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OPEN ACCESS

**DOI:**

dx.doi.org/10.17504/protocols.io.eq2lypq1mlx9/v1

External link:

https://www.ups.com/ship/guided/origin?tx=82244453079841633&loc=en_US&WT.mc_id=ds_gclid:EAIalQobChMlxJSh9Xj_AIVRXUAR3bnQIrEAYASAAEgJ9IPD_BwE:dscid:7170000031307143:searchterm:ups&WT.srch=1

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International Shipping Documentation

Integrated Islet Distribution Program¹

¹Integrated Islet Distribution Program, City of Hope, Duarte, CA

Integrated Islet Distribution Program

Tech. support email: iidp-email@coh.org



Integrated Islet Distribution Program

Integrated Islet Distribution Program, City of Hope

ABSTRACT

This SOP defines the completion of International Documentation necessary for the shipment of human islets and biospecimens to investigators outside of the United States for use in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored research in the Integrated Islet Distribution Program (IIDP) using the United Parcel Service (UPS) as a courier. This is SOP is to be used in conjunction with other relevant IIDP SOPs previously published for shipping tissues using Federal Express for shipments within the United States:

- [Packaging and Cold Shipping of Human Islets](#)
- [Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic \(Acinar\) Tissue](#)
- [Packaging and Shipping of Flash Frozen Non-Islet Pancreatic \(Acinar\) Tissue](#)
- [Collection, Broadcast, Packaging and Shipping of Non-Islet Biospecimens](#)

This protocol is written to assist the participating islet isolation centers who are part of this program.

Note

Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387)

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CITATIONS

David W. Scharp, Jayagowri Arulmoli, Kelly Morgan, Hannah Sunshine, Ergeng Hao.
Advances in Human Islet Processing: Manufacturing Steps to Achieve Predictable Islet Outcomes from Research Pancreases
[10.21926/obm.transplant.1901052](https://doi.org/10.21926/obm.transplant.1901052)

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We use this protocol and it's working

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GUIDELINES

Responsibilities:

- It is the responsibility of the IIDP CC to both follow and ensure adherence to the procedures outlined in this SOP. In order to accomplish this, the IIDP CC will interact with the relevant personnel from each of the participating centers.
- It is the responsibility of each IIDP center to follow the procedures listed in this SOP and to work to the best of their ability to follow all requirements.

Definitions:

- **Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387):** The IIDP is a program commissioned and funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK Project Scientist and Program Official, the External Evaluation Committee and the CC at City of Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.
- **IIDP Coordinating Center (CC):** Joyce Niland, Ph.D., and Carmella Evans-Molina, M.D., Ph.D., IIDP Principal Investigators, lead CC staff to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.
- **Islet Equivalent (IEQ):** An IEQ is defined as an islet with a diameter of 150 microns. The number of IEQ in each size class is calculated by multiplying the number of islets by a conversion factor for each micron size.
- **Approved International Investigators:** Researchers conducting experiments outside of the United States, who have requested islets from the IIDP for basic science studies and whose research protocols have been reviewed and approved by the IIDP.
- **Islet Allocation System (IA):** This is the online system administered by the IIDP to allow fair distribution of basic science islets to approved investigators. This interactive System is used by the IIDP Centers and the Approved Investigators facilitates and tracks the distribution of human islets.
- **Commercial Invoice (CI):** The Commercial Invoice is a document provided by Federal Express that must be completed by all centers when shipping islets internationally for the IIDP. It provides the contact information for both the islet provider and the islet

recipient. The estimated value of the package should be listed as \$10.00 USD. This document should be completed through your Federal Express Account by clicking on Electronic Trade Documents and following the instructions.

- **Certificate of Origin (COO):** A certificate of origin is a document that verifies the manufacturing country of the items being shipped. The item's origin and destination determine if the certificate is required. Generally, if the country of origin is the U.S., a certificate will be needed.
- **Harmonized Code:** The Harmonized Code is a specific group of numbers that informs customs what is contained in the package. In the case of human islet shipments, the code number is 3002.90.5150 which designates human tissue. It is used on the Certificate of Origin document.

MATERIALS

MATERIALS

- ☒ Dynamic Diagnostics TransPak™ Pre-filled 10% Neutral Buffered Formalin (NBF) **Fisher Scientific Catalog #22-899-402**
- ☒ Corning™ Ciprofloxacin Hydrochloride **Fisher Scientific Catalog #MT61277RG** (Corning™ 61277RG)
- ☒ Human AB Serum (ABS) HI **Gemini Bioproducts Catalog #100-512**; Heat Inactivated
- ☒ PIM(G)® (5 mL Glutamine/Glutathione) **Prodo Laboratories, Inc Catalog #PIM(G)®**
- ☒ PIM(T)® **Prodo Laboratories, Inc Catalog # PIM(T)®**

Equipment

Phase 22 PCM Flex Pack

NAME

Phase 22 cold packs to maintain temperature at 22C

TYPE

TCP Reliable Manufacturing

BRAND

FMIS76000

SKU

<https://www.cryopak.com/packaging-and-refrigerants/phase-change-materials/phase-22/>

LINK

- Most used for applications that need to maintain a controlled room temperature
- Phase change temperature is 22°C
- Provides thermal protection when shipping products between 15-30°C

SPECIFICATIONS



Equipment

Thermo Scientific™ Nalgene™ Square PETG Media Bottles with Closure

NAME

30 mL PETG Media Bottles with Closure

TYPE

Thermo Scientific™ Nalgene™

BRAND

03-311-1V

SKU

<https://www.fishersci.com/shop/products/nalgene-square-petg-media-bottles-closure/033111V#?keyword=true>

LINK

30 mL PETG Media Bottles

SPECIFICATIONS



Equipment

PETG Media Bottles with Closure

60 mL PETG Media Bottles with Closure

NAME

Thermo Scientific™ Nalgene™ Square PETG Media Bott

BRAND

03-311-1W

SKU

<https://www.fishersci.com/shop/products/nalgene-square-petg-media-bottles-closure/033111W#?keyword=true>

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PETG Media Bottles

SPECIFICATIONS



Equipment

Media Bottles with Closure

125 mL PETG Media Bottles with Closure

NAME

Thermo Scientific™ Nalgene™

BRAND

03-312-1

SKU

<https://www.fishersci.com/shop/products/nalgene-square-petg-media-bottles-closure/033121#?keyword=true>

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PETG Media Bottles

SPECIFICATIONS



Equipment

Durasorb™ Underpads

Underpads

NAME

Covidien

TYPE

22-031-340

BRAND

<https://www.fishersci.com/shop/products/covidien-durasorb-underpads/22031340#?keyword=22+031+340>

SKU

Wings™ Fluff Underpad 17 x 24 in.

SPECIFICATIONS



Equipment

Reclosable Zip Bags

Clear Reclosable Zip Bags

NAME

RD Plastics

TYPE

19-130-6043

BRAND

<https://www.fishersci.com/shop/products/rd-plastics-clear-reclosable-zip-bags-6/191306043?keyword=true>

SKU

PE (Polyethylene) Reclosable bag (8 x 10 in.)

SPECIFICATIONS



Equipment

Uline Corrugated Boxes

Corrugated Boxes (Inner Shipping Box)

Uline

S-4344

<https://www.uline.com/Product/Detail/S-4344/Corrugated-Boxes-200-Test/7-x-5-x-5-Corrugated-Boxes?keywords=S-4344+7+x+5+x+5%22+Corrugated+Boxes>

7 x 5 x 5" Corrugated Boxes

SPECIFICATIONS



Equipment

Insulated Foam Shipping Kit

Insulated Foam Shipping Kit

Uline

S-7359

<https://www.uline.com/Product/Detail/S-7359/Insulated-Shippers-and-Supplies/Insulated-Foam-Shipping-Kit-8-x-6-x-9?keywords=S-7359>

Insulated Foam Shipping Kit - 8 x 6 x 9"

SPECIFICATIONS



Equipment

Uline Cold Pack

NAME

Cold Pack

TYPE

Uline

BRAND

S-7361

SKU

<https://www.uline.com/Product/Detail/S-7361/Insulated-Shippers-and-Supplies/Cold-Packs-8-oz?keywords=S-7361>

LINK

Reusable, leakproof refrigerant gel stays colder than ice. Thick 4 mil poly. 6 x 4 x 3/4"

SPECIFICATIONS



Equipment

Uline Industrial Tape

Uline Industrial Tape - 2 Mil, 2" x 110 yds, Clear

NAME

Uline

TYPE

S-423

BRAND

<https://www.uline.com/Product/Detail/S-423/Carton-Sealing-Tape/Uline-Industrial-Tape-2-Mil-2-x-110-yds-Clear?keywords=S-423>

LINK

2 Mil, 2" x 110 yds, Clear. DURABLE: Industrial Tape stands up to heat, humidity and cold.

SPECIFICATIONS



Equipment

Custom Cold Chain Complete Card

Temperature Monitoring system

NAME

Tip TEMPerature Products

TYPE

WMSSEN044;

BRAND

<https://www.tiptemp.com/>

SKU

Custom Cold Chain Complete Card

SPECIFICATIONS



Equipment

Tip TEMPerature Products

WarmMark Ascending Temperature indicator

NAME

WarmMark Ascending Temperature indicator

TYPE

WMSSEN009

BRAND

<https://www.tiptemp.com/Products/Rising-Time-Temperature-Indicating-Labels/WMSSEN009-WarmMark-with-Trigger-Temperature-37C-99F.html>

LI
N
K

Maximum exposure above 37°C/99°F

SPECIFICATIONS



Equipment

ColdMark Descending Temperature Indicator

NAME

Descending Temperature Indicator

TYPE

Tip TEMPerature Products

BRAND

CLMSEN004

SKU

<https://www.tiptemp.com/Products/Falling-Temperature-Indicating-Labels/CLMSEN004-Temperature-Label-ColdMark-2C-36F.html>

LI
NK

Falling Temp Monitor Changes Color Permanently; 2°C/36°F

SPECIFICATIONS



Equipment

Laser Labels

Uline Laser Labels - White, 8 1/2 x 11"

NAME

Uline

TYPE

S-5045

BRAND

<https://www.uline.com/Product/Detail/S-5045/Laser-Labels/Uline-Laser-Labels-White-8-1-2-x-11?keywords=S-5045+Uline+Laser+Labels+-+White%2c+8+1%2f2+x+11%22>

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Box of 100 Single Labels, White, 8 1/2 x 11"

SPECIFICATIONS



SAFETY WARNINGS

- ! These reagents are documented in the Shipping SOP,

 SDS-61-277-AGHS-EN-2014Jul22.pdf**Ciprofloxacin Hydrochloride**

Precautionary statements:

- P280 - Wear protective gloves and eye/face protection
- P305 + P351 + P338 - IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
- P337 + P313 - If eye irritation persists: Get medical advice/attention.
- P273 - Avoid release to the environment.

 sds_100-512_gemcell_hsab.pdf**GemCell™ U.S. Origin Human Serum AB**

GemCell™ human serum AB is collected from healthy male donors of the AB serotype at FDA-licensed facilities in the United States.

Hazardous Components:

- Biohazard contains human source material. Handle as though capable of transmitting infectious agents.
- Toxicity: Not Established.
- Target Organs/Systems: Product could possibly irritate the skin, eyes and respiratory system. Do not ingest this product.

BEFORE START INSTRUCTIONS

CITATION

David W. Scharp, Jayagowri Arulmoli, Kelly Morgan, Hannah Sunshine, Ergeng Hao (2019). Advances in Human Islet Processing: Manufacturing Steps to Achieve Predictable Islet Outcomes from Research Pancreases. *OBM Transplantation*.

LINK

[10.21926/obm.transplant.1901052](https://doi.org/10.21926/obm.transplant.1901052)

Materials

- 1 The IIDP will provide each center with the supplies necessary for shipments as listed in the materials section. Standard lab supplies will be provided by the IIDP Centers as listed below.

The following SOPs may be implemented for these shipments. This protocol is written to assist the participating islet isolation centers who are part of this program.

- [Packaging and Cold Shipping of Human Islets](#)
- [Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic \(Acinar\) Tissue](#)
- [Packaging and Shipping of Flash Frozen Non-Islet Pancreatic \(Acinar\)Tissue](#)
- [Collection, Broadcast, Packaging and Shipping of Non-Islet Biospecimens](#)



1.1 Shipping Supplies provided by the IIDP Centers:

- Completed UPS or FedEx Shipping Labels

- Islet Allocation Tissue Shipment Forms for appropriate recipients

Create a UPS Account and Shipment

- 2 The IIDP recommends UPS for most international shipments because UPS is the typical courier outside of the United States. FedEx is not typically used for international shipments but is acceptable for shipping to Canada. Each center may use whichever shipping vendor is most feasible for them. These steps follow the UPS website which is a dynamic website. The FedEx instructions are similar.

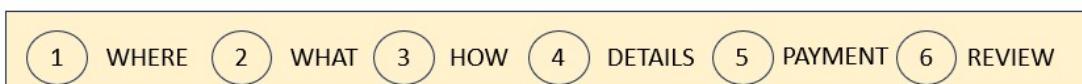
Go to the [UPS site](#) and [log in](#). If you do not have an account, follow the instructions in 2.1 to [create an account](#).

2.1 *Create UPS Account*

For IIDP shipments of islets or tissues to international investigators, a UPS account must be set up by each IIDP Islet Isolation Center (IIC) in order to access the documentation needed to send an international shipment and to charge the investigator (the payer) for the shipment.

- Review [International Shipping Guide](#) for more detailed information.
- Each step below is hyperlinked to the appropriate address of the website (url) within the UPS site, at time of this publication. Since this is a dynamic site, it may have been upgraded or internal links may have changed.

- 3 Click on **SHIP** on the home page. ***Create a Shipment***



UPS Steps Needed to Complete Shipment as listed below.

4 ♦ **1 WHERE:**

Complete the following information for **Shipper and Consignee/Importer**

Shipper

[Where are you shipping from?](#)

- Fill in Country, Company Name, Address, Email, Phone Number
- Indicate if you would like UPS to send status updates on the shipment

- Must declare ID/EIN: for USA for your institution
- Save the new entry and the default return address for later shipments.

4.1 ***Consignee/Importer***

Where is your shipment going?

- Obtain information from the IIDP Investigator Shipping Information from Shipment Confirmation Page.
- Fill in Country, Company Name, Address, Email, Phone Number
- **Include EORI/Tax ID from IIDP Investigator.** (*Note: EORI is the Economic Operator Registration and Identification*) This is only needed when shipping to European Union countries. There is not a place on the FedEx form, so note in the reference area of form.
- All new entries should be saved for later shipments.

5 ◆ 2 WHAT:

Use the following information for the **Type of Packaging**:

- My packaging (Islet Shipper (S-7359): **11 L x 9W x 12 H**
- Weight (Weight will impact shipping cost): **Use 8 lbs.**
- Total Package Value (impacts customs taxes): **Use \$10 USD.**
- For UPS: **It is easiest to use the UPS Tracking number.** Alternatively, the Islet or Biospecimens RRID number could be used (SAMN...).

6 ◆ 3 HOW:

Specify the **Shipment Preference**:

- Drop off or include it in another pickup OR
- Schedule a new Pickup
- Estimated Ship Date (optional)

6.1 ***Delivery Schedule***

- When would you like it delivered?
- Recommended: UPS Worldwide Saver

7 ◆ 4 DETAILS:

The following information can be used for documentation.

7.1 ***International Shipping Details***

- What best describes this shipment? From drop down list choose: **None of these reasons apply.**
- What are you shipping? Max 35 characters: **Noninfectious human lab material**

7.2

Commercial Invoice

- Complete with guidance will provide the following questions:
- See "An Easy Guide to International Shipping"
- **Required** to export anything other than documents (including personal items and goods not for sale).
- Description of Goods: **Non-infectious human material for lab testing only. NEGATIVE for COVID-19.**
- **HS Code: Harmonized Tariff Code Number:** The Harmonized Code is a specific group of numbers that informs customs what is contained in the package. In the case of human islet shipments, the code number is **3002.90.5150** which designates human tissue. It is used on the Certificate of Origin document.
- Unit of Measure (How is this product packaged or sold (dropdown list)): **Each**
- Unit Value **10 USD**
- Country of origin? Where was this product made or assembled? **United States**
- Save Product As* **Product Name/Part Number;** Product ID (**Primary Identifier, sent to Customs, could be tracking number**). Alternatively, the Islet or Biospecimens RRID number could be used (SAMN...).
- Number of Units (Quantity): **1**

7.3

UPS recommends U.S. Certificate of Origin; however, it is included in the Commercial Invoice under "An Easy Guide to International Shipping" in Step 7.2  [go to step #7.2](#)

- Optional: only for UPS, not needed for FedEx.



US cert_of_origin.pdf 56KB

▪

7.4

Complete this form using the following information:

- Non-infectious human material for lab testing only.
- NEGATIVE for COVID-19.
- Valued at 10.00 USD.

7.5

Other Available Documents:

- **Access International Forms as needed UPS or FedEx shipping label containing bar code.**
- **3 copies of the Commercial Invoice, each attached to a smaller version of shipping label (containing bar codes).** Take these 3 copies to FedEx for shipping. They will verify that the Commercial Invoice is correct. These will go in a resealable pouch supplied by FedEx.
- Include Tissue Shipment Form (IIDP TSF) in box.
- Standard Goods Permit (for Australian recipients only). Each Australian investigator must provide their own form. An example of a redacted form is attached.



7.6 ***Tracking Notifications:***

- Add or modify email notifications for tracking.

8 ♦ **5 PAYMENT**

Choose to **Bill Other Account** in order to charge the recipient for the shipment

8.1 ***Bill Other Account:***

- Your account is required to verify charges to someone else.
- + Add an Existing Account
- + Create a New Account

8.2 ***Import Charges***

- How would you like to pay import charges?
- Dropdown: **Charge receiver for duties and taxes**

Create a FedEx Account and Shipment

- 9 We recommend UPS for most international shipments because UPS is not a typical courier outside of the United States. FedEx is acceptable for shipping to Canada.

Go to the [FedEx home](#) and follow instruction which should be similar to UPS.

Please note the special islet shipment parameters listed in Step 7.2 above.

Packaging of Islets

- 10 Stage all materials needed for packaging the islets and ensure all ice packs and CryoPak pouches are at the proper temperature. The following is a summary of the steps detailed in the following Packaging and Cold Shipping of Human Islets SOP:

- Packaging and Cold Shipping of Human Islets <https://www.protocols.io/view/packaging-and-cold-shipping-of-human-islets-ewov18o7ogr2/v2>

- The Cold Chain Complete Card is shipped with the WarmMark Indicator attached. *Adhere the ColdMark indicator to the card and activate the WarmMark indicator.*
- Immediately place the Cold Chain Complete Card along with the islet shipping bottles into a Ziploc bag and seal.
- Line the inner cardboard (S-4434) box with absorbent pad.
- Place the bagged shipping bottle(s) containing the islets in the Ziploc bag into the lined inner cardboard box.
- Surround bottle with six 8°C cold packs, one on bottom, one on each of the four sides and one on top as directed in the Shipping SOP.
- Mark the direction for upright bottle. Seal the inner box with shipping tape and stand upright.
- Place one 8°C CryoPak pouch and one 8°C cold pack (stored in the refrigerator) in the bottom of the Styrofoam box.
- Place the inner cardboard box containing the islets on top of the pouch and pack, ensuring that the bottle inside is standing upright and centered in the shipping container.
- Place one 8°C CryoPak TCP pouch and one -20°C frozen ice pack on each long side of the inner box. (Packs/pouches are placed in the larger gap between the inner box and the insulated shipping container.)
- Place one 8°C CryoPak TCP pouch and one 8°C cold pack on the top of the inner box. **NOTE**-All packs should be placed in an alternating method, to ensure two of the same packs are not next to each other in the configuration.
- Place the Styrofoam lid on top. Place Tissue Shipment Form on top of Styrofoam lid.
- Close the flaps of the shipping box and seal with shipping tape. Add Live Cells box label to the box.
- Attach FedEx or UPS label with recipient FedEx or UPS number to box and ship **priority overnight**.

Completing the Distribution Records

- 11 The allocation system will enter the IEQ determined to be shipped on the "Confirm Recipient Screen". However, the Center can change the number, based on the recipient profile or additional IEQ requested, for distribution. The final shipment amount must be confirmed and entered, along with the UPS or FedEx tracking numbers.