Monitoring Plan

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Locations

{Specify Hospital location in which study will be conducted at}

Massachusetts General Hospital
55 Fruit Street
Boston, MA
02114-2622

Brigham and Women's Hospital
75 Francis Street
Boston, MA 02115

Section 1 Trial Management

Purpose

{Explain Purpose of Monitoring Plan, for example:}

The purpose of this Monitoring Plan is to describe the rationale and process for the collection, recording, and verification of data for the {Trial Name}

Objectives

{Specify objectives, for example:}

- To establish a monitoring plan to ensure the data is in compliance with Good Clinical Practice (GCP), Partners Institutional Review Board (IRB) policies, and Federal regulations.
- To standardize the clinical data monitoring
- To ensure the validity, accuracy and integrity of the data

Study Staff Responsibilities and Training

{Record any protocol specific training or delegated responsibilities requiring special licensure}

CITI Training

The investigators and all staff involved in the study will have completed their required Collaborative IRB Training Initiative (CITI).

Protocol Procedure Training

Study staff delegated to conduct specific study procedures will be trained on these procedures individually or in a group format. Delegation of responsibility will be documented on the Study Staff Signature and Delegation of Responsibility Log.

Section 2 CRFs and Source Data

Source Documentation and Case Report Forms

{Indicate who is responsible for data collection and how often he/she will review the data for accuracy and completion}

IRB Documentation

{Indicate who is responsible for maintaining IRB Correspondence. Specify which IRB approved documents will be maintained as part of the study}

Section 3 Quality Assurance & Quality Control

Study Files

{Indicate who is responsible for monitoring the study files. Specify how often this individual will monitor the files in order to ensure the appropriate regulatory and IRB documentations are on file and up to date.}

{Specify what aspect of the study files will be monitored. For example:}

Partners Human Research Committee (IRB):

- All IRB Correspondence is on file
- The study staff are IRB approved prior to performing any study procedures
- Adverse events and deviations are reported to IRB per current guidelines
- All versions of the IRB protocols and informed consent forms are on file

FDA

- Signed 1571 and 1572 on file (note: Sponsors of device studies must obtain a signed agreement containing information similar to that requested on the 1572)
- All FDA correspondence (amendments, safety reports, annual review, associated 1571 and 1572) is on file
- Documentation of serious adverse events that are unexpected and related are reported to FDA within 7 calendar days
- Annual Report is on file and completed in a timely fashion

Other documents:

- CVs for all study staff are on file and updated every 2 years
- Medical licenses for the Co-Investigators are on file and updated prior to expiration
- Delegation Log is updated as new staff are added or removed from the study or new procedures are added
- Financial disclosures for PIs and those listed on the 1572 are on file
- All other essential documents have been prepared and completed as appropriate

Study Documentation

{Indicate who will be responsible for ensuring proper study documentation in order to verify compliance with IRB, FDA and Good Clinical Practice (GCP) guidelines in the following areas:

Informed Consent - In situations for which written consent is obtained:

- Ensure that subject identification is on all pages of the ICF
- There is documentation that the subject is given a copy of the consent form
- Clinic note documenting informed consent process
- The subject and study representative signed and dated the consent form for him/herself.
- The subject initialed and dated all appropriate pages on the informed consent form.
- Note to file made for any informed consent deviations.
- Ensure a valid (current version date) copy of the consent form was used

Protocol:

- Confirm that the study staff is conducting the study in compliance with the protocol approved by IRB and if applicable, FDA.
- The protocol deviations (exceptions and violations) are documented in the subject chart and reported to IRB as required.

Source Documents:

- Review subject charts to ensure that accuracy, completeness and legibility of the data
- Any correction made to the source documents is dated, initialed, and explained. The original entry should not be obscured.
- The protocol specific source documents are on file.
- Source documents are completed in ink
- Note to files are made for missing or incomplete data and to explain any discrepancies or additional comments.

Electronic Case Report Forms (eCRF) – if applicable:

- Ensure the data reported on the eCRF is consistent with the source documents.
- Discrepancies between the source documents and eCRF are explained in a note to file or captured in a comment in the eCRF.

Query Management (If Applicable)

{Specify, if there is an outside monitoring group (e.g. sponsor's monitor, CRO) who is responsible for ensuring data accuracy and integrity. Indicate how data queries will be generated, processed, and responded to by the site.} Specify what may be queried, for example:

- Non-compliance to protocol
- Missing data
- Out-of-range data
- Out-of-window visits
- Data inconsistent with the source documents
- Data clarification

Section 4 Safety Monitoring

Adverse Event Procedures

{Indicate the process for identifying, recording and reporting adverse events (per sponsor, IRB, and FDA reporting guidelines.}

Specific Roles for Adverse Event Recording and Monitoring

{Indicate each staff members role in the adverse event reporting process}

The **research coordinator** will complete the AE Tracking Log; assist the PI to notify the IRB, FDA, DSMB of all SAEs, and assist them to prepare SAE reports to IRB, FDA, and/or DSMB.

The **Project Manager** and **Principal Investigator** will confirm that all AEs are correctly entered into the AE log by the coordinator; be available to answer any questions that the coordinators may have concerning AEs; notify the IRB, FDA and/or DSMB of all SAEs and AEs as appropriate;

The M**onitor** will confirm that the AEs are correctly entered into the Adverse Event log. The Monitor will confirm that the adverse events are consistent with the source documents and are reported to the appropriate regulatory bodies, as required.

Section 5 Monitoring Activities

{Summarize monitoring activities: Who will conduct the monitoring, what will be monitored, frequency of monitoring, and how will findings/observations be documented}.

{Consider adding a flow chart to further illustrate the process}

Section 6 Study Completion

{Specify how study close-out process will occur (e.g maintenance of study files and data retention}