICAL RESEARCH PROTOCOLS:**

* **PROTOCOL**

File a copy of the complete final protocol for this study. If required by the sponsor, ensure that the protocol title page has been signed and dated by the Principal Investigator (PI).

* **PROTOCOL AMENDMENTS**

Retain copies of any amendments to the original final protocol made by the sponsor or the investigator. Modifications may be in the form of new pages to be inserted in the protocol, an addendum to the protocol in the form of a letter, or contained in the body of an amended protocol. All three types of modifications should be filed.

* **CURRICULUM VITAES AND CREDENTIALS**

Include copies of the current CVs for all personnel listed on the Delegation of Authority Log. If all CVs are kept in a central location, a Note to File can be placed in the regulatory binder stating the location of these documents. A copy of all investigators’ license and Financial Disclosure forms will also be kept on file.

* **IRB CORRESPONDENCE**

File all correspondence between the investigator and the IRB regarding the protocol. Examples of documents to retain are: IRB submission application, IRB board roster, IRB approval letter(s), comments from the IRB on the consent form or the protocol, advertisements and any patient-facing material for the study approved by the IRB, renewals of approval, site updates to the IRB, Serious Adverse Event reports, notification to the IRB of IND safety reports, and a letter notifying the IRB of the completion of the study.

* **IRB-APPROVED INFORMED CONSENT FORM AND HIPAA AUTHORIZATION FORM**

The original approved IRB consent form(s)/HIPAA authorization form(s) should be filed, as well as any amended consent/HIPAA authorization forms.

* **DELEGATION OF AUTHORITY LOG**

File a list of all research team members delegated specific tasks by the Principal Investigator. Note: the sponsor may request that each delegated staff member complete a signature log if they entered, edited or deleted study data in the source documents or Case Report Forms.

* **SAE REPORTS and SAFETY REPORTS**

All Serious Adverse Events (SAEs) must be reported promptly to the sponsor and, if applicable, to the IRB. Copies of SAE reports should be retained in site regulatory files, unless filed in subject research records. Copies of all IND, IDE safety reports or SUSARs should also be filed.

* **SCREENING AND ENROLLMENT LOG**

Retain a list of all subjects who signed the Informed Consent Form and were screened for entry into the study. A list of the subjects who were enrolled, as well as those who did not meet the entry criteria,

must be retained. Note: this may be kept with the subject research files for the research study or with the regulatory file.

* **FINAL STUDY REPORT**

A copy of the final clinical study report provided by the sponsor should be retained in site files.

**THE FOLLOWING DOCUMENTS SHOULD BE RETAINED, *IF APPLICABLE* TO THE CLINICAL RESEARCH PROTOCOL:**

* **INVESTIGATOR'S BROCHURE and OTHER STUDY MANUALS**

File the most recent version of the Investigator's Brochure and any other study specific manuals, such as Pharmacy Manual, Device Manual, or Imaging Manual, along with all previous versions.

* **CASE REPORT FORMS**

Retain a complete blank set of all Case Report Forms used for data collection in the study.

* **FORM FDA 1572 or INVESTIGATOR’S AGREEMENT**

A copy of the signed original FDA Form 1572 Statement of Investigator or Investigator’s Agreement should be filed in this section. The form should list the name of the Principal Investigator and include any Sub-Investigators, if applicable. Any changes to the FDA Form 1572 should be submitted to the sponsor and to the IRB.

* **MONITORING LOG**

At each visit from the sponsor, the log sheet should be signed and dated by all sponsor personnel and the purpose of the visit noted.

* **SPONSOR CORRESPONDENCE**

File all correspondence between the investigator and sponsor, except for items dealing with financial matters (which are filed separately).

* **INVESTIGATIONAL PRODUCT ACCOUNTABILITY**

Items to be included in this section are the sponsor investigational product shipping inventory, investigational product accountability and management log, and return shipment documentation.

* **LABORATORY CERTIFICATION**

A copy of the most recent certificates issued showing the expiration date. If all laboratory information is kept in a central location, a Note to File can be placed in the regulatory binder stating the location of these documents.

* **RANGE OF NORMAL VALUES**

A copy of the range of normal laboratory values used for the study will be filed. If the units or ranges differ from those previously supplied to the sponsor, these must be submitted to the sponsor and a copy filed in this section. Retain the previous listing and ensure that the revised listing incorporates the effective date of change. If all laboratory information is kept in a central location, a Note to File can be placed in the regulatory binder stating the location of these documents.