CIT-07

STUDY-SPECIFIC MANUAL OF PROCEDURES

VERSION 8.0

SEPTEMBER 26, 2013

CONFIDENTIAL

1 CIT-07 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-07 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-07 DCC Protocol Coordinator:

Julie Qidwai
Phone: 319-384-4165
Fax: 319-353-3960
Cell/pager: 319-321-5692
Email: julie-qidwai@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 Green	(301) 594-8815	greenne@niddk.nih.gov
Allison Priore	(301) 560-4513	priorea@niaid.nih.gov

Assignments					
MM: Tom Eggerman PM: Neal Green		MM: Nancy Bridges PM: Allison Priore		MM: Nancy Bridges PM: Allison Priore	
Protocol:	Site Name	Protocol:	Site Name	Protocol:	Site Name
99, 02, 06	Miami	07	Miami	99, 03	Minnesota
99, 05, 06	Penn	07	Penn	99, 03	Northwestern
99, 02, 06	UIC	07	UIC	99, 03	UCSF
06	Edmonton	99, 04, 07	Edmonton		
06	Minnesota	07	Minnesota		
06	Northwestern	07	Northwestern		
06	UCSF	07	UCSF		
06	Emory	99, 04, 07	Emory		

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.