

**The NIH CIT Consortium Chemistry Manufacturing Controls Monitoring Committee:**

J. Ansite, A.N. Balamurugan, B. Barbaro, J. Battle, D. Brandhorst, J. Cano, X. Chen, S. Deng, D. Feddersen, A. Friberg, T. Gilmore, J.S. Goldstein, E. Holbrook, A. Khan, T. Kin, J. Lei, E. Linetsky, C. Liu, X. Luo, K. McElvaney, Z. Min, J. Moreno, D. O’Gorman, K.K. Papas, G. Putz, C. Ricordi, G. Szot, T. Templeton, L. Wang, J.J. Wilhelm, J. Willits, T. Wilson, X. Zhang

**The NIH CIT Consortium**

**Emory University:** J. Avila, B. Begley, J. Cano, S. Carpentier, E. Holbrook, J. Hutchinson, C.P. Larsen, J. Moreno, M. Sears, N.A. Turgeon, D. Webster

**Massachusetts General Hospital:** S. Deng, J. Lei, J.F. Markmann

**NIAID:** N.D. Bridges, C.W. Czarniecki, J.S. Goldstein, G. Putz, T. Templeton, T. Wilson

**NIDDK:** T.L. Eggerman

**Northwestern University:** P. Al-saden, J. Battle, X. Chen, A. Hecyk, H. Kissler, X. Luo, M. Molitch, N. Monson, E. Stuart, A. Wallia, L. Wang, S. Wang, X. Zhang

**University of Alberta, Edmonton:** D. Bigam, P. Campbell, P. Dinyari, T. Kin, N. Kneteman, J. Lyon, A. Malcolm, D. O’Gorman, C. Onderka, R. Owen, R. Pawlick, B. Richer, S. Rosichuk, D. Sarman, A. Schroeder, P.A. Senior, A.M.J. Shapiro, L. Toth, V. Toth, W. Zhai

**University of California–San Francisco:** K. Johnson, J. McElroy, A.M. Posselt, M. Ramos, T. Rojas, P.G. Stock, G. Szot

**University of Illinois, Chicago:** B. Barbaro, J. Martellotto, J. Oberholzer, M. Qi, Y. Wang

**University of Iowa (Data Coordinating Center):** L. Bayman, K. Chaloner, W. Clarke, J.S. Dillon, C. Diltz, G.C. Doelle, D. Ecklund, D. Feddersen, E. Foster, L. G. Hunsicker, C. Jaspersen, D-E Lafontant, K. McElvaney, T. Neill-Hudson, D. Nollen, J. Qidwai, H. Riss, T. Schwieger, J. Willits, J. Yankey

**University of Miami:** R. Alejandro, A.C. Corrales, R. Faradji, T. Froud, A.A. Garcia, E. Herrada, H. Ichii, L. Inverardi, N. Kenyon, A. Khan, E. Linetsky, J. Montelongo, E. Peixoto, K. Peterson, C. Ricordi, J. Szust, X. Wang

**University of Minnesota:** M.H. Abdulla, J. Ansite, A.N. Balamurugan, M.D. Bellin, M. Brandenburg, T. Gilmore, J. V. Harmon, B.J. Hering, R. Kandaswamy, G. Loganathan, K. Mueller, K.K. Papas, J. Pedersen, J.J. Wilhelm, J. Witson

**University of Pennsylvania:** C. Dalton-Bakes, H. Fu, M. Kamoun, J. Kearns, Y. Li, C. Liu, E. Luning-Prak, Y. Luo, E. Markmann, Z. Min, A. Najji, M. Palanjan, M. Rickels, R. Shlansky-Goldberg, K. Vivek, A.S. Ziaie

**University of Wisconsin:** L. Fernandez, D.B. Kaufman, L. Zitur

**Uppsala University:** D. Brandhorst, A. Friberg, O. Korsgren

*Supported by grants from the National Institute of Allergy and Infectious Diseases and the National Institute for Diabetes and Digestive and Kidney Diseases.*

- At Emory University, U01AI089317.
- At Northwestern University, U01AI089316.
- At the University of Alberta, Edmonton: U01AI065191.
- At the University of California, San Francisco, U01DK085531.
- At the University of Illinois, Chicago, 5U01DK070431-10.
- At the University of Iowa, U01DK070431.
- At the University of Miami, U01DK070460.
- At the University of Minnesota, U01AI065193.
- At the University of Pennsylvania, U01DK070430.
- At Uppsala University, U01AI065192.

*In addition, the study was supported by the following GCRC and CTSA awards:*

- At Emory University: UL1TR000454.
- At Northwestern University: 5UL1RR025741 and 8UL1TR000150.
- At the University of California, San Francisco, UL1TR000004.
- At the University of Illinois, Chicago, UL1TR000050.
- At the University of Miami: 1UL1TR000460.
- At the University of Minnesota: 5M01-RR000400 and UL1TR000114.
- At the University of Pennsylvania: UL1TR000003.

Address correspondence to: Camillo Ricordi MD, Chairman, CIT Steering Committee,  
ricordi@miami.edu

## To cite this article

*Purified Human Pancreatic Islets, CIT Culture Media with Lisofylline or Exenatide – Standard Operating Procedure of the NIH Clinical Islet Transplantation Consortium*

CellR4 2017; 5 (3): e2377

**DAIT, NIAID, NIH**

**SOP  
ATTACHMENT**



<b>Document No.</b> 3106, B07	<b>Revision Number</b> 00	<b>Effective Date</b> 07 July 2008	<b>Supersedes Date</b> N/A	<b>Page 1 of 2</b>
----------------------------------	------------------------------	---------------------------------------	-------------------------------	--------------------

**Document Title:**

**PURIFIED HUMAN PANCREATIC ISLETS,  
CIT CULTURE MEDIA  
WITH LISOFYLLINE OR EXENATIDE**

Manufacturing Site: \_\_\_\_\_ Date: \_\_\_\_\_

This lot will be made with:      Lisofylline                      or                      Exenatide                      (Circle One)

1.      **Materials:**

<b>Material</b>	<b>Source</b>	<b>Lot #</b>	<b>Expiration Date</b>	<b>Quantity Required</b>	<b>Quantity Used</b>
<b>CMRL 1066, Supplemented</b>				500 mL	mL
<b>Albumin Human USP, 25% Solution</b>				10 mL	mL
<b>Heparin Sodium Injection USP</b>	_____ Units/mL			5,000 units (_____ mL)	mL
<b>Lisofylline, 60 mg/mL</b>	Cell Therapeutics Formula #0109-00			240 µL	µL
<b>Exenatide, 250 µg/mL</b>	Amylin Pharmaceuticals NDC # 66780-210-07			170 µL	µL
<b>Hydrochloric Acid, 1 N</b>				0.2 mL	mL
<b>Sterile Water for Injection</b>				20 mL	mL
<b>IGF-1, 1 mg/vial</b>	Cell Sciences Cat. #CM001			50 µL	µL

2.      **Procedure**

- 2.1      In a BSC place a 500 mL bottle of CMRL 1066, Supplemented.
- 2.2      Add 10 mL of Albumin Human USP, 25% Solution, to the bottle.
- 2.3      Add 5,000 Units of Heparin to the bottle.
- 2.4      Add 240 µL of 60 mg/mL lisofylline or 170 µL of 250 µg/mL exenatide. Cross out, initial and date the one **not** used.

Islets Lot Number: \_\_\_\_\_

<b>Document No.</b> 3106, B07	<b>Revision Number</b> 00	<b>Effective Date</b> 07 July 2008	<b>Supersedes Date</b> N/A	<b>Page 2 of 2</b>
<b>Document Title:</b>				
<b>PURIFIED HUMAN PANCREATIC ISLETS, CIT CULTURE MEDIA WITH LISOFYLLINE OR EXENATIDE</b>				

- 2.5 Separately, add 0.2 mL of 1 N Hydrochloric Acid to 20 mL of Sterile Water for Injection to make 10 mM HCl solution. Reconstitute one 1 mg vial of IGF-1 with 1.0 mL of the 10 mM HCl solution. Add 50 µL of the IGF-1 solution to the beaker or flask. Aliquot the remaining IGF-1 solution into 19 small sterile vials and store below -20°C. Cap the bottle and label it with:
- "CIT IGF-1 Solution, 50 µL, "
  - Islets Lot Number (for traceability of preparation record)
  - "Store below -20°C"
  - Date Prepared
  - Expiration Date (3 months after preparation)
  - Initials of the person who prepared the solution
- 2.6 Cap the bottle and mix by gentle inversion at least five times.
- 2.7 Cap the bottle and label it with:
- "CIT Culture Media with Lisofylline"
  - or
  - "CIT Culture Media with Exenatide"
  - Islets Lot Number
  - "Store at 2°C to 8°C"
  - Date Prepared
  - Expiration Date (the end of the day after preparation)
  - Initials of the person who prepared the solution
- 2.8 Store the bottle of solution at 2°C to 8°C before use.

Total volume prepared: \_\_\_\_\_ mL

Prepared by: \_\_\_\_\_

Date: \_\_\_\_\_

Reviewed by: \_\_\_\_\_

Date: \_\_\_\_\_

Islets Lot Number: \_\_\_\_\_