



Standard Operating Procedure for International Shipping Documentation			<i>SOP #:</i> SHP-003-01
<i>Version:</i> 01	<i>Supersedes:</i> NA	<i>Issue Date:</i> 9/6/12	<i>Effective Date:</i> 9/10/12
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Integrated Islet Distribution Program
City of Hope

STANDARD OPERATING PROCEDURE (SOP)
International Shipping Documentation
(For IIDP Centers)
Version: SHP-003-01



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1.0 Objective

- 1.1 The goal of the Integrated Islet Distribution Program (IIDP) is to provide quality islets to all approved domestic and international investigators. The objective of this Standard Operating Procedure (SOP) is to provide instructions for completing proper documentation for international shipping of human islet through Federal Express for all the subcontracted IIDP centers that will result in minimal loss of quality or quantity of shipped islets provided to international approved IIDP researchers.
- 1.2 This SOP was developed based on training and information given to the Coordinating Center of the IIDP by the Regulatory branch of Federal Express.

2.0 Scope and Applicability

- 2.1 This SOP applies to the IIDP Coordinating Center (CC) and to any center using funds from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) that provides islets for basic research studies to IIDP approved international investigators.
- 2.2 This SOP will require participation from all participating IIDP centers.

3.0 Responsibilities

- 3.1 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.
- 3.2 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.

4.0 Definitions

- 4.1 Integrated Islet Distribution Program (IIDP): The IIDP is a grant funded program commissioned 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 Officer (PO), NIDDK Scientific Officer (SO) the External Evaluation Committee (EEC) and the CC at City of Hope (COH). The IIDP



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CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.

- 4.2 IIDP Coordinating Center (CC): Joyce Niland, Ph.D. is the Principal Investigator for the IIDP CC and leads staff from the Department of Research Information Sciences at COH to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.
- 4.3 Approved International Investigators: Researchers conducting experiments outside of the United States, who have a collaboration with a U.S. investigator, and who have requested islets from the IIDP for basic science studies and whose research protocols have been reviewed and approved by the NIDDK PO and/or SO.
- 4.4 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 used by the IIDP Centers and the Approved Investigators tracks not only the distribution of islets but the return of the shipping materials to the IIDP centers.
- 4.5 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 \$48.00 USD. More details are listed below(See 6.1.3 and 6.1.6).
- 4.6 Declaration of Biological Shipment (DB): This is a form recommended by the Federal Express Regulatory Team to give more information to customs agents when inspecting the packages and it allows for quicker processing of international shipments.
- 4.7 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.

5.0 Materials

- 5.1 Federal Express Label (Waybill) Document (Attachment1).
- 5.2 Commercial Invoice (Attachment 2).
- 5.3 Declaration of Biological Shipment (Attachment 3).



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6.0 Procedures

6.1 Documentation for international shipping requires a few steps in addition to the routine Federal Express shipments within the United States. The following steps outline the procedure.

6.1.1. Log into the Federal Express website with your log in and password and click on **Create a Shipment**.

6.1.1.1. View Section 1 and confirm that your information is correct.

6.1.2. If the recipient is already in your profile, then click on the name and the pre-entered shipping address will populate Section 2. If the recipient is a new one, enter their name and address in Section 2.

6.1.2.1. There is no need to enter a **Recipient Tax ID #**.

6.1.2.2. **Check Government List of Unacceptable Trading Partners** is not applicable.

6.1.3. Complete Section 3. Enter the following for these categories:

6.1.3.1. **No. of Packages:** *1*

6.1.3.2. **Weight:** *3 lbs*

6.1.3.3. **Declared Value:** *\$48.00 US Dollars*

6.1.3.4. **Service Type:** *International Priority*

6.1.3.5. **Package Type:** *Your Packaging*

6.1.3.6. **Dimensions:** *14x14x15 in.* Check **Save dimensions profile**.

6.1.3.7. **Profile Name:** *isletbox*

6.1.3.8. **Package Contents:** *Products/Commodities*

6.1.3.9. **Shipment Purpose:** *Commercial*

6.1.3.10. **Total Customs Value:** *48.00 US Dollars*

6.1.3.11. Do not create a return shipment for international packaging. It is too costly for the IIDP to have the gel packs returned.



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- 6.1.4. Enter the information for the recipient for **Billing Details** in Section 4.
 - 6.1.4.1. It is not necessary to complete any other special instructions. Go to Section 5.
- 6.1.5. Click **Continue** your Shipment in Section 5. This will take you to the next page of the Fed Ex form.
- 6.1.6. For Section 6, select **Add a New Commodity** for your first time shipping or **Select/Create** if you have already entered the commodity. Then enter the following information:
 - 6.1.6.1. **Commodity Description:** *Non-hazardous human cells*
 - 6.1.6.2. **Unit of Measure:** *each*
 - 6.1.6.3. **Quantity:** *1*
 - 6.1.6.4. **Commodity Weight:** *1*
 - 6.1.6.5. **Customs Value:** *48.00 USD*
 - 6.1.6.6. **Country of Manufacture:** *United States*
 - 6.1.6.7. **Harmonized Code:** *3002.90.5150*
 - 6.1.6.8. Check **Save/Update Commodity Profile** and **Add this Commodity**
 - 6.1.6.9. Add **Product Name:** *Non-hazardous human cells* then click **Add this Commodity**.
- 6.1.7. For Section 7, check **Commercial Invoice**.
 - 6.1.7.1. For **Terms of Sale**, check *Free Carrier (FCA/FOB.)*
 - 6.1.7.2. Three copies of the **Commercial Invoice** must be placed in clear Fed Ex pouch with Shipping Label. (See Attachment 2.)
- 6.1.8. For Section 8, IIDP shipments are exempt so nothing needs to be checked in this section. If necessary, check **No EEVSED required** the code for this section is *30.37a*, meaning the commodity is less than \$50.00.



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6.1.9. For Section 9, click on **Create a Shipment Profile** (for later access) and for **Profile Name** type in the name of the recipient.

6.1.9.1. Click on **Ship**.

6.1.10. Print Shipping Label and place in clear pouch and attach to package. (See Attachment 1.)

6.1.11. Print Commercial Invoice. Make 3 copies and place all in clear pouch attached to package. (See Attachment 2.)

6.2. In addition to the Federal Express online documents, it is advisable to complete a Declaration of Biological Shipment (see Attachment 3). The majority of this document can be completed ahead of time as a generic document and copied. Information in red below indicates data to be entered at time of shipment and not included in the generic version.

6.2.1. Fill in all your **Shipper Information** excluding **Waybill#**.

6.2.2. Optional: Fill in Consignee information for each of the international recipients ahead of time and make copies for each of them.

6.2.3. For **Reason for Export**: check - **Sample for Research**.

6.2.4. For **The above shipment contains (check all that apply)** check - **Human; Qty in Milliliters - 120ml (if one bag); LOT Number – put in isolation or UNOS #; Control # - put in NA**.

6.2.5. Check **Non-infectious**.

6.2.6. Check **Parts of Human Body** and after it there should be a line but just write or type in: *Pancreatic Islets*.

6.2.7. There is nothing else to be filled in until **Description of Packaging** where the following should be entered: *islets in a culture bag, sealed in waterproof zip-lock bag, absorbent pads, temperature control gel packs, Styrofoam box inside a corrugated cardboard box*.

6.2.8. Next check *Room Temperature* for **Special Handling**.

6.2.9. Fill in **Declarants Name, Signature, Title, and Date**. (Note: The declarant is the person completing the paperwork.)



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6.2.10. Fill in **Emergency Contact, Email, Phone/Fax.** (*Note: This should be an after-hours contact name, email, and number.*)

6.2.11. When completed, a copy should be placed in the clear pouch with the 3 copies of the Commercial Invoice and Fed Ex Shipping Label.

6.3. If there are problems completing the Federal Express on-line form or if there are other questions, contact the Federal Express International Regulatory team at **1-800-851-3336**.

7.0 References

- 7.1 Federal Express website for help in international shipping:
http://www.fedex.com/us/international/index.html?lid=learn_starting_international
- 7.2 Federal Express website for help in documentation:
<http://www.fedex.com/us/international/trade-documents/>

8.0 Attachments

- 8.1. Federal Express Shipping Label - Example
- 8.2. Commercial Invoice - Example
- 8.3. Declaration of Biological Shipment – Fillable
- 8.4. Commercial Invoice - Fillable