Monitoring Plan

CIT-07
Islet Transplantation in Type I Diabetes

NIAID & NIDDK /NIH

Monitoring Plan Template Approval:

This Monitoring Plan Template has been read and approved by:

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CIT-07 Protocol Monitoring Plan

CLINICAL ISLET TRANPLANTATION PROTOCOL CIT-07

Islet Transplantation in Type 1 Diabetes

The DCC will conduct Good Clinical Practice (GCP) monitoring at all active sites according to the following plan:

- **Intent # 1 - To ensure that all subjects are being consented appropriately**
  - The DCC will review 100% of the informed consents (enrollment and post-randomization) to ensure that subjects are consented in accordance to GCP standards and prior to study related procedures being performed.
  - The DCC will confirm that the informed consent documents used are approved by the local IRB/ethics committee.
- **Intent # 2 - To ensure that all subjects meet protocol inclusion and exclusion criteria**
  - The DCC will monitor the inclusion and exclusion criteria for 100% of the randomized subjects.
  - Each inclusion and exclusion criterion must be addressed in the supporting source documents
  - The DCC will determine if protocol specific procedures are being performed within allowed time frames, and that documentation is complete, accurate, and verifiable.
- **Intent # 3 - To ensure that the subjects are followed and retained per the protocol's requirements**
  - At each site, the DCC will monitor all subjects randomized and transplanted to the phase 3 study to completion of all study visits.
  - The DCC will also monitor all randomized subjects for 100% of all source documents including review of medical records for reported and unreported SAE's and data listings of all available data (all eCRFs) at that monitoring visit that has not been previously monitored.
  - The DCC will monitor all pharmacy records for 100% of subjects and islet transplantation records (excluding the Manufacturing Production Batch Record) for 100% of subjects.

- **Timing of CIT monitoring visits**
  - In the event that new sites are added to participate in CIT-07, the NIH and the DCC will conduct site initiation visits prior to the sites being activated and beginning enrollment into the trial.
    - The DCC will communicate with the NIH, study coordinators, and principal investigators to schedule the site initiation visits.
  - Interim monitoring visits will be conducted every six months or after 4 additional subjects have been randomized to either the Phase 2 or Phase 3 protocol at the site.
    - The DCC will communicate directly with the study coordinators and the principal investigators to schedule the interim monitoring visits.

Note: The DCC may schedule additional or fewer visits or specific monitoring assignments as needed over the course of the study based on site enrollment, site issues, etc. The DCC may recommend that additional or fewer visits be conducted as well. The Monitoring Plan may be modified at the request of the NIH/DCC to meet the needs of the study.