

# **CIT-05**

## **STUDY-SPECIFIC MANUAL OF PROCEDURES**

**VERSION 2.0**

**MARCH 19, 2008**

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## 1. CIT-05 Protocol Communication Plan

TOPIC/RELATED QUESTIONS	STUDY ROLE AND CONTACT INFORMATION	
<ul style="list-style-type: none"> <li>• Serious Safety Concerns</li> <li>• Publications</li> <li>• Statistical Questions</li> <li>• Endpoint Questions</li> <li>• Major Protocol Deviations</li> <li>• Clinical Care Questions/Concerns</li> <li>• SAE Review and Reporting</li> <li>• Grantee Budgets</li> </ul>	<p><b>Thomas L. Eggerman MD, PhD</b> <b>Medical Monitor</b></p> <p>Director Islet Transplantation Program DDEMD/NIDDK/NIH 6707 Democracy Blvd. Room 697 Bethesda, MD 20892 Phone: 301-594-8813 Fax: 301-480-3503 <a href="mailto:eggermant@extra.niddk.nih.gov">eggermant@extra.niddk.nih.gov</a></p>	
<ul style="list-style-type: none"> <li>• Day to Day Site Activities</li> <li>• Informed Consent</li> <li>• Protocol Deviations</li> <li>• Amendments to Protocol</li> <li>• Enrollment/Screening</li> <li>• Investigator Meetings/Teleconferences</li> <li>• Site Visit Concerns</li> <li>• Clinical Protocol Issues</li> <li>• Protocol Development / Finalization</li> <li>• Protocol Compliance</li> <li>• Data Compliance</li> </ul>	<p><b>Neal Green</b> <b>NIDDK Project Manager</b></p> <p>Clinical Islet Transplantation Consortium DDEMD/NIDDK/NIH 6707 Democracy Blvd. Room 686A Bethesda, MD 20892 Phone: 301-594-8815 Fax: 301-480-3503 <a href="mailto:green@niddk.nih.gov">green@niddk.nih.gov</a></p>	
<ul style="list-style-type: none"> <li>• eCRF / Data Entry Questions</li> <li>• Data Management / Query Resolution</li> <li>• CIT Web-site Questions and Postings</li> <li>• Study Material Supplies (binders, QOLs, source documents etc.)</li> <li>• General MOP questions</li> </ul>	<p><b>Holly Riss, B.A.</b> <b>CIT05 Protocol Coordinator</b></p> <p>Clinical Trials Statistical Data Management Center University of Iowa 2400 UCC Iowa City, IA 52242 Phone: 319-353-4267 Fax: 319-353-3960 <a href="mailto:holly-riss@uiowa.edu">holly-riss@uiowa.edu</a></p>	<p><b>Traci Ripperda, MA</b> <b>Protocol Coordinator</b></p> <p>Clinical Trials Statistical Data Management Center University of Iowa 2400 UCC Iowa City, IA 52242 Phone : 319-384-4180 Fax : 319-353-3960 <a href="mailto:traci-ripperda@uiowa.edu">traci-ripperda@uiowa.edu</a></p>

TOPIC/RELATED QUESTIONS	STUDY ROLE AND CONTACT INFORMATION		
<ul style="list-style-type: none"> <li>Statistical Questions in Parallel with NIH Medical Monitors</li> </ul>	<table border="0"> <tr> <td> <b>Kathryn Chaloner, PhD</b>  <b>DCC Statistician</b>   University of Iowa  Department of Biostatistics  C22-1-GH  Iowa City, IA 52242  Phone: 319-384-5029  Fax: 319-335-6535  <a href="mailto:kathryn-chaloner@uiowa.edu">kathryn-chaloner@uiowa.edu</a> </td><td> <b>Bill Clarke, PhD</b>  <b>DCC Statistician</b>   University of Iowa  Department of Biostatistics  2400 UCC  Iowa City, IA 52242  Phone: 319-384-5027  Fax: 319-335-6535  <a href="mailto:william-clarke@uiowa.edu">william-clarke@uiowa.edu</a> </td></tr> </table>	<b>Kathryn Chaloner, PhD</b> <b>DCC Statistician</b>  University of Iowa Department of Biostatistics C22-1-GH Iowa City, IA 52242 Phone: 319-384-5029 Fax: 319-335-6535 <a href="mailto:kathryn-chaloner@uiowa.edu">kathryn-chaloner@uiowa.edu</a>	<b>Bill Clarke, PhD</b> <b>DCC Statistician</b>  University of Iowa Department of Biostatistics 2400 UCC Iowa City, IA 52242 Phone: 319-384-5027 Fax: 319-335-6535 <a href="mailto:william-clarke@uiowa.edu">william-clarke@uiowa.edu</a>
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<ul style="list-style-type: none"> <li>SAE/AE notification</li> </ul>	<b>Larry Hunsicker, MD</b> <b>DCC Clinical Trial Physician</b>  Department of Internal Medicine T304 GH University of Iowa Hospitals and Clinics Iowa City, IA 52242 Phone: 319-356-4763 Fax: 319-353-4231 <a href="mailto:Lawrence-hunsicker@uiowa.edu">Lawrence-hunsicker@uiowa.edu</a>		
<ul style="list-style-type: none"> <li>Manufacturing</li> <li>Out of Specs (OOS) for Manufacturing</li> <li>Regulatory</li> <li>cGCP/cGMP</li> <li>Drug Accountability/Reconciliation</li> <li>Drug Stability Issues</li> <li>Shipping of Drugs and Islets</li> </ul>	<table border="0"> <tr> <td> <b>Julia Goldstein, MD</b>  <b>Senior Regulatory Affairs Officer</b>   DAIT/NIAID/NIH  6610 Rockledge Drive  Room 3044  Bethesda, MD 20892  Phone: 301-451-3112  Fax: 301-480-1537  <a href="mailto:goldsteinj@niaid.nih.gov">goldsteinj@niaid.nih.gov</a> </td><td> <b>Christine W. Czarniecki, PhD</b>  <b>Chief, Regulatory and Industry Affairs</b>   DAIT/NIAID/NIH  6610 Rockledge Drive  Room 3059  Bethesda, MD 20892  Tel: 301-451-4407  Fax: 301-402-2571  <a href="mailto:cczarniecki@niaid.nih.gov">cczarniecki@niaid.nih.gov</a> </td></tr> </table>	<b>Julia Goldstein, MD</b> <b>Senior Regulatory Affairs Officer</b>  DAIT/NIAID/NIH 6610 Rockledge Drive Room 3044 Bethesda, MD 20892 Phone: 301-451-3112 Fax: 301-480-1537 <a href="mailto:goldsteinj@niaid.nih.gov">goldsteinj@niaid.nih.gov</a>	<b>Christine W. Czarniecki, PhD</b> <b>Chief, Regulatory and Industry Affairs</b>  DAIT/NIAID/NIH 6610 Rockledge Drive Room 3059 Bethesda, MD 20892 Tel: 301-451-4407 Fax: 301-402-2571 <a href="mailto:cczarniecki@niaid.nih.gov">cczarniecki@niaid.nih.gov</a>
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<ul style="list-style-type: none"> <li>Collection of Regulatory Documents</li> </ul>	<b>Deb Feddersen, R.N., ARNP</b> <b>Lead DCC Regulatory Coordinator</b>  Clinical Trials Statistical & Data Management Center University of Iowa 2400 UCC Iowa City, IA 52242 Phone: 319-353-4240 Fax: 319-353-3960 <a href="mailto:deb-feddersen@uiowa.edu">deb-feddersen@uiowa.edu</a>		

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<ul style="list-style-type: none"> <li>Scheduling of Site Monitoring Visits</li> </ul>	<p><b>Christine Lu</b>  <b>Monitoring CRA</b></p> <p>PPD  141 East New Street  Mountville, PA 17554  Phone: 717-285-2541  Fax: 919-654-7744  <a href="mailto:Christine.Lu@wilm.ppd.com">Christine.Lu@wilm.ppd.com</a></p>	<p><b>Mary Hale</b>  <b>Lead CRA</b></p> <p>PPD  12 Elbow Lane  Sicklerville, NJ 08081  Phone: 856 740-0073  Fax: 919 654-8866  <a href="mailto:Mary.Hale@columbia.ppd.com">Mary.Hale@columbia.ppd.com</a></p>