CIT-03

STUDY-SPECIFIC MANUAL OF PROCEDURES

VERSION 7.0

MARCH 14, 2013

CONFIDENTIAL

CIT-03 Protocol Communication Plan

See last page for Islet Manufacturing Communication Plan

Who do I contact?

Site investigators should contact the NIH MM, Nancy Bridges, directly for:

- **urgent safety or eligibility issues not addressed by the protocol or questions requiring medical judgment**
- **publication questions** (publication notification forms, publication policy questions, etc.)

Site investigators or coordinators should contact the NIH PM, Allison Priore, directly for:

- review and approve any revision to your Informed Consents prior to IRB submission.
- NIH budget questions

Otherwise, the site investigator or coordinator should contact the DCC Protocol Coordinator for all CIT-03 protocol questions and concerns, including:

- Subject Recruitment: Screening process, enrollment, protocol eligibility, transplant wait list, blood sugar records, diabetologist certifications, central lab results, etc.
- Protocol Implementation: Study visits, prophylactic meds, prohibited meds, graft failures, study assessments, SAE reporting, deviations, logistics, source documentation, participant concerns, etc.
- Protocol Content: Statistics, endpoint analysis, rationale, background, etc.
- Data Management: Website access, electronic case report forms, queries, etc.
- Study drug: Shipments, storage, drug shipment requests, ancillary supplies, etc.
- Specimen Coordination: Kits, supplies, sampleminded, specimen shipping and processing, timing of specimen collection, core labs, etc.
- Study Supplies: Glucometers, test strips, CGMS, etc.
- Study Documents: Brochures, protocol booklets, MOP, lab manual, participant ID cards, etc.
- Regulatory Documentation: IRB approvals, delegation log, expiring documents, documentation requirements, conflict of interest, financial disclosure, etc.
    - **All Health Authority communications must go through NIH.**

Contact information for your CIT-03 DCC Protocol Coordinator:

Holly Riss
Phone: 319-353-4267
Fax: 319-353-3960
Cell/pager: 319-321-7185
Email: holly-riss@uiowa.edu

When to contact the NIH Project Manager directly:

- The NIH PM must review and approve any revision to your Informed Consents prior to IRB submission.
- NIH Budget questions should be sent to your NIH Project Manager.

Contact Info: **Email is the best way to communicate with the MMs*		
Thomas Eggerman MD, PhD*	(301) 594-8813	eggermant@extra.niddk.nih.gov
Nancy Bridges, MD*	(301) 451-4406	nbridges@niaid.nih.gov
Neal V. Green	(301) 594-8815	greenne@niddk.nih.gov
Allison Priore	(301) 560-4513	priorea@niaid.nih.gov

Islet Laboratory Personnel:

Questions about islet potency and the islet manufacturing process should be addressed to the NIH Senior Regulatory Officer.

- Questions about completing Certificates of Analysis, Batch record completion, etc.
  - Submission and QA of manufacturing documents (COA, BR, etc.) are addressed separately in the manufacturing SOP.
- Clarifications to manufacturing process
- Questions about enzymes
- Manufacturing deviations

Contact information for the NIH Senior Regulatory Officer:

Julia Goldstein
Office: 301-451-3112
Fax: 301-402-2571
Email: jgoldstein@niaid.nih.gov

To place an enzyme order:

- Contact the Serva representative and copy Dixie Ecklund and Julia Goldstein.