1. Research Ethics Board – REB Documents

**Approval Letters and Renewals**

* Initial REB approval letter (original) for protocol, for consent form(s) any related documents that require REB review
* Any amendments identified by protocol number and/or title and date of approval
* Patient recruitment advertisement approvals and corresponding REB letter(s)
* Annual REB membership list
* REB attestation (if applicable)
* Progress reports and annual REB renewals

**Ongoing REB Communication**

* REB correspondence—letters of submission (includes any institution application)
* REB notification of and responses to serious adverse events at your institution (file in Safety Section in binder)
* Documentation of submission of safety reports to REB and REB responses (file in Safety Section in binder)
* Close out/final report notice

1. Informed Consent

**Includes all but not limited to the following documents:**

* All consent versions, past and current
* All variations: Healthy Controls, Participants
* All signed originals consent by the participants (or can store in a separate binder in a secured location for privacy reasons)
* Consent version tracking log re: consents sent/approved by REB
* Consent version tracking log re: consents signed by participants

1. Recruitment and Other Participant Materials

* All past and current versions of **Study Recruitment Materials** used (e.g. Posters, Brochures, Handouts/Flyers, Mass Media (Newspaper, TV, Radio, Online/Social Media advertisements), Recruitment letters (patient and physician), etc.)
* All past and current version of **Study Participant Tools** used (e.g. patient diaries, questionnaires, etc.)

1. Protocol

* Current approved Protocol and/or amendments
* Signature page(s) for the protocol and any amendments
* Included tracking of changes or summary of changes
* Previously approved protocol and/or amendments may be kept in separate binder (insert a note in this section indicating location of documents)
* Protocol Deviation Log

1. Product Information
   * The most updated, currently approved Investigator Brochure/Product Monograph/Device Manual version
   * All previous versions of the investigational product documentation
2. Safety Reports

* This will include reports and notifications received from sponsor/other sites (IND, CIOMS, MedWatch) if more than one site and also SAE reports
  + Including those sent to Health Canada that are applicable
  + Internal and external reports to REB
  + Safety reports sent to sponsor
  + Any logs tracking these reports
* Master serious adverse event (SAE) reporting form and instructions for completion
* DSMB reports and correspondence
* DSMB Charter if separate from protocol
* List of DSMB members and affiliations
* Other related correspondence
* Pregnancy reporting forms (if applicable)

\* These may be filed in separate Safety Binder for this study (insert a note in this section indicating location of documents)

1. Case Report Forms

* Current and complete set of blank case report forms (CRFs)
* All previous versions of CRFs
* Source document list

1. Screening/Recruitment and Enrollment Logs

**Screening/Recruitment Log** - list all participants screened, regardless of their enrollment status

* Potential participants
* Should include why they did not participate (helps for future recruitment strategies)

**Enrollment Log**

* Participants who have been consented and enrolled
* Log often faxed to sponsor (no subject identifiers are included) to track recruitment and meeting enrollment requirements

**Research Participant Identification Log**

* This is for the site only, monitors will check that you have this but will not copy this (PHI)
* Used at study close out to be able to track participants in case it is necessary to contact them

1. Standard Operating Procedures (SOPs)

* Current version of SOPs
* All previous versions of SOPs

1. Notes-To-File

* A note or memo that documents and explains any discrepancies, clarifies any questionable data, or study procedures.
* A note or memo that documents where certain documents are stored in places other than the regulatory binder(s) (e.g. a note to file that the signed CRFs are kept in the participants’ files, etc.)

1. Study/Participant Documents

* Blank copies of surveys, diaries, and questionnaires
* Participant Inclusion/Exclusion checklists
* Study visit checklist

1. Signature Logs

**Delegation of Responsibility Log/Form**

* Outlines the specific study related procedures that each member of the site staff is allowed to perform
* In addition to their name and signature, there should be a place for the PI to initial that he/she agrees to assign this person these responsibilities.
* Start and end dates for those responsibilities

1. Study Team Information

**Includes but not limited to the following documents:**

* Curricula vitae for all principal and sub-investigators and site staff
* Copy of Medical license/ regulated health profession license of research team members, for all principal and sub-investigators and appropriate site staff (if applicable) at start of study and annual updates

**Training Records**

* Training certificates for all principal and sub-investigators and site staff (e.g. GCP, TCPS2, Site SOPs, etc.)

1. Site Initiation Visit

* Agenda
* Attendance log
* Minutes
* Protocol and study procedure(s) related training, certificates/logs

1. Study Agreements

* Signed Clinical Study Agreement [CSA] (If Clinical Study Agreement is filed elsewhere, insert a note to file in this section indicating where the contract is located)
* Signed Confidentiality Disclosure Agreement (If CDA is filed elsewhere, insert a note in this section indicating location of documents); this may also be part of CSA.

1. Sponsor Correspondence

**All correspondence with sponsor including**:

* Enrollment confirmation faxes
* Randomization, screening and enrollment reports
* Emails, faxes, memoranda, and letters
* Telephone logs and written documentation of discussion
* Meeting notes/minutes
* Newsletters
* Courier waybills, fax confirmations, etc.

**Study Reports**

* Copy of all study reports including final report provided by the sponsor

1. Health Canada

**Clinical Trial Application (CTA) and Amendments (CTA-A)**

* Clinical Trials Application and all correspondence to and from Health Canada (or if filed separately, indicate this in a note to file)
* Qualified Investigator Undertaking (QIU)
* Clinical Trial Site Information Form
* Other applicable forms

**Approval**

* Copy of No Objection Letter (NOL)

**Notifications**

* Clinical Trial Notification and all correspondence to and from Health Canada (or if filed separately, indicate this in a note to file)

**Correspondence**

* Include Clarifaxes, emails, and letters

**Inspections**

* Notification
* Report
* Findings
* Corrective action plan

1. US Regulatory Oversight

* FDA form 1572 (or waiver to participate as a foreign clinical trial site)
* Financial disclosure forms for all investigators

1. Monitoring

**Reports**

* Monitoring report copies
* Audit reports
* Other

**Site Visit Log**

* signatures of monitors, auditors, all other personnel performing a site visit include the date(s) and purpose of the site visit

1. Investigational Product Storage and Accountability – includes drug, device, and Natural Health Product

* IP accountability logs
* IP order forms
* IP shipment records
* Disposition and/or return of unused or damaged study kit records
* Information on drug storage conditions (e.g., temperature logs)
* Drug return to the sponsor for destruction form (if applicable)

\* May be kept in pharmacy if drug ((insert a note in this section indicating location of documents)

1. Laboratory

* A copy of the most recent certificate issued showing the expiration date for labs used in research study
* Lab normal ranges for all tests performed in study
* CV of Director of Lab
* Sample requisition

\* These may be centrally filed (insert a note in this section indicating location of documents)

1. Diagnostic Imaging

* Provider agreement(s)
* Radiation safety approval
* Sample requisition

1. Equipment and Supplies

* Calibration logs
* Temperature logs
* Receipts
* Other

1. Institutional Approvals

* AHS and other operational agreements
* Research agreement(s)
* Administrative approval
* Other