

Standard Operating F Packing of IIDP Shipping Islet Distribution and the	SOP #: SHP-001-07		
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Integrated Islet Distribution Program City of Hope

STANDARD OPERATING PROCEDURE (SOP) Standardized Packing of IIDP Shipping Container Used for Research Islet Distribution and the Return of Packaging Materials (For IIDP Centers) Version: SHP-001-07



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1.0 Objective

- 1.1 The goal of the Integrated Islet Distribution Program (IIDP) is to develop a uniform standardized shipping method among all the subcontracted IIDP centers that will result in minimal loss of quality or quantity of shipped islets (as compared to control islets remaining at the IIDP center). The objective of this Standard Operating Procedure (SOP) is to establish a standardized method for packing and shipping research quality islets to approved investigators.
- 1.2 This SOP was developed based on results from preliminary studies conducted by the Islet Cell Resource Consortium (ICR) and commissioned by the original IIDP Project Officer (PO), and External Evaluation Committee (EEC). It is the prototype for standardization and will be modified as future methods are tested and approved by the PO, the Scientific Officer (SO) and EEC.

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 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.
- 3.3 It is the responsibility of each approved investigator receiving islets through the IIDP to cooperate in returning the shipping boxes and shipping materials to the center supplying the islets.

4.0 Definitions

4.1 <u>Integrated Islet Distribution Program (IIDP)</u>: The IIDP is a contracted 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 PO, SO, the EEC and the CC at City of



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Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP centers.

- 4.2 <u>IIDP Coordinating Center (CC)</u>: 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 <u>Approved Investigators</u>: Researchers who have requested islets from the IIDP for basic science studies and whose research protocols have been reviewed and approved by the EEC.
- 4.4 <u>Islet Allocation System (IA)</u>: 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.

5.0 Materials

5.1 The IIDP will provide each center with the following equipment necessary for shipments:

Company/Manufacturer	Order#	Item Description
Name		
TipTemp	TLCSEN 364A	Ascending and descending
		disposable temperature indicators
Aremco Scientific	Thermosafe -Model	14"x14"x14 5/6" OD Thermosafe
	#355	container
Haemonetics (was SEBRA)	THER1290	Ambient temperature packs
Cryopack	TCP 22	Small ambient temperature packs
Taylor Packaging	1093	Durasorb Underpads
Taylor Packaging	BW/rolls	Bubble Wrap 1/2 "x 12"x125'/
		Roll
Bioexpress	C-3317-5	50 ml centrifuge tubes
Origen	EV120	EVO Origen Bags (120 ml
		optimum volume)
Bioexpress	191306043	Quart Ziplock Bags
Mediatech	99-603-CV	Connaught Medical Research
		Laboratories (CMRL)1066
Gemini Bio Products	100106	Fetal Bovine Serum (FBS) HI-
		BenchMark



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Gemini Bio Products	100512	Human AB Serum (ABS)HI- LOT
		# HIJMUJA
COH Pharmacy/APP	NDC# 63323-543-02	Heparin - Preservative Free 5000
	Product # 504302	USP units/.5ml – 2ml vial
Cellgro, Inc	61-277RG	Ciprofloxacin Hydrochloride – 5
-		gm bottle
COH Printing	NA	IIDP Labels for Outside Boxes

- 5.2 Supplies provided by the IIDP Centers:
 - 5.2.1. Islets for distribution
 - 5.2.2 Completed FedEx Shipping Labels and Return Labels to your center
 - 5.2.3 Islet Allocation Tissue Shipment Forms for appropriate recipients
 - 5.2.4 Packing tape for sealing boxes
 - 5.2.5 Markers for labeling vessels
 - 5.2.6 Supplies for transferring islets

6.0 Procedures

6.1 **Receipt of Supplies**

The majority of supplies should be stored in appropriate dry, temperature-controlled environments (room temperature 16-28°C).

- 6.1.1 The TipTemp Tempasure disposable indicators should be stored at 4°C until use. Note: Extra care should be taken in handling the TipTemp Tempasure disposable indicators. They will register color changes if handled improperly after activation and come in contact with temperatures exceeding 29°C or below 15°C. (See Attachment 8.1)
- 6.1.2. Haemonetics Ambient Gel Packs can be stored at room temperature (16-28°C) Note: Per J. Hertzel from SEBRA Development, the phase change (frozen solid to liquid) for the ambient gel packs occurs at $19.6^{\circ}C \pm 1^{\circ}C$. Charging to solidity is not necessary for proper temperature control. Solidity is only required if packs are needed to cool contents (see 6.2.1 below).
- 6.1.3 The Connaught Medical Laboratory (CMRL 1066), the Heparin, and the Ciprofloxacin (Cipro) should be stored between 2 and 8° C upon receipt.
- 6.1.4 The Fetal Bovine Serum (FBS) and the AB serum should be stored at -5 to -20° C. (*The FBS should be thawed and aliquoted into 50 ml conical tubes and refrozen upon receipt of the 500ml bottles. One conical can be thawed each Confidential Information*Integrated Islet Distribution Program
 City of Hope 1500 East Duarte Road Duarte, CA 91010-3000



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time a bottle of CMRL is prepared, reducing the need for continual freeze/thaw of the FBS.)

6.2 Media Preparation

Origen EV120 tissue culture bags are the standardized shipping vessel to be used for the IIDP distribution program. Each bag can hold up to 20,000 IEQs. The bag should be filled with 120 ml of shipping media regardless of the number of IEQs. CMRL 1066, without sodium bicarbonate is the base media provided by the IIDP for islet distribution. Additives provided by the IIDP include FBS or ABS to be used at 10% v/v, Heparin to be used at 10u/ml, and Cipro to be used at 10mg/ml. The following instructions should be followed for media preparation.

- 6.2.1 Obtain a 500ml bottle of CMRL 1066. Remove 51 ml from the bottle and discard.
- 6.2.2 Add 50ml of either FBS or ABS to the CMRL 1066. (*The choice of using FBS or ABS was based on the cGMP rules of the specific facilities.*)
- 6.2.3 Add 0.5 ml of Heparin (10u/ml) to the media bottle.
- 6.2.4 Add 0.5 ml of Cipro (10mg/ml) to the media bottle.
- 6.2.5 Use CMRL Complete (base media plus all additives) at 120 ml per Origen EV120 bag.

6.3 Packing Instructions

Carefully read and follow the packing instructions below. *Note: Care should be taken to limit the packaged time prior to Fed Ex pick up.*

- 6.3.1 A minimum of 6 Ambient Gel Packs per shipment should be readied for shipment. If extreme temperatures are expected during shipment route, additional packs may be added to help stabilize the shipment. *Note: as of May 9th, 2012 Haemonetics is no longer producing the Sebra Thermasure Ambient Gel Packs. Please see section 6.3.1.4 for instructions to substitute the Sebra Thermasure Ambient Gel Packs with the Cryopack Phase 22 pouches.
 - 6.3.1.1 For shipments where expected temperatures are below 5°C (41°F) gel packs should be warmed to 25-28°C before packing. *Note: The Ambient Gel Packs may be placed in or run under warm running water or placed in a 37*°C *incubator until target temperature is met. The contents of the Ambient Gel Packs will be completely liquid at*



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this point. (See page 13 of Sebra Thermasure Manual for details-Attachment 8.2).

- 6.3.1.2 For shipments where expected temperatures are above 30°C (86°F) gel packs should be refrigerated before shipment to allow contents of gel packs to become slushy before packing. *Note: Ambient Gel Packs may be placed in the refrigerator (for less than an hour) or the -20°C freezer (for less than 30 minutes) several hours to lower the temperature to between 18-21°C to attain a semi-solid consistency. (Actual refrigeration time may vary depending on initial room storage temperature at your laboratory.)*
- 6.3.1.3 For shipments where no extreme temperatures are expected, the gel packs, can be packed directly from room temperature storage or after a brief time in the freezer or refrigerator until a slightly slushy consistency is attained. (20-24°C). (Again, actual refrigeration time may vary depending on initial room storage temperature at your laboratory.) Note: Gel packs should never be used above or below the shipping temperature ranges we are trying to maintain (15-29°C).
- 6.3.1.4 If a center finds themselves short of the standard number of Thermasure Ambient Gel Packs (6) per shipping box, on Thermasure pack may be substituted with four (4) Cryopack Phase 22 gel pouches, place together to cover approximately the same area as the single Thermasure pack. *Note: As many as possible Thermasure Gel Packs should be used in each shipping box, only using the Cryopack Phase 22 pouches when necessary. The Cryopack Phase 22 pouches can be prepped the same as the Sebra Thermasure Ambient Gel Packs listed above.

EXAMPLE: If there are 10 boxes to send out and a center has only 48 Thermasure Se bra Ambient Gels packs in stock, they should divide them in the following manner:

2 boxes with 4 Thermasure and 8 Cryopack Phase 22 pouches 8 boxes with 5 Thermasure and 4 Cryopack Phase 22 pouches This will insure that each box has a majority of the standard Thermasure Ambient Gel Packs supplemented by the smaller Cryopack Phase 22 pouches.

6.3.2 Islets are to be counted and tested for quality control post culturing and prior to shipping. These results should be re-entered into the broadcast system



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during confirmation of final shipping numbers. (Sterility testing can be done on the final preparation on the day of isolation.) Aliquot the appropriate amounts of islet equivalents (IEQs) into the Origen EV120 shipping bags as determined by the Islet Allocation System. Label islet vessels with Isolation Number, Amount of IEQs, and recipient PI name. *Note: Islets must be cultured for at least 12 hours post isolation and must have a viability of greater than 80% and purity greater than 50% in order to be reimbursed by the IIDP.

- 6.3.3 Gather the rest of the materials listed in 5.0 and prepare for packaging. Open one Thermosafe container and remove Styrofoam lid. Cushion bottom of the container with a layer of bubble wrap and one Durasorb Underpad for absorption if leaking should occur.
- 6.3.4 Place two (2) ambient temperature packs on top of the underpad.
- 6.3.5 Obtain TipTemp Tempasure indicator and activate per insert instructions (Pull tab out of the indicator) and tape onto the islet vessel.

Note: See Attachment 8.1. Handle disposable indicator with care in order to avoid triggering of high temperature indicator with body heat.

- 6.3.6 Place pre-loaded islet vessel into a quart bag and seal. Place on the two bottom ambient temperature packs.
- 6.3.7 Place two more Ambient Gel Packs next to the islet vessel, one on each side.
- 6.3.8 Place the final two Ambient Gel Packs on top of the islet vessel.
- 6.3.9 Pack more bubble wrap around the islets and packs to stabilize the package and avoid movement during shipping. Add a second Durasorb Underpad to the top of the contents for padding and leak protection.
- 6.3.10 Replace Styrofoam lid and place completed FedEx Return Material Shipping Label, Instruction Sheet for Material Return, and a Tissue Shipment Form on top before closing outside cardboard box. Secure outside box with packing tape and affix FedEx Shipping Label to outside.

6.4 **Return and Tracking of Shipping Boxes and Supplies**

The Islet Allocation System will help in the tracking and return of supplies to the Islet Isolation Centers from the Approved Investigators. The IIDP will be responsible for the cost of returning the Standardized Shipping Box and Supplies back to their center by



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reimbursement for the shipping costs when an invoice and copies of the FedEx waybills are supplied to Cindy Palmer, Administrative Manager of the IIDP. The following is the course of events to be followed for all shipments within the United States:

(Note: For international FedEx shipments please refer to SOP SHP-003-01.)

6.4.1 The shipping center will enter the IEQs to be shipped (Confirm Recipient screen) and will enter both FedEx tracking numbers (Islet Tracking and Material Tracking) into the Islet Allocation System. In addition, the shipping center should process the shipment by using the on-line FedEx process and click the prompt to alert the recipient of the FedEx tracking number. This will help the recipient investigator follow their shipment through the Fed Ex system and free up time for the centers and the IIDP.

Note: If the investigator has picked up the islets at the distributing center then the center should check "Yes" in the "Direct Pickup" column and "Yes" under "Islets Shipped?" once they are picked up. The box under "Material Shipping Tracking #" will then say "NA" and no further tracking of supplies will be needed.

- 6.4.2 As soon as the center has entered the # IEQs shipped and indicated that the investigator will be shipped islets, the investigator's account will be set automatically to "ineligible". This will act like "on hold" preventing the investigator from receiving additional offers, open or targeted until the User Feedback Form has been completed and the shipping materials have been returned to the supplying Center.
- 6.4.3 The shipping center will include a return FedEx label for the investigator to easily send the shipping materials back using the tracking number created by the center. This will also serve as a receipt to use to invoice the IIDP for each return shipment of shipping material.
- 6.4.4 The investigators will have both FedEx tracking numbers listed in their History of Islet Offers table. Next to the two numbers, is a third column for "Date Materials Returned to Shipping Center". The investigators will enter a date when they send their materials back to the shipping center using the enclosed label and predetermined tracking number. An email will automatically be sent to the shipping center to alert them of the pending shipment.

Note: See Attachment 8.4 "User Guide for Broadcasting Staff 2010" and Attachment 8.5 "User Guide for Investigators 2010" for detailed reference. Confidential Information Integrated Islet Distribution Program City of Hope – 1500 East Duarte Road – Duarte, CA 91010-3000



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- 6.4.5 As soon as possible, the investigator will complete the on-line User Feedback Form (UFF). A copy of this form will be automatically sent to the supplying center as well as the IIDP for tracking purposes.
- 6.4.6 Entering the "Date of Materials Returned to the Shipping Center" and Completion of the UFF will change the investigator's account status from "ineligible" to "eligible".

Note: See Attachment 8.6 "UFF User Guide for Broadcasting Staff" and Attachment 8.7 "UFF User Guide for Investigators" for detailed reference.

6.5 Future Shipments

The IIDP has supplied each shipping center with equipment to begin the Standardization of Shipping Containers. The IIDP will assist each center with helping to ensure that supplies are returned to the originating center through tracking of islet shipments through the Islet Allocation system.

6.5.1 The IIDP will help track the supplies at each by subtracting those needed per shipment from the originally provided. The IIDP Compliance Administrator (Barbara Olack) will be in charge of ordering all supplies for the individual centers and will coordinate needs through center representatives on a routine basis. If a special need arises, the shipping center representative should contact Barbara Olack at 618-539-3969, bolack@coh.org.

7.0 References

- 7.1 SEBRA website: <u>http://www.sebra.com/thermasu.htm</u>
- 7.2 Thermosafe website: <u>http://www.polyfoam.com/content.cfm/cong_othersizes</u>
- 7.3 Tip Temperature Products website: <u>http://www.tiptemp.com/Product.aspx?ProductID=17344</u>
- 7.4 Islet Shipping Container Evaluation (UW).ppt presented at the ICR SCM 5/26/07.
- 7.5 ICR SOP STDY-001-03.
- 7.6 ICR Shipping Study Subcommittee Minutes H:\ABCC\Subcommittees\Shipping: 8/3/07
- 7.7 IATA Guidance Document, Infectious Substances from the 50th Edition (2009) of the IATA Dangerous Goods Regulations (DGR)
- 7.8 University of Wisconsin ITP SOP 001 (Islet Shipping) v3

8.0 Attachments

8.1 Tempasure Plus Handling Instructions



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- 8.2 Ambient Pack Thermasure Instructions
- 8.3 IATA Guidance Document, Infectious Substances IATA, 1/1/009
- 8.4 User's Guide for Broadcasting Staff 2010
- 8.5 User's Guide for Investigators 2010
- 8.6 UFF User's Guide for Broadcasting Staff
- 8.7 UFF User's Guide for Investigators
- 8.8 User Instruction Sheet.
- 8.9 Minimum Required Assessments for Islet Distribution
- 8.10 Ciprofloxacin Stock Preparation

TEMPASURE PLUS Handling Instructions

The TEMPASURE+ combines the ability to accurately record both a critical descending cold temperature and a critical ascending hot temperature in a single miniature plastic housing.



Allow sensor to stabilize at product temperature. Pull safety TAB to activate sensor. Attach with self-adhesive backing.



Tempasure+ Activated ! Low & Hot Temp windows stays clear to indicate acceptable storage.



Permanent visual record of damaging high temp.

Permanent visual record of damaging low temp.



Permanent visual record of damaging high & low temp

Pre-Use Conditioning

To prevent premature response, the TEMPASURE PLUS indicators must be conditioned prior to removing the activation tab and activating the indicators. Condition indicators for a minimum of two hours in a suitable refrigerator, freezer or chamber at or below the temperature shown on the product.

Once conditioned and ready for use, the indicators can be maintained at any temperature below their trigger temperature.

Note: It is the indicator that must be cooled to the conditioning temperature that is going to be monitored. The product need only be maintained below its critical temperature.

Correct Surface Temperature During Indicator Activation

At the moment the TEMPASURE PLUS is activated by pulling the activation tab. The surface to which it is attached (carton, instruction card, product itself, etc.) must be at a temperature below the threshold temperature of the indicator. Otherwise, the heat from the carton or card could be enough to cause a premature triggering of the indicator.

Activation

After proper pre-use conditioning, the monitoring process is started by simply pulling the side tab off. The TEMPASURE PLUS is now set and will trigger if it exposed to a temperature above or below its trigger temperature (this depends on whether the product is an ascending or descending unit).

Storage

TEMPASURE PLUS Temperature indicators can be stored at 22°C (72°F) and 20-60% relative humidity prior to activation. Keep away from heat, such as, heating vents, hot pipes or direct sun.

Hot temperature indicator

Incorporated into the TEMPASURE PLUS is a single level, non-reversible temperature label. This label will change color from a white/silver to a dark silver/black when it is exposed to its trigger temperature.

You should be careful not to place your fingers on these labels, as it is possible to trigger them with the heat from your body.



IATA Dangerous Goods Regulations

50th Edition (English) Effective 1 January 2009

ADDENDUM

Posted 23 December 2008

Users of the IATA Dangerous Goods Regulations are asked to note the following amendments and corrections to the 50th Edition, effective from 1 January 2009.

Where appropriate, changes or amendments to existing text have been highlighted (in yellow - PDF or grey - hardcopy) to help identify the change or amendment.

New or Amended State Variations (Section 2.9.2)

Amend BEG (Belgium)

Amend BEG-05 to read:

BEG-05 The following requirements apply to aircraft registered:

- a) in Belgium no matter where they are operating; and
- b) in a State other than Belgium and which are not required to operate under and in accordance with Annex III to Council Regulation (EC) NO. 3922/1991 of 16 December 1991 on the harmonization of technical requirements and administrative procedures in the field of civil aviation ("EU-OPS"), when they are operating in Belgium:

Aircraft may only carry dangerous goods with the prior approval of the Civil Aviation Authority. Carriage of such goods must be in compliance with the ICAO Technical Instructions.

Application for a general or special authorisation must be submitted to:

Belgian Civil Aviation Authority Operations Department-Dangerous Goods CCN – 2nd Floor Vooruitgangstraat 80 –Bus 5 B-1030 Brussels Belgium

Telephone: + 32 2 277 43 58 Fax: +32 277 42 57 E-mail: koenraad.clerbout@mobilit.fgov.be

This variation does not apply:

- a) to aircraft registered in a State other than Belgium and which are required to operate under and in accordance with EU-OPS providing an approval granted by such a State is held and a copy of this approval is submitted to the Belgian Civil Aviation Authority
- b) unless otherwise specified in the ICAO Technical Instructions, to dangerous goods in the case of overflight of the Belgian territory by foreign operators, provided the operator has a permission from its State of Registry to carry dangerous goods in accordance with the provisions of these Instructions.
- c) to the transport of Dry Ice (carbon dioxide, solid), UN 1845, when used for cooling purposes in combination with goods not subject to the ICAO Technical Instructions. All other requirements of these Instructions concerning the transport of Dry Ice remain applicable.



New or Amended Operator Variations (Section 2.9.4)

Amend 5X (United Parcel Service)

5X-02 Shipments of Dangerous Goods in the UPS Small Package service with an origin and/or destination outside the USA, including shipments of Excepted Quantities, and Biological Substances, Category B, will be accepted by contract only. Combination packagings must be used and packages must not exceed 30 kg gross weight. When applicable, not more than three compatible different dangerous goods may be contained in one outer packaging (5.0.2.11). Other than specifically approved shipments of Dangerous Goods in Excepted Quantities, the following classes/divisions of Dangerous Goods are prohibited from UPS international small package service:

- Class 1 (Explosives)
- Division 2.3 (Toxic Gas)
- Division 4.2 (Spontaneously Combustible)
- Division 4.3 (Dangerous When Wet)
- Division 5.1 (Oxidizer)
- Division 5.2 (Organic Peroxide)
- Division 6.1—Substances requiring a "Toxic" label
- Division 6.2 (Infectious Substances, Category A)
- Class 7—Substances requiring a "Radioactive" White–I, Yellow–II, Yellow–III, or Fissile label.
 - Radioactive Material, Excepted Package shipments are also prohibited.

Add new BZ (BLUE DART AVIATION LTD)

BZ-01 Dangerous goods falling under Class 1, explosives will not be accepted for carriage or handling by Blue Dart Aviation.

BZ-02 Dangerous goods in airmail will not be accepted.

BZ-03 Class 7, only the following radioactive materials will be accepted with effect from June 2009.

- Radioactive material in "excepted packages";
- "Other form" radioactive material packaged in Type A packagings, not exceeding the A₂ values or Transport Index 10;
- The Shipper's Declaration accompanying each shipment of radioactive material in categories I, II or III, must show the following endorsement "This radioactive material is intended for use in, or incidental to, research or medical diagnosis or treatment."

BZ-04 Radioactive & fissile wastes will not be accepted for carriage

BZ-05 The shipper must provide a 24-hour emergency telephone number of a person/agency who is knowledgeable of the hazards, characteristics & actions to be taken in case in the case of an accident or incident concerning each of the dangerous goods being transported. This telephone number, including the country & area code, preceded by the word "Emergency Contact" of "24-Hour number" must be inserted in the Shipper's Declaration for Dangerous Goods, in the "handling information" box.

A "24 hour" emergency telephone number is not required for shipments that do not require a Shipper's Declaration for Dangerous Goods.

BZ-06 Prior clarification must be taken from the operator for sending shipments containing magnets under UN 2807. Refer to instructions under Packing Instruction 902.

BZ-07 Infectious substances, patient specimens, diagnostic specimens, clinical specimens & biological substances (human or animal) will only be accepted if assigned to UN 2814 or UN 2900, as appropriate. The only exceptions to this variation are:



- Dried blood spots, collected by applying a drop of blood onto absorbent material.
- Pathogen –free blood or blood components collected for transfusion or for the preparation of blood products to be used for human or animal transfusion or transplantation.
- Any tissue or organs intended for use in human or animal transplantation.

In these cases, the air waybill must bear a detailed description to enable identification as non regulated material (see Packing Instruction 602 & 8.2)

Amend IJ (Great Wall Airlines)

IJ-01 Only explosives of Division 1.4S packed for passenger and cargo aircraft will be accepted and these must be loaded in the lower deck of all aircraft.

IJ-02 Items with a primary or subsidiary risk of Division 2.1, Class 3, Class 4 and Class 5, when packed for Cargo Aircraft Only, will not be accepted for carriage.

Amend LH (Deutsche Lufthansa / Lufthansa Cargo AG)

Amend LH-03

LH-03 Infectious substances, UN 2814, UN 2900 and UN3373 will not be accepted in air mail.

Delete LH-07 to LH-13.

Amend SQ (Singapore Airlines / Singapore Airlines Cargo)

Amend SQ-06

SQ-06 <u>UN3356</u> Oxygen Generator, Chemical will not be accepted.

Amend US (US Airways)

Amend US-01

US-01 <u>US Airways will not accept shipments for carriage</u> which contain articles and substances listed in these regulations and / or DOT Hazardous Materials Regulations, and revisions thereto, except for the following:

- Articles listed as not restricted or non-regulated in said regulations.
- Carbon dioxide, solid (Dry Ice) in individual packages with <u>5.5 pounds per package / 2.5 kilos</u> or less cooling non-restricted contents.
- Environtainer Unit Load Device equipment with Dry Ice cooling non-restricted contents.
- US Airways Company Material transported as aircraft replacement items.

ACKNOWLEDGEMENTS

Pg. xvii - Insert Dangerous Goods Board member as shown:

Mr. A. McCulloch, United Parcel Service, Louisville, USA

Section 1

Pg. 6 – In Table 1.5.A insert "x" into column 8 for row "Limitations".



Section 2

Pg. 12 – Amend 2.3.2.2 as shown:

2.3.2.2 Wheelchairs/Mobility Aids with Non-spillable Batteries

Wheelchairs or other battery-powered mobility aids with non-spillable batteries (see Packing Instruction 806 and Special Provision A67), provided that the battery is disconnected, the battery terminals are protected from short circuits, e.g. by being enclosed within a battery container, and the battery is securely attached to the wheelchair or mobility aid (see 9.3.15.4 and Figure 9.3.G). Operators must ensure that wheelchairs or other battery-powered mobility aids are carried in such a manner so as to prevent unintentional operation and that the wheelchair/mobility aid is protected from being damaged by the movement of baggage, mail, stores or cargo.

Wheelchairs/mobility aids with gel type batteries do not require the battery to be disconnected provided the battery terminals are insulated to prevent accidental short circuits.

Pg. 14 – Amend Table 2.3.A as follows:

NO	YES	NO	ΥES	NO	Wheelchairs or other battery-powered mobility devices with non-spillable batteries (see Packing Instruction 806 and Special Provision A67), provided the battery terminals are insulated to prevent accidental short circuits, e.g. by being enclosed within a battery container, and the battery is securely attached to the wheelchair or mobility aid. Operators must ensure that wheelchairs or other battery-powered mobility aids are carried in such a manner so as to prevent unintentional operation and that the wheelchair/mobility aid is protected from being damaged by the movement of baggage, mail, stores or cargo.
					Note: Wheelchairs/mobility aids with gel type batteries do not require the battery to be disconnected provided the battery terminals are insulated to prevent accidental short <mark>circuits.</mark>

Section 4

Pg. 214 – Add EQ Codes against UN 2478, Isocyanate solution, flammable, toxic, n.o.s.. For PG II add "E2" and for PG III add "E1".

Pg. 214 – Add EQ Codes against UN 2206, Isocyanates solution, toxic, n.o.s.. For PG II add "E4" and for PG III add "E1".

Pg. 222 – Add EQ Codes against UN 3336, Mercaptans, liquid, flammable, n.o.s.. For PG I add "E3", for PG II add "E1".

Pg. 247 – Add EQ Codes against UN 3259, Polyamines, solid, corrosive, n.o.s.. For PG I add "E0", for PG II add "E1".

Pg. 317 – Amend Special Provision A44 as follows:

A44 The entry chemical kits or first aid kits is intended to apply to boxes, cases, etc. containing small quantities of one or more compatible items of dangerous goods which are used for example for medical, analytical or testing or repair purposes. The only dangerous goods, which are permitted in the kits, are substances which may be transported as:

- excepted quantities as specified in Column F of Table 4.2, providing the inner packagings and quantities are as prescribed in 2.7.5.1<u>Table2.7.A</u> and 2.7.8.22.7.5.1(a);
- limited quantities under 2.8.1 2.8.2.1.



Pg. 320 – Amend Special Provision A99 as follows:

A99 Irrespective of the limit specified in Column L of the List of Dangerous Goods (Subsection 4.2), a lithium battery or battery assembly that has successfully passed the tests specified in the UN Manual of Tests and Criteria, Part III, sub-section 38.3 and that meets the requirements of Packing Instruction <u>903</u> <u>965 for lithium</u> <u>ion batteries, and Packing Instruction 968 for lithium metal batteries</u> as prepared for transport may have a mass exceeding 35 kg G, if approved by the appropriate authority of the State of origin. A copy of the document of approval must accompany the consignment.

Pg. 322 – Amend Special Provision A123 as follows:

A123 This entry applies to Batteries, electric storage, not otherwise listed in Subsection 4.2 – List of Dangerous Goods. Examples of such batteries are: alkali-manganese, zinc-carbon, nickel-metal hydride and nickel-cadmium batteries. Any electrical battery or battery powered device, equipment or vehicle having the potential of a dangerous evolution of heat must be prepared for transport so as to prevent

- (a) a short-circuit (e.g. in the case of batteries, by the effective insulation of exposed terminals; or, in the case
 of equipment, by disconnection of the battery and protection of exposed terminals) is forbidden from
 transport; and
- (b) accidental activation.

Pg. 322 – Amend Special Provision A130 as follows:

A130 When this material meets the definitions and criteria of other classes or divisions as defined in Section 3, it must be classified in accordance with the predominant subsidiary risk. Such material must be declared under the proper shipping name and UN number appropriate for the material in that predominant class or division, with the addition of the name applicable to this radioactive material according to Column B in Subsection 4.2 – List of Dangerous Goods, and must be transported in accordance with the provisions applicable to that UN number. In addition, all other requirements specified in 10.5.9 must apply, except 10.8.3.9.1, Step 3 10.3.11 apply.

Pg. 325 – Amend Special Provision A163 as follows:

A163 (340) Chemical kits, first aid kits and polyester resin kits containing dangerous goods in inner packagings which do not exceed the quantity limits for excepted quantities applicable to individual substances as specified in Column F of Table 4.2 may be transported in accordance with 2.7. Division 5.2 substances, although not individually authorized as excepted quantities in Table 4.2, are authorized in such kits and are assigned Code E2 (see 2.7.1.1 2.7.4.1).

Section 5

Pg. 330 – Amend 5.0.2.3 as follows:

Unless otherwise provided for, the UN specification packagings detailed in the packing instructions must meet the performance test requirements of the relevant packing group shown in Column F <u>E</u> of the List of Dangerous Goods for the particular article or substance.

Pg. 373 – Amend Packing Instruction 306 to add the following two new UN numbers:

NNER PACKAGINGS									
Desc.	Glass, Earthenware	Plastic	Metal (not aluminium)	Aluminium	Glass ampoule	PPR (see below)			
Spec.	IP1	IP2	IP3	IP3A	IP8				
Unit	L	L	L	L	L				
UN 1250	1.0	F	1.0	F	0.5	5			
UN 1305	1.0	F	1.0	F	0.5	5			



Pp. 437/438 – Amend Packing Instruction 602 as follows:

This instruction applies to UN 2814 and UN 2900.

Packagings must meet the requirements of 6.5 and must be marked as required by 6.0.6 6.5.3.1.

•••

Substances consigned refrigerated or frozen (wet ice, prefrozen packs, Carbon dioxide, solid [dry ice]): Ice, Carbon dioxide, solid (dry ice) or other refrigerant must be placed around the secondary packaging(s) or alternatively in an overpack with one or more complete packages marked in accordance with <u>6.0.6 6.5.3.1</u>. Interior support must be provided to secure the secondary packaging(s) or packages in the original position after the ice or Carbon dioxide, solid (dry ice) has dissipated. If ice is used, the outer packaging or overpack must be leak-proof. If Carbon dioxide, solid (dry ice) is used, the outer packaging or overpack must permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging must maintain their integrity at the temperature of the refrigerant used.

Pg. 511, 512, 514, 515, 517, 519 – Amend Part 1 of Packing Instructions 965 to 970 as follows:

General requirements

Cells and batteries must be packed in strong outer packagings that conform to 5.0.2.4, 5.0.2.6.1 and 5.2.12.1 5.0.2.12.1.

Insert the following new text into Part 1 of Packing Instructions 965, 967, 968 and 970 as follows:

<u>Overpacks</u>

Individual packages each complying with the requirements of Part 1 may be placed in an overpack. The overpack may also contain packages of dangerous goods or goods not subject to these Regulations provided that there are no packages enclosing different substances which might react dangerously with each other. An overpack must be marked with the word "Overpack" and labelled with the lithium battery label (Figure 7.4.I), unless the label(s) on the package(s) inside the overpack are visible.

Any person preparing or offering cells or batteries for transport must receive adequate instruction on these requirements commensurate with their responsibilities.

Pg. 513 – Amend Packing Instruction 966 as follows:

Part 2

Part 2 requirements apply to each cell or battery type that has been determined to meet the criteria for assignment to Class 9.

Each cell or battery must:

- 1. Be of the type proven to meet the requirements of each test in the UN *Manual of Tests and Criteria*, Part III, subsection 38.3.
- 2. Incorporate a safety venting device or be designed to preclude a violent rupture under conditions normally incident to transport and be equipped with an effective means of preventing external short circuits.

Each battery containing cells or series of cells connected in parallel must be equipped with an effective means, as necessary, to prevent dangerous reverse current flow (e.g. diodes, fuses).

Additional requirements

- all lithium ion cells and batteries prepared for transport as Class 9 must be protected against short circuits;
- the completed package for the cells or batteries must meet Packing Group II packaging standards;
- each completed package containing lithium cells or batteries must be marked and labelled in accordance with the applicable requirements of Section 7;
- the equipment and the packages of lithium cells or batteries must be placed in an overpack. The overpack must bear applicable marks and labels as set out in 7.1.4 and 7.2.7;
- for the purpose of this packing instruction, "equipment" means apparatus requiring the lithium batteries with which it is packed for its operation.



COMBINATION PACKAGINGS								
	Quantity per package Passenger aircraft	Quantity per package Cargo Aircraft Only						
Quantity of lithium ion cells and batteries per overpack, excluding weight of equipment	5.0 kg	35.0 kg						

OUTER	РАСКА	GINGS													
Туре	Drums					Jerricans			Boxes						
<u>Desc</u>	<u>Steel</u>	<u>Alum-</u> inium	<u>Ply-</u> wood	<u>Fibre</u>	Plastic	<u>Other</u> metal	<u>Steel</u>	Alum- inium	Plasti c	<u>Steel</u>	Alum- inium	<u>Wood</u>	<u>Ply-</u> wood	Recon- stituted wood	<mark>Fibre-</mark> board
Spec	<u>1A2</u>	<u>1B2</u>	<u>1D</u>	<u>1G</u>	<u>1H2</u>	<u>1N2</u>	<u>3A2</u>	<u>3B2</u>	<u>3H2</u>	<u>4A</u>	<u>4B</u>	4 <u>C1</u> 4C2	<u>4D</u>	<u>4F</u>	4G

Pg. 518 – Amend Packing Instruction 969 as follows:

Part 2

Additional requirements

- all lithium metal cells and batteries prepared for transport as Class 9 must be protected against short circuits;
- the completed package for the cells or batteries must meet Packing Group II packaging standards;
- each completed package containing lithium cells or batteries must be marked and labelled in accordance with the applicable requirements of Section 7;
- the equipment and the packages of lithium cells or batteries must be placed in an overpack. The overpack must bear
 applicable marks and labels as set out in 7.1.4 and 7.2.7;
- for the purpose of this packing instruction, "equipment" means apparatus requiring the lithium batteries with which it is packed for its operation.

Lithium metal cells and batteries prepared for transport on Passenger Aircraft as Class 9:

- must be packed in rigid metal intermediate or outer packaging;
- cells and batteries must be surrounded by cushioning material that is non-combustible and non-conductive, and placed inside an outer packaging.

COMBINATION PACKAGINGS									
	Quantity per package	Quantity per package							
	Passenger aircraft	Cargo Aircraft Only							
Quantity of lithium metal cells and batteries per overpack, excluding weight of equipment	5.0 kg	35.0 kg							

OUTER PACKAGINGS																
Туре	Drums				Jerricans			Boxes								
<u>Desc</u>	<u>Steel</u>	Alum- inium	<u>Ply-</u> wood	<u>Fibre</u>	Plastic	Other metal	<u>Steel</u>	Alum- inium	Plasti c	<u>Steel</u>	Alum- inium	<u>Wood</u>	<u>Ply-</u> wood	Recon- stituted wood	<mark>Fibre-</mark> board	Plastic
Spec	<u>1A2</u>	<u>1B2</u>	<u>1D</u>	<u>1G</u>	<u>1H2</u>	<u>1N2</u>	<u>3A2</u>	<u>3B2</u>	<u>3H2</u>	<mark>4A</mark>	<u>4B</u>	4 <u>C1</u> 4C2	4D	4F	4G	<mark>4H1</mark> 4H2

Section 7

Pg. 576 – Revise requirements for lithium battery label as follows:

Colour: The border of the label must have red diagonal hatchings. Text and symbols black on a white <u>contrasting</u> background.

Section 10

Pg. 645 - In paragraph 10.3.11.1.3(b) and 10.3.11.1.3(c) amend "Table 10.3.C" to read "Table 10.3.D".

Plasti 4H1 4H2



Pg. 645 – Amend paragraph 10.3.11.1.5 as follows:

10.3.11.1.5 Empty Packages

An empty packaging which had previously contained radioactive material with an activity not exceeding the limit specified in the column headed "Instruments and Articles Materials — Package Limits" in Table 10.3.C 10.3.D may be classified as UN 2908, Radioactive material, excepted package empty packaging, provided that:

Appendix G.3

Pg. 815 – Add Austrian Airlines to the list of currently validated airlines.



Integrated Islet Distribution Program

ISLET DATA ENTRY SYSTEM

USER GUIDE for Broadcasting Staff 2010

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1.0. General Guidelines

1.1. Navigation

The Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Main Menu (e.g. access the Enter New Isolation data form). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for completing each section of the Enter New Isolation Data Form are presented in the remaining sections of this User's Guide.

1.2. Screens

1.2.1 Screen Format

All of the Islet Allocation data entry screens are designed to be a 'single page' in which the data for each section of the IDES data form are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

1.2.2 Data Entry Formats

Different formats are used within the IDES Data Form to capture the data.

- 1.2.2.1 Text Boxes
 - o Data must be typed in
 - o Used to capture text, dates, and numeric values such as a laboratory value
 - Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- o Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- o Click on the arrow to display the list choices
- o Click on the desired option and it will be displayed in the box

1.2.2.3 Check Boxes

- Used when one of several options must be chosen e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- There are instances when multiple check boxes can be checked in response to the question

1.3 System Messages

1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the

validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1 Date Field Formats

	(mm/dd/yy)
	The system will automatically enter the forward slashes (/) as you enter the date.
1.3.1.2	Time Field Formats
	(hh:mm)
	The system will automatically enter the colon (:) as you enter the time.
1.3.1.3	Date Field Ranges
	06/04/2010 (mm/dd/yy)
	The system will display a message that the date is out of range and that the latest date that may be entered is the current date.
1.3.1.4	Numeric Field Formats
	Percent of Trapped Islets (xxx.xxx)
	This is one example of a numeric field format within the ICP Data Form.
1.3.1.5	Numeric Field Ranges
Acceptable Numeric Value	→Percent of Trapped Islets 75.34 % (xxx.xxx)
Numeric Value Out of Range	Percent of Trapped Islets 110.93 % (xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

Acceptable

2.0 Login to the Islet Data Entry System (IDES)

Login Screen - The system displays the login screen. Enter your username and password and then click on Login. IIDP assigns the username and password.



Main Page for the Islet Data Entry System (IDES) - Click on [IIDP Home] at any time to return to the Main Page.



3.0 New Process Options – Quick Broadcast or Complete a Distribution Record



Main Page - Click on the menu option [Enter New Distribution Record] under [Record for All Isolations].

The system will then display the screen to select whether to broadcast an isolation or to complete a distribution record.

Click on **[Quick Broadcast]** to broadcast an isolation OR click on **[Complete a Distribution Record]** to complete a distribution record.

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egrated Islet Distribution Program (IIDP) of Hope ghts reserved. ning Site
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4.0 Broadcast an Isolation – Quick Broadcast

Main Page - Click on the menu option [Enter, New Distribution Record] under [Record for All Isolations].

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	Records for All Isolations	Documentation		
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	Integrated Islet Distribution Pro-	P Developed and maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved. Training Site		3
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The system will then display the screen to select whether to broadcast an isolation or to complete a distribution record.

Click on [Quick Broadcast] to broadcast an isolation.



The system will display the UNOS ID and Islet isolation ID screen.

UNOS ID and Islet Isolation ID Screen - Enter the UNOS ID number and the Islet Isolation ID number and select the Islet Source for the new Islet Isolation and then click on **[Submit].** Click on **[Cancel]** to return to the Main Page.

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The system will compare the newly entered ID numbers with existing ID numbers in the system to prevent duplication of IDES data forms.

If the system finds a match with existing ID number(s), the system will display a message that the ID number(s) entered match existing ID number(s) – Refer to page 12.

If the system does not find a match, the system will display the Quick Broadcast Detail Summary screen – refer to page 15.

Click on [Edit ID] to re-enter the UNOS ID number and the Isolation ID number – Refer to page 11.

OR

Click on [View All Entries] to view all the Islet Allocation and/or IDES data forms that exist in the system - Refer to page 13.



View All Entries screen - This system displays all of the Distribution Records entered for your specific institution. Click on any of the Headers to sort by the designated header (e.g., click on **[UNOS ID #]** to sort the entries by the UNOS ID #).

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	2	[Edit]	AKJ_TEST_877	877_test_akj	IIDP	*	01/16/2010	Basic Science Research	University of Miami	Amy Jacobs		
	з	[Edit]	WYX456	h567	CIT	*	01/14/2010	Basic Science Research	University of Miami	Barbara Olack		
	4	[Edit]	AKJ_TEST_676	676_test_akj		*	01/09/2010	Clinical Transplant	University of Miami	Amy Jacobs		
	5	[Edit]	AKJ_TEST_878	878_test_akj	IIDP	*	01/09/2010	Basic Science Research	University of Miami	Amy Jacobs		
	6	[Edit]	M008	M008	IIDP	*	01/08/2010	Basic Science Research	University of Miami	Staff Member		
	7	[Edit]	M009	M009	IIDP	*	01/08/2010	Basic Science Research	University of Miami	Staff Member		
	8	[Edit]	FF01	FF01	IIDP	*	01/07/2010	Basic Science Research	University of Miami	Staff Member		
	9	[Edit]	XYZ098	h786	IIDP	*	01/06/2010	Basic Science Research	University of Miami	martha antler		
	10	[Edit]	ABC567	h234	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Barbara Olack		
	11	[Edit]	JEN0104	104	CIT	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	12	[Edit]	JEN123	12345	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	13	[Edit]	JEN321	32111	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		

NOTE: In these examples screens, because it is from the training site (identical to the production ('real') site) all of the IDES data forms entered from the University of Miami. However, in the production ('real') site, users of each institution will only be able to see IDES data forms for their institution.

View All Entries screen - Find the desired Distribution Record and click on [Edit] to view and/or edit the Distribution Record.

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	2	[Edit]	AKJ_TEST_877	877_test_akj	IIDP	*	01/16/2010	Basic Science Research	University of Miami	Amy Jacobs		
	3	[Edit]	WYX456	h567	СІТ	*	01/14/2010	Basic Science Research	University of Miami	Barbara Olack		
	4	[Edit]	AKJ_TEST_676	676_test_akj		*	01/09/2010	Clinical Transplant	University of Miami	Amy Jacobs		
	5	[Edit]	AKJ_TEST_878	878_test_akj	IIDP	*	01/09/2010	Basic Science Research	University of Miami	Amy Jacobs		
	6	[Edit]	M008	M008	IIDP	*	01/08/2010	Basic Science Research	University of Miami	Staff Member		
	7	[Edit]	M009	M009	IIDP	*	01/08/2010	Basic Science Research	University of Miami	Staff Member		
	8	[Edit]	FF01	FF01	IIDP	*	01/07/2010	Basic Science Research	University of Miami	Staff Member		
	9	[Edit]	XYZ098	h786	IIDP	*	01/06/2010	Basic Science Research	University of Miami	martha antler		
	10	[Edit]	ABC567	h234	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Barbara Olack		
	11	[Edit]	JEN0104	104	CIT	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	12	[Edit]	JEN123	12345	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
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The system will display the **Distribution Record Detail Summary** screen - refer to page 63.

Quick Broadcast Detail Summary - Click on [Edit] to display the desired section to complete.

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Save Record & Broadcast Now									

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Integrated Is	slet Distribu	tion Program	Note: The Additional Islet Islet Assessments – Final will be non-functional unt	t Assessment ; and Optiona il after the Qu	s – Preliminary; Additional Il Islet Assessments sections ick Broadcast is complete.				
The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast.									
The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast.									
Menu ready for use	Menu ready for use The Optional Islet Assessments is optional and can be completed any time after the Quick Broadcast.								

Quick Broadcast Detail Summary - The system will display the **Status** of each section as '**New'**, '**Complete'**, or '**Incomplete'**. The Donor Information, Characterization of Islets for Distribution Information, and Research Islet Transportation Information sections need to be '**Complete'** for the Quick Broadcast Form to be considered complete.

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			Section	Section Status					
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	Edit]	Additional Islet As	sessments - Final	New					
	Edit	Optional Islet Asse	essments	New					
		8	ave Record & Broadcast Now						
Integrated Islet Distribution Program Note: The Additional Islet Assessments – Preliminary; Additional Islet Assessments sectio will be non-functional until after the Quick Broadcast is complete. The Additional Islet Assessments – Preliminary section must be completed within 10 days of the Quick Broadcast. The Additional Islet Assessments – Final section must be completed within 30 days of the Quick Broadcast. The Optional Islet Assessments is optional and can be completed									
E Menu ready for use	Menu ready for use any time after the Quick Broadcast.								

NOTE: The user may randomly select the order in which to complete each section (e.g., Donor Information section, then the Research Islet Transportation Information section, and then the Characterization of Islets for Distribution Information section). However for the purpose of this User's Guide, the sections will be discussed in the order as listed above.
Donor Information section - Complete the questions in the Donor Information section. Place the cursor on the question mark (2) icon to receive instructions on how to answer the questions

(?) ICON to receive instructions on how to answ	ver the questions.	
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NOTE: The UNOS ID number and are displayed in the top left hand	the Isolation ID number corner of every section.	Islet Shipment SummaryIIDP Islet Cap:2,000,000IIDP Islets Remaining:1,928,000CIT Islet Cap:500,000
		CIT Islets Remaining: 482,000
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 Image: Second state in the second state is a second state in the second state is a second	will auto-fill with the UNOS and umbers initially entered. as for research purposes obtained by the OPO and obtained in order to broadcast an en the other questions are not herefore, just need to click on ge for the message that will be Pink indicates a required field.	AKJ_TEST_877 B77_test_akj No Yes Ves
9. 2 Ethnicity/Race: 10. 2 CMV Status: 11. 2 ABO Blood Group: 12. 2 HLA Information: 12.1 Class I		
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Each section in the form is considered a 'single page'. You can use the **scroll bar** to scroll down to the bottom of the section. The **Donor Information section** is continued on the next page.

Consent Not Obtained - This message will be displayed if 'No' is checked for question 3. Refer to **4.1 Consent Has Not Been Obtained.**

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Donor Information section (continued)

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			Positive	Negative	Not Documented	Cannot Disclose	Not Done	Indeterminate		
		HTLV I/II	Positive	Negative	Not Documented	Cannot Disclose	Not Done	Indeterminate		
		Syphilis	📃 Positive	Negative	Not Documented	Cannot Disclose	Not Done	Indeterminate		
		HbsAg	Positive	🗌 Negative	Not Documented	Cannot Disclose	Not Done	🔲 Indeterminate		
		HBc	📃 Positive	🗌 Negative	Not Documented	Cannot Disclose	📃 Not Done	🔲 Indeterminate		
		? нсv	🔲 Positive	🔲 Negative	Not Documented	🔲 Cannot Disclose	🔲 Not Done	🔲 Indeterminate		
	14.	Cause of Dea	th: Gr	ay indicates a	conditional field. A fie	ld		~		
		14.1 If	OTHER, spe ba	at is gray may used on the ans	turn pink and be requin swer to another question	on.				
	15.	Medical Histor	y:							
	16.	🕐 Was this pane	reas obtained fro	om a suspected Ty	pe II diabetic donor?		No	T Yes	~	
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Donor Information section (continued)

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	16. 🕐 Was thi	s pancreas obtained	from a suspected Typ	pe II diabetic donor?		No No	🗖 Yes	^
	16.1	? If YES, indic	ate why you suspect	this pancreas as being from	n a TYPE II diabeti	c donor (Check all that	t apply):	
			16.1.1	Family History of	Diabetes			
			16.1.2	Serum HbA1c val	ues			
				16.1.2.1		*		
			16.1.3	Other				
				16.1.3.1	If OTHER,			
	17. ? Was thi	s papereas obtained	from a confirmed Tv	pe II diabetic dopor?	specify.	N o	T Yes	
	17.1	If YES, indic	ate how you confirme	ed this pancreas as being fr	rom a TYPE II diabi	etic donor (Check all t	hat apply):	
			17.1.1	Donor charts and	/or hospital files do	ocumented diabetes st	atus	
			17.1.2					
				17.1.2.1	If OTHER,			
				1111111	specify:	I		_
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		Т	TD	Developed and maintaine	d by the Integrated	d Islet Distribution Pro	gram (IIDP)	
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on [Edit] to complete the next section. Please note the change in 'Status' of the Donor Information section.

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[Edit]	Research Islet Transportation Information	New		
[Edit]	Additional Islet Assessments - Preliminary	New		
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The user may close out of a Quick Broadcast Form at any time - click on **[Save Record & Broadcast Now]** to submit the Islet Cell Processing Data Form to the system. The system will display the **[Broadcast Message]** screen – refer to page 31.

Characterization of Islets for Distribution Information section - Complete the questions in the Characterization of Islets for Distribution Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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4. 💽 Date and t 5. Enter islet cou	ime dissection in lab s nts below for the fract	tarted:	system for distri	bution, e.g., mos	Hour clock) t pure fractio	on, less pure frac	v tion, and impure	Not Documented fraction:	
When the co tak	n was Label this islet fraction as unt one of the cen? following	Total IEQs available for shipping	Islet Viability: Indicate Inclusion Dye used:	Islet Viability: Indicate Exclusion Dye used:	Islet ¥iability	Islet Purity: Percent dithizone positive cells:	Islet Purity: Percent beta cells:		
Add	Islet Count		Submit						
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Click on **[Add Islet Count]** to enter data about an islet count. The system will display a separate screen to enter the islet count data – refer to the next page.

Characterization of Islets for Distribution Information section (continued): [Add Islet Count] screen – Complete the questions in the Islet Count screen. Place the cursor on the question mark (?) icon to receive instruction on how to answer the questions.

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Label this fraction as one of the following:	
Total IEQs available for shipping:	= Uot
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2. Indicate	
2.1 If Off	
3. Duratio If OTHER, specify:	
Islet Viability:	Net Date
4. 2 Date an	Jot mented
5. Enter islet (Not Done
Islet Purity: Percent beta cells:	Not Done
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Click on **[Add Islet Count]** to add the Islet Count to the form. The system will add the islet count data to the form – refer to the next page.

Characterization of Islets for Distribution Information section (continued) – Islet Count added to the Characterization of Islets for Distribution Information section

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	2.1	IF OTHE	R, describe:										
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5	5. Enter	islet co	unts below for	the fractions e	entered in the	system for dist	ribution, e.g., n	nost pure fra	action, less pur	e fraction, an	id impure f	raction:	
	[When was	Label this	Total IEQs	Islet	Islet	Islet	Islet	Islet			
			the islet count	fraction as one of the	available for	Viability: Indicate	Viability: Indicate	Viability	Purity: Percent	Purity: Percent			
			taken?	following	shipping	Inclusion	Exclusion Dve used:		dithizone nositive	beta cells:			
						.,	5,0 0000		cells:				
		[Edit]	Post- Purification	Most Pure	20000	Syto Green	Trypan Blue	94	95	74	[Delete]		
		[Edit]	Post-Culture	Less Dure	20000	Acridine	Propidium	95	94	73	[Delete]		
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Click on [Add Islet Count] to enter additional islet count data. Click on [Delete] to delete the islet count data previously entered. Click on [Submit] to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on [Edit] to complete the next section. Please note the change in 'Status' of each section.



The user may close out of an Quick Broadcast Form at any time - click on [Save Record & Broadcast Now] to submit the Quick Broadcast Form to the system. The system will display the Broadcast Message screen – refer to page 31.

Research Islet Transportation Information section - Complete the questions in the Research Islet Transportation Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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	IIDP Islets Remaining: 1,842,975	
	CIT Islet Cap: 500,000	
	CIT Islets Remaining: 418,000	
Unos ID: AJ_TEST3845 Isolation ID: test3845_akj		
1. Indicate the type of islets you are willing to provide from this isolation (Check all that apply):		
1.1 Fresh (in culture media for local pick up only)		
1.2 Cultured		
1.2.1 If CULTURED, what is the estimated length of time the islets will be cultured prior to shipment?	Days Hours	
2. Specify the shipping media formulation:		
2.1 2 Select base medium used for shipping:	Connaught Medical Research Laboratories (CMRL) 1066	2
2.1.1 If OTHER, specify:		
2.1.2 If CMRL is NOT selected, enter the reason for deviating from the standard islet shipping protocol:		
2.2 Select the serum used as an additive for shipping:	▼	
2.2.1 If OTHER, specify:		
2.2.2 If OTHER, enter the reason for deviating from the standard shipping protocol:		~
Done	😜 Internet	🐴 = 🔍 100% · 💡

Research Islet Transportation Information section (continued) – If 'Yes' is selected for question 2.5, then the system will make guestion 2.5.1 functional – refer to the next page.

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2.3 Was Ciprofloxacin added to the shipping medium?	, No	Ves		^
2.3.1 If NO, enter the reason for deviating from the standard shinning protocol:				
2.4 [2] we used a deduct the relation of derivating from the standard shipping protocol.		•		
2.4 Lis was reparin added to the shipping medium?	L No	Yes		
2.4.1 If NO, enter the reason for deviating from the standard shipping protocol:				
2.5 Were any other additives added by your laboratory?	🗖 No	Yes	Not	
2.5.1 If YES, select ALL the additives that were used and indicate the amount of each:			Documented	
Glutathione				
HEPES				
Insulin Transferrin Selenium (ITS)	Amount use	d (ontional)		=
L-glutamine (Glutamate, Glutamax)	Amount use	a (optional)		
Click on an additive to add. Above is a list of selected additives.				
Add other additives				_
Specify additional additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the ad	ditive to the list. Repeat as nee	ded.):		
3. Indicate the type of vessel and the amount of media to be used for islet shipping:	×	mL		
3.1 If OTHER vessel, specify:				
4. LS Shipping vessel should be packaged per IIDP Standardized Shipping SOP using:	6 Ambient shipping pack	5 🚩		~
Done		😜 Internet		100% 🔹 💡

Research Islet Transportation Information section (continued) – If 'Yes' is selected for question 2.5, the system will make question 2.5.1 functional. Select the additive(s) from the drop down list and/or enter another additive by the 'Add other additives' process. Click on the selected additive to enter the amount used in the textbox. Repeat the process for each additive selected.

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# IIDP - Islet Cell Processing Data Form: Research Islet	6	• 🔊 - 🖃 🖶	🔹 Page 🔹 Safety 👻 Tools 👻 🕡	• »
2.3 2 Was Ciprofloxacin added to the shipping medium?	No	Ves		^
2.3.1 If NO, enter the reason for deviating from the standard shipping protocol:				
2.4 2 Was Heparin added to the shipping medium?	No	Ves		
2.4.1 If NO, enter the reason for deviating from the standard shipping protocol:				
2.5 Were any other additives added by your laboratory?	No	Ves	Not	
2.5.1 If YES, select ALL the additives that were used and indicate the amount of each:			Documented	
Glutathione HEPES Insulin-Like Growth Factor-1 (IGF-1) L-glutamine (Glutamate, Glutamax) Nicotinamide (Niacinamide)	30 Amount use	d (optional)		
Click on an additive to add. Above is a list of selected additives.				
Add other additives Specify additional additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additives (Enter an additives) (Enter an addi	dditive to the list. Repeat as nee	ded.):		
3. LE Indicate the type of vessel and the amount of media to be used for islet shipping:	×	mL		
3.1 If OTHER vessel, specify:				
4. I Shipping vessel should be packaged per IIDP Standardized Shipping SOP using:	6 Ambient shipping pack	s 💌		
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Research Islet Transportation Information section (continued)

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 4. If OTHER vessel, specify: 4. Shipping vessel should be packaged per IIDP Standardized Shipping SOP using: 4.1 If OTHER, specify: 4.2 If 6 Ambient shipping packs is NOT selected, enter the reason for deviating from the standard islet shipping protocol: 5. Indicate the estimated date and time you plan to start packaging these islets for shipment (i.e., deadline when you need a finalized list of investigators who will be shipped islets): 6. Comments: 	6 Ambient shipping packs ▼	
Developed and maintained by the Integrated I at City of Hope © 2010 All rights rese Training Sit	Islet Distribution Program (IIDP) e erved. te	
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on [Edit] to complete the next section. Please note the change in 'Status' of each section.

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		Section	Section Status		
	[Edit]	Donor Information	Complete		
	[Edit]	Characterization of Islets for Distribution Information	Complete		
	[Edit]	Research Islet Transportation Information	Complete		
	[Edit]	Additional Islet Assessments - Preliminary	New		
	[Edit]	Additional Islet Assessments - Final	New		
	[Edit]	Optional Islet Assessments	New		
Integrated Islet	Distribu	DP Developed and maintained by the Integr at City of © 2010 All right tion ProgramFrainin	ated Islet Distribution Hope s reserved. g Site	Program (IIDP)	
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The user may close out of a Quick Broadcast Form at any time - Click on **[Save Record & Broadcast Now]** to submit the Quick Broadcast Form to the system. The system will display the **Broadcast Message** screen - refer to the next page.

Islet Availability Broadcast Message – The system will display the Broadcast Message screen when a new Islet Cell Processing Data Form has been submitted and islets are available. [Confirm Contact Information] and [Review Isolation Data] should be reviewed and/or edited as needed prior to clicking on [Broadcast Now] to broadcast the message about the availability of islets. Refer to the message on the Broadcast Message screen – essentially that it is important to review the information before clicking on [Broadcast Now] because once the message is broadcast, you cannot re-broadcast the message if changes are later made to the contact or islet isolation data.



IIDP Approved Broadcast Staff Contact Information – Edit the contact information as needed. The IIDP Approved Broadcast Staff entering the Islet Isolation data and preparing to send the Broadcast Message is automatically pre-populated as the Primary Contact.

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IIDP - Islet Cell Processing Data Form: Confirm Contact	😰 Help Desk	
Confirm Authorized Data Entry Staff Contact Information and Set Automatic Email Notifi	ications	
Primary Contact:		
First Name: Amy Last Name: Jacobs		
E-mail address: ajacobs@coh.org		
Automatic E-mail Notifications: On 🗸		
Additional Contact (1)		
Contact Person: martha antler 🗸		
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Additional Contact (2)		
Contact Person: Edward Lee		
Automatic E-mail Notifications: Off 🐱		
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Developed and maintained by the Integrated Islet Distribution Pro at City of Hope © 2010 All rights reserved.	ogram (IIDP)	
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Click on [Submit] to return to the [Broadcast Message] screen.

Islet Availability Broadcast Message – The system returns the user to the Broadcast Message screen after [Confirm Contact Information] and/or [Review Isolation Data] review.

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Upon clicking on the "Broadcast Now" button below, a notification will be se all qualified investigators on the approved investigator list stating that islets available from your laboratory. Shortly, you and/or other center represent will receive a list of interested investigators who have responded to your po requested islets. Before submitting this data for broadcast, please make sure your entered all available isolation information and that all staff con information has been verified. Once you broadcast this announceme will <u>not</u> have the opportunity to rebroadcast the posting at a later tim <u>Confirm Contact Information</u> Review Isolation Data Broadcast Now Developed and maintained by the Integrated Islet D <u>at City of Hope</u> © 2010 All rights reserved. Training Site-	nt out to are now itatives sting and have that nt, you e.		
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Click on **[Broadcast Now]** to send the Islet Availability Broadcast Message to the designated IIDP Approved Investigators. The system will then display a confirmation message – refer to the next page.

Islet Availability Broadcast Message – The system will display a confirmation message that the Broadcast Message has been sent.



Click on [Return to menu] and the system returns the user to the Main Page.

Islet Offer Accepted Email Message – this is an example of an email message that the IIDP Broadcast Staff receives when a PI accepts an islet offer.

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🚯 This message was se	ent with high importance.			
From:	iidp-email@coh.org [iidp-email@coh.org]		Sent: Sat 1/9/2010 4:42	2 PM
To:	Jacobs, Amy			
Cc:	Teleb Office Associated			
Subject:	Islet Offer Accepted			
Accachiments.				
		Islet Offer Accepted		
The following	islet offer has been accepted:			
UNOS ID: AKJ_	_TEST_878			
Amount Accel	ed. 9000 nted: 5000			
PI Name: Mich	hael L. McDaniel			
Institution: Ur	niversity of Miami			
Shipping Add	ress: Dept. of Pathology & Immunology			
	4566 Scott Ave.			
	St. Louis, MO.63110			
Diance legin to	the Jelet Data Fature Custom for further			
Please login to	the <u>Islet Data Entry System</u> for further	uetan.		
Dope				own Zone (Mived)
- Done				own zone (mixed)

4.1 Consent Has Not Been Obtained

Consent Not Obtained – This message will be displayed if 'No' is checked for question 3. The rest of the questions will not need to be completed. Click on **[Submit]** at the end of the page. Refer to the next page for the next step in the process.

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	CIT Islets Remaining: 482,000
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1. INOS ID Number:	877
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3. Was the informed by your If consent for research was not obtained and confirmed, then the islets may not be shipped throug	h the Distribution
System.	
4. LLI Age:	
5. [?] Gender:	
6. Reight:	~
7. 💽 Weight:	~
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9. Ithnicity/Race:	✓
10. 🕐 CMV Status:	✓
11. 🕐 ABO Blood Group:	✓
12. Il HLA Information:	
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The **Distribution Record Form Detail Summary** screen will be displayed with the default of 'No' to the question "Do you want to broadcast an isolation?". The Distribution Record can now be completed – **refer to 5.0 Complete the Distribution Record.** If the user wants to broadcast an isolation, the user must click on 'Yes' to the question "Do you want to broadcast an isolation?" AND must have obtained consent in order to broadcast an isolation.

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		Note: If you click on 'Yes Do you wan	would like to broadcast an offer from within a ' for 'Do you want to broadcast an isolation'? t to broadcast an isolation?	batch record,]	Note:	lf 'N	lo' is cha	ange	d	1
			Section	Section Status	i I t	o 'Yes	s' th	en the th	nree	(3)	
	[Edit]		General Information	New	1 1	orms	req	uired to	be		
	[Edit]		Organ Recovery Information	New		compl	etec	l to broa	dcas	st	
	[Edit]		Pancreas Characterization in your Laboratory	New		an iso	latio	on, as we	ell as		
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	[Edit]		Digestion Information	New		he ne	xt n	age.			-
	[Edit]		Islet Characterization Post Digestion	New							
	[Edit]		Purification Information	New							
	[Edit]		Islet Microbiology Results Information	New							
	[Edit]		Mouse Data Information	New							
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This **Distribution Form Detail Summary** screen will be displayed if 'Yes' is selected for "Do you want to broadcast an isolation?" within the Distribution Record. **Refer to 6.0 Broadcast an Isolation from within the Distribution Record.**

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	To broadcast an isolation, complete the first three sections (Donor nformation, Characterization of Islets for Distribution Information, a pasic Science Islet Transportaion Information) and click on [Save Re & Broadcast Now]. No you want to broadcast an isolation?	ind ecord	<u>~</u>
	Section	Section Status	1
[Edit]	Donor Information*	New	
[Edit]	Characterization of Islets for Distribution Information*	New	
[Edit]	Research Islet Transportation Information*	New	
[Edit]	Additional Islet Assessments - Preliminary	New	
[Edit]	Additional Islet Assessments - Final	New	
[Edit]	Optional Islet Assessments	New	
[Edit]	General Information*	New	-
[Edit]	Organ Recovery Information*	New	
[Edit]	Pancreas Characterization in your Laboratory	New	
[Edit] [Add Lo	t] Collagenase Information	New	
[Edit]	Pancreas Distention Information*	New	
[Edit]	Digestion Information	New	
[Edit]	Islet Characterization Post Digestion	New	
[Edit]	Purification Information	New	
[Edit]	Islet Microbiology Results Information	New	
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4.2 Complete Additional and Optional Islet Assessments

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	To navigate through the system, select from choice. To report problems or questions by	m the options in the above blue panel by "clicking" directly on the desired email, click on "Help Desk"		
	Records for All Isolations	Documentation		
	 Enter a New Distribution Record Edit/View Existing Quick Broadcas Edit/View Existing Distribution Record View Islet Offer Confirm Authorized Data Entry Staff Cont Download Islet Notify System Previously Broadcasted Isolations and Flag 	 Standard Operating Procedures (SOPs) tact Information ash Frozen Islet Inventory 		
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The system will display the list of existing quick broadcasts for your institution – refer to the next page.

Existing Quick Broadcasts – Click on **[Edit]** of the desired quick broadcast to view and/or complete the additional islet assessments.

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			UNOS ID#	Isolation ID#	Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author		
	1	[Eait]	AKJ_TEST_878	878_test_akj	IIDP	*	01/09/2010	Basic Science Research	University of Miami	Amy Jacobs		
	2	[Edit]	M008	M008	IIDP	*	01/08/2010	Basic Science Research	University of Miami	Staff Member		
	3	[Edit]	M009	M009	IIDP	*	01/08/2010	Basic Science Research	University of Miami	Staff Member		
	4	[Edit]	FF01	FF01	IIDP	*	01/07/2010	Basic Science Research	University of Miami	Staff Member		
	5	[Edit]	XYZ098	h786	IIDP	*	01/06/2010	Basic Science Research	University of Miami	martha antler		
	6	[Edit]	ABC567	h234	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Barbara Olack		
	7	[Edit]	JEN0104	104	СІТ	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	8	[Edit]	JEN123	12345	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	9	[Edit]	JEN321	32111	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	10	[Edit]	JEN333	33333	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	11	[Edit]	JEN555	555	IIDP	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang		
	12	[Edit]	TEST01042010	TEST01042010	IIDP	*	01/04/2010	Basic Science Research	University of Miami	James Cravens		
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The system will display the Quick Broadcast Detail Summary – refer to the next page.

Quick Broadcast Form Detail Summary - Click on [View] to review a previously completed section or [Edit] to complete an Additional Islet Assessments section. For this example, click on [Edit] of Additional Islet Assessments – Preliminary – refer to the pert page

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		Section		Section Status		
	[View]	Donor Information		Complete		
	[View]	characterization of Islets for Distribution	on Information	Complete		
	[View]	Research Islet Transportation Informat	ion	Complete		
	[Edit]	Additional Islet Assessments - Prelimin	ary	New		
	[Edit]	Additional Islet Assessments - Final		New		
	[Edit]	Optional Islet Assessments		Optional		
		Save Record				
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Note: The Donor Information, Characterization of Islets for Distribution Program, and Research Islet Transportation Information sections information are 'View only' since the quick broadcast has been completed.			The Optican be Broadca	tional Islet Asses completed any til	esments is optional and me after the Quick	
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Additional Islet Assessments – Preliminary – Complete the questions in this section. Place the cursor on the question mark (2) icon to receive instructions on how to answer the questions

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TINP Developed and maintained by the Integrated Islet Dist at City of Hope	ribution Program (IIDP)

Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on [View] to review a previously completed section or [Edit] to complete the next section. Please note the change in 'Status' of each section.

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	E. J.	Section	Section Status		
	[View]	Donor Information	Complete		
	[View]	Characterization of Islets for Distribution Information	Complete		
	[View]	Research Islet Transportation Information	Complete		
		Additional Islet Assessments - Preliminary	Complete		
		Additional Islet Assessments - Final	Optional		
Note: The Donor Information, Characterization of					
Islets for Distribution Program, and Research Islet Transportation Information sections information are 'View only' since the quick broadcast has been completed.	slet Distribut	Developed and maintained by t © 2010 tion Program The A must Broa	The Additional minary section m of the Quick Bro Additional Islet A be completed wi dcast.	l Islet Assessments – nust be completed within badcast. ssessments – Final secti ithin 30 days of the Quicl	10 ion k
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Click on **[Save Record]** to save the record in the system. The system will display the confirmation message – refer to the next page.

Additional Islet Assessments – Preliminary - Confirmation Message – This message will be displayed to confirm that the information has been submitted and saved in the system

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Correction - Correction - Correction - Complete.aspx?df=1621&r=1&c=0&n=1	💌 🔒 😽 🗙 Live Search	P -
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IIDP - Islet Cell Processing Data Form	🚺 Help Desk	<u>^</u>
In order for this Quick Broadcast form to be complete you must complete the Final list Assessments form with 30 days of the broadcast. Core	on Program (IIDP)	100%

Click on **[Done]** and the system will return the user to the Main Page.

Main Page - Click on the menu option [Edit/View Existing Quick Broadcast] under [Record for All Isolations].



Existing Quick Broadcasts – Click on [Edit] of the desired quick broadcast to view and/or complete the additional islet assessments.

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Quick Broadcast Form Detail Summary - Click on **[View]** to review a previously completed section or **[Edit]** to complete the next section. Please note the change in **'Status'** of each section. For this example, click on **[Edit]** of Additional Islet Assessments – Final.

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Additional Islet Assessments – Final – Complete the questions in this section. Place the cursor on the question mark (2) icon to receive instructions on how to answer the questions.

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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

Quick Broadcast Form Detail Summary - Click on [View] to review a previously completed section or [Edit] to complete the next section. Please note the change in 'Status' of each section.

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Click on **[Save Record]** to save the record in the system. The system will display the confirmation message – refer to the next page.

Additional Islet Assessments - Final - Confirmation Message - This message will be displayed to confirm that the information



Click on [Done] and the system will return the user to the Main Page.

Main Page - Click on the menu option [Edit/View Existing Quick Broadcast] under [Record for All Isolations].



Existing Quick Broadcasts – Click on **[Edit]** of the desired quick broadcast to view and/or complete the additional islet assessments.

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Optional Islet Assessments – Complete the questions in this section. Place the cursor on the question mark

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Click on **[Add Islet Assessment]** to enter an islet assessment test information – refer to the next page.

Optional Islet Assessments – Complete the questions in this section.

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Click on [Add Islet Assessment] to enter the islet assessment test information into the table/system – refer to the next page.

Optional Islet Assessments – Click on **[Add Islet Assessment]** to add another islet assessment and repeat the process as needed for all islet assessments that were performed.

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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Quick Broadcast Form Detail Summary.

12/20/2011 Islet Data Entry System (IDES)

Quick Broadcast Form Detail Summary - Click on [View] to review a previously completed section or [Edit] to complete the next section. Please note the change in 'Status' of each section.

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Click on **[Save Record]** to save the record in the system. The system will display the confirmation message – refer to the next page.

12/20/2011 Islet Data Entry System (IDES)

Optional Islet Assessments - Confirmation Message - This message will be displayed to confirm that the information has been

submitted and saved in the system.

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Click on **[Done]** and the system will return the user to the Main Page.

Main Page - Click on any menu option as needed OR click on **J** og off] to log out of the system.



5.0 Complete a Distribution Record

Main Page - Click on the menu option [Enter New Distribution Record] under [Record for All Isolations].



Click on [Complete a Distribution Record] to complete a distribution record - refer to the next page.



UNOS ID and Islet Isolation ID Screen - Enter the UNOS ID number and the Islet Isolation ID number and select the Islet Source for the new Islet Isolation and then click on **[Submit]**. Click on **[Cancel]** to return to the Main Page. Refer to pages 11 – 14 for information regarding if a duplicate UNOS ID and/or Isolation ID is entered.



The **Distribution Record Form Detail Summary** screen will be displayed with the default of 'No' to the question "Do you want to broadcast an isolation?". The Distribution Record can now be completed. Click on **[Edit]** of a designated section to display the form to complete.

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	N c E	lote: If you lick on 'Yes)o you wan	i would like to broadcast an offer from within a s' for Do you want to broadcast an isolation'? t to broadcast an isolation?	batch record,		
			Section	Section Status		
	[Edit]		General Information	New		
	[Edit]		Organ Recovery Information	New		
	[Edit]		Pancreas Characterization in your Laboratory	New		
	[Edit]	[Add Lot]	Collagenase Information	New		
	[Edit]		Pancreas Distention Information	New		
	[Edit]		Digestion Information	New		
	[Edit]		Islet Characterization Post Digestion	New		
	[Edit]		Purification Information	New		
	[Edit]		Islet Microbiology Results Information	New		
	[Edit]		Mouse Data Information	New		
	[Edit]		Clinical Islet Transportation Information	New		
			Save Record		-	
	TT	n	Developed and maintained by the Integra	ated Islet Distribution	Program (IIDP)	
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Distribution Record Form Detail Summary - The system will display the **Status** of each section as '**New**', '**Complete**', or '**Incomplete**'. All sections need to be '**Complete**' for the Distribution Record to be considered complete.

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Note: If you would like to broadcast an offer from within a batch record, click on 'Yes' for 'Do you want to broadcast an isolation'? Do you want to broadcast an isolation?								
		Section	Section Status					
	[Edit]	General Information	New					
	[Edit]	Organ Recovery Information	New					
	[Edit]	Pancreas Characterization in your Laboratory	New					
	[Edit] [Add L	ot] Collagenase Information	New					
	[Edit]	Pancreas Distention Information	New					
	[Edit]	Digestion Information	New					
	[Edit]	Islet Characterization Post Digestion	New					
	[Edit]	Purification Information	New	Note: In the Conorol				
	[Edit]	Islet Microbiology Results Information	New	Note: In the General				
	[Edit]	Mouse Data Information	New	Question 3.2 if 'Clinical				
	[Edit]	Clinical Islet Transportation Information	New 🗲	Transplant' is not				
Save Record Save Record Save Record Selected, then this section on the Distribution Detail Summary screen will not be displayed. Souther the section on the Distribution Detail Summary screen will not be displayed.								
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NOTE: The user may randomly select the order in which to complete each section (e.g., General Information section, then the Collagenase Information section, then the Pancreas Characterization at ICR section, etc.). However for the purpose of this User's Guide, the sections will be discussed in the order as listed above.

12/20/2011 Islet Data Entry System (IDES)

General Information section – Complete the questions in the General Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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NOTE: The UNOS ID	number and the Isolation ID number	Islet Shipment Summary
are displayed in the t	op left hand corner of every section.	IIDP Islet Cap: 2,000,000
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	1	CIT Islet Cap: 500,000
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Unts ID: AKJ_TEST_676 Isola	tion ID: 676_test_akj	
1. 🕐 UNOS ID Number:	These fields will auto-fill with the LINOS and	AKJ_TEST_676
2. ? Islet Isolation ID number:	Isolation ID numbers initially entered.	676 test aki
3. For what purpose was the pancreas	rocessed?	
3.1 Intended for:		
3.2 🕐 Used for:	Pink indicates a required field.	Research 💌
IF Used For Clinical Transpl	int:	
3.2.1 🕐 Were islets transplant	ed under the CIT protocol?	🗖 No 🗖 Yes
3.2.1.1 ? If NO, sp	ecif Gray indicates a conditional field. A field	
3.2.1.2 ? If OTHER	based on the answer to another question.	
IF Used For Research:		
3.2.2 Was the informed cor and confirmed by your st	sent to use the pancreas for research purposes obtained by th aff?	e OPO
3.2.3 ? Source of islets broad	casted through the distribution program:	
3.2.3.1 ? Number	of approved studies that received islets from this isolation:	
3.2.4 ? Were islets given to i	vestigators outside of the Islet Allocation System?	🗖 No 🗖 Yes
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Each section in the form is considered a 'single page'. You can use the **scroll bar** to scroll down to the bottom of the section. The **General Information section** is continued on the next page.

12/20/2011 Islet Data Entry System (IDES)

General Information section (continued)

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	3.2.5	? How m	nany IEQs were used for QC purposes?		IEQs	Not Documented		
		3.2.6	? How many IEQs were used for your research?		IEQs	☐ Not Documented		
	IF Not	t Used At	All:					
	3.2.7	? Provid	e a reason why pancreas was not used:					
	3.2.8	? Select Recovery,	ALL the sections that CANNOT be completed with the existing data abo and Pancreas Characterization in your laboratory sections must be co	ut the pancreas (NOTE: mpleted):	The General	Information, Organ		
		3.2.8.1	Collagenase Information section					
		3.2.8.2	F Pancreas Distention Information section					
		3.2.8.3	🖵 Digestion Information section					
		3.2.8.4	Islet Characterization Post Digestion section				≡	
		3.2.8.5	Purification Information section					
		3.2.8.6	Islet Microbiology Results Information section					
		3.2.8.7	Mouse Data Information section					
			Submit					
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Form Detail Summary.

Distribution Record Detail Summary - Click on **[Edit]** to complete the next section. Please note the change in **'Status'** of the General Information section.

General mormation section.					
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	Do you want to broa	adcast an isolation?	✓ No Yes		
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	[Edit]	General Information	Complete		
	[Edit]	Organ Recovery Information	New		
	[Edit]	Pancreas Characterization in your Laboratory	New		
	[Edit] [Add Lot] Collagenase Information	New		
	[Edit]	Pancreas Distention Information	New		
	[Edit]	Digestion Information	New		
	[Edit]	Islet Characterization Post Digestion	New		
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Organ Recovery Information section – Complete the questions in the Organ Recovery Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj					
 Pate and time of cross clamp: Pate and time of pancreas recovery: Answer the following questions about the overall condition of the pancreas documented in the OPO paperwork: 3.1 Was the organ intact? Was there any macroscopic damage on the organ (hematoma, bruise, extensive cauterization)? Was there any edema? Was an additional treatment performed on the pancreas prior to preservation? If YES, select the additional treatment performed: If OTHER, specify: 	after organ procurement b	(24 hour clock) (24 hour clock) ut before trans Yes Yes Yes Yes	k) Not Documer sport to your laboratory as Not Documer Not Documer Not Documer Not Documer	nted Inted Inted Inted	
5. Describe pancreas preservation below:					~
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Organ Recovery Information section (continued)

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	5. Desc	ribe panc	reas preser	vation below:								~
	5.1	? Dat shippin	e and time g:	pancreas placed	l in preservation so	lution for			(24 hour clock)	Documented	🗖 Not Done	
	5.2	? Des	cribe the pr	eservation solu	tion used for shippi	ng:		~				
		5.2.1	If OTHER,	specify:				-				
		5.2.2	? If TWO	D LAYER								
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	5.3	? One differer	ce received nt preservat	at your laborato ion solution afte	ory, was the pancre r shipping?	as placed in a	🗖 No		T Yes			
		5.3.1	If YES, ar	swer the follow	ing questions:							
			5.3.1.1	Pate and preservation	time pancreas plac solution at your lab	ed in the oratory:			(24 hour clock)	*	Not Documented	
			5.3.1.2	? Describe your laborato	the preservation so ry:	lution used in		~				
				5.3.1.2.1	If OTHER, specify	y:						
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Organ Recovery Information section (continued)

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		5.3.1.2 ? Describe your laborate	the preservation so ory:	olution used in	~				<u>^</u>
		5.3.1.2.1	If OTHER, specif	у:					
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	5.3.2 ? Durat	ion of time pancreas in s	hipping preservatio	n solution:	Hours	Minutes	Not Documented	📕 Not Done	
	6. 🕐 Pancreas pro	ocurement team:						*	
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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	[Edit]	General Information	Complete		
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	[Edit]	Pancreas Characterization in your Laboratory	New		
	[Edit] [Add Lot]	Collagenase Information	New		
	[Edit]	Pancreas Distention Information	New		
	[Edit]	Digestion Information	New		
	[Edit]	Islet Characterization Post Digestion	New		
	[Edit]	Purification Information	New		
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Pancreas Characterization at Center section – Complete the questions in the Pancreas Characterization at Center section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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Unos ID: AKJ_/EST_676 Isolation ID: 676_test_akj	
 Answer the following questions about the overall condition of the pancreas upon arrival at your laboratory: Was the organ intact? Was there any macroscopic damage on the organ (hematoma, bruise, extensive cauterization)? Was there any edema? Describe the surface fat of the pancreas (select one): Describe the fat infiltration of the pancreas (select one): Comments regarding pancreas characterization: 	No Yes Not Documented No Yes Not Documented No Yes Not Documented
Submit	
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

12/20/2011 Islet Data Entry System (IDES)

Distribution Record Detail Summary - Click on [Edit] to complete the next section. Please note the change in 'Status' of each section.

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	Do you want to	broadcast an isolation? Section	✓ No Yes Section Status		
	[Edit]	General Information	Complete		
	[Edit]	Organ Recovery Information	Complete		
	[Edit]	Pancreas Characterization in your Laboratory	Complete		
	[Edit] [Add	Lot] Collagenase Information	New		
	[Edit]	Pancreas Distention Information	New		
	[Edit]	Digestion Information	New		
	[Edit]	Islet Characterization Post Digestion	New		
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Collagenase Information section – Complete the questions in the Collagenase Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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1. 🙎 Collagenase Lots and Cor	centrations:			
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Manufacturer:				
1.1.1	If OTHER, specify:			
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1,2 Collagenase Type:		*		
1.2.1	If OTHER, specify:			
1.3 ? What base medium		∼		
collagenase?				
1.3.1	If OTHER, specify:			
1.4 🕐 Were any additives a	dded by your 🛛 🔽 No	T Yes	🔲 Not Documented	
laboratory?				
1.4.1 ? If YES, sele	ct ALL the additives that were added and indica	te the amounts of each:		
Aprotinin (Tracylol)		Г		
Calcium Chloride (CaCl		l	mount used (optional)	
Ciprofloxacin		4	anouncuseu (optional)	
DNAse (Pulmozyme)				N
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Collagenase Information section continued – Question 1.4 – Additives Used – refer to the next page.

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1.4 Were any additives added by your Image: No Image: Not Documental laboratory? 1.4.1 Image: Image: Not Documental laboratory? Image: Not Documental laboratory? 1.4.1 Image: Image: Not Documental laboratory? Image: Not Documental laboratory?	d
Aprotinin (Trasylol) Calcium Chloride (CaCl) Ciprofloxacin DNAse (Pulmozyme) Henarin	
Above is a list of available additives. Click on an additive to add. Add other additives Specify additional additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additive to the list. Repeat as needed	Refer to age.
1.5 [?] Collagenase Vendor Lot Number:	
Collagenase Concentration	
1.5.1 Pased on calculations using manufacturer data (i.e. certificate of analysis), how much collagenase was used?	/d
1.5.2 Was in-house laboratory INO Ves testing performed on the collagenase to confirm manufacturer specifications?	
1.5.2.1 If YES, answer the following questions:	
1.5.2.1.1 ? What was the measured collagenase activity, as determined by in-house laboratory testing? Image: Collagenase activity in the second	formed
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Collagenase Information section continued – Question 1.4 – Additives Used – refer to the note.

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Г	1.3.1 If OTHER,	specify:					~
	1.4 ? Were any additives added by your laboratory?	🗖 No		Yes	🗖 Not Do	cumented	
	1.4.1 ? If YES, select ALL the add	litives that were added and indicate t	he amount	ts of each:			
	Aprotinin (Trasylol) Calcium Chloride (CaCl) Ciprofloxacin Heparin HEPES Above is a list of available additives. Click on an additive to add. Add other additiv Specify additional additives (Enter an additi	Above is a list o	zyme) i selected Id other add	additives. itives' button to add	100 Amount used (optional) the additive to the list. Repeat a:	s needed.):	III
	 1.5 Collagenase Vendor Lot Number: Collagenase Concentration 1.5.1 Based on calculations using manufacturer data (i.e. 			NOTE: If 'Y additives us list or enter [Add other	es' is selected for 1 sed can be selected ed in the textbox an additives]. The sele	.4, then the from the pick d then click of cted additive	k on s
	certificate of analysis), how much collagenase was used? 1.5.2 ? Was in-house laboratory testing performed on the collagenase to confirm manufacturer specifications?	No	E	are added t to remove a needed.	o the middle textbox additives from that te	c with the abi extbox as	lity
ê	1.5.2.1 If YES, an 1.5.2.1.1	swer the following questions: What was the measured collagenase activity, as determined in-house laboratory testing?	j by	amount use process as for each se	ed – this is optional. needed to enter the lected additive.	Repeat the amount used	tne d

Collagenase Information section (continued)

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		1.5.2.1 If YES, an:	swer the following questions:		2
		1.5.2.1.1	What was the measured collagenase activity, as determined by in-house laboratory testing?	~	Testing Not Performed
		1.5.2.1.2	What was the measured weight or volume of the vial of collagenase, as determined by in-house laboratory testing?	~	Testing Not Performed
	Neutral Pro	otease Concentration			
	1.5.3	Was neutral protease added to the collagenase solution (either in addition to or in lieu of a purchased collagenase/neutral protease blend)?	no No	T Yes	▶ Not Documented
		1.5.3.1 If YES, an:	swer the following questions:		
		1.5.3.1.1	Neutral protease manufacturer:	~	
			1.5.3.1.1.1	If OTHER, specify:	
		1.5.3.1.2	Neutral protease type:		
			1.5.3.1.2.1	If OTHER, specify:	
		1.5.3.1.3	? Neutral Protease Lot Number:		
		1.5.3.1.4	Based on calculations using manufacturer data (i.e. certificate of analysis), how much neutral protease was used?	~	
	1.5.4	Was in-house laboratory testing performed on the neutral protease to confirm manufacturer specifications?	No No	T Yes	
		1.5.4.1 If YES, an:	swer the following guestions:		
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Collagenase Information section (continued)

IIDP Website - Islet Cell Processing Data Form: Col	lagenase Information - Microsoft Internet Explorer	
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1.5.4 🕐 Was in-house laboratory testing performed on the neutral protease to confirm manufacturer specifications?	No Yes	~
1.5.4.1 If YES, ans	wer the following questions:	
1.5.4.1.1	What was the measured neutral protease activity, as determined by inhouse laboratory testing?	Testing Not Performed
1.5.4.1.2	What was the measured weight or volume of the vial of neutral protease, as determined by in-house laboratory testing?	Testing Not Performed
1.6 ? Final volume of collagenase solution:	mL Not Documented	
1.7 ? Comments regarding the collagenase:		
	Submit Add Another Lot	
JID.	Developed and maintained by the Integrated Islet Distribution Pro at City of Hope © 2010 All rights reserved.	ngram (IIDP)
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

OR

Click on [Add Another Lot] to complete the questions for an additional Collaganese Lot number. - refer to next page.

12/20/2011 Islet Data Entry System (IDES)

Additional Collagenase Lot Number - Complete the questions for an additional Collagenase Lot Number. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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						Islet Shipm	ent Summary	
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Ur	nos ID: AK	J_TEST_676 Is	olation ID: 676	test_akj				
	1.1 Collage	enase Manufacturer:		*				
	1.1.1		If OTHER, specify:					
	1.2 Collage	enase Type:		~				
	1.2.1		If OTHER, specify:					
	1.5 Collage	enase lot number:					Not Documented	
	Collagena:	se Concentration						
	1.5.1	Based on calculations manufacturer data (i.e analysis), how much c used?	using e. certificate of ollagenase was	✓			Not Documented	
	1.5.2	Was in-house laborato performed on the colla confirm manufacturer	ry testing agenase to specifications?	No No	T Yes			
		1.5.2.1	If YES, answer the	following questions:				
			1.5.2.1.1	What was the measured collagenase activity, as determined by in-house laboratory testing?		~		
							Testing Not	~
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Additional Collagenase Lot Number (continued)

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			1.5.2.1.2	What was the measured weight or volume of the vial of aollagenase, as determined by in- house laboratory testing?	~	Performed Testing Not Performed	^
	Neutral Pi	rotease Concentratio	n				
	1.5.3	Was Neutral Protease collagenase solution (to or in lieu of a purch collagenase/neutral p	added to the either in addition nased rotease blend)?	No	T Yes	☐ Not Documented	
		1.5.3.1	If YES, answer the	e following questions:			
			1.5.3.1.1	Neutral protease manufacturer:	~		
				1.5.3.1.1.1	If OTHER, specify:		
			1.5.3.1.2	Neutral protease type:		*	
				1.5.3.1.2.1	If OTHER, specify:		
			1.5.3.1.3	Netural Protease lot number:			
			1.5.3.1.4	Based on calculations using manufacturer data (i.e. certificate of analysis), how much Netural Protease was used?	~		
	1.5.4	Was in-house laborate performed on the Net confirm manufacturer	ory testing ural Protease to specifications?	No No	T Yes		
		1.5.4.1	If YES, answer the	e following questions:			
			1.5.4.1.1	What was the measured neutral protease activity, as determined by in-house laboratory testing?	~	Testing Not Performed	
			1.5.4.1.2	What was the measured weight or volume of the vial of neureal protease, as determined by in-house laboratory testing?	~	Testing Not	~
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Additional Collagenase Lot Number (continued)

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				1.5.3.1.2.1	If OTHER, specify:		^
			1.5.3.1.3	Netural Protease lot number:			
			1.5.3.1.4	Based on calculations using manufacturer data (i.e. certificate of analysis), how much Netural Protease was used?	×		
	1.5.4	Was in-house l performed on t confirm manuf	aboratory testing he Netural Protease to acturer specifications?	No	T Yes		
		1.5.4.1	If YES, answer t	he following questions:			
			1.5.4.1.1	What was the measured neutral protease activity, as determined by in-house laborator testing?	ry	Testing Not Performed	
			1.5.4.1.2	What was the measured weight or volume of the vial of neureal protease, as determined b in-house laboratory testing?	by	Testing Not Performed	
				Submit Add Another Lot			
		Integrate	LIDF d Islet Distribution Progra	Developed and maintained by the Integrat at City of H © 2010 All rights m	ed Islet Distribution Program (IID lope reserved. Site	P)	
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

OR

Click on **[Add Another Lot]** to complete the questions for an additional Collaganese Lot number. Repeat the process as many times as needed.

Distribution Record Detail Summary WITHOUT an additional collagenase lot number – Click on **[Edit]** to complete the next section. Click on **[Add Lot]** to add another collagenase lot number.

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	Note: If you 'Do you wa Do you war	u would like to broadcast an nt to broadcast an isolation nt to broadcast an isolation	n offer from within a batch rec '? ?	ord, click on 'Yes' for ☑No □Yes		
			Section	Section Status		
	[Edit]	General Informa	ation	Complete		
	[Edit]	Organ Recovery	/ Information	Complete		
	[Edit]	Pancreas Chara	cterization in your Laboratory	Complete		
	[Edit]	[Add Lot] Collagenase Inf	ormation	Complete		
	[Edit]	Pancreas Dister	tion Information	New		
	[Edit]	Digestion Inform	nation	New		
	[Edit]	Islet Characteri	zation Post Digestion	New		
	[Edit]	Purification Info	rmation	New		
	[Edit]	Islet Microbiolog	y Results Information	New		
	[Edit]	Mouse Data Info	ormation	New		
		DP Developed	Save Record and maintained by the Integra at City of	ated Islet Distribution P Hope	rogram (IIDP)	×
Done					😜 Internet	🖌 🔹 🔍 100% 🔹 🛒

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Batch Record has been submitted if all the sections do not have a '**Complete**' status.

12/20/2011 Islet Data Entry System (IDES)

Distribution Record Detail Summary WITH an additional collagenase lot number – Click on **[Edit]** to complete the next section. Click on **[Add Lot]** to add another collagenase lot number. Click on **[Delete]** to remove an additional collagenase lot number. Please note the change in **'Status'** of each section.

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	Note: If you wou 'Do you want to Do you want to b	Id like to broadcast an offer from within a batch i broadcast an isolation'? proadcast an isolation?	record, click on "	Yes' for Yes					
		Section	Section Status						
	[Edit]	General Information*							
	[Edit]	Organ Recovery Information*	Complete		[Note: The user has			
	[Edit]	Pancreas Characterization in your Laboratory	Complete			the ability to delete			
	[Edit] [Add Lot]	Collagenase Information	Complete	•		additional			
	[Edit]	Collagenase Lots 1	Complete	[Delete]		collagenase lot(s) as			
	[Edit]	Pancreas Distention Information*	New			needed.			
	[Edit]	Digestion Information	New		L				
	[Edit]	Islet Characterization Post Digestion	New						
	[Edit]	Purification Information	New						
	[Edit]	Islet Microbiology Results Information	New						
	[Edit]	Mouse Data Information	New						
Done	חדד	Save Record			s Ir	nternet 🕢 🕶 🕄 100% 🔻 .:			

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Batch Record has been submitted if all the sections do not have a '**Complete**' status.

Pancreas Distention Information section – Complete the questions in the Pancreas Distention Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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				IIDP Islets	Remaining: 1,968,000	
				CIT Islet Ca	ap: 500,000	
				CIT Islets R	emaining: 500,000	
Unos ID: Ak	(J_TEST_676 Isolation	ID: 676_test_akj				
1. ? Date	and time pancreas removed			~	Not Documented	
from the	preservation solution:		(24 hour clock)			_
2. 🕐 Dura	tion of time pancreas in your			Not Documented	Not Done	
laborator	ry preservation solution:	Hours	Minutes	Not Docamented	Not Done	
3. 7 Total	duration of nancreas			Net Desumented		
preserva	tion:	Hours	Minutes			
4. Cate started:	and time dissection in lab		(24 hour clock)	×	🔲 Not Documented	
E 3			(24 HOUR CLOCK)		-	
pancreas	; was the temperature of the	(°Celsius)			🔲 Not Measured	
6. ? Date	and time dissection	1200			Not Documented	
complete	ed:		(24 hour clock)			
7. ? What	was the temperature of the		(21 11021 01001)		—	
pancreas	post-dissection?	(°Celsius)			Not Measured	
8. 🕐 Dura	tion of dissection:	Hours	Minutes	Not Documented		
		nours	minutes	-		
9. 🔀 What	was the pre-distention weight noreas? (Refer to the	gm	🔲 Not Documented	🔲 Not Measured		
mouseov	er definition.)					~
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Pancreas Distention Information section (continued) - Click on [Add Perfusion] to add Perfusion Data - refer to the next

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11	L.	? Date a injection (and time of initial col start of perfusion):	lagenase		(24 hour clock)		~	🗖 Not Documented	~
12	2.	Were in temperature collected of	multiple measureme ure, pressure, and/or during perfusion?	nts of 🛛 🗖 I r flow rate	No	Ves				
		12.1	? If YES, complet	e the following ta	able:					
			Perfusion Data							
			Time (24 hour clock)	Body & Tail Temp (C)	Body & Tail Pressure (mmHg)	Body & Tail Flow Rate (mL/min)	Head Temp (C)	Head Pressure (mmHg)	Head Flow Rate (mL/min)	
									Add Perfusion	
13	3.	? Descri	ibe the quality of the	distention:						
		13.1	Body and Tail:		~					
		13.2	Head:		~					
14	1 .	? Date a	and time perfusion e	nded:		(24 hour clock)			🗖 Not Documented	
15	5.	? Durati	on of perfusion:		Hours	Minutes			🗖 Not Documented	
16	5.	? Was th chamber?	ne pancreas cut into	pieces prior to b	eing placed into the dig	estion 🔲 No		Yes	Not Documented	
		16.1	If YES, answer the	following questic	ons:					
			16.1.1	₽ H	low many pancreatic pi loaded into the chamb	eces er?	~			
			16.1.2	ר ע פון ע	Vhat was the average le e pancreatic pieces?	ngth	~			
17	7.	? Comm	nents regarding the p	oancreas distenti	on process:					~
Done	-								🔒 🥝 Internet	

Pancreas Distention Information section [Add Perfusion] - Complete the questions for the Perfusion Data.

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		IIDP - Islet Cell Processing Data Form: Perfusion Data	ent Summary	
		Linos ID: AK1 TEST 676 Isolation ID: 676 test aki	2,000,000	
			500,000	
		Perfusion Data	ining: 500,000	
Un	nos ID: AKJ_TEST_	Time (24 hour clock)		
1.	Pate and time	Body and Tail Temperature	Not Documented	
	from the preservat	Body and Tail Pressure mmHg Not Documented Not Done	Not Documented	
2.	Duration of tim laboratory preserv	Body and Tail Flow Rate	Not Done	
з.	Total duration of preservation:	Head Temperature		
	preservation.	Head Pressure mmHa Not Documented Not Done		
4.	Pate and time started:	Head Flow Rate	Not Documented	
5.	What was the t pancreas pre-disse		Not Measured	
6.	? Date and time completed:	Add Perfusion	Not Documented	
7.	What was the t pancreas post-diss		Not Measured	
8.	Duration of dis:			
9.	? What was the p of the pancreas? (F mouseover definition	e-distention weight gm Not Documented Not Measured		
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Click on **[Add Perfusion]** to add Perfusion Data - refer to the next page.

Pancreas Distention Information section (continued) - The system adds the measurements to the table.

Click o	n [E	Edit] to	edit th	ne measure	ments or cl	ick on [Delete]	to delete the me	easurem	ents from the	table. (The data	a is fictior	nal.)
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	12.	? Were temperat rate colle 12.1	multiple ire, pre ited dur ? If Y	e measurement ssure, and/or f ring perfusion? ES, complete th	s of 🛛 🗖 No low ne following tab	le:	Ves Yes					<u>^</u>
			Pertusi	on Data Time (24 hour clock)	Body & Tail Temp (C)	Body & Tail Pressure (mmHg)	Body & Tail Flow Rate (mL/min)	Head Temp (C)	Head Pressure (mmHg)	Head Plow Rate (mL/mm)		
			[Edit]	15:30	22.00	33.00	15	24.00	44.00	20	[Delete]	
	13.	 ? Descr 13.1 13.2 ? Dette 	ibe the Body a Head:	quality of the d nd Tail:	istention:	~				Add Feil		
	141			e periosion eno	eu.		(24 hour clos			Not Do	cumented	
	15.	<table-cell> Durat</table-cell>	ion of p	erfusion:		Hours	Min	utes		🗖 Not Do	cumented	
	16.	Wast chamber?	he panc '	reas cut into pi	eces prior to be	ing placed into the o	digestion 🔽 No		T Yes	🗖 Not Do	cumented	
		16.1	If YES,	answer the foll	owing question:	s:						
			16.1.1		? Ho were la	w many papereatic p baded into the cham	bieces ber?	~				
			16.1.2		? Wh of the	at was the average pancreatic pieces?	length	*				
	17.	Comn	nents re	garding the par	ncreas distentio	n process:						~
ど Done										📄 💧 🕹	Internet	

Repeat the [Add Perfusion] process as needed to enter all the measurements collected.

Pancreas Distention Information section (continued)

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	14.	? Date	e and time perfusi	ion ended:			(24 hour clock)		🔽 Not Documented		
	15.	<table-cell> Dura</table-cell>	ation of perfusion:	:	Hours		Minute	s	🗖 Not Documented		
	16.	? Was chambe	the pancreas cut r?	into pieces pr	ior to being placed	into the digestion	🗖 No	🔽 Yes	📕 Not Documented		
		16.1	If YES, answer	r the following	questions:						
			16.1.1		How many p were loaded into	ancreatic pieces the chamber?		~			
			16.1.2		Yhat was the of the pancreation	e average length c pieces?		~			
	17.	Com?	nments regarding	the pancreas	distention process:					1	
						Submi	it				
Done											
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.
Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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	'Do you want to b Do you want to br	roadcast an isolation? roadcast an isolation?	✓ No	Yes		
		Section	Section Status			
	[Edit]	General Information*	Complete			
	[Edit]	Organ Recovery Information*	Complete			
		Pancreas Characterization in your Laboratory	Complete			
			Complete	[Delete]		
	[Edit]	Pancreas Distention Information*	Complete	[Delete]		
	[Edit]		New			
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Done					Thernet 🐨	AU + A 100% + 1

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Digestion Information section – Complete the questions in the Digestion Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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			IIDP Islets Remaini	ng: 1,968,000	
			CIT Islet Cap:	500,000	
			CIT Islets Remainin	ig: 500,000	
	Un	os ID: AKJ_TEST_676 Isolation ID: 676_test_akj			
	1.	What digestion method vasued?			
		1.1 If OTHER, specify:			
	2.	? Date and time digestion phase started (Re-circulation Phase 1):	(24 hour clock)	Not Documented	
	з.	Cate and time digestion phase stopped:	(24 hour clock)	Not Documented	
	4.	2 Duration of digestion phase: Hours	Minutes	Documented	
	5.	Indicate how cold ischemia time was defined (select one):			
		5.1 If OTHER, describe:			
	6.	Duration of cold ischemia: Hours	Minutes	Not Documented	
	7.	🕐 Specify the criteria used to determine the start of dilution (i.e. switch time)? (Check ALL that apply):			
		7.1 Two of free islets observed			
		7.2 St. of embedded idlets absorved			~
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Digestion Information section (continued)

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7. 🕄 Specify the criteria used to determine the start of dilution (i.e. switch time)? (Check ALL that apply):	^
7.1 \Box % of free islets observed	
7.2 T % of embedded islets observed	
7.3 Dize of islets	
7.4 Cother	
7.4.1 If OTHER,	
8. Chate and time dilution phase started (Phase II):	
9. Date and time dilution phase Not Stopped:	
10. Duration of dilution phase: Hours Minutes Not Documented	
11. 🕐 Type of solution used for dilution:	
11.1 If OTHER, specify:	
11.2 ? Were any additives INO Yes Ocumented Documented	
11.2.1 If YES, select ALL the additives that were added and indicate the amount of each:	
Ciprofloxacin DNAse (Pulmozyme)	
Dulbecco's Phosphate-Buffered Saline (DPBS)	
Heparin	
Above is a list of available additives. Above is a list of selected	×

Digestion Information section (continued)

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	Above is a list of available additives. Click on an additive to add. Add other additives.	^
	Specify additional additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the additive to the list. Repeat as needed.):	
:	12. ? Describe the quality of the digestion:	
:	13. ? What was the approximate dry weight of the total tissue left in the chamber at the end of digestion?	
	14. 🕐 What was the approximate % of remaining digestible pancreatic tissue? ————————————————————————————————————	
	Submit	
	Developed and maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved.	
	Integrated Islet Distribution Program	~
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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	[Edit]	General Information*	Complete		
	[Edit]	Organ Recovery Information*	Complete		
	[Edit]	Pancreas Characterization in your Laboratory	Complete		
	[Edit] [Add Lot]	Collagenase Information	Complete		
	[Edit]	Collagenase Lots 1	Complete [Delet	e]	
	[Edit]	Pancreas Distention Information*	Complete		
	[Edit]	Digestion Information	Complete		
	[Edit]	Islet Characterization Post Digestion	New		
	[Edit]	Purification Information	New		
	[Edit]	Islet Microbiology Results Information	New		
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Islet Characterization Post Digestion Information section – Complete the questions in the Islet Characterization Post Digestion section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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		IIDP Islets Remaining: 1,928,000	
		CIT Islet Cap: 500,000	
		CIT Islets Remaining: 500,000	
Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj			
 ? Was a total actual islet count performed after digestion (pre-purification)? If YES, indicate the total actual islet count: ? Was a total islet IEQ count performed after digestion (pre-purification)? ? If YES, indicate the total IEQs: ? Was a post digestion Islet Score taken? ? If YES, convert that score using the scale of 1.0 - 10.0 (1 worst and 10 best) and enter the number in the textbox: ? Were there any other islet characterization parameters measured after digestion (pre-purification)? If YES, answer the following questions: 	No Yes	☐ Not Documented	
4.1.1 ? Total packed cell volume:	mL	Not Not Documented Done	
4.1.3 Cross Clumping Evident:	No Yes	Not Not Documented Done	
4.1.4 ? Insulin Content:			~
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Islet Characterization Post Digestion Information section (continued)

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4.1.4	? Insulin Cor	ntent:		µU/IEQ	Not Documented	☐ Not Done	~
4.1.5	? DNA Conte	ent:		ng/IEQ	Not Documented	Done	
4.1.6	Islet Purity:						
	4.1.6.1	? Percent dithi	zone positive cells:	%	☐ Not Documented	☐ Not Done	
4.1.7	Islet Viability:						
	4.1.7.1	Indicate incl	usion dye used:		~		
		4.1.7.1.1	If OTHER, specify:		_		
	4.1.7.2	? Indicate exc	lusion dye used:	~			
		4.1.7.2.1	If OTHER, specify:				
	4.1.7.3	? Islet Viability	a.	%	☐ Not Documented		
5. <table-cell> Comments req post digestion:</table-cell>	garding islet ch	naracterization					
			Submit				
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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	'Do you want to broadcast an isolation'? Do you want to broadcast an isolation?	✓ No □Yes	
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	[Edit] General Information*	Complete	
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	[Edit] Pancreas Characterization in your Laboratory	Complete	
	[Edit] [Add Lot] Collagenase Information	Complete	
	[Edit] Collagenase Lots 1	Complete [Delete]	
	[Edit] Pancreas Distention Information*	Complete	
	[Edit] Digestion Information	Complete	
	[Edit] Islet Characterization Post Digestion	Complete	
	[Edit] Purification Information	New	
	[Edit] Islet Microbiology Results Information	New	
	[Edit] Mouse Data Information	New	
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Purification Information section - Isolation Process Flow section – Complete Steps 1 and 4 in the Isolation Process Flow. Step 2 and Step 3 are conditional based on the answer to question 1 in Step 1 – General Purification Data. Refer to the next page.

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Step 2: Purification / Rescue Run Data		
Step 3: Culture Data		
Step 4: Final Islet Preparation Data [Islet Characterization Results] (Not Started)		
Submit		
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Purification Information section - Complete the answers in Step 1 - Purification Information section of the Isolation Process Flow. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj 1. Islet purification: 1.1 If OTHER, specify:	If 'Density Gradient' of the rest of the question and 2 WILL need to be	or 'Other' is selectors in this step (or 'Other' is selectors in this step (e completed - re	he next page. Sted for question Step 1) and also fer to page 107	1, then Steps 2
2. 2 Was a COBE used?		T Yes		
2.1 If YES, answer the following questions: 2.1.1 Provide the following questions:	rmed?	Y		
2.1.2 Answer the following questions for eac	ch COBE run performed:			
What was the packed cell volume per COBE run?	Type of gradient used:	Describe gradient:	If OTHER, specify:	
mL	~	*		
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Purification Information section (continued)

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2.1.1 now many CODE runs were per	ronneu?	Y		•
2.1.2 Answer the following questions for a	each COBE run performed:			
What was the packed cell volume per COBE run?	? Type of gradient used:	2 Describe gradient:	If OTHER, specify:	
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mL	✓	*		
mL	*	*		
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Click on [Submit] to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

This is an example of the conditional answer in Step 1 that will determine if Step 2 and Step 3 need to be completed or not. Step 2 and Step 3 of the Isolation Process Flow will NOT NEED to be completed if question 1 of the Purification Information section is answered with '**Not Done**'. Refer to page 107

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				3
1. 2 Islet purification: Not Done				
1.1 If OTHER, specify:				
2. 🕐 Was a COBE used?		└ Yes		
2.1 If YES, answer the following questions:				
2.1.1 Plow many COBE runs were perfo	rmed?	~		
2.1.2 Answer the following questions for ea	ch COBE run performed:			
What was the packed cell volume per COBE run?	? Type of gradient used:	? Describe gradient:	If OTHER, specify:	
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Purification Information section (continued)

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2.1.1 International Code runs were pe	normeu?	×		<u>^</u>	
2.1.2 Answer the following questions for	each COBE run performed:				
What was the packed cell volume per COBE run?	Type of gradient used:	Describe gradient:	If OTHER, specify:		
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Click on [Submit] to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

Isolation Process Flow screen - The user WILL NOT need to complete Step 2 or Step 3 and can proceed to Step 4 – refer to the

next page.	
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Step 2: Purification / Rescue Run Data	
Step 3: Culture Data	
Step 4: Final Islet Preparation Data [Islet Characterization Results] (Not Started)	
Submit	
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Final Islet Preparation – Islet Characterization – If 'No' is selected for Question 1, then the rest of the questions in this form do not need to be completed. However, if 'Yes' is selected for Question 1, then complete the applicable questions then click on **[Submit]** at the end of the form and the system will then display the Isolation Process Flow screen – refer to the next pages.

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Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj			
1. ? Were there any final islet characterization measurements taken immediately before transplant (or before final release for research) of the entire islet product batch?) that are representative	No No	🗖 Yes
1.1 If YES, answer the following questions:			
1.1.1 Was a final islet characterization islet score taken?	No Yes		
1.1.1.1 If YES, convert the score using a scale of 1.0 - 10.0 (1 worst - 10 best) and enter the number in the textbox:			
1.1.2 Total packed cell volume:	mL	Not Documented	Not Done
1.1.3 Percent Trapped Islets:	%	Not Documented	Not Done
1.1.4 Total Actual Islet Count:		Not Documented	Not Done
1.1.5 Gross clumping evident:	No Yes	Not Documented	Not Done
1.1.6 Total IEQs:	IEQ	Not Documented	Not Done
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Final Islet Preparation – Islet Characterization (continued)

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Final Islet Preparation – Islet Characterization (continued)



Click on [Submit] to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

Isolation Process Flow screen - This section is now complete. Click on **[Submit]** to return to the Distribution Record Detail Summary screen.

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Step 1: General Purification Data [Purification Information] (Completed) Step 2: Purification / Rescue Run Data Step 3: Culture Data Step 4: Final Islet Preparation Data [Islet Characterization Results] (Completed) Submit		
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Distribution Record Detail Summary – Click on [Edit] to complete the next section. Please note the change in 'Status' of each section.

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Done		Save Record		🖨 Internet 🏾 📣 👻 10	0% •

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Batch Record has been submitted if all the sections do not have a **'Complete'** status.

This is an example of the conditional answer in Step 1 that will determine if Step 2 and Step 3 need to be completed or not. Step 2 and Step 3 of the Isolation Process Flow will NEED to be completed if Question 1 of the Purification Information is answered with **'Density gradient' or 'Other'**.

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1. ? Is	let purification: Density gradient 💌				
1.1	If OTHER, specify:				
2. ? w	'as a COBE used?		Ves		
2.1	If YES, answer the following questions:				
	2.1.1 Pow many COBE runs were performed	rmed?	¥		
	2.1.2 Answer the following questions for ea	ch COBE run performed:			
	What was the packed cell volume per COBE run?	Type of gradient used:	Pescribe gradient:	If OTHER, specify:	
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Click on [Submit] to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen.

Isolation Process Flow screen - The user will need to complete Step 2 and/or Step 3 of the Isolation Process Flow. Click on **[Add Purification Fraction]** to complete the data for a Purification Run.

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[Add Purification Fraction]	[Add Rescue Fraction]		
Available for culture Not available for culture			
Cult	ure		
Step 4: Final Islet Preparation Data [Islet Characterization Results] (Not Started)			
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Islet Characterization Post Purification – Purification Run - Complete the questions for a Purification Run. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj				
1. Each purification fraction should be labeled in the system to help distinguish data from multiple fractions. Please select a label for this fraction:	Most Pure 💌			
1.1 If OTHER, specify:				
2. 2 Was a post-purification Islet Score taken?	🗖 No 🗖 Yes			
2.1 If YES, convert the score using the scale of 1.0 - 10.0 (1 worst - 10 best) and select the number from the drop down be	DX:			
3. Total packed cell volume:	mL	Not Documented	Done Not	
4. Percent Trapped Islets:	%	Not Documented	Done Not	
5. 7 Total Actual Islet Count:		Not Documented	Done Not	
6. 7 Gross clumping evident:	No Ves	Not Documented	Done Not	
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Islet Characterization Post Purification – Purification Run (continued)

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11.2 Percent beta callor			
	%	Documented	Done
12. Islet Viability:			
12.1 [?] Indicate inclusion dye used:		~	
12.1.1 If OTHER, specify:			
12.2 Indicate exclusion dye used:		*	
12.2.1 If OTHER, specify:			
12.3 Itelet Visbility:	, 	E.	
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13. 2 Temperature during purification:		Not Measured	
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Islet Characterization Post Purification – Purification Run (continued)

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13.1 [?] If temperature entered above, select how the temperature during purification was determined:		
13.1.1 If OTHER, specify:		
14. [2] Indicate below ALL types of supplemental islet processing performed (OR check box to the right for Not Done):		Not Done
14.1	Culture	
? 14.2	Cryopreservation	
14.3	I rradiation	
14.4	Gene Transfer	
14.5	Other	
14.5.1 If OTHER, specify:		
Submit		
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at City of Hope © 2010 All rights reserved.		
Integrated Islet Distribution Program		
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen. Refer to next page.

Isolation Process Flow screen - The system will display that a Purification Fraction(s) has/have been added and that Culture data needs to be completed.

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Available for outure	
Not available for culture	
Step 3: Culture Data	
Culture	
Most Pure Fraction	
(Not Started)	
[Add Culture Batch]	

Isolation Process Flow screen - To link the fraction (container) with the culture (culture flask) click on the container in the Purification Fraction box and drag the container down into the culture flask. The Purification Fraction (e.g., Most Pure Fraction) is now linked with the designated culture batch.



To complete the culture information for the Most Pure Fraction click on the **[Edit]** icon in the top right hand corner of the culture flask box - refer to the next page.

Culture Information - Complete the questions for the culture information for Most Pure Fraction. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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		CIT Islets Remaining: 418,000	
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1. I Specify the culture formulation:			
1.1 Select base medium used for culture:			
×			
1.1.1 If OTHER, specify:			
1.2 🥐 Were any additives added by your laboratory?	Ves	Not Documented	
1.2.1 [?] If YES, select ALL the additives that were added and indicate the a	mount of each:		
AB SERUM Antibiotic Antimycotic Solution Bovine Serum Albumin (BSA) Ciprofloxacin Dulbecco's Phosphate-Buffered Saline (DPBS)		Amount used (optional)	
Above is a list of available additives. Click on an additive to add.	Above is a list of selected additives.		
Add other additives			~
Done		😜 Internet 🧳 🗸	💐 100% 🔻 💡

Culture Information continued - Click on [Add Culture Vessel] to enter Culture Parameter and Culture Period Data - refer to the next page.

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1.3 For each culture parameter, select the type of vessel use each vessel. Click on [Add another vessel] to add as ma culture period, the length of the culture period, and if the parameter. <u>Culture Vessels:Culture Periods:</u>	ed, the number of ve any parameters that ere were any change	essels, enter the volume of r were used to culture the isle as to the culture formulation.	media used in each vessel, and enter the ets. For the culture periods of each param . Click on [Add another culture period], to	average number of IEQs placed in heter, complete the temperature of th b add as many culture periods for eac	e :h						
Type of vessel Select the # of this Vo used type	olume of media used	Average number of IEQs	Total culture time for this parameter								
		Add Culture Vee		_							
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2. 2 Was a post-culture islet score taken?	No No	Yes									
2.1 If YES, convert the score using the scale of 1.0 - 10.0 (1 worst - 10 best) and enter the number in the textbox:	0										
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Culture Information (continued) – Complete the information for the Culture Parameter.

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Click on [Add Culture Parameter] - refer to the next page. Repeat the process as needed for each culture parameter.

Culture Information (continued) – click on [Add Culture Period] to add the culture period(s) for the culture parameter.

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Culture Information (continued) – Add culture period – Click on [Add Culture Period] to add a culture period - refer to the next page.



Culture Information (continued) – Add culture period – Complete the culture period form.

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III IIIDP - Islet Cell Processing Data Form: Islet Processing Information - Culture Period 1.3 For each culture parameter each vessel. Click on [Add culture period, the length of parameter. Culture Vessels:Culture Period Type of vesse used IIIOP - Islet Cell Processing Data Form: Islet Formulation during the culture Period? 2. [Was a post-culture Islet Score (1 worst - 10 best) and enter (1 worst - 10 best) and enter (1 worst - 10 best) and enter (2 Total packed cell volume: (3 Percent Trapped Islets: (5 Protein Formulation Count: (5 Protein Formulation Processing Developed and maintained by the Integrated Islet Distribution Program (IIDP) (1 Protein Formulation Processing Data Form: Proc	PP)
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Click on **[Add Culture Period]** to add the culture period to the culture period. Repeat the process as needed to add as many culture periods as applicable to the culture parameter - refer to the next page.

Culture Information (continued) – Add culture period - Click on [Edit Culture Period] to edit the culture period information OR click on [Delete] to delete the culture period.

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Click on [Add Culture Period] to add another culture period OR click on [Done] to proceed to the next step - refer to the next page.

Culture Information (continued) – Click on [Add Culture Vessel] to add another culture parameter AND/OR click on [Add Culture Period] to add another culture period to a culture parameter.

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1.3 For each culture parameter, select the type of vessel used, the number of vessels, enter the volume of media used in each vessel, and enter the average number of IEQs placed in each vessel. Click on [Add another vessel] to add as many parameters that were used to culture the islets. For the culture periods of each parameter, complete the temperature of the culture period, the length of the culture period, and if there were any changes to the culture formulation. Click on [Add another culture period], to add as many culture periods for each									<u> </u>				
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Culture Information (continued)

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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen - refer to next page.
Isolation Process Flow screen – Scroll down the page to the Final Islet Preparation section.

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Click on the **[Islet Characterization Results]** to complete Step 4 of the Purification Section - refer to the next page.

Final Islet Preparation –Islet Characterization - Complete the questions for the Final Islet Preparation - Step 4 of the Isolation Process Flow. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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Final Islet Preparation - Islet Characterization (continued)

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Final Islet Preparation - Islet Characterization (continued)

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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Isolation Process Flow screen - refer to next page.

12/20/2011 Islet Data Entry System (IDES)

Isolation Process Flow screen - Click on **[Add Rescue Fraction]** if you need to complete the information for a Rescue Run – refer to the next page.

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IIDP - Islet Cell Processing Data Form: Isolation Process Flow	▲
Step 1: General Purification Data [Purification Information] (Completed) Step 2: Purification / Rescue Run Data Purification Fraction(s) [Add Purification Fraction] [Add Rescue Fraction] [Add Rescue Fraction] [Add Purification Fraction] [Add Rescue Fraction] [Available for culture Not available for culture	Note: If click on [Add Rescue Fraction], the system will display the Islet Characterization Post Purification section questions.
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Isolation Process Flow screen – The Rescue Run is now added to the culture section to complete as needed.

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Isolation Process Flow screen – The Rescue Run can be 'dragged and dropped' into the culture flask as discussed on page 114.

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[Add Purification Fraction] [Add Rescue Fraction]	•
Available for culture Not available for culture	
Step 3: Culture Data	
Culture	
Most Pure Fraction Most Pure Rescue	
Fraction	
Most Pure Fraction	
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Isolation Process Flow screen – Click on the [Delete [X]] icon to delete a Purification Fraction and/or Rescue Fraction. Then confirm if you definitely want to delete a fraction.

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[Purification Information] (Completed)	·
Step 2: Purification / Rescue Run Data	
Purification Fraction(s) Rescue Fraction	(s)
[Add Purification Fraction]	[Add Rescue Fraction]
Available for culture Not available for culture Message from webpage	
Step 3: Culture Data O you want to c	elete this rescue fraction?
Most Pure Fraction Most Pure Rescue Fraction	Cancel
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Isolation Process Flow screen (continued) - Click on [Add Culture Batch] if you need to add another culture

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C Step 3: Culture Data	
Culture	
Most Pure Fraction	
Most Pure Fraction (Complete)	Culture Batch 1 Culture Batch 1 Culture Information section
Step 4: Final Islet Preparation Data [Islet Characterization Results] (Completed) Submit	questions.
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Click on the **[Remove ()]** icon in the bottom right hand corner of the culture flask box to remove a culture as needed. **OR**

Click on **[Submit]** to submit/save the Isolation Process Flow (Steps 1 - 4) data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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	Do you want to b	roadcast an isolation? roadcast an isolation? Section	No Yes Section Status	
	[Edit]	General Information*	Complete	_
	[Edit]	Organ Recovery Information*	Complete	
	[Edit]	Pancreas Characterization in your Laboratory	Complete	=
	[Edit] [Add Lot]	Collagenase Information	Complete	
	[Edit]	Collagenase Lots 1	Complete [De	elete]
	[Edit]	Pancreas Distention Information*	Complete	
	[Edit]	Digestion Information	Complete	
	[Edit]	Islet Characterization Post Digestion	Complete	
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Islet Microbiology Results Information section – Complete the questions in the Islet Microbiology Results Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions. Refer to the next page when 'Yes' is selected for question 2.

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Unos	s ID: AKJ_TEST_	_676 Isolation ID: 676_te	est_akj				
							=
1.	? Were islets take	en from the final preparation for is	let release and/or quality control testing?	No	Ves	Not Done	
1	L.1 If	YES, answer the following question	ons:				
	1	.1.1	How many IEQs were taken from the final preparation for islet release and/or quality control testing?		Not Documented	Not Done	
	1	.1.2	Were the islets that were used for quality control testing purposes included as part of the final islet preparation count?	No	☐ Yes		
2.	? Were microbiolo	ogy samples taken at any point du	ring the transportation and/or isolation process?	No No	Yes		
2	2.1 If	YES, indicate ALL time points at v	vhich samples were taken:				
	[2.1.1	Transportation Fluid:				
	1	2.1.2	Post-Digestion:				
	1	2.1.3	Post-Purification:				
	[3	2.1.4	Post-Culture:				
							×
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Islet Microbiology Results Information section (continued) – When 'Yes' is selected for question 2, then select when the microbiology samples were taken. For those microbiology samples, the system will display the microbiology questions to complete for each sample.

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	2. ? Were microbiology samples taken at an	y point during the	transportation and/or isolation process?	No Ye	35	^
	2.1 If YES, indicate ALL time p	oints at which san	nples were taken:			
	2.1.1	Trans	sportation Fluid:			
		2.1.1.1	Gram Stain:	×		
			2.1.1.1.1	If POSITIVE, specify:		<u> </u>
		2.1.1.2	? Aerobic Culture:	×		
			2.1.1.2.1	If POSITIVE, specify:		-
		2.1.1.3	Anaerobic Culture:	×	4	
			2.1.1.3.1	If POSITIVE, specify:		
		2.1.1.4	Pungal Culture:	•	1	
			2.1.1.4.1	If POSITIVE, specify:		
		2115	2 M			
		2.1.1.0				
	7003		2.1.1.5.1	If POSITIVE, specify:		
	2.1.2	Post-	Digestion:			
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Islet Microbiology Results Information section (continued)

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	2 2.1.4	Post-0	Culture:					<u>^</u>
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		2.1.4.3	? Anaerobic Culture:		×			
			2.1.4.3.1		If POSITIVE, specify:			
		2.1.4.4	Pungal Culture:		×			
			2.1.4.4.1		If POSITIVE, specify:			
		2.1.4.5	Mycoplasma:		×			
			2.1.4.5.1		If POSITIVE, specify:			
	? 2.1.5	Final I	Preparation					
	2.1.6	C Other	:					
	3. I Total endotoxin units in final preparation:			×	Not Documented	Not Done		
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				Submit				
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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	Note: If you would 'Do you want to b Do you want to br	d like to broadcast an offer from within a batch r roadcast an isolation'? roadcast an isolation?	ecord, click on '	Yes' for Yes		
		Section	Section Status			
	[Edit]	General Information*	Complete			
	[Edit]	Organ Recovery Information*	Complete			
	[Edit]	Pancreas Characterization in your Laboratory	Complete			
	[Edit] [Add Lot]	Collagenase Information	Complete			
	[Edit]	Collagenase Lots 1	Complete	[Delete]		
	[Edit]	Pancreas Distention Information*	Complete			
	[Edit]	Digestion Information	Complete			
	[Edit]	Islet Characterization Post Digestion	Complete			
	[Edit]	Purification Information	Complete			
	[Edit]	Islet Microbiology Results Information	Complete			
	[Edit]	Mouse Data Information	New			
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Mouse Data Information section – Complete the questions in the Mouse Data Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.

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	Islet Shipment Summary	
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	IIDP Islets Remaining: 1,842,975	
	CIT Islet Cap: 500,000	
	CIT Islets Remaining: 418,000	
Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj		
1. Was a mouse bioassay conducted as a potency assay for quality control?	No Yes	
1.1 If YES, please answer the following summary questions regarding the mouse bioassay:		
1.1.1 Mouse Experiment ID:		
1.1.2 Indicate the mouse model used:	~	_
1.1.2.1 If OTHER, specify:		
1.1.3 I Number of mice transplanted:		
1.1.4 ? Number of IEQ transplanted per mouse?	IEQ	
1.1.5 Into which organ were the islets transplanted?		
1.1.5.1 If OTHER, specify:		
1.1.6 ? Route of transplantation:		
1.1.6.1 If OTHER, specify:		
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Mouse Data Information section (continued)

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1	1.1.6.1	If OTHER, specify:			
1.1.7	? Percentage of mice cu	red:		%	
1.1.8	? Select ALL the outcom	e variables used to iudoe a cu	re		
	1.1.8.1		Blood Glucose permanently < 200 mg/dL		
	1.1.8.2		Insulin permanently > 5 µU/L		
	1.1.8.3		C-peptide permanently >1 ng/mL		
	1.1.8.4		Cother		
		1.1.8.4.1	If OTHER, specify:		
				P.C.	
			Submit		
1			Cabine		

Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

Distribution Record Detail Summary – Click on **[Edit]** to complete the next section. Please note the change in 'Status' of each section.

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		Pancreas Characterization in your Laboratory	Complete		
		Collagenase Information	Complete		
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	[Edit]	Pancreas Distention Information*	Complete		
	[Edit]	Digestion Information	Complete		
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	[Edit]	Mouse Data Information	Complete		
		Save Record			
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The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

Confirmation screen – Incomplete data fields - The system will display this confirmation message when [Save Record] is clicked on and there are required fields that are not complete. Refer to 7.0 Edit/View an Existing Distribution Record for more detail on editing or adding data to an existing data form.



Click on **[Done]** and the system will return the user to the Main Page.

Confirmation screen – Complete Data Fields – The system will display this confirmation message when [Save Record] is



Click on **[Done]** and the system will return the user to the Main Page.

Main Page – Click on any menu option as needed OR click on [Log off] to log out of the system.



Addendum – If the Islets had been used for Clinical Transplant (Question 3.2 in the General Information section) then an additional section will need to be completed – **Clinical Islet Transportation Information section** - refer to the next page.

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		Section	Section Status		
	[Edit]	General Information	New		
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	[Edit]	Pancreas Characterization in your Laboratory	New		
	[Edit] [Add Lo] Collagenase Information	New		
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	[Edit]	Digestion Information	New		
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	[Edit]	Purification Information	New		
	[Edit]	Islet Microbiology Results Information	New		
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Clinical Islet Transportation Information section – Complete the questions in the Clinical Islet Transportation Information section. Place the cursor on the question mark (?) icon to receive instructions on how to answer the questions.



Click on [Add Container] to complete the volume information for each suspension container used. Refer to the next page.

Clinical Islet Transportation Information section (continued) - Enter the volume of the suspension container and the IEQs per container.

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IIDP - Islet Cell Processing Data Form: Clinical Islet Tr	https://stage.coh.org/iidp_new/popup_suspcontainer.aspx?df=1604&contid=1	🔄 🔂 - 🖃 🚔 + Page + Safety + Tools + 🕡 + 🂙
	IIDP - Islet Cell Processing Data Form: Islet Processing Information - Container	
Unos ID: AKJ_TEST_676 Isolatio	Unos ID: AKJ_TEST_676 Isolation ID: 676_test_akj For each container used, indicate the volume of the suspension/container and the number of IEQs/container: mL IEQs/container Add Container	slet Shipment Summary Islet Cap: 2,000,000 Islets Remaining: 1,842,975 slet Cap: 500,000 slets Remaining: 418,000
1.1 ? What type of suspension conta 1.1.1 If OTHER, specify: 1.2 ? For each container used, indic 1.3 ? What type of transplant media	Developed and maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved. Training Site-	Add Container
1.3.1 If OTHER, specify: 1.4 2 Were any additives added by 1.4.1 2 If YES, relect ALL the Cinrofloxacin	Done	Not Documented

Click on [Add Container] - refer to the next page.

Clinical Islet Transportation Information section (continued) – The system adds the suspension container volume and IEQs per container to the table. Click on **[Edit]** to edit the volume amount or click on **[Delete]** to delete the container added.



Click on [Add Container] to add additional container information as needed OR continue completing the rest of the form.

Clinical Islet Transportation Information section (continued)

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# IIDP - Islet Cell Processing Data Form: Clinical Islet Tr		🔹 🔝 🖃 🖶 👻 Page 🗸 Safety 🗸 To	ols • 🕜 • 👋
1.4 2 Were any additives added by your laboratory to the transplant media base?	No Yes	Not Documented	^
1.4.1 If YES, select ALL the additives that were added and indicate the amount of each:			
Ciprofloxacin Heparin HEPES Human Serum Albumin (HSA) Recipient Serum (form transplant recipient)	Amount used (optional)	
Above is a list of available additives. Above is a list of selected addit	tives.		
Add other additives Specify additional additives (Enter an additive in the text box and then click on the 'Add other additives' button to add the	e additive to the list. Repeat as needed.):		
1.5 How long was the suspension in the container(s) before being infused into the patient (i.e. time in container to start of infusion)?	Hours Minutes	Not Documented	
1.6 What was the total volume of solution used to rinse the suspension container(s) during and/or after the islet infusion?	mL	Not Not Documented Done	
1.7 2 Date and time when Infusion started:	(24 hours	Not Documented clock)	
1.8 2 Date and time when Infusion ended:	(24 hour o	Not Documented	
1.8.1 If exact infusion time is not known, indicate the total estimated ischemia time (cross-clamp to end of Infusion):	Days Hours	Not Documented	
IF Shipped to a remote site for tansplantation:			
1.9 2 What type of transport container was used?	×		
1.9.1 If OTHER, specify:			*
Done		😜 Internet 🦓 🔹 🤅	100% ×

Clinical Islet Transportation Information section (continued)

C IIDP - Islet Cell Processing Data Form: Clinical Islet Transportation Infor	mation - Windows Internet Explor	er			- 7 🛛
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1.10 ? For each transport container shipped, indicate the volum	ne of media and the number of IEQs/	container:			<u></u>
Container ID	Volume	I	Qs/container		
				Add Container	
1.11 ? What type of transport media base was used?		*			
1.11.1 If OTHER, specify:					
			_	_	
1.12 [2] Were any additives added by your laboratory to the tra	nsport media base?	No No	Yes	Not Documented	
1.12.1 ? If YES, select ALL the additives that were added	I and indicate the amount of each:				
AB Serum					
Glutathione (L-glutathione)			Amount used (optio	nal)	
Heparin					
Above is a list of available additives.	Above is a list of sele	cted additives.			
Add other additives					
Specify additional additives (Enter an additive in the text box and th	en click on the 'Add other additives' butto	n to add the additive to the list. R	epeat as needed.):		
1.13 2 What was the temperature of the islet preparation durin	g shipping?			¥	=
1.13.1 If OTHER, specify:					
1 14 2 How loss was the idet properties hold in the transact	containers?			F	
The How long was the islet preparation held in the transport	containers?	Hours	Minutes	Not Documented	
	Submit				
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Click on **[Submit]** to submit/save the data to the system. The system will return the user to the Distribution Record Detail Summary.

12/20/2011 Islet Data Entry System (IDES)

Distribution Record Detail Summary – Click on [Edit] to complete the next section. Please note the change in 'Status' of each section.

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	Note: If you would	d like to broadcast an offer from within a batch i	record, click on "	Yes' for		
	'Do you want to b	roadcast an isolation'?				
	Do you want to b	roadcast an isolation?	✓ No	Yes		
		Section	Section Status			
	[Edit]	General Information*	Complete			
	[Edit]	Organ Recovery Information*	Complete			
	[Edit]	Pancreas Characterization in your Laboratory	Complete			
	[Edit] [Add Lot]	Collagenase Information	Complete			
	[Edit]	Collagenase Lots 1	Complete	[Delete]		
	[Edit]	Pancreas Distention Information*	Complete			
	[Edit]	Digestion Information	Complete			
	[Edit]	Islet Characterization Post Digestion	Complete			
	[Edit]	Purification Information	Complete			
	[Edit]	Islet Microbiology Results Information	Complete			
	[Edit]	Mouse Data Information	Complete			
	[Edit]	Clinical Islet Transportation Information	Complete			
		Save Record				
						~
Done					😜 Internet 🦓 👻 🎕	100% -

The user may close out of a Distribution Record at any time - Click on **[Save Record]** to submit the Distribution Record to the system. The system will display a confirmation message that an Incomplete Distribution Record has been submitted if all the sections do not have a **'Complete'** status.

6.0 Broadcast an Isolation from the Distribution Record

Click on [Complete a Distribution Record] to broadcast an isolation .



UNOS ID and Islet Isolation ID Screen - Enter the UNOS ID number and the Islet Isolation ID number and select the Islet Source for the new Islet Isolation and then click on **[Submit].** Click on **[Cancel]** to return to the Main Page. Refer to pages 11 – 14 for information regarding if a duplicate UNOS ID and/or Isolation ID is entered

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	Islet Isolation ID Number:		
	? Enter Islet Source:		
	Submit Canad		
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This is the default Distribution Record Form Summary Detail Screen that is displayed when **[Complete a Distribution Record]** is selected. In order to broadcast an isolation from within the Distribution Record, 'Yes' must be selected for "Do you want to broadcast an isolation?" - refer to the next page.

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	Note: If yo	u would lik	e to broadcast an offer from within a batch rec	ord, click on 'Yes' for		
	'Do you wa	ant to broa	dcast an isolation'?			
	Do you wa	nt to broad	dcast an isolation?	✓ No Yes		
-			Section	Section Status	-	
	[Edit]		General Information	New		
	[Edit]		Organ Recovery Information	New		
	[Edit]		Pancreas Characterization in your Laboratory	New		
	[Edit]	[Add Lot]	Collagenase Information	New		
	[Edit]		Pancreas Distention Information	New		
	[Edit]		Digestion Information	New		
	[Edit]		Islet Characterization Post Digestion	New		
	[Edit]		Purification Information	New		
	[Edit]		Islet Microbiology Results Information	New		
	[Edit]		Mouse Data Information	New		
	[Edit]		Clinical Islet Transportation Information	New		
			Save Record			
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The three (3) required broadcast forms are now displayed in the Summary Detail screen. An isolation can be broadcast within the distribution record at any time as long as the three required broadcast forms have been completed. **Refer to 4.0 Broadcast an Isolation – Quick Broadcast** for information regarding completion of the broadcast forms and **refer to 5.0 Complete a Distribution Record** for information regarding completion of the Distribution Record.

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	Do you want to broadcast an isolation?		✓ Yes		^			
		Section	Section Status	4				
	[Edit]	Donor Information*	New	7				
1	[Edit]	Characterization of Islets for Distribution Information*	New					
	[Edit]	Research Islet Transportation Information*	New					
	[Edit]	Additional Islet Assessments - Preliminary	New					
	[Edit]	Additional Islet Assessments - Final	New					
	[Edit]	Optional Islet Assessments	New					
	[Edit]	General Information*	New					
	Edit] Organ Recovery Information*		New					
	[Edit]	Pancreas Characterization in your Laboratory	New					
	[Edit] [Add Lot]	Collagenase Information	New					
	[Edit]	Pancreas Distention Information*	New					
	[Edit]	Digestion Information	New					
	[Edit]	Islet Characterization Post Digestion	New					
	[Edit]	Purification Information	New					
	[Edit]	Islet Microbiology Results Information	New					
	[Edit]	Mouse Data Information	New					
		Save Record & Broadcast Now Save Record						
Done				💓 Internet 🦷 👻 100%	•			

Click on [Save Record and Broadcast Now] or [Save Record]. [Save Record and Broadcast Now] will save the Distribution Record in the system and will broadcast the isolation – refer to pages 15 – 34 in 4.0 Broadcast an Isolation – Quick Broadcast. [Save Record] will save the Distribution Record in the system and will be available to edit/view as needed – refer to 7.0 Edit/View Existing Distribution Record.

7.0 Edit/View Existing Distribution Record

Main Page - Click on the menu option [Edit/View existing distribution record] under [Records for All Isolations] to display the existing data entry forms entered in to the system for islet isolations.



The system will then display all of the distribution records entered for your specific institution.

Existing Distribution Records - The system will display the list of Distribution Records that have been entered into the system for your institution. Incomplete forms will be 'flagged'. Click on any of the Headers to sort by - for example the UNOS ID # as previously described on page 13.

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UNOS ID# Isolation	ID# Source	Incomplete	Date Submitted	Pancreas Used For	Institution	Author	
1 [Edit] AKJ_TEST_680 680_test_	akj IIDP	*	01/30/2010	Basic Science Research	University of Miami	Amy Jacobs	
2 [Edit] AKJ_TEST3845 test3845_	akj IIDP	*	01/30/2010	Basic Science Research	University of Miami	Amy Jacobs	=
3 [Edit] M014 M014	IIDP	*	01/28/2010	Basic Science Research	University of Miami	Staff Member	
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9 [Edit] AKJ_TEST_877 877_test_	akj IIDP	۲.	01/16/2010	Basic Science Research	University of Miami	Amy Jacobs	
10 [Edit] WYX456 h567	CIT	۳.	01/14/2010	Basic Science Research	University of Miami	Barbara Olack	
11 [Edit] AKJ_TEST_676 676_test_	akj	۲.	01/09/2010	Clinical Transplant	University of Miami	Amy Jacobs	
12 [Edit] AKJ_TEST_878 878_test_	akj IIDP	*	01/09/2010	Basic Science Research	University of Miami	Amy Jacobs	
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18 [Edit] JEN0104 104	CIT	*	01/04/2010	Basic Science Research	University of Miami	Jenny Chuang	~
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Click on **[Edit]** of the desired Distribution Record to edit and/or add data to the form. The system will display the Distribution Record Detail Summary screen for the user to select the section(s) to edit and/or add data.

Distribution Record Detail Summary WITH a Broadcast - Click on [Edit] to display the desired section to complete.

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		Section	Section Status			
[View]		Donor Information	Complete			
[View]		Characterization of Islets for Distribution Information	Complete			
[View]		Research Islet Transportation Information	Complete			
[Edit]		Additional Islet Assessments - Preliminary	New			
[Edit]		Additional Islet Assessments - Final	New			
[Edit]		Optional Islet Assessments	Optional			
[Edit]		General Information	New			
[Edit]		Organ Recovery Information	New			
[Edit]		Pancreas Characterization in your Laboratory	New			
[Edit]	[Add Lot]	Collagenase Information	New			
[Edit]		Pancreas Distention Information	New			
[Edit]		Digestion Information	New			
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[Edit]		Mouse Data Information	New			
Save Record						
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Distribution Record Detail Summary WITHOUT a Broadcast - Click on [Edit] to display the desired section to complete.

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	Section	Section Status				
[Edit]	General Information*	Complete				
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[Edit]	Pancreas Distention Information*	Complete				
[Edit]	Digestion Information	Complete				
[Edit]	Islet Characterization Post Digestion	Complete				
[Edit]	Purification Information	Complete				
[Edit]	Islet Microbiology Results Information	Complete				
[Edit]	Mouse Data Information	Complete			_	
[Edit]	Clinical Islet Transportation Information	Complete				
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The system will display the desired section in the Edit/Add Mode. Edit and/or Add data as needed.

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 1. Answer the following questions about the overall condition of the pancreas upon arrival at your laboratory: 1.1 Was the organ intact? Was there any macroscopic damage on the organ (hematoma, bruise, extensive cauterization)? Was there any edema? 2. Pescribe the surface fat of the pancreas (select one): Describe the fat infiltration of the pancreas (select one): Pescribe the fat infiltration of the pancreas (select one): Comments regarding pancreas characterization: testing 	No Yes Not Documented No Yes Not Documented No Yes Not Documented Light Yes Patchy
Done	V <p< th=""></p<>

Click on **[Submit]** to submit the edits and/or additions to the system. The system will return the user to the Distribution Record Detail Summary.
Distribution Record Detail Summary – Repeat the process as needed to edit and/or add data to the Distribution Record sections.

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8.0 View Islet Offer

Main Page - Click on the menu option [View Islet Offer] under [Records fro All Isolations] to view the Islet Offer(s).



The system will then display the Islet Offer(s) – refer to the next page.

View Islet Offer – The system displays all of the islet offers that are in the system. Click on [Click Here] to display the designated islet offer.

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[# of IIDP Approved Basic Science Investigators offered islets] indicates the number of PIs who received the offer – whether the offer was sent to a predetermined number (e.g., seven (7) PIs) or if the offer was sent to all of the PIs (e.g., Mass Offer).

Islet Offer screen - The system will display the islet offer of the designated UNOS ID and Type of Fraction. The system will display the names and associated information of the Principal Investigators who have been sent the broadcast message regarding the availability of islets.

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Most Pure	Debbie C. Thurmond	University of Indiana School of Medicine	No	Yes	Yes	IIDP	1000	NA	NA	NA	NA	NA
Most Pure	Michael L. McDaniel	Washington University in St. Louis	No	Yes	No	IIDP	9000	5000	NA	NA	NA	NA
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Click on **[Next]** to proceed to the shipping information screen – refer to the next page. Click on **[Return to offer list]** to view the list of all of the islet offers in the system – refer to page 163.

Islet Offer Shipping Information – Click on the **icon** to display the PI(s) shipping information regarding the islet offer – refer to the next screen.

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Predetermined PI Shipping List – The system displays the PI name(s) and associated shipping information. Click on the **[pencil icon]** to display the screen in edit mode to enter the required data fields – refer to pages 168 – 169.

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Predetermined PI Shipping List in edit mode – the system will display the shipping in the edit mode. Enter the [Direct Pickup by PI], [Copy Islet Shipping Tracking # Here], [Copy Materials Shipping Tracking # Here], [Post Culture Purity], [Post Culture Viability], [Amount to be shipped by Center] and [Islets Shipped]. Click on the [Save icon] to save the information or click on the [Cancel icon]. Repeat the process as needed for each PI to receive islets.



Predetermined PI Shipping List in edit mode (continued)

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Predetermined PI Shipping List in edit mode - Example of an [Copy Islet Shipping Tracking # Here] entered into the data

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Predetermined PI Shipping List in edit mode – Examples of [Post-Culture Purity], [Post-Culture Viability], and [Amount to be shipped by Center] entered into the data field.

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Predetermined PI Shipping List – Click on the [Save] icon to save the information in the system – refer to the next page.

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Click on [Shipment forms] - refer to the next page.

Predetermined PI Shipping List –Click on **[Print]** to print an individual Tissue Shipment Form (TSF) or click on **[Print ALL Shipment Forms]** to print all of the applicable Tissue Shipment Forms (TSF).

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	Shamblott	Turc	Central City, CA 91010	Baltimore MD 21214	5740		5857-6				
				555-555-5555							
[Print]	Francis S. Collins	Most Pure	Building 50, Room 5312 50 South Drive, MSC 8004	Apt. 302 4820 Chevy Chase Dr.	301-496 -0844	FCollins@testallocationsystem.com	Fed- Ex/1859-	test95844	test39455	10000	test
			Bethesda, MD 20892	Chevy Chase, MD 20815			4532-4				
[Print]	Marvin Gershengorn	Less Pure	Elizabeth Geras-Raaka/NIH/NIDD 50 south Drive, Rm 4132	Elizabeth Geras-Raaka 212 Cork Tree Lane	301-451 -6305	MGershengorn@testallocationsystem.com	Fed- Ex/2367-	test5984737	test384757	10000	test
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Click on [**Print ALL Shipment Forms**] when ready to print the shipment forms – refer to the next page. Click on [**Return to offer list**] to return to the list of all of the islet offers in the system – refer to page 163.

Print Shipment Forms – Click on **[Open**] to view and then print the Tissue Shipment Forms (TSF) – refer to the next page. Click on **[Save]** to save the Tissue Shipment Forms or click on **[Cancel**] to cancel opening the Tissue Shipment Forms (TSF).

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Click [Print] to print ind	vidual shipment forms or click [Print All Shipment Forms] to prin Int All Shipment Forms Return to offer list Developed and maintained by the Integrated Islet Dist at City of Hope © 2010 All rights reserved. Training Site	it all confirmed s ribution Program (shipments. IIDP)				
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Tissue Shipment Form - The system displays the tissue shipment form(s) to be printed. Use the scroll bar on the right hand side to view all of the tissue shipment form. Print the form like any Word document. Close out of the form when finished.

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	Integrated later C	Distribution Program				
2	Tissue Shipment Form	To Be Completed By Center				
A	Tile of Project	Whole Genome Expression and Gene Reputation in Typ				
<u> </u>	Date and Time of Shipment	1/31/2010 10:00:00 AM				
8	Donori	information				
	UNOS Id	AKI_TEST3845				
9	Batch type	Most Pure				
ABC	Date of Cross Clamp	1/28/2010 8:00:00 AM EST.				
~	Processing Date	1/28/2010 2:00:00 PM EST.				
	Total Cold Preservation Duration (hours)					
	Age (Years)	48.00 Years				
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43	Cause of Dearn	Cerecrovascuaristoke				
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Tissue Shipment Form (continued)

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	Tissue Shipment Form T	o Be Completed By Center	
43	Principle Investigator	Michael J. Shambiott	
	Title of Project	Derivation of Glucose-Responsive Insulin Producing	
	Date and Time of Shipment	1/31/2010 10:00:00 AM	
<u>~</u>	Donorin	formation	
10 -	UNOS Id	AKJ_TEST8845	
<i>´</i>	paiuri ype	MOBI PUP	
6-	Processing Date	1/28/010 20000 PM EST.	
0	Total Cold Preservation Duration (hours)		
2	Age (Years)	48.00 Years	
	Sex	Male	
	Race	Black or Atrican American	
	Weight	210.0 lbs	
	Height	72.00 Inches	
==	BMI	28.50	
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Tissue Shipment Form (continued)

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ABC	Cultured Islets? Erseh Islats?	Yes	
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	Principle Investigator	Marvin Gershengorn	
	The of Project	Generation of Human Islet Precursor Cells by Epith	
X	Date and Time of Shipment	1131/2010 10:00:00 AM	
	Donorin		
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~0	Date of Cross Clamp	1/28/2010 8:00:00 AM EST.	
	Processing Date	1/28/2010 2:00:00 PM EST.	
	Total Cold Preservation Duration (hours)		~
"	Age (Years)	48.00 Years	±
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	Race	Black or African American	Ŧ
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Tissue Shipment Form (continued)

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1	Cause of Death	Cerebroyascularistroke	
	Medical History	HTN	
V	Type II Diabetic Donor Status	No	
0 -	Pre-Shipmer	nt information	
_	Cultured latels?	Yes	
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	Broadcast Viability %	95%	
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Islet Shipping Information screen – The system returns the user to the screen for the islet shipping information. Repeat the process as needed to print the shipment forms. Click on [**Return to offer list**] to return to the Islet Offers screen – refer to the next page.

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IIDP -	Shipment Fo	orms						Help Des	k		
	Attn: Name (PI Name)	Fraction	Weekday Shipping Address	Weekend Shipping Information	Phone Number	Email	Shipping Vendor Name and Account #	Islet Shipping Tracking #	Material Shipping Tracking #	Amount to be shipped by Center	Special instructions
[Print]	Michael J. Shamblott	Most Pure	123 Islet Way Street Central City, CA 91010	Brad Pitt 2811 Halcyon Ave. Baltimore, MD 21214 555-555-5555	410-371 -9746	MJShamblott@testallocationsystem.com	Fed- Ex/1734- 5857-6	test19294	test302948	10000	test
[Print]	Francis S. Collins	Most Pure	Building 50, Room 5312 50 South Drive, MSC 8004 Bethesda, MD 20892	Apt. 302 4820 Chevy Chase Dr. Chevy Chase, MD 20815	301-496 -0844	FCollins@testallocationsystem.com	Fed- Ex/1859- 4532-4	test95844	test39455	10000	test
[Print]	Marvin Gershengorn	Less Pure	Elizabeth Geras-Raaka/NIH/NIDD 50 south Drive, Rm 4132 Bethesda, MD 20892	Elizabeth Geras-Raaka 212 Cork Tree Lane Rockville, MD 20850	301-451 -6305	MGershengorn@testallocationsystem.com	Fed- Ex/2367- 2308-9	test5984737	test384757	10000	test
Click [Print] to print individual shipment forms or click [Print All Shipment Forms] to print all confirmed shipments. Print All Shipment Forms Return to offer list											
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View Islet Offer – Repeat the process as just described above as needed. Select from a menu option – [IIDP Home], [Log off], or [Help Desk] to proceed to the next desired function.

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Institution	UNOS ID#	Source of Islets	Type of Fraction	Date of Broadcast	IEQs Available	# of IIDP Approved Investigators offered islets	# of Investigators that accepted offer	IEQs Accepted	IEQs sent	Send islets to investigators and/or view prioritized islet allocation investigator list	¥iew User Feedback Form(s)
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University of Miami	JEN555	IIDP	Most Pure	01/07/2010	250000	5	1	20000	20000	[Click Here]	[Click Here]
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9.0 Confirm Authorized Broadcast Staff Contact Information

Main Page - Click on the menu option [Confirm Authorized Data Entry Staff Contact Information] under [Records for All Isolations] to confirm the contact information.

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User Profile User Information CHANGE PASSWORD CHANGE PASSWORD User Information CHANGE PASSWORD Developed and maintained by the Integrated Islet Distribution Program (IIDP) a City of Hope © 2010 All rights reserved. 	 Enter a New Distribution Record Edit/View Existing Quick Broadcast Edit/View Existing Distribution Record View Islet Offer Confirm Authorized Data Entry Staff Contac Download Islet Notify System Previously Broadcasted Isolations and Flash 	 Standard Operating Procedures (SOPs) t Information Frozen Islet Inventory
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Confirm Contact Information screen – The system displays the contact information screen.

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Confirm Authorized Data Entry Staff Contact Information and Set Automatic Email Notification Primary Contact: Birst Name: Jacobs Last Name: Jacobs E-mail address: ajacobs@coh.org Automatic E-mail Notifications: Of Image: Contact Person: Additional Contact (1) Contact Person: Automatic E-mail Notifications: Of Image: Contact Person: Automatic E-mail Notifications: Of Image: Contact Person: Edward Lee Automatic E-mail Notifications: Off Image: Contact Person: Edward Lee Automatic E-mail Notifications: Off Image: Contact Person: Submit Developed and maintained by the Integrated Islet Distribution Program at City of Hoge (2010 All rights reserved.) Integrated Islet Distribution Program	n (IIDP)	

Confirm Contact Information screen – Click on the drop down list to change the **[Automatic E-mail Notification]** and/or click on the drop down list to display and then select the name of the **[Contact Person]**.

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Confirm Authorized Data Er	Amy Jacobs	ation and Set Automatic Email Notifications
Drimary Contact	John Kaddis	
First Name:	Aisha Khan	
Last Name:	Edward Lee	
E-mail address:	Staff Member	
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Additional Contact (1)	Joyce Niland Barhara Olack	
Contact Person:	barbara olack	
Automatic E-mail Notifications:	Dajun Qian	
	Camillo Ricordi	
Additional Contact (2)	Nora Ruel	
	Heather Sibley Testing	
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Confirm Contact Information screen – Edit as needed.

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Confirm Authorized Data Entry Staff Contact Information and Set Automatic Email Notifications	
First Name: Amy	
Last Name: Jacobs	
Automatic E-mail Notifications: On V	
Additional Contact (1) Contact Person: martha antler	
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Additional Contact (2)	
Contact Person: Edward Lee	
Submit	
Developed and maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved.	
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Click on **[Submit]** to save any changes and return to the Main Page.

10.0 View/Change your User Profile

Main Page - Click on [User Information] to display the User Information screen or click on [CHANGE PASSWORD] to display the change password screen.



User Information - The system will display the User Profile if the user clicks on [User Information].



Review the information and click on [Edit] to make changes as needed -refer to the next page.

OR

Click on another menu option, if there are no required changes.

User Information - The system will display the User Profile information in the Edit Mode. Edit the User Profile as needed.

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Extension:								
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Email:	ajacobs@coh.org							
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Click on **[Submit]** to submit the changes to the system.

User Information - The system will display the changed User Profile information for the user to review. If additional changes are needed, click on **[Edit]** and repeat the process to edit the User Profile information. Click on **[IIDP Home]** to return to the Main Page.

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	User	Profile	
	Username:	ajacobs	
	First Name:	Amy	
	Middle Initial:	К	
	Last Name:	Jacobs	
	Title:	Senior Systems Analyst	
	Phone:	703-402-8697	
	Extension:		
	Fax:	703-891-6401	
	Email:	ajacobs@coh.org	
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Change Password - The system will display the Change User Password if the user clicks on [CHANGE PASSWORD].

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Confirm New Password:	
Sub	mit
IIIDP Developed and mai	ntained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved. Training Site
Menu ready for use	

Change password and then click on **[Submit]**. The system returns the user to the Main Page.

Main Page - Click on another menu option as desired to continue in the system OR click on [Log off] to exit the system.



11.0 Submit Help Desk Requests to the Integrated Islet Distribution Program (IIDP)



Help Desk Request - The system will display the help desk request box to enter and submit your help desk request to IIDP. Select the type of issue from the drop down list - refer to the next page.



Help Desk Request – Enter a brief description in the textbox to explain the type of issue.



Click on [Submit] to send the help desk request to IIDP. A confirmation message will then be displayed - refer to the next page.

Help Desk Request – Confirmation Message - This message will be displayed to inform you that your help desk request has been submitted to IIDP. Click on the [X] in the upper right hand corner to close the confirmation message.



The system will also send an email message that the help desk request has been submitted – refer to the next page.

Email Message Confirmation - The system will send an email message to the person who submitted the help desk request.

🖹 https://email2.coh.org - Help Desk Submission - Microsoft Internet Explorer				
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This message was sent with high importance.				
From:	iidp-email@coh.org [iidp-email@coh.org]	Sent: Sun 1/17/2010 9:56 PM		
10: Cc:	Jacobs, Amy IIDP-email			
Subject:	Help Desk Submission			
Attachments:				
	Help Desk			
Amy Jacobs,				
You have submitted the following issue: test				
Category: Display Problems				
We will notify you of the status of the issue and/or when the issue has been resolved.				
Sincerely, -IIDP Staff				
E Done		🔒 Unknown Zone (Mixed)		
12.0 Other Functions

Main Page - Refer to the notes below.



Islet Offer screen – Click on [Click Here] under [View User Feedback Form(s)] – refer to the UFF User Guide for Broadcasting Staff.

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13.0 Log out of the Islet Data Entry System (IDES)

Main Page - click on [Log off] to log out of the Islet Data Entry System (IDES).



The system logs the user out of the system and displays the Login Screen. Click on the [X] to close out of the browser.



14.0 Frequently Asked Questions (FAQs)

- Q1: Am I required to have a User ID and Password to access the system?
- A1: You need a User ID and Password to access the Islet Data Entry System (IDES). The IIDP staff will assign you a User ID and Password.
- Q2: What if I cannot complete the Quick Broadcast or Distribution Record at one time (e.g. do not have the data available or need to stop to proceed to another task (e.g. go to a meeting)).
- A2: 1. Click on **[Submit]** of the designated section being completed.
 - 2. Click on [Submit] on the Distribution Detail Summary screen.
 - 3. The system will display a confirmation message that the data form is only partially completed.
 - 4. When you are ready to complete the Islet Isolation Data Form, click on [Edit/Add Existing Distribution Record] under [Records for All Isolations] on the Main Page.
 - 5. The system will display a list of all the Distribution Records in the system.
 - 6. Find the desired UNOS ID# and/or Isolation ID # of the Data Form that you were completing and click on [Edit].
 - 7. The system will display the desired Distribution Record.
- Q3: When I am completing the form, how do I go back to a previous section to edit and/or add data to that previous section?
- A3: Click on **[Submit]** in the current section. The system will return you to the Distribution Record Detail Summary or Quick Broadcast Detail Summary screen based on the form you are completing. Then you may click on **[Edit]** of the desired section to edit and/or add data.



Integrated Islet Distribution Program

ISLET DATA ENTRY SYSTEM

User Guide for Investigators 2010 for Acceptance of Islets Via the Web

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1.0. General Guidelines

1.1. Navigation

The Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Islet Offer screen (e.g. accept islet offer, change user profile, submit a help desk request, etc.). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for accepting an islet offer is primarily presented in the majority of the remaining sections of this User's Guide.

1.2. Screens

1.2.1 Screen Format

All of the IDES data entry screens are designed to be a 'single page' in which the data for each section of the IDES data form are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

1.2.2 Data Entry Formats

Different formats are used within the IDES Data Form to capture the data.

- 1.2.2.1 Text Boxes
 - o Data must be typed in
 - o Used to capture text, dates, and numeric values such as a laboratory value
 - Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- o Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- o Click on the arrow to display the list choices
- o Click on the desired option and it will be displayed in the box

1.2.2.3 Check Boxes

- Used when one of several options must be chosen e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- There are instances when multiple check boxes can be checked in response to the question

1.3 System Messages

1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the

validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1 Date Field Formats

		(mm/dd/yy)	
	The system will automatica	ally enter the fo	rward slas
1.3.1.2	Time Field Formats		
		(hh:mm)	
	The system will automatica	ally enter the co	olon (:) as
1.3.1.3	Date Field Ranges		
	06/04/2010	(mm/dd/yy)	
	The system will display a m be entered is the current da	nessage that th ate.	ne date is o
1.3.1.4	Numeric Field Formats		
	Percent of Trapped Islets		(xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

2.0 Receive Broadcast Message about Islet Availability

Email Broadcast Message - This is the email Broadcast Message that the designated investigator(s) will receive about the availability of islets. Click on the URL link in the broadcast message or cut and paste the URL into the browser – refer to the next page.

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🔁 Reply 🔗 Reply to all 🚔 Forward 🚔 💽 🖄 😤 🔺 🔷 🕐 🔞 Help								
(1) This message was sent with high importance								
From:	iidp-email@cob.org [iidp-email@coh.org]	Sent: Sat 1/9/2010 2:36 PM						
To:	MMcDaniel@yestallocationsystem.com							
Cc:	Sibley, Heather; Jacobs, Amy							
Subject:	Targeted Offer (IIDP) - University of Miami - Islets for Research							
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You have until: 1/9/20	10.9-36-03 PM EST, to accept this offer							
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Thank you.								
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This is an automated e	mail. Please DO NOT reply to this message.							
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Login Screen - The system displays the login screen. Enter your username and password and then click on Login. IIDP assigns the username and password.



The islet offer will then be displayed – refer to the next page.

Islet Offer - Click on the radio button to the left of the PI name. Then click on one of the three (3) function buttons – [Learn More About Offer], [Reject Offer], or [Accept Offer].

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Accept Offer - Once you [Accept Offer], this screen is displayed and you will need to [Confirm Shipping Information] AND [Confirm Islet Offer]. Click on [View] to confirm shipping information. Please note the expiration time of the islet offer.

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[Return to Offers] [User Profile] [User Guide] [Center Contact Info] [Flash Frozen Islet Inventory] [Log off] 🚺 Help Desk	
	_
Confirmation of Islet Offe	
Before you accept this islet offer, please confirm the following two (2) items. Once both items have been confirmed, click on the [Accept Islets for Shipping] button to complete the process.	
1. Confirm Shipping Information View	
2. Confirm Islet Offer	
Offer expires in: 1 Hours, 55 Minutes, 24 Seconds.	
Accept Islets For Shipping	
TTDD Developed and maintained by the Integrated Islet Distribution Program (IIDP)	
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Integrated Islet Distribution ProgramTraining Site	
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(a) Menu ready for use	

Confirm Shipping Information – The system displays your shipping information that has been entered into the system. Review the information and edit and /or add to the data as needed.

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	INVESTIC		ODMATION					
	1. Princi	ipal Investigator:	ORMATION					
	1.1	Name:				Michael L. McDaniel		≡
	1.2	Telephone Numb	er:			314-362-7435		
	1.3	Cell Phone Provi	der:			Verizon 🗸		
	1.4	Cell Phone Numb	per:					
	1.5	Pager Number:						
		(Format: xxxxxx	xxxx@pagerservid	ce.com)				
	1.6	Fax Number:				123-555-1212		
	1.7	Email Address:				MMcDaniel@testallocatio		
	2. Instit	ution:				Washington University in {		
	3. Mailir	ng Address:						
	3.1	Address 1:				Dept. of Pathology & Imm		
	3.2	Address 2:				Campus Box 8118, 660 S		
	3.3	City:				St. Louis		
	3.4	State (if US):				MO V		
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	3.5	state (ir other th	an US);				~	~
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Use the **scroll bar** to scroll down to the bottom of the page. The **[Confirm Shipping Information]** screen continues on the next page.

Confirm Shipping Information (continued)

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	3.6	Province (if CAN):	<u>~</u>					
	3.7	Zip Code: 63110						
s	SHIPPING I	INFORMATION						
4	1. Expres	ss Shipping Vendor Used: Fed-Ex 💌						
	4.1	If OTHER, specify:						
5	5. Expres	ss Shipping Account Number: 0630-3320-0						
6	ó. Weekd	day Delivery Shipping Address (if different from mailing address):						
	6.1	Address 1: Dept. of Pathology & Imm						
	6.2	Address 2: 4566 Scott Ave.						
	6.3	City: St. Louis	=					
	6.4	State (if US): MO 🛩						
	6.5	State (if other than US):						
	6.6	Province:						
	6.7	Zip Code: 63110						
7	7. Weeke	end Delivery Shipping Address (if different from weekday shipping address):						
	7.1	Contact Name (if different from PI): Wendy Weekend						
	7.2	Address 1: 12439 Betsy Ross Lane						
	7.3	Address 2:						
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Use the **scroll bar** to scroll down to the bottom of the page. The **[Confirm Shipping Information]** screen continues on the next page.

Confirm Shipping Information (continued)

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		6.7	Zip Code: 63110			~			
7. Weekend Delivery Shipping Address (if different from weekday shipping address):									
		7.1	Contact Name (if different from PI): Wendy Weekend						
		7.2	Address 1: 12439 Betsy Ross Lane						
		7.3	Address 2:						
		7.4	City: St. Louis						
		7.5	State (if US):						
		7.6	State (if other than US):	1					
		7.7	Province:	1					
		7.8	Zip Code: 63146						
8		Weeker	kend Telephone Number (if different from telephone number):						
			Confirm						
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Click on [Confirm] to confirm your shipping information – refer to the next page OR click on [Cancel] to return to the [Accept Offer] screen – refer to page 8.

Accept Islet Offer – After confirming your shipping information the system returns you to the [Accept Islet Offer] screen. Please not the change in the function button for the shipping information from [View] to [Confirmed].

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[Return to Offers] [User Profile] [User Guide] [Center Contact Info] [Flash Frozen Islet Inventory] [Log off] 🛛 🕅 Help Desk						
Confirmation of Islet Offer						
Before you accept this islet offer, please confirm the following two (2) items. Once both items have been confirmed, click on the [Accept Islets for Shipping] button to complete the process.						
1. Confirm Shipping Information Confirmed						
2. Confirm Islet Offer						
Offen engine in 1 Hours 54 Minutes 6 Seconds						
Accept Islets For Shipping						
Developed and maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved. 						
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Click on [View] for the [Confirm Islet Offer] to proceed to the next step of the islet acceptance process – refer to the next page.

Confirm Islet Offer – The system displays the Islet Offer screen. Complete the **Special Packaging Requests** data field and the **Number of Islets Accepted** data field.

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Is	Islet Purity 95										
Is	slet Viability	94									
	hipping Information										
S Di	pecial Packaging Requests (may ot be accommodated)										
S	lamber of Islets Requested per Shipment	min: 5000 / max: 40000									
N	lumber of Islets being Offered	9000									
N	lumber of Islets Accepted										
A	sttn: Name (PI Name)	Michael L. McDaniel									
s	hipping Address	Dept. of Pathology & Immunology 4566 Scott Ave. St. Louis MO 63110									
P	hone Number	314-362-7435 💌									
S N	Shipping Vendor Name/Account Fed-Ex: 0630-3320-0										
D	ate Islets will be delivered on	1/11/2010 10:30:00 PM									
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Click on **[CONFIRM]** to confirm the islet offer – refer to the next page **OR** click on **[CANCEL]** and not confirm the islet offer – refer to page 8.

Accept Islet Offer – Once the shipping information and the islet offer have been confirmed, then the [Accept Islets For Shipping] button will be functional Click on [Accept Islets For Shipping] to complete the last step of the islet offer acceptance process.

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Confirmat	on of Islet Offer
Before you accept this islet offer, please confirm the following tw Islets for Shipping] button to complete the process.	o (2) items. Once both items have been confirmed, click on the [Accept
1. Confirm Shipping Information Confirmed 2. Confirm Islet Offer Confirmed	
Offer expires in: 1 H	lours, 53 Minutes, 8 Seconds.
Accept Is	lets For Shipping
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Accept Islet Offer Confirmation Message – The system will display a confirmation message that the islet offer has been accepted and saved in the system. Click on [Return to Offers] or [Close] to return to the islet offer – refer to the next page.

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Accept Islet Offer Confirmation Message	
Thank you for accepting this offer. Because islet offers are generally made based on post-purification counts, the final amount you receive may change once islets are re-counted post-culture. If islets cannot be shipped because of a loss of islets you will be notified.	
Close	
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Islet Offer screen - Click on **[Log off]** to log out of the system – refer to the next page.

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					There are	e currently no i	slet offers avai	lable to you.					
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			HISLOFY OF 1	siet Offers (Includ	ies all target	eu oriers and	ассертей ор	en otters seleci	led by the Al	nocation Sy	stem)		
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	Michael L. McDaniel	Targeted Offer	CIT	40000	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
N	Michael	Targeted	IIDP	40000	Not	Not	Most Pure	Cultured	University	1/7/2010	1/8/2010	NA	NA
	L. McDaniel	Offer			Documented	Documented			or Miami	PM PST.	PST.		
N	Michael	Targeted	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University	1/10/2010	1/11/2010	testship999333	test
	McDaniel	Oller							or miarri	PM EST.	EST.		
N	Michael	Targeted Offer	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University of Miami	1/31/2010	2/1/2010	NA	NA
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Islet Offer screen (continued) - Note the **[Status]** column (the status of the acceptance of the islet offer) - the default value of 'No Response' had been updated to 'Accepted'. If the islet offer had been rejected then the status value would have been changed to 'Rejected'.

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• Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	EQs Shipped	Learn More About Offer	Complete User Feedback Form			
1/5/2010	NA	NA	NA	No	NA	[Click Here]	NA			
12:00:00 PM				Response						
PS1.						Tab. L. a. J				
1/8/2010 5:00:00 PM	NA	NA	NA	No Response	NA		NA			
PST.										
1/11/2010	testship999333	testship3838833		Accepted	000	[Click Here]	[Part I] [Part II] [View]			
10:30:00 PM EST.			-							
2/1/2010	NA	NA	NA	No	NA	[Click Here]	NA			
10:00:00 AM				Response		[]				
ES1.										
							>			

Login Screen – The system displays the log in screen. Log in OR click on the [X] to close the browser.



Learn More About Offer – The system displays more information about the islet offer to review before making a decision to accept or reject the islet offer – continued on next page.

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Dates NOT AVa	illable for Shipping			
		Broadcast Message Regarding Availability of Islets for Resea	rch	
	Date:	1/30/2010 6:55:04 AM		
	Please review ALL of the information below	v and then select one of the following: [Accept Offer & Confirm Shipping Infor	mation] or [NOT Willing or Unable to Acept Offer]	
	Information Regarding Islets Availabl	le for Research		
	SUPPLIER AND GENERAL INFORMATION	N		
	Islet laboratory supplying islets:	University of Miami		
	Unos Id:	AKJ_TEST3845		
	Isolation ID#:	test3845_akj		
	PANCREAS DONOR INFORMATION			
	Date and time of cross clamp:	Jan 28 2010 8:00AM		
	Duration of cold ischemia:	Not Documented		
	Definition of cold ischemia:	Time from aortic cross clamp to the t of digestion	n (Phase I)	
	Age:	48.00 Years		
	Gender:	Male		
	Height:	72.00 inches		
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Learn More About Offer (continued) – refer to the next page.

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				Safety - Tools - 0 - »
	Weight:	210.0 lbs		<u>^</u>
	BMI:	28.50		
	Ethnicity/Race:	Black or African American		
	CMV status:	Negative		
	ABO Blood Group:	0		
	HLA Class 1 - A:	22,23		
	HLA Class 1 - B:	24,25		
	HLA Class 1 - C:	26,27		
	HLA Class 2 - DR:	28,29		
	Serology - HIV I/II:	Negative		
	Serology - HTLV I/II:	Negative		=
	Serology – Syphillis:	Negative		
	Serology – HbsAg:	Negative		
	Serology - HBc:	Negative		
	Cause of death:	Cerebrovascular/stroke		
	Medical history:	HTN		
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	PRE-SHIPMENT INFORMATION			
	Islets cultured prior to shipment:	Yes		
	Estimated culture time prior to shipment:	1 Day(s) 15.00 Hours(s)		
	Islets cryopreserved prior to shipment:			
	Islets shipped fresh:	Yes		~
Done			😜 Internet	- • • • 100% •

Learn More About Offer (continued)

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Comments:	test	
SHIPPING INFORMATION		
Total IEQs available for shipping:	20000	
Broadcast Islet Viability:	95	
Post Culture Islet Viability:		
Islet Viability staining method:	Inclusion Dye: Syto Green 13 / Exclusion Dye: Trypan Blue	
Broadcast Islet Purity:	94	
Post Culture Islet Purity:		
Base medium used for shipping:	Connaught Medical Research Laboratories (CMRL) 1066	
Additives to base medium:	Insulin Transferrin Selenium (ITS)	
Type of vessel used for shipping:	Cryo	
Packing of shipping vessel:	No ice	
Date and time islets available for shipping:	1/31/2010 10:00:00 AM	
Accept Offer & Confirm	Shipping Information NOT Willing or Unable to Accept Offer	
)	
│ / (∭), [[]) H	Developed and maintained by the Integrated Islet Distribution Program (IIDF at City of Hope	2)
	© 2010 All rights reserved.	
Done		Unternet

Click on [Accept Offer & Confirm Shipping Information] to accept the islet offer – refer to pages 8 - 17. Click on [NOT Willing or Unable to Accept Offer] to reject the islet offer – refer to the next page.

Reject Offer or NOT Wiling or Unable to Accept Offer – Select the rejection reason from the drop down menu – refer to the next page

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Reject Offer Reason	
Please enter your reason for not being willing or unable to accept the available islets at this time.	
Not performing islet experiments at this time	
If Other, specify:	
Submit	
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Reject Offer or NOT Wiling or Unable to Accept Offer – refer to the next page.

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Reject Offer Reason		
Not performing islet experiments at this time		
Not performing islet experiments at this time		
No staff available		
Out of office/town		
Other		
Developed and maintained by the Integrated Islet Distribution Program (IIDP)		
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Reject Offer or **NOT Wiling or Unable to Accept Offer –** Select the rejection reason from the drop down menu. If 'Other' is selected, enter the 'Other' reason in the textbox.

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[Return to Offers] [User Profile] [User Guide] [Center Contact Info] [Flash Frozen Islet Inventory] [Log off]	😰 Help Desk 🗠
Reject Offer Reason	
Please enter your reason for not being willing or unable to accept the available islets at this time:	
Not performing islet experiments at this time	
If Other specify:	
Submit	
at City of Hope	(IIDP)
© 2010 All rights reserved.	
Integrated Islet Distribution ProgramTraining SiteTraining Site	
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Click on **[Submit]** to submit the rejection reason to the system – refer to the next page.

Rejection of Islet Offer Confirmation Message – The system displays a message that the islet offer has been rejected. Click on **[Return to Offers]** or **[Close]** to return to the islet offer – refer to the next page.

IDP Website - Reject Offer - Microsoft Internet Explorer	- 7 🛛
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Reject Islet Offer Confirmation Message	
Thank you for submitting your response regarding the availability of islets for research.	
(Developed and maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope	
© 2010 All rights reserved.	
Integrated Islet Distribution ProgramTraining Site	
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Islet Offer screen - Click on **[Log off]** to log out of the system – refer to the next page Or select another menu option.

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🕥 Da	ates NOT Ava	ailable for (Shipping												
							Is	let Offer	s (includes t	ooth target	ed and ope	n offers)			
								There a	re currently n	o islet offers	available to	you.			
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Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status
♥	Debbie C. Thurmond	Targeted Offer	IIDP	300	89	98	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response
•	Debbie C. Thurmond	Targeted Offer	IIDP	1000	80	85	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA	NA	No Response
۹.	Debbie C. Thurmond	Targeted Offer	IIDP	1000	95	94	Most Pure	Fresh Cultured	University of Miami	1/10/2010 10:30:00 PM EST.	1/11/2010 10:30:00 PM EST.	NA	NA	NA	Rejected
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Login Screen – The system displays the log in screen. Log in OR click on the [X] to close the browser.

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Norton + 🕝 + 🕝 Cards & Log-ins +		
Welcome to the IIDP Welcome Investigators Trems of Use: Please note that this is the secure component of the IIDP, website. This system is only accessible to authorized members of the IIDP, Care must be taken at all times to protect the clinical and research data that is entered into the system. Username: Password: Description Porgot your password? Login Provember 4 maintained by the Integrated Left Set Set Set Set Set Set Set Set Set Se)	
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3.0 Return Shipping Materials to Center

Islet Offer screen – Shipping Materials – The islet shipping materials should be shipped back to the Center within 48 hours – refer to the next page.

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					There are	e currently no i	slet offers ava	llable to you.					
			History of I	slet Offers (inclu	des all target	ed offers and	l accepted op	en offers selec	ted by the A	llocation Sy	stem)		
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Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	ŧ Mai
	Michael L. McDaniel	Targeted Offer	CIT	40000	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010 12:00:00 PM PST.	1/5/2010 12:00:00 PM PST.	NA	NA
N	Michael	Targeted Offer	IIDP	40000	Not	Not	Most Pure	Cultured	University of Miami	1/7/2010	1/8/2010	NA	NA
	McDaniel	oner			Docamented	Documented			or marm	PM PST.	PST.		
	Michael	Targeted Offer	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University of Miami	1/10/2010	1/11/2010 10:30:00 PM	testship999333	test
	McDaniel	oner							or marm	PM EST.	EST.		
	Michael L. McDaniel	Targeted Offer	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University of Miami	1/31/2010 10:00:00 AM EST.	2/1/2010 10:00:00 AM EST.	NA	NA
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Islet Offer screen - Shipping Materials - The islet shipping materials should be shipped back to the Center within 48 hours.

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🟉 IIDP Website - O	🖗 IIDP Website - Offers												
ystem)	Note: N/A is entered in the [Material Shipping Tracking #] and [Date Materials Returned to Center] if the islets were picked up directly by the investigator or if the investigator did not respond to or rejected the islet offer.												
Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form						
1/5/2010 12:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA						
1/8/2010 5:00:00 PM PST.	NA	NA	NA	No Response	NA	[Click Here]	NA						
1/11/2010 10:30:00 PM EST.	testship999333	testship3838833		Accepted	5000	[Click Here]	[Part I] [Part II] [View]						
2/1/2010 10:00:00 AM	NA	NA	NA	No Response	NA	[Click Here]	NA						
EST.													
EST.							>	*					

Islet Offer screen – Shipping Materials – Click on the **[pencil icon]** for the system to change the desired islet offer to edit mode for the investigator to enter the date in the **[Date Materials Returned to Center]** data field – refer to the next page.

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			History of I	slet Offers (includ	des all target	ed offers and	accepted op	en offers select	ed by the A	location Sy	stem)		
Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mai
	Michael	Targeted	CIT	40000	89%	98%	Most Pure	Fresh	University	1/4/2010	1/5/2010	NA	NA
	L. McDaniel	Offer							of Miami	12:00:00 PM PST.	12:00:00 PM PST.		
	Michael	Targeted	IIDP	40000	Not	Not	Most Pure	Cultured	University	1/7/2010	1/8/2010	NA	NA
	L. McDaniel	Offer			Documented	Documented			of Miami	5:00:00 PM PST.	5:00:00 PM PST.		
	Michael	Targeted	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University	1/10/2010	1/11/2010	testship999333	test
	L. McDaniel	Offer							of Miami	10:30:00 PM EST	10:30:00 PM		
	Michael	Targeted		10000	9/%	05%	Less Dure	Fresh Cultured	University	1/31/2010	2/1/2010	NA	NA
	L.	Offer	IIDF	10000	54 /6	5576	Less Fulle	Tresh Cultureu	of Miami	10:00:00	10:00:00 AM		110
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Islet Offer screen – Shipping Materials – Click on the [calendar icon] to select a date to enter in the [Date Materials Returned to Center] data field then click on the [Save icon] (on the previous page of the first part of the Islet Offer screen) – refer to the next page.

🏉 IIDP Website -	Offers - Windows Internet E	xplorer					
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2 Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
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12:00:00 PM	10		10	Response	100	[enex nere]	
PST.							
1/8/2010	NA	NA	NA	No	NA	[Click Here]	NA
5:00:00 PM				Response			
PST.							
1/11/2010	testship999333	testship3838833	[mmm]	Accepted	5000	[Click Here]	[Part I] [Part II] [View]
10:30:00 PM							
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2/1/2010	NA	NA	NA	No	NA	[Click Here]	NA
10:00:00 AM				Response			
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Islet Offer screen – Shipping Materials – The date the shipping materials were returned to the Center has been entered and saved in the system – refer to the next page.

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			History of I	slet Offers (inclue	des all target	ed offers and	l accepted op	oen offers select	ted by the A	llocation Sy	rstem)		
Edit / Save	PI	Offer Type	Source of Islets	Amount Offered	Islet Purity	Viability	Batch Type	Type Of Islets	Institution	Ship Date	Delivery Date	Islet Shipping Tracking #	Mat
	Michael	Targeted	CIT	40000	89%	98%	Most Pure	Fresh	University	1/4/2010	1/5/2010	NA	NA
	L. McDaniel	Offer							of Miami	12:00:00 PM PST.	12:00:00 PM PST.		
N	Michael	Targeted	IIDP	40000	Not	Not	Most Pure	Cultured	University	1/7/2010	1/8/2010	NA	NA
	L. McDaniel	Offer			Documented	Documented			of Miami	5:00:00 PM PST.	5:00:00 PM PST.		
N	Michael	Targeted	IIDP	9000	95%	94%	Most Pure	Fresh Cultured	University	1/10/2010	1/11/2010	testship999333	test
	L. McDaniel	Offer							of Miami	10:30:00 PM EST.	10:30:00 PM EST.		
	Michael	Targeted	IIDP	10000	94%	95%	Less Pure	Fresh Cultured	University	1/31/2010	2/1/2010	NA	NA
	L. McDaniel	Offer							of Miami	10:00:00 AM EST.	10:00:00 AM EST.		
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Islet Offer screen – Shipping Materials – The date is saved in the system and the system will send a notification email message to the Center that the shipping materials have been returned by the investigator – refer to the next page.

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e Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking a	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form	
1/5/2010	NA	NA	NA	No	NA	[Click Here]	NA	
PST.				Response				
1/8/2010 5:00:00 PM	NA	NIA				Fabric States		
5:00:00 PM		NA	NA	No	NA	[Click Here]	NA	
PST.		NA	NA	No Response	NA	[Click Here]	NA	
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PST. 1/11/2010 10:30:00 PM	testship999333	testship3838833	NA 1/13/2010	No Response Accepted	NA 5000	[Click Here] [Click Here]	NA [Part I] [Part II] [View]	
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PST. 1/11/2010 10:30:00 PM EST. 2/1/2010 10:00:00 AM EST.	testship999333 NA	testship3838833 NA	NA 1/13/2010 NA	No Response Accepted No Response	NA 5000 NA	[Click Here] [Click Here] [Click Here]	NA [Part I] [Part II] [View] NA	
PST. 1/11/2010 10:30:00 PM EST. 2/1/2010 10:00:00 AM EST.	testship999333 NA	testship3838833 NA	NA 1/13/2010 NA	No Response Accepted No Response	NA 5000 NA	[Click Here] [Click Here] [Click Here]	NA [Part I] [Part II] [View] NA	
PST. 1/11/2010 10:30:00 PM EST. 2/1/2010 10:00:00 AM EST. C	testship999333 NA	NA testship3838833 NA	NA 1/13/2010 NA	No Response Accepted No Response	NA 5000 NA	[Click Here] [Click Here] [Click Here]	NA [Part I] [Part II] [View] NA	

Islet Offer screen – Shipping Materials – The email message that the system sends to the Center when a date is entered in the **[Date Materials Returned to Center]** data field by the investigator.

C Shipment is in transit - Wir	ndows Internet Explorer							
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🕰 Reply 🖓 Reply to all 🙈 Forward	🗼 Reply 🖓 Reply to all 🛱 Forward 🛃 🖄 🏠 🖄 🔺 🔺 🧶 🛞 Help							
This message was sent with high i	mportance.							
From:	iidp-email@coh.org [iidp-email@coh.org]		Sent: Wed 2/10/2010 10:25 PM					
To: Cc:	Jacobs, Amy							
Subject:	Shipment is in transit							
Attachments:								
Michael L. McDaniel has sh	ipped the islet shipping materials back to you.							
If you do not recieve the ma	terials in the next 48 hours, please use the [Materials Shipping Tracking #] which is testship3838833 to de	termine the status of the sh	ipment.					
If you have any additional qu	uestions or issues, please notify IIDP at iidp-email@coh.org							
Dana								

Islet Offer screen – Shipping Materials – The email message that the system sends to an investigator when a date has not been entered in the [Date Materials Returned to Center] data field within 48 hours of the date in the [Delivery Date] data field.

https://email2.coh.or	g - Targeted Offer (IIDP) - University of Miami - Islet	ts for Research - Microsoft Internet Explorer 📃 🖻 🔀					
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1) This message was sent with high importance.							
From: To: Cc: Subject: Attachments:	iidp-email@coh.org [iidp-email@coh.org] MMcDaniel@testallocationsystem.com Sibley, Heather; Jacobs, Amy Return of Shipping Materials	Sent: Sat 1/9/2010 2:36 PM					
Dear Michael L. McDaniel, A date has not been entered in the [Date Materials Returned to Center] data field in the Islet Offer History screen. Please enter the date when you returned the islet shipping materials to the center. You will not be eligible for additional targeted islet offers until the shipping materials have been returned AND the User Feedback Form has been completed. If you did not receive the islet shipment or if you directly picked up the islets from the center or if you have any questions, please notify the IIDP at <u>iidp- email@coh.org</u> . Thank you.							
I nank you, IIDP							

This is an automated es	mail. Please DO NOT reply to this message. ************************************						
This is an automated email. Please DO NOT reply to this message. ************************************							
Done		🔒 Unknown Zone (Mixed)					

4.0 View/Change your User Profile

View/Change your User Profile - Click on [User Profile] to display the options of [Change User Information] and [Change Password].

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Change User Information - Click on [Change User Information] to display the User Information screen – refer to the next page.

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	Username:	WMoore							
	Name:	Wayne Moore							
	Telephone Number:	816-983-6640							
	Cell Phone Provider:								
	Cell Phone Number:								
	Pager Number:								
	Fax Number:	123-555-1212							
	Email Address:	WMoore@testallocationsystem.com							
	Mailing Address								
	Address 1:	Janette Williams							
	Address 2:	2146 W 39th Ave MS 3051 Room 2016							
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Review the information and click on [Edit] to make changes as needed - refer to the next page.

OR

Click on another menu option, if there are no required changes.

Islet Data Entry System (IDES)

User Information - the system will display the User Profile information in the Edit Mode. Edit the User Profile as needed – continued on the next page.

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Click on [Submit] to submit the changes to the system.

User Information - The system will display the changed User Profile information for the user to review. If additional changes are needed, click on **[Edit]** and repeat the process to edit the User Profile information. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.

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	Telephone Number:	816-983-6640	
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	Pager Number:		
	Fax Number:	123-555-1212	
	Email Address:	WMoore@testallocationsystem.com	
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Change Password – Click on **[Change Password]** to display the Change Password screen – refer to the next page.

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Change Password -The system will display the Change User Password screen.

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Change password and then click on [Submit]. The system will return the user to the Islet Offers screen.

Islet Offers screen - The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.

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5.0 View the User Guide

User Guide – Click on [User Guide] to display the User Guide to review – refer to the next page.

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User Guide – Click on [Open] to display the user guide – refer to the next page. Click on [Save] to save the user guide or click on [Cancel] to cancel opening the user guide.

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User Guide – The system displays the User Guide. Use the scroll bar on the right to scroll through and view the document. Save the document if desired or click on the **[Back]** button in the upper left hand corner to return to the Islet Offers screen

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Islet Offers screen - The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.

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6.0 Submit a Help Desk Request

Help Desk Request – Click on [Help Desk] icon to display the Help Desk Request screen – refer to the next page.

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**Help Desk Request** – The system displays the **[Help Desk]** screen. Select the issue from the drop down list – refer to the next page. Enter a brief description of the issue in the textbox. Click on **[Submit]** to submit the help desk request to the system – refer to page 48.

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Help Desk Request – The system displays the issues selection in the drop down list – refer to page 46.

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Help Desk Request – The system displays the help desk request confirmation message. Click on **[X]** to close the confirmation message screen – refer to the next page.

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## 7.0 Dates Not Available for Shipping

Dates Not Available for Shipping – Click on [Dates NOT Available for Shipping] icon to display the screen to enter dates when not available – refer to the next page



**Dates Not Available for Shipping** – Enter the **[Start Date]** and **[End Date]** for the time when you will not be available to receive islets. Click on **[Add date range]** to submit and add the date range to the system – refer to the next page.

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**Dates Not Available for Shipping** – The system displays the date range that has been entered. Click on **[Delete]** to delete a date range from the system. Repeat the process as needed for adding and/or deleting other date ranges of unavailability. Click on **[Return to Offers]** when you have finished the process of adding and/or deleting date ranges – refer to the next page.

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**Dates Not Available for Shipping** – The system returns the user to the Islet Offers screen. Click on another menu option as desired to continue in the system or click on **[Log off]** to exit the system.

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## 8.0 Other Functions

Islet Offer screen - Refer to the notes below and to the next page.

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#### **Islet Offer screen –** Refer to the note below.

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**Integrated Islet Distribution Program** 

# User Feedback Form User Guide for Broadcasting Staff

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2.0	Login to the Islet Data Entry System (IDES)	5
3.0	View Completed User Feedback Form (UFF)	6
#### **1.0 General Guidelines**

#### 1.1. Navigation

The Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Main Menu (e.g. access the Enter New Isolation data form, View Islet Offers, etc.). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for viewing completed User Feedback Forms (UFFs) are presented in the remaining sections of this User's Guide.

#### 1.2. Screens

#### 1.2.1 Screen Format

All of the User Feedback Form (UFF) data entry screens are designed to be a 'single page' in which the data for each section of the User Feedback Form (UFF) are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

#### 1.2.2 Data Entry Formats

Different formats are used within the User Feedback Form (UFF) to capture the data.

1.2.2.1 Text Boxes

- o Data must be typed in
- o Used to capture text, dates, and numeric values such as a laboratory value
- Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

#### 1.2.2.2 Pick Lists

- o Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- Click on the arrow to display the list choices
- o Click on the desired option and it will be displayed in the box

#### 1.2.2.3 Check Boxes

- o Used when one of several options must be chosen e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- $\circ$   $\;$  There are instances when multiple check boxes can be checked in response to the question

#### 1.3 System Messages

#### 1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1	Date Field Formats
	(mm/dd/yy)
	The system will automatically enter the forward slashes (1) as you enter the date.
1.3.1.2	Time Field Formats
	(hh:mm)
	The system will automatically enter the colon (:) as you enter the time.
1.3.1.3	Date Field Ranges
	06/04/2010 (mm/dd/yy)
	The system will display a message that the date is out of range and that the latest date that may be entered is the current date.
1.3.1.4	Numeric Field Formats
	Percent of Trapped Islets (xxx.xxx)
	This is one example of a numeric field format within the Batch Record Data Form.
1.3.1.5	Numeric Field Ranges
Acceptable Numeric Value	→Percent of Trapped Islets 75.34 % (xxx.xxx)
Numeric Value Out of Range	Percent of Trapped Islets 110.93 % (xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

# 2.0 Login to the Islet Data Entry System (IDES)

This is the Login Screen to access the Islet Data Entry System (IDES). IIDP will issue each user a Username and Password. Enter your username and password and click on [Login]. The system will display the Main Page – refer to the next page.



# 3.0 View Completed User Feedback Form (UFF)

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	To navigate through the system, select from the options in the above blue panel by "clicking" directly on the desired choice. To report problems or questions by email, click on "Help Desk"		
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	<ul> <li>Enter a New Distribution Record</li> <li>Edit/View Existing Quick Broadcast</li> <li>Edit/View Existing Distribution Record</li> <li>View Islet Offer</li> <li>Confirm Authorized Data Entry Staff Contact Information</li> <li>Download Islet Notify System</li> <li>Previously Broadcasted Isolations and Flash Frozen Islet Inventory</li> </ul>		
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#### Main Page – To view completed user feedback form(s), click on [View Jslet Offer] under [Records for All Isolations] - refer to the next page.

Islet Offer screen - Click on [Click Here] under the [View User Feedback Form(s)] column of the designated islet offer to view the completed user feedback form(s) that have been completed for that islet offer – refer to the next page.

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View User Feedback Form screen – If no User Feedback Form(s) (UFF(s)) has/have been submitted for an offer, this is what will be displayed. Refer to the next page for submitted UFF(s).

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View User Feedback Form screen - User feedback form(s) (UFF) that have been completed for the designated islet offer – Click on [View] of the designated UFF to view the completed UFF - refer to the next page.



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[ IIDP Home ] [ Log off ]		
User Feedback Form		
Recipient Informa	ation	
1. UNOS ID:	AKJ_TEST3845	
2. Today's date:	02/01/2010	
3. Title of project:	test	
4. Principal Investigator:	Francis S. Collins	
5. Date tissue received:	01/31/2010	
6. Shipment received from (Name of center):	University of Miami	
Islet Assessment (evaluate	d by recipient)	
Condition of Shipment		
1. Select if the islets were shipped to you or if you picked up the islets directly:	Shipped	
2. Were the islets packed in a cardboard covered styrofoam box?	Yes	
2.1 If NO, specify the type of packaging used:		
3. Temperature indicator activation status:	Activated low temperature (Red)	
4. Select the type of vessel the islets were shipped in and enter the volume of the vessel:	Permalife PL 120 bag 125 mLs	
4.1 If OTHER, specify what type of vessel used:		
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#### **Completed UFF – Screenshot 1 of 4** – Use the scroll bar on the right hand side to view the entire form.

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5. Were ambient temperature gel packs used?	Yes	^
5.1 If NO, enter the type of temperature control devices used (enter 'NONE' if nothing was included):		
5.2 If YES, continue with the questions below:		
5.2.1 Were the islets packed with six(6) gel packs?	Yes	
5.2.1.1 If NO, specify number of gel packs used:		
5.2.2 Record the number of gel packs next to their condition upon arrival:		
5.2.2.1 Hard	3	
5.2.2.2 Soft	3	
5.2.2.3 Slushy	0	
5.2.2.4 Liquid	0	
6. Were the islets packed with absorbent material?	Yes	
6.1 If NO, specify what packing material was used:		
Condition of Islets (evaluation	n by recipient)	
1. Select your perceived quality of the islets at the time of arrival - general (select one):	Excellent	
1.2.1.1 If FAIR, POOR, or OTHER, specify reason:		
2. Were the islets used in experiments?	Yes	
2.1 If NO, specify the reason:		
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#### **Completed UFF (continued) – Screenshot 2 of 4** – Use the scroll bar on the right hand side to view the entire form.

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2.2 If YES, were the experiments successful?		Yes			^
2.2.1 If not, can you attribute the lack of success	s to the quality of the islets from this shipment?				
2.3 After using the islets in your experiments, select	your perceived quality of the islets:	Excellent			
2.3.1 If FAIR, POOR, or OTHER, specify reason:		,			
2.4 Please provide as much detail as you feel necess	ary to describe the success of your experiments	test			
and/or the quality of the islets from this shipment	:				
3. Was morphology and/or functional integrity assessed	after shipment?	Yes			
3.1 If YES, identify tests used in evaluation and the m	esults of these tests:				
Test Type	Test Name		Test Desults		
Morphology	test A		test A results		=
4. Was an islet count performed after the shipment was	received?	Vec			
4.1 If YES, provide the following information:		165			
4.1.1 Islet Count - IEQs:		10000			
4.1.2 Was the counter trained to count Human If	Qs?	Yes			
4.1.2.1 What specific counting method v	vas used in your training?	test			
4.1.3 How long were the islets incubated before	counting?	4 Hours			
					~
Done			😜 Internet	<u></u> •	100% 🔹 📑

# **Completed UFF (continued) – Screenshot 3 of 4** – Use the scroll bar on the right hand side to view the entire form.

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5. Purity (evaluated by recipient laboratory):	95 % Assessment not performed	
5.1 Purity assessment method(s):	test	
6. Viability (evaluated by recipient laboratory):		
6.1. Vishility accessment method(s):	Assessment hot performed	
0.1 Viability assessment method(s).	test	
<ol><li>Did the last shipment meet your expectations?</li></ol>	Yes	
7.1 If NO, define the problem encountered:		
8. Additional comments:	testing	
	Person Completing the Form	
1. Name:	Amy K. Jacobs	
2. Telephone Number:	555-555-3333	
	Print CLOSE	
	Developed and maintained by the Integrated Islet Distribution Program (IIDP)	
	at City of Hope	
e	Internet	🖌 - 🔍 100% -

#### **Completed UFF (continued) – Screenshot 4 of 4** – Use the scroll bar on the right hand side to view the entire form.

Click on [Print] to print the UFF OR click on [Close] to close the UFF and return to the View User Feedback Form screen – refer to the next page.

View User Feedback Form screen – Click on [View] to view another completed UFF OR click on [Return to offer list] to return to the View Islet Offer screen – refer to the next page OR click on [IIDP Home] to perform other actions OR click on [Log off] to log out of IDES.

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	User Feedback Form	PI Name	Institution	Date Submitted	Status - Part I	Status - Part II	
	[Part I] [Part II] [View]	Francis S. Collins	University of Miami	02/01/2010	Submitted	Submitted	
	Int	Egrated Islet Distribution Progr	Developed and maintai	er list ined by the Integrated Islet at City of Hope © 2010 All rights reserve Training Site	Distribution Program (IIDF d.	2)	√2 × € 100% ×

Islet Offer screen - Click on [Click Here] under the [View User Feedback Form(s)] column of the designated islet offer to view another completed UFF and repeat the process OR click on [IIDP Home] to perform other actions – refer to the next page OR click on [Log off] to log out of IDES.

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#### Main Page - Click on another action as applicable OR click on [Log off] to log out of IDES.



**Integrated Islet Distribution Program** 

# **Electronic User Feedback Form User Guide for Investigator**

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1.0	General Guidelines	3
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#### **1.0 General Guidelines**

#### 1.1. Navigation

The Principal Investigator (PI) section of the Islet Data Entry System (IDES) has several components available to the users. You can navigate around in the system from the Islet Offer Screen (e.g. access the User Feedback Form (UFF)). The computer mouse or tab button is used to move from items on a screen and to activate the buttons on each screen. Instructions for completing each section of Part I and Part II of the User Feedback Form (UFF) are presented in the remaining sections of this User's Guide.

#### 1.2. Screens

#### 1.2.1 Screen Format

All of the User Feedback Form (UFF) data entry screens are designed to be a 'single page' in which the data for each section of the User Feedback Form (UFF) are captured on one screen. You may use the scroll bar to scroll down to the bottom of the screen as needed.

#### 1.2.2 Data Entry Formats

Different formats are used within the User Feedback Form (UFF) to capture the data.

1.2.2.1 Text Boxes

- o Data must be typed in
- o Used to capture text, dates, and numeric values such as a laboratory value
- Data can either be entered as free text, such as a comment or entered according a designated format, such as dates (mm/dd/yy) or numeric value formats (xxx.xx)

1.2.2.2 Pick Lists

- o Also referred to as 'drop down boxes', 'pull-down lists', or 'combo lists'
- Click on the arrow to display the list choices
- o Click on the desired option and it will be displayed in the box

#### 1.2.2.3 Check Boxes

- o Used when one of several options must be chosen e.g. Unknown or Not Done
- There are instances when only one check box can be checked in response to the question
- o There are instances when multiple check boxes can be checked in response to the question

#### 1.3 System Messages

#### 1.3.1 Consistency Checks/Field Validation Messages

While you enter data, the system performs field validation checks on certain fields (e.g. check formats for dates, times and numeric values and check the acceptable ranges of numeric values) and consistency checks between select fields (e.g. the date and time combination of pancreas recovery must be later than the date and time combination of cross clamp). The system will display a message if your data entry does not pass the validation or consistency checks. You must modify the data to resolve the incorrect data entry. The following are examples of correct data entry formats:

1.3.1.1	Date Field Formats
	(mm/dd/yy)
	The system will automatically enter the forward slashes (/) as you enter the date.
1.3.1.2	Time Field Formats
	(hh:mm)
	The system will automatically enter the colon (:) as you enter the time.
1.3.1.3	Date Field Ranges
	06/04/2010 (mm/dd/yy)
	The system will display a message that the date is out of range and that the latest date that may be entered is the current date.
1.3.1.4	Numeric Field Formats
	Percent of Trapped Islets (xxx.xxx)
	This is one example of a numeric field format within the Batch Record Data Form.
1.3.1.5	Numeric Field Ranges
Acceptable Numeric Value	→Percent of Trapped Islets 75.34 % (xxx.xxx)
Numeric Value Out of Range	Percent of Trapped Islets 110.93 % (xxx.xxx)

The system will display a message that the numeric value is out of the acceptable range for those numeric values that are out of range.

# 2.0 Login to the Islet Data Entry System (IDES)

This is the Login Screen to access the Islet Data Entry System (IDES). IIDP will issue each user a Username and Password. Enter your username and password and click on [Login]. The system will display the Islet Offer screen – refer to the next page.

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# **Islet Offers screen** – The system displays the Islet Offers screen. Refer to the next sections regarding completing Part I and Part II of the User Feedback Form (UFF) and viewing completed UFFs.

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# 3.0 Complete Part I of the User Feedback Form (UFF)

**Islet Offers screen** – Under the History of Islet Offers, select the designated Islet Offer to complete the User Feedback Form (UFF). There are two parts of the UFF. Complete Part I and then Part II can be completed. There is also the option to [View] completed UFFs. Refer to the next page to view where to access the UFF.

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Islet Offer screen (continued) – Under the column [Complete User Feedback Form], click on [Part I] to complete Part I of the UFF – refer to the next page. Until Part I has been completed and submitted, the links for [Part II] and [View] will be nonfunctional ('grayed' out').

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Delivery Date	Islet Shipping Tracking #	Materials Shipping Tracking #	Date Materials Returned to Center	Status	IEQs Shipped	Learn More About Offer	Complete User Feedback Form
1/5/2010	NA	NA	NA	No	NA	[Click Here]	NA
PST.				Response			
1/7/2010	NA	NA	NA	No	NA	[Click Here]	NA
CST.				Response			
1/8/2010	NA	NA	NA	No	NA	[Click Here]	NA
PST.				Response			
1/29/2010 12:00:00 PM	test	test		Accepted	20025	[Click Here]	[Part I] [Part II]
PST.				Offer			
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**Part I of the User Feedback Form** – Screenshot 1 of 4 of Part I of the UFF – Complete the data fields of the form. All data fields are required except for the 'Comments' data field at the end of the form and the conditional fields of 'If NO,.....' or 'If YES,....' Refer to screenshots 2, 3, and 4 on the following pages. Use the scroll bar on the right hand side to navigate through the form.

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[Return to Offers] [User Profile] [User Guide] [Center Contact Info] [Flash Frozen Islet Inventor	y] [Log off]
IIDP User Feedback Form	
Recipient Information	ation
1. UNOS ID:	M014
2. Today's date:	02/08/2010
3. Title of project:	
4. Principal Investigator:	Nathan Goodman
5. Date tissue received:	
6. Shipment received from (Name of Center):	University of Miami
Islet Assessment (evaluate	ed by recipient)
Condition of Shipment	
1. Select if the islets were shipped to you or if you picked up the islets directly:	Shipped 💌
2. Were the islets packed in a cardboard covered styrofoam box?	
2.1 If NO, specify the type of packaging used:	
3. Temperature indicator activation status:	
4. Select the type of vessel the islets were shipped in and enter the volume of the vessel:	mLs
4.1 If OTHER, specify what type of vessel used:	
Done	🔪 Internet 🦓 👻 100% 🔻 🙀

C IIDP Website - User Feedback Form - Part I - Windows Internet Explorer	
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Ge IIDP Website - User Feedback Form - Part I	Note: Required data fields are »
5. Were ambient temperature gel packs used?	that are not required to be
5.1 If NO, enter the type of temperature control devices used (enter 'NONE' if nothing was included):	completed are nonfunctional ('graved out').
5.2 If YES, continue with the questions below:	
5.2.1 Were the islets packed with six(6) gel packs?	Y
5.2.1.1 If NO, specify number of gel packs used:	
5.2.2 Record the number of gel packs next to their condition upon arrival:	
5.2.2.1 Hard	
5.2.2.2 Soft	
5.2.2.3 Slushy	
5.2.2.4 Liquid	
6. Were the islets packed with absorbent material?	×
6.1 If NO, specify what packing material was used:	
Condition of Islets (evaluation by r	ecipient)
1. Select your perceived quality of the islets at the time of arrival - general (select one):	
1.2.1.1 If FAIR, POOR, or OTHER, specify reason:	
2. Were the islets used in experiments?	✓
2.1 If NO, specify the reason:	
Done	🌑 Internet 🦓 🔹 🕄 100% 💌

#### Part I of the User Feedback Form - Screenshot 2 of 4 of Part I of the UFF - refer to the next page.

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<i> (</i> IIDP Website - User	Feedback Form - Part I	🦄 👻 🖾 👘 👻 Page 👻 Safety 👻 Tools 👻 🔞 👻	»
4. Wasa	an islet count performed after the shipment was received?	×	^
4.1	If YES, provide the following information:		
4	.1.1 Islet Count - IEQs:		
4	.1.2 Was the counter trained to count Human IEQs?		
	4.1.2.1 What specific counting method was used in your training?		
4	How long were the islets incubated before counting?	Hours	
5. Purity	(evaluated by recipient laboratory):	% Assessment not performed	
5.1 F	Purity assessment method(s):		
6. Viabil	ity (evaluated by recipient laboratory):	% Assessment not performed	
6.1 \	/iability assessment method(s):		
7. Did th	e last shipment meet your expectations?		
7.1 I	f NO, define the problem encountered:		
8. Additi	onal comments:		
			-
1 Name	. Person Completing t	he Form	
1. Name			~
Done	hone Number		

#### Part I of the User Feedback Form - Screenshot 3 of 4 of Part I of the UFF - refer to the next page.

#### Part I of the User Feedback Form - Screenshot 4 of 4 of Part I of the UFF.

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		^
<ol><li>Viability (evaluated by recipient laboratory):</li></ol>	% Assessment not performed	
6.1 Viability assessment method(s):		
7. Did the last shipment meet your expectations?		
7.1 If NO, define the problem encountered:		
8. Additional comments:		
Person Com	pleting the Form	
1. Name:		
2 Telephone Numbert		
Print Save	Save and Submit	
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	at City of Hope © 2010 All rights reserved.	
Integrated Islet Distribution Program	Training Site	
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Click on [Save] to save Part I of the UFF and complete at a later time - refer to the confirmation message on the next page OR click on [Save and Submit] to save and submit the completed Part I of the UFF - refer to the confirmation message on page 14.

<b>Confirmation message</b> - Part I of the UFF has	been saved in the system and is incomplete. Click on [Close] to return to the islet Offers s	creen – refer to page 7.
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	Save User Feedback Form	
	The User Feedback Form has been saved in the system but has not been submitted. Return to the PI Islet Offer History screen and click on [Part I] or [Part II] of the designated islet offer to complete and/or submit the form. Please contact iidp- email@coh.org if you have any questions or concerns.	
	CLOSE	
	Developed and maintained by the Integrated Islet Distribution Program (IIDP)	
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Confirmation Massage Thank you for submitting Part I of the User Feedback form. You will now be eligible to provide a stational of the shipping metrics have also been provide Part II of the User Feedback form. Please contact info- please complete Part II of the User Feedback form. Please contact info- email@cb.org if you have any questions or concerns. CLOSE Developed and maintained by the Integrated Talet Distribution Program (IIDP) a City of Hope © 2010 All rights reserved. Training Site	🖉 IIDP Website - User Feedback Form - Part I			🟠 • 🔊 - 🖃 🖶 •	Page 🔹 Safety 👻 Tools 🔹 🕢 🍟
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# 4.0 Complete Part II of the User Feedback Form (UFF)

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<b>N</b>	Nathan Goodman	Targeted Offer	CIT	20025	89%	98%	Most Pure	Fresh	University of Miami	1/4/2010	1/5/2010 12:00:00 PM	NA	NA
										PM PST.	PST.		
<b>N</b>	Nathan	Targeted	IIDP	20025	89%	98%	Most Pure	Cultured	University	1/6/2010	1/7/2010	NA	NA
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	Nathan	Targeted	IIDP	20025	80%	85%	Most Pure	Cultured	University	1/7/2010	1/8/2010	NA	NA
	Goodman	Offer							of Miami	3:00:00 PM PST.	3:00:00 PM PST.		
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<ul> <li>System)</li> <li>Delivery Date</li> <li>1/5/2010</li> <li>12:00:00 PM</li> <li>PST.</li> </ul>	Islet Shipping Tracking #	Materials Shipping Tracking #	<b>Date Materials Returned to Center</b> NA	Status No Response	IEQs Shipped NA	Learn More About Offer [Click Here]	Complete User Feedback Form
<ul> <li>System)</li> <li>Delivery Date</li> <li>1/5/2010</li> <li>12:00:00 PM</li> <li>PST.</li> <li>1/7/2010</li> </ul>	Islet Shipping Tracking # NA	Materials Shipping Tracking # NA	Date Materials Returned to Center NA	Status No Response No	IEQs Shipped NA	Learn More About Offer [Click Here] [Click Here]	Complete User Feedback Form
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST	Islet Shipping Tracking # NA NA	Materials Shipping Tracking # NA NA	Date Materials Returned to Center NA NA	Status No Response No Response	IEQs Shipped NA NA	Learn More About Offer [Click Here] [Click Here]	Complete User Feedback Form NA NA
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST.           1/0/2010	Islet Shipping Tracking # NA NA	Materials Shipping Tracking # NA NA	Date Materials Returned to Center NA NA	Status No Response No Response	IEQs Shipped NA NA	Learn More About Offer [Click Here] [Click Here]	Complete User Feedback Form NA NA
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST.           1/8/2010           3:00:00 PM	Islet Shipping Tracking # NA NA NA	Materials Shipping Tracking # NA NA NA	Date Materials Returned to Center NA NA NA	Status No Response No Response	IEQs Shipped NA NA NA	Learn More About Offer [Click Here] [Click Here] [Click Here]	Complete User Feedback Form NA NA
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST.           1/8/2010           3:00:00 PM           PST.	Islet Shipping Tracking # NA NA NA	Materials Shipping Tracking # NA NA NA	Date Materials Returned to Center NA NA NA	Status No Response No Response	IEQs Shipped NA NA NA	Learn More About Offer [Click Here] [Click Here] [Click Here]	Complete User Feedback Form NA NA
<ul> <li>System)</li> <li>Delivery Date</li> <li>1/5/2010</li> <li>12:00:00 PM</li> <li>PST.</li> <li>1/7/2010</li> <li>5:00:00 PM</li> <li>CST.</li> <li>1/8/2010</li> <li>3:00:00 PM</li> <li>PST.</li> <li>1/29/2010</li> <li>12:00:00 PM</li> </ul>	Islet Shipping Tracking #         NA         NA         NA         test	Materials Shipping Tracking # NA NA NA	Date Materials Returned to Center NA NA NA	Status No Response No Response Accepted Oper	IEQs Shipped NA NA NA 20025	Leari More About Offer [Click Here] [Click Here] [Click Here]	Complete User Feedback Form NA NA NA [Part I] [Part II] [View]
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST.           1/8/2010           3:00:00 PM           PST.           1/29/2010           12:00:00 PM           PST.	Islet Shipping Tracking # NA NA NA test	Materials Shipping Tracking # NA NA NA test	Date Materials Returned to Center NA NA NA	Status No Response No Response Accepted Open Offer	IEQs Shipped NA NA NA 20025	Leari More About Offer [Click Here] [Click Here] [Click Here] [Click Here]	Complete User Feedback Form         NA         NA         NA         Part I] [Part II] [View]
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST.           1/8/2010           3:00:00 PM           PST.           1/29/2010           12:00:00 PM           PST.	Islet Shipping Tracking # NA NA NA test	Materials Shipping Tracking # NA NA NA test	Date Materials Returned to Center NA NA NA	Status No Response No Response Accepted Open Offer	IEQs Shipped NA NA NA 20025	Learn More About Offer [Click Here] [Click Here] [Click Here] [Click Here]	Complete User Feedback Form NA NA NA [Part I] [Part II] [View]
System)           Delivery Date           1/5/2010           12:00:00 PM           PST.           1/7/2010           5:00:00 PM           CST.           1/8/2010           3:00:00 PM           PST.           1/8/2010           3:00:00 PM           PST.           1/29/2010           12:00:00 PM           PST.	Islet Shipping Tracking # NA NA NA test	Materials Shipping Tracking # NA NA NA test	Date Materials Returned to Center NA NA NA	Status No Response No Response Accepted Open Offer	IEQs Shipped NA NA NA 20025	Leari More About Offer [Click Here] [Click Here] [Click Here]	Complete User Feedback Form NA NA [Part I] [Part II] [View]

#### Islet Offer screen (continued) - Click on [Part II] to complete Part II of the UFF - refer to the next page.

#### Part II of the UFF – Part I data fields are 'read only' – refer to the next page.

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	1.	UNOS ID:	M014					
	2.	Today's date:	02/08/2010					
	з.	Title of project:	test QA					
	4.	Principal Investigator:	Nathan Goodma	in				
	5.	Date tissue received:	02/01/2010					
	6.	Shipment received from (Name of center):	University of Mia	ami				
		Islet Assessment (evaluated by recipient)						
	Cond	ition of Shipment						
	1.	Select if the islets were shipped to you or if you picked up the islets directly:	Shipped					
	2.	Were the islets packed in a cardboard covered styrofoam box?	Yes					
		2.1 If NO, specify the type of packaging used:						
	з.	Temperature indicator activation status:	Inactivated (No	color)				
	4.	Select the type of vessel the islets were shipped in and enter the volume of the vessel:	Lifecell 300 ml t	310	mLs			
		4.1 If OTHER, specify what type of vessel used:						
	-	···· · · · · · · · · · · · · · · · · ·						~
Done						😜 Internet	- A	100% -

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5. Were ambient temperature gel	packs used?	Yes		_		
5.1 If NO, enter the type o	f temperature control devices used (enter 'NONE' if nothing was included):					
5.2 If YES, continue with th	e questions below:					
5.2.1 We	re the islets packed with six(6) gel packs?	Yes				
5.2	.1.1 If NO, specify number of gel packs used:					
5.2.2 Re	cord the number of gel packs next to their condition upon arrival:					
5.2	.2.1 Hard	2				
5.2	.2.2 Soft	2				
5.2	.2.3 Slushy	1				
5.2	.2.4 Liquid	1				
6. Were the islets packed with abs	orbent material?	Yes				
6.1 If NO, specify what page	king material was used:					
Condition of Islets (evaluation by recipient)						
1. Select your perceived quality of	the islets at the time of arrival - general (select one):	Excellent				
1.2	.1.1 If FAIR, POOR, or OTHER, specify reason:					
	Part II					
2. Were the islets used in experiment	s? Yes 🗸			~		
Done			😜 Internet 🦓 🗸 🤨	100% -		

#### Part II of the UFF - Part I data fields are 'read only'. Part II required data fields are in pink - refer to the next page.

**Part II of the UFF** – Part II required data fields are in pink and conditional data fields are nonfunctional ('grayed out'). If 'Yes' is selected for Question 3 of Part II, then Question 3.1 will become functional. Then click on **[Add integrity test]** to add an integrity test. Repeat the process as needed for each integrity test – refer to the next page.

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Part II		<u>^</u>				
2. Were the islets used in experiments? Yes 💌						
2.1 If NO, specify the reason:		-				
2.2 If YES, were the experiments successful?						
2.2.1 If not, can you attribute the lack of success to the quality of the islets from this shipment?						
2.3 After using the jelets in your experiments, callect your perceived quality of the jelets						
	_					
2.3.1 If FAIR, POOR, or OTHER, specify reason:						
2.4 Please provide as much detail as you feel necessary to describe the success of your experiments and/or the quality of the islets from this shipment:						
3. Was morphology and/or functional integrity assessed after shipment?						
3.1 If YES, identify tests used in evaluation and the results of these tests:						
Integrity Tests Performed						
Delete Test Type Test Name	Test Results	1				
Test Type Test Name	Test Results					
Morphology 💌						
Add integrity test						
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Part II of the UFF – Refer to Questions 3 and 3.1 - click on [Add integrity test] to add an integrity test. Repeat the process as needed for each integrity test – refer to the next page.

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2. Were the islets used in experiments?					
2.1 If NO, specify the reason:					
2.2 If YES, were the experiments successful? Yes ♥					
2.2.1 If not, can you attribute the lack of success to the quality of the islets from this shipment?					
2.3 After using the islets in your experiments, select your perceived quality of the islets: Excellent 🗸					
2.3.1 If FAIR, POOR, or OTHER, specify reason:					
2.4. Please provide as much detail as you feel necessary to describe the success of your experiments					
and/or the quality of the islets from this shipment:					
3. Was morphology and/or functional integrity assessed after shipment?					
2.1. If VES, identify tests used in evaluation and the results of these tests:					
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Part II of the UFF – Refer to Questions 3 and 3.1 – Click on [Delete] of an integrity test if an integrity test that was entered needs to be deleted. Repeat the [Add integrity test] process to add additional integrity test(s) - refer to the next page.

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	101111				~	
2. Were the islets used in experiments?		Yes 💌				
2.1 If NO, specify the reason:						
2.2 If YES, were the experiments successful?		Yes 💙				
2.2.1 If not, can you attribute the lack of success to	the quality of the islets from this shipment?					
2.3 After using the islets in your experiments, select your	perceived quality of the islets:	Excellent 💌				
2.3.1 If FAIR, POOR, or OTHER, specify reason:						
2.4 Please provide as much detail as you feel necessary to describe the success of your experiments test						
and/or the quality of the islets from this shipment:						
3. Was morphology and/or functional integrity assessed afte	shipment?	Yes ¥				
2.1. If VES identify tests used in evaluation and the results of these tests						
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Delete Test Typ	e Test Na	me	Test Results			
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4. Was an islet count performed after the shipment was received?	Yes				
4.1 If YES, provide the following information:					
4.1.1 Islet Count - IEQs:	32000				
4.1.2 Was the counter trained to count Human IEQs?	Yes				
4.1.2.1 What specific counting method was used in your training?	test				
4.1.3 How long were the islets incubated before counting?	10 Hours				
5. Purity (evaluated by recipient laboratory):	93 % 🗆 Assessment not performed				
5.1 Purity assessment method(s):	test				
6. Viability (evaluated by recipient laboratory):	94 % 🗆 Assessment not performed				
6.1 Viability assessment method(s):	test				
7. Did the last shipment meet your expectations?	Yes				
7.1 If NO, define the problem encountered:					
8. Additional comments:	test				
Person Col	npleting the Form				
1. Name:	Amy K. Jacobs				
2. Telephone Number:	7034028697				
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#### Part II of the UFF - Proceed through Part I questions that are 'read only' - refer to the next page.
<b>Part II of the UFF</b> – Proceed through the Part I questions that are 'read only'.		
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<ul> <li>6. Viability (evaluated by recipient laboratory):</li> <li>6.1 Viability assessment method(s):</li> <li>7. Did the last shipment meet your expectations?</li> <li>7.1 If NO, define the problem encountered:</li> <li>8. Additional comments:</li> </ul> Person Corol. Name:	94 % Assessment not performed test Yes test test	
2. Telephone Number: Print Save Control of the second seco	7034028697         a         Save and Submit         d maintained by the Integrated Islet Distribution Program (IIDP) at City of Hope © 2010 All rights reserved.         -Training Site	
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Click on [Save] to save Part II of the UFF and complete at a later time - refer to the confirmation message on the next page OR click on [Save and Submit] to save and submit the completed Part II of the UFF - refer to the confirmation message on page 25.

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Commutation message - Part II of the OPP has been saved and submitted in the system. Click of [Close]	to return to the <b>islet Oriers</b> screen – it	
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Confirmation Message		
Thank you for submitting Part II of the User Feedback Form. You will now b to receive additional islet shipments if the shipping materials have also bee returned to the center. Please contact iidp-email@coh.org if you have any o or concerns.	be eligible an questions	
CLOSE		
Developed and maintained by the Integrated Islet I	Distribution Program (IIDP)	
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### Confirmation message - Part II of the UFF has been saved and submitted in the system. Click on [Close] to return to the Islet Offers screen - refer to page 15

## 5.0 View Completed User Feedback Form (UFF)

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	Nathan Goodman	Targeted Offer	IIDP	20025	89%	98%	Most Pure	Cultured	University of Miami	1/6/2010 5:00:00 PM CST.	1/7/2010 5:00:00 PM CST.	NA	NA
<b>N</b>	Nathan Goodman	Targeted Offer	IIDP	20025	80%	85%	Most Pure	Cultured	University of Miami	1/7/2010 3:00:00 PM PST.	1/8/2010 3:00:00 PM PST.	NA	NA
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**Islet Offer screen** – Viewing a completed UFF instructions are outlined. Scroll down to the desired islet offer UFF – refer to the next page.

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1/7/2010 5:00:00 PM CST.	NA	NA	NA	No Response	NA	[Click Here]	MA
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### Islet Offer screen - Click on [View] of the desired islet offer completed UFF - refer to the next page.

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L	User Feedback Form				
	Recipient Informat	on			
1.	UNOS ID:	M014			
2.	Today's date:	02/08/2010			
3.	Title of project:	test QA			
4.	Principal Investigator:	Nathan Goodman			
5.	Date tissue received:	02/01/2010			
6.	Shipment received from (Name of center):	University of Miami			
	Islet Assessment (evaluated	by recipient)			
Co	ondition of Shipment				
1.	Select if the islets were shipped to you or if you picked up the islets directly:	Shipped			
2.	Were the islets packed in a cardboard covered styrofoam box?	Yes			
	2.1 If NO, specify the type of packaging used:				
3.	Temperature indicator activation status:	Inactivated (No color)			
4.	Select the type of vessel the islets were shipped in and enter the volume of the vessel:	Lifecell 300 ml bag	310	mLs	
	4.1 If OTHER, specify what type of vessel used:				
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### **Completed UFF** – Page 1 of 4 - Scroll through the UFF to review the completed data in 'read only' mode – refer to the next page.

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5. Were ambient temperature gel packs used?	Yes	<u>^</u>
5.1 If NO, enter the type of temperature control devices used (enter 'NONE' if nothing was included):		
5.2 If YES, continue with the questions below:		
5.2.1 Were the islets packed with six(6) gel packs?	Yes	
5.2.1.1 If NO, specify number of gel packs used:		
5.2.2 Record the number of gel packs next to their condition upon arrival:		
5.2.2.1 Hard	2	_
5.2.2.2 Soft	2	
5.2.2.3 Slushy	1	
5.2.2.4 Liquid	1	
6. Were the islets packed with absorbent material?	Yes	
6.1 If NO, specify what packing material was used:		
Condition of Islets (evaluatio	on by recipient)	
1. Select your perceived quality of the islets at the time of arrival - general (select one):	Excellent	
1.2.1.1 If FAIR, POOR, or OTHER, specify reason:		
2. Were the islets used in experiments?	Yes	
2.1 If NO, specify the reason:		
2.2 If YES, were the experiments successful?		✓
Done	😜 Internet 🦷 🗸	🔍 100% 🔹 🔡

Completed UFF - Page 2 of 4 - Scroll through the UFF to review the completed data in 'read only' mode - refer to the next page.

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2.2.1 If not, can you attribute the lack of success to the quality of the islets from this sl	nipment?
2.3 After using the islets in your experiments, select your perceived quality of the islets:	Excellent
2.3.1 If FAIR, POOR, or OTHER, specify reason:	
2.4 Please provide as much detail as you feel necessary to describe the success of your exp	periments test
and/or the quality of the islets from this shipment:	
3. Was morphology and/or functional integrity assessed after shipment?	Yes
3.1 If YES, identify tests used in evaluation and the results of these tests:	
Test Type Test f	Name Test Results
Functionality tes	t a test a results
4. Was an islet count performed after the shipment was received?	Yes
4.1 If YES, provide the following information:	
4.1.1 Islet Count - IEQs:	32000
4.1.2 Was the counter trained to count Human IEQs?	Yes
4.1.2.1 What specific counting method was used in your training?	tost
4.1.3. How long were the islets incubated before counting?	
Hits now long were the lates incubated before counting:	10 Hours
5. Purity (evaluated by recipient laboratory):	93 % C Assessment not performed
Done	😜 Internet 🥠 🔹 🕄 100% 👻

#### **Completed UFF** – Page 3 of 4 - Scroll through the UFF to review the completed data in 'read only' mode – refer to the next page.

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5.1 Purity assessment method(s):	test	
6. Viability (evaluated by recipient laboratory):	94 % Assessment not performed	
6.1 Viability assessment method(s):	test	
7. Did the last shipment meet your expectations?	Vas	
7.1 If NO, define the problem encountered		
8. Additional comments:	test	
P	erson Completing the Form	
1. Name:	Amy K. Jacobs	
2. Telephone Number:	7034028697	
	1034020031	
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	eloped and maintained by the Integrated Islet Distribution Program (IIDP)	
STIDI	© 2010 All rights reserved.	
Integrated Islet Distribution Program	Training Site	
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### Completed UFF - Page 4 of 4 - Scroll through the UFF to review the completed data in 'read only' mode.

Click on [Print] to print the completed UFF OR click on [Close] to close the completed UFF and return to the Islet Offers screen – refer to the next page.

**Islet Offers screen** - Repeat the process as needed to complete Part I and/or Part II UFF(s) and/or view completed UFF(s) for other islet offers OR select another function from the menu bar OR click on **[Log off]** to log out of the system.

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Dates NOT Available for Shipping							
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History of Islet Offers (includes all targeted offers and accepted open offers selected by the Allocation System)							
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Nathan Goodman         Targeted Offer         CIT         20025         89%         98%         Most Pure         Fresh         University of Miami         1/4/2010         1/5/2010         NA	NA						
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Goodman Offer 20025 89% 96% Most Pure Cultured Oniversity 1/6/2010 1/7/2010 MA	NA						
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Nathan Goodman         Open Offer         IIDP         20025         100%         100%         Most Pure         Fresh Cultured         University of Miami         1/28/2010         1/29/2010         1/29/2010         test	test						
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Attachment - 8 User Instructions for Islet Decanting and Return of Shipping Materials to the IIDP

- 1. Upon receipt of the IIDP package, remove the islet vessel, wipe with disinfectant and place under sterile hood.
- 2. Remove cap on port of bag, add luer tubing, and drain islet preparation into a sterile 250 ml conical.
- 3. Using a sterile syringe, add approximately 20 ml of media to the shipping bag. Rinse and decant.
- 4. Repeat as necessary to remove all the islets. Centrifuge the suspension at 1,000 rpm (280g) for one minute (at room temperature) or gravity settle for 10 minutes. Remove supernatant and discard in appropriate waste. Resuspend cells in appropriate media/solution for studies.
- 5. Remove Tissue Shipment Form and file in your records.
- 6. Complete the User Feedback Form on line at http://iidp.coh.org It is mandatory to complete Part I of this form to maintain your eligibility for future islet shipments. It is recommended to complete Part II as soon as your results are finalized.
- 7. Check the contents of the Standardized Shipping Box and note the activation status of the temperature indicator and the number and quality of the Ambient Gel Packs. Dispose of the absorbent packing pads if wet or soiled and the disposable temperature indicator after documentation of activation status on the User Feedback Form.
- 8. Remove the enclosed FedEx Return Shipping label and affix to outside of the Shipping Box.

Note: If the outer, cardboard box was damaged beyond use during shipping, please send the Ambient Gel Packs back in another appropriately sized container and alert the center and the IIDP (mantler@coh.org).

It is essential that the both parts of the User Feedback Forms be completed on line and that the Shipping Boxes and the Ambient Gel Packs be returned to the supplying IDDP as soon as possible. Users will be ineligible for additional islet shipments if the above materials are not returned to the supplying IIDP.

Thank you for your help in keeping the costs of this project reduced by returning all supplies promptly!



Minimum Assessment Requirements

Details:

Minimum Required Assessments for Islet Distribution

- **1.0** To insure consistent purity and viability, the following analyses are the minimum requirements to be performed by subcontractors on all islet preparations provided to the IIDP.
 - **1.1 Islet Quantification:** Dithizone-staining, cell size and enumeration evaluation using light microscopy with visual examination by 2 qualified personnel (or double counting by one individual of a duplicate sample.) This should be performed within 6 hours of shipping. Most studies show that the maximum loss of islets is over the first 12 hours after isolation so the IIDP require holding islets at 37° C in culture medium for at least 12 hours before shipping.
 - **1.1.1** Counting should be performed and reported after the incubation.
 - **1.2 Islet Purity:** Dithizone-staining and determination of acinar-free islets using visual examination under microscope by 2 qualified personnel (or double counting by one individual of a duplicate sample.)
 - **1.2.1** Purity determination should be performed and reported after culture and prior to shipping.
 - **1.2.2** Human islet preparations will contain ≥80% for "most pure" and ≥50% for "impure" islet tissue as determined by dithizone staining and light microscopy in order to qualify for islet reimbursement
 - **1.3 Viability:** Fluorescent dye method using fluorescein diacetate and propidium iodide with visual examination by 2 qualified personnel (or double counting by one individual of a duplicate sample.) (Dyes can be substituted for other inclusion and exclusion dyes with the permission of the IDCC.)
 - **1.3.1** Viability determination should be performed and reported after culture and prior to shipping.
 - **1.3.2** Human islet preparations will consist of $\geq 80\%$ viable islet particles as determined by fluorescence microscopy.
 - **1.4 Sterility:** Testing for microbial (both aerobic and anaerobic) and fungal contamination must be performed on the final preparation.
 - **1.4.1** Preliminary results must be supplied to the IIDP within 10 days of shipping. Final results must be supplied within 30 days of shipping.



Details:

Minimum Assessment Requirements

- **1.4.2** A sentinel flask of ≥ 100 IEQ should be aliquoted at the time of shipping and kept in house for 3 days at 24° C in the media used for shipping, in order to monitor islet quality in the event of complaints by the receiving investigators concerning contamination or islet quality.
- **1.5 Potency:** A Glucose Stimulated Insulin Release (GSIR) Assay, a functionality assay that compares the amount of insulin secreted at a resting stage (low glucose concentration) of an islet preparation to the amount of insulin secreted during a stimulated stage (high glucose concentration), must be performed on the final islet preparation on the day of shipping.
 - **1.5.1** The resulting ratio is called the Stimulation Index and must be reported to the IIDP within 10 days of broadcast.
- **1.6 Optional Assessments:** Although optional, documentation of any additional quality assessments that a subcontractor normally performs on their preparations and is willing to share with the islet recipients and the IIDP is encouraged. These assessments should be entered into the IIDP database under Optional Assessments in the Quality Assessments section of the database and will be shared with the recipients who accepted islets from that broadcast.



Ciprofloxacin Stock Preparation

Details:

Ciprofloxacin Stock Preparation

Note: Ciprofloxacin is no longer available through the COH pharmacy and therefore the IIDP will purchase powdered Ciprofloxacin Hydrochloride from Cellgro and request that the individual centers prepare a 10mg/ml stock using, filter sterilize and freeze for future use in preparing shipping media for the islets.

1.0 Cellgro Website Description for Ciprofloxacin:

Description:	Ciprofloxacin Hydrochloride Cat #:	61-277
Formula:	C17H18FN2O3*HCI*H20	
Formula Weight:	385.82	
CAS#:	86393-32-0	
MSDS:	Available upon request	
Shipping:	Ambient	
Storage:	Store ambient at 15 - 30°C. Protect from light and excessive heat.	
Stability:	Avoid moisture uptake, as this can decrease the product's potency.	
Applications:	Ciprofloxacin HCI is a highly active fluoroquinolone antibiotic effective against a broad spect mycoplasma. There are few resistant strains. The antibiotic is effective at low concentration buffered media and can effectively eradicate Mycoplasma in as little as 12 days. Cells are s Ciprofloxacin HCI freshly added at 10ug/ml. Replacement of medium or subculturing of cells days. After 14 days, it is no longer necessary to include Ciprofloxacin HCI in the media.	rum of bacteria and is (10ug/ml) in water, eeded into media with s may be done in 3 to 4

2.0 Preparation of New Ciprofloxacin Powder for Addition to Media:

- 2.1 Remove 1 gm (1000mg) of ciprofloxacin hydrochloride from the bottle and QS to 100 ml with distilled water. This will give a stock concentration of 10mg/ml.
- 2.2 Mix with a stir bar and stirring plate until totally dissolved.
- 2.3 Filter sterilize the solution using a 0.2µm filter.



Ciprofloxacin Stock Preparation

- 2.4 Aliquot into sterile tubes, 5 ml samples, label, and freeze for later use.
- 2.5 Diluted solution is good for 1 year frozen and 1 month thawed.

Details:

3.0 Addition to Media:

- 3.1 Thaw aliquotted sample and label with thaw date.
- 3.2 Follow SOP SHP 001 Section 6.2 Media Preparation instructions.
 - 3.2.1 Add 0.5ml of ciprofloxacin stock to each 500 ml bottle of CMRL 1066 Supplemented for islet shipping.