REGULATORY FILES CHECKLIST

STATEMENT OF INVESTIGATOR AND CURRICULUM VITAE

This section should contain the following:

- Copy of Signed Form FDA 1572 for the Investigator
- Copy of Signed Revised Form FDA 1572 (if applicable)
- Current Curriculum Vitae for the Investigator and for each Sub-Investigator
- Copy of Medical License for the Investigator and for each Sub-Investigator

INVESTIGATIONAL NEW DRUG FILING/INVESTIGATION DEVICE EXEMPTION *(If Investigator-Initiated IND/IDE Trial)*

This section should contain the following:

- Investigational New Drug (IND) Application/Investigational Device Exemption (IDE)

FOOD AND DRUG ADMINISTRATION CORRESPONDENCE

(If Investigator-Initiated IND/IDE Trial)

This section should contain the following:

- All Correspondence between the Food and Drug Administration (FDA), the Sponsor, and/or the Site

FOOD AND DRUG ADMINISTRATION ANNUAL REPORTS

(If Investigator-Initiated IND/IDE Trial)

This section should contain the following:

- All FDA Annual Reports and Related Correspondence

INVESTIGATOR'S BROCHURE/DEVICE MANUAL

This section should contain the following:

- Investigator's Brochure or Package Insert
- Revised Investigator's Brochure(s) or Package Insert (If Applicable)

PROTOCOL and AMENDMENTS

This section should contain the following:

- Copy of Final Protocol and Signed Protocol Signature Page
- Copy of all Protocol Amendments and Signed Protocol Amendment Signature Pages (If Applicable)

APPROVED INFORMED CONSENT DOCUMENT AND INFORMATION GIVEN TO SUBJECTS

This section should contain the following:

- Blank Copy of Institutional Review Board (IRB)-Approved Informed Consent Document (ICF), any other Written Information given to Subjects (If Applicable), and Advertisement for Subject Recruitment (If Applicable)
- Blank Copy of IRB-Approved Revised ICF, any other Written Information given to Subjects, and Advertisement for Subject Recruitment (If Applicable)
- Blank Copy of IRB-Approved Authorization for Use and Disclosure of Protected Health Information (If Separate from ICF)

SCIENTIFIC RESEARCH REVIEW COMMITTEE

This section should contain the following:

- Scientific Research Review Committee approvals and correspondence

INSTITUTIONAL REVIEW BOARD COMMITTEE DOCUMENTATION

This section should contain the following:

- Institutional Review Board Membership List covering the Entire Interval of the Study (or Regulatory Agency Registry Number)
- IRB Correspondence, Including the Following:
    - IRB Approval of Protocol, Informed Consent Document (ICF), Any other Written Information given to Subjects (If Applicable), and Advertisement for Subject Recruitment (If Applicable)
    - IRB Approval of Amendments to Protocol, ICF, Any other Written Information given to Subjects, and Advertisements for Subject Recruitment (If Applicable)
    - IRB Approval of Authorization for Use and Disclosure of Protected Health Information (If Separate from the ICF)
    - Investigator Annual Report to IRB
    - IRB Approval of Protocol for Study Continuation
    - Notification to IRB of Serious Adverse Events, as Documented in Tab 11, Safety Information (If Applicable)
    - Notification to IRB of Unanticipated Problems Involving Risks to Subjects and Others (If Applicable)
    - Notification to IRB of Study Completion and Site Final Study Report

SAFETY INFORMATION

This section should contain the following:

- Copy of Serious Adverse Event (SAE) Reports (If Applicable) and any Safety Information
- All Correspondence Between the Sponsor/CRO and the Sites that Concerns SAE Reports and any Safety Information (If Applicable)
- All Correspondence with Regulatory Agencies Regarding Safety Information (If Applicable)

SAFETY AND DATA MONITORING COMMITTEE

This section should contain the following:

- Safety and Data Monitoring Committee (SDMC) Reports and Correspondence

CLINICAL TRIAL MATERIAL DOCUMENTATION

This section should contain the following:

- Records of Receipt of Clinical Trial Material (CTM) and Trial-Related Materials (If Applicable)
- CTM Dispensing/Accountability Records (If Dispensing/Accountability Records are Filed in the Pharmacy, Photocopies of these Records should be made at Study Completion and Inserted in the Regulatory Binder. Please State the Location of Original Records.)
- Documentation of CTM destruction if performed at the site

BIOLOGICAL SAMPLES DOCUMENTATION

This section should contain the following:

- Copies of Biological Sample Transmittal Forms that Accompanied the Shipment to the External Laboratory (If Applicable). (If not kept within the Regulatory Binder, Please State the Location.)
- Correspondence Regarding Biological Samples
- Record of Retained Body Fluids/Tissue Samples (If Applicable)

LABORATORY DOCUMENTATION

This section should contain the following:

- Laboratory Certification (Including Updates Throughout the Study Duration)
- Laboratory Normal Reference Range (Including Updates Throughout the Study Duration)
- Central Laboratory Information (If Applicable)

STUDY PROCEDURE MANUAL

This section should contain the following:

- Study Procedures Manual and Nay Revisions (If Applicable). (If not kept within the Regulatory Binder, Please State the Location). If No Study Procedure Manual was used for the Study, Please Note This.

SOURCE DOCUMENTATION

This section should contain the following:

- Source Document Template and any Revisions
- Completed Source Documents for each Subject. (If not kept in the Regulatory Binder, Please State the Location)

BLANK CASE REPORT FORM

This section should contain the following:

- Blank Case Report Form including any Amended Page(s) (If Applicable). Please Note If Electronic Data Capture is used for this Study.

SUBJECT ACCOUNTABILITY RECORDS

This section should contain the following:

- Subject Screening and Enrollment Logs (List of Subjects Screened for Entry as well as Enrolled in the Study)
- Medical Exception Forms
- Subject Identification Code List (List of Subjects Enrolled in the Study and Identified by a Unique Number) NOTE: This is a Confidential List and should be Maintained only at the Site.
- Signed Institutional Review Board-Approved Informed Consent Document and Authorization for Use and Disclosure of Protected Health Information for each Subject Screened for Entry into the Study. (If not kept in the Regulatory Binder, Please State the Location)
- Copy of Completed Case Report Forms (CRFs) for each Subject with any Related Data Clarification Requests (If Applicable). (If not kept in the Regulatory Binder, Please State the Location)

- Copy of Completed CRF Transmittal Forms (If Applicable). If not kept within the Regulatory Binder, Please State the Location.
- Copy of Completed CRF Edit Logs (If Applicable). If not kept within the Regulatory Binder, Please State the Location.

STUDY STAFF INFORMATION

This section should contain the following:

- Study Staff Responsibilities and Signature Form
- Study-Specific Training Records (If Applicable)

MONITORING ACTIVITIES

This section should contain the following:

- Monitoring Log
- Monitor Correspondence (Site Visit Confirmation and Follow-Up Correspondence)
- Site Initiation Visit Report

INVESTIGATOR AND INSTITUTION AGREEMENT(S), FINANCIAL INFORMATION, AND INSURANCE INFORMATION

This section should contain the following:

- Financial Disclosure/Certification for all investigators (if applicable). If not kept with the Regulatory Binder, Please State the Location.
- Clinical Study Agreement (CSA) (If Applicable)
- Insurance or Indemnification Statement (If Separate from CSA) (If Applicable)
- Data Use Agreement (If Separate from CSA)

GENERAL CORRESPONDENCE

This section should contain the following:

- All Correspondence Between the Sponsor/CRO and the Site Concerning the Study (Except Correspondence Concerning Serious Adverse Events and Safety Information that should be Filed Behind Tab 11, Safety Information; and Monitor Correspondence that should be Filed behind Tab 21, Monitoring Activities)
- Site-Generated Telephone Contact Reports or Logs

CLINICAL STUDY REPORT

This section should contain the following:

- Clinical Study Report (If Applicable)

NOTES TO FILE AND OTHER INFORMATION

This section should contain the following information:

- Notes to File (If Applicable)
- Other Information Felt Necessary to Retain but not Filed Elsewhere in the Regulatory Binder