

Summary of Protocol Changes from v1.7 to v2.0

Section/Topic	Protocol Version	Details of Changes Made
1. Background and Purpose	2.0	<ul style="list-style-type: none"> ○ Added description of islet cell transplantation (ICT), including broad goals of ICT ○ Participation statement moved to this section from previous version ○ Location of past annual reports added with link
2. Components of the Registry	2.0	<ul style="list-style-type: none"> ○ Section added ○ Describes the 2 main components of the registry: 1) data on allograft procedures and 2) data on autograft procedures ○ Includes information on donor data collection
3. Site participation and Eligibility	2.0	<ul style="list-style-type: none"> ○ Section added ○ Lists requirements for participation by a site or center in CITR ○ Describes CITR's role as a registry
4. Study Organization and Governance	2.0	<ul style="list-style-type: none"> ○ Expanded description (from v1.7) of Scientific Advisory Committee (SAC) ○ Expanded description of the Executive Committee (EXCOM) ○ List and description of ad-hoc subcommittees added ○ Relationship with UNOS and ABCC described
Figure 1	2.0	<ul style="list-style-type: none"> ○ Expanded to better illustrate relationship of Coordinating Center (Emmes), SAC, EXCOM, UNOS, ABCC, CIT, other subcommittees and individual centers
5. Research Goals and Questions	2.0	<ul style="list-style-type: none"> ○ Renamed section (v1.7 was 'Hypotheses and Questions') ○ No other changes

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6. Methods	2.0	<ul style="list-style-type: none"> ○ Expanded with subsections for A. Site Recruitment, B. Data Collection, Use and Sharing, and C. Coordinating Center Procedures ○ Subsection B has included methods for collection of: 1. Donor Data, 2. Islet Data, 3. Recipient Data ○ Donor Data is uploaded into registry from UNOS and CITR-Coordinating Center ○ Recipient data methods include procedures for collection of data from current patients and abstraction of historical islet recipient information ○ Endpoints for data collection termination expanded but not fundamentally altered ○ Coordinating center procedures describes Emmes' capabilities and strengths as a Coordinating center
7. Statistical Analysis	2.0	<ul style="list-style-type: none"> ○ Section expanded ○ CITR analyses to include data quality, study progress, and clinical outcomes. ○ Generation of an annual report, monthly database assessments, and any unplanned analyses as required by registry
8. Publication and Dissemination of results	2.0	<ul style="list-style-type: none"> ○ New section describing the annual report ○ Annual report is drafted and reviewed by Publications and Presentations (P&P) committee and then by the SAC ○ Final version is publicly available ○ P&P approves all requests for analysis and focus topic
9. Confidentiality	2.0	<ul style="list-style-type: none"> ○ New section now encompasses all privacy concerns in 2 sections, A. Patient Data and B. Privacy Act ○ Patient Data outlines CITR's adherence to GCP and de-identification of patient and donor data ○ Privacy act describes the compliance with Federal regulations for maintenance of privacy