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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.

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To cite this article

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

CellR4 2017; 5 (3): e2385

DAIT, NIAID, NIH

**SOP
ATTACHMENT**



Document No.
3106, B09

Revision Number
00

Effective Date
07 July 2008

Supersedes Date
N/A

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Document Title:

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

Manufacturing Site: _____

Date: _____

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

1. Materials:

Material	Source	Lot #	Expiration Date	Quantity Required	Quantity Used
CMRL 1066 Transplant Media, contains HEPES and without Sodium Bicarbonate	Mediatech 98-291-L			500 mL	mL
Albumin Human USP, 25% Solution				50 mL	mL
Lisofylline, 60 mg/mL	Cell Therapeutics Formula #0109-00			260 µL	µL
Exenatide, 250 µg/mL	Amylin Pharmaceuticals NDC # 66780-210-07			190 µL	µL

2. Procedure

- 2.1 In a BSC place a 500 mL bottle of CMRL 1066 Transplant Media, contains HEPES and without Sodium Bicarbonate.
- 2.2 Add 50 mL of Albumin Human USP, 25% Solution to the bottle.
- 2.3 Add 260 µL of 60 mg/mL Lisofylline or 190 µL of 250 µg/mL Exenatide. Cross out, initial and date the one **not** used.
- 2.4 Cap the bottle and mix by gentle inversion at least five times.

Islets Lot Number: _____

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Document Title:				
PURIFIED HUMAN PANCREATIC ISLETS, CIT TRANSPLANT MEDIA WITH LISOFYLLINE OR EXENATIDE				

- 2.5 Cap the bottle and label it with:
- "CIT Transplant Media with Lisofylline"
 - or
 - "CIT Transplant 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
- 2.6 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: _____