Jul 15, 2020

Packaging and Shipping of Flash Frozen Non-Islet Pancreatic (Acinar)Tissue

Integrated Islet Distribution Program[1]

[1]Integrated Islet Distribution Program, City of Hope

1 Works for me dx.doi.org/10.17504/protocols.io.bhtrj6m6

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Integrated Islet Distribution Program, City of Hope

ABSTRACT

To define a standardized method for packaging and cold shipping of research quality non-islet pancreatic (acinar) tissue (NIPT) to approved investigators for use in the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) sponsored research in the Integrated Islet Distribution Program (IIDP). This will also include reference to flash frozen NIPT tissue. **This SOP replaces the IIDP SOP: SHP-007 Cold Shipping of Flash Frozen Non-Islet Pancreatic (Acinar)Tissue**

Note: This SOP was developed based on the Prodo Labs, Inc. shipping protocol and results from preliminary studies conducted by the IIDP and commissioned by the original IIDP Project Officer, and External Evaluation Committee (EEC).

This protocol provides an opportunity for the isolating centers to recoup expenses for isolated NIPT that cannot be placed through the normal distribution system at the time of isolation. It also may provide a less expensive and more advantageous method to investigators that need non-viable islet tissue for gene panel research, RNA expression, and other experiments where viable islets and fresh NIPT are not necessary. This protocol also allows the storage of NIPT for supplemental experiments that may be realized at a later date, after the original distribution has been completed.

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

EXTERNAL LINK

https://iidp.coh.org/Investigators/Policies-Standard-Operating-Procedures

DOI

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PROTOCOL CITATION

Integrated Islet Distribution Program 2020. Packaging and Shipping of Flash Frozen Non-Islet Pancreatic (Acinar)Tissue. **protocols.io** dx.doi.org/10.17504/protocols.io.bhtrj6m6

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KEYWORDS

flash frozen, Human Non-Islet Pancreatic (Acinar) Tissue, Human Acinar, Acinar, Exocrine

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38481

GUIDELINES

Responsibilities

- It is the responsibility of the IIDP Coordinating Center (CC) to both follow and ensure adherence to the procedures outlined in this SOP. In order to accomplish this, the IIDP CC will interact with the relevant personnel from each of the participating centers.
- It is the responsibility of each IIDP center to follow the procedures listed in this SOP and to work to the best of their ability to follow all requirements.
- It is the responsibility of each approved investigator receiving flash frozen (FF) Non-Islet Pancreatic (Acinar) Tissue (NIPT) through the IIDP to cooperate in providing feedback to the IIDP on the condition of the FF NIPT upon receipt and to reuse and recycle all shipping materials to the best of their ability.

Definitions

- ***Integrated Islet Distribution Program (IIDP) (RRID:SCR_014387):*** The IIDP is a program funded by the NIDDK to provide quality human islets to the diabetes research community to advance scientific discoveries and translational medicine. The IIDP consists of the NIDDK Project Officer (PO), the External Evaluation Committee (EEC) and the IIDP Coordinating Center (CC) at City of Hope (COH). The IIDP CC integrates an interactive group of academic laboratories including the subcontracted IIDP Islet Isolation Centers (IIC) and the Human Islet Phenotyping Program (HIPP).
- ***IIDP Coordinating Center (CC):*** Joyce Niland, Ph.D. is the Principal Investigator for the IIDP CC and leads staff from the Department of Diabetes and Cancer Discovery Science, Diabetes and Metabolism Research Institute at COH to coordinate the activities of the IIDP and assist the participating centers and investigators in the distribution of human islets.
- ***Approved Investigators***: Researchers who have requested islets from the IIDP for basic science studies and whose research protocols have been reviewed and approved by the IIDP.
- ***Islet Allocation System (IA)***: This is the online system administered by the IIDP to allow fair distribution of basic science islets to approved investigators. This interactive system is used by the IIDP centers and the approved investigators facilitates and tracks the distribution of human islets and NIPT.
- ***Non-Islet Pancreatic (Acinar) Tissue (NIPT)***: During a standard human islet isolation, the digested tissue goes through a purification process that allows the majority of the isolated islets to be separated from the acinar and other pancreatic tissues. This is commonly done using a continuous density gradient and a COBE®2991 cell processor. The lighter density tissues, including the majority of human islets, are collected from the lighter gradients, leaving the remaining pancreatic tissue, in the COBE processor bag that still holds the denser gradients and tissue. This non-islet pancreatic tissue is commonly referred to as the “Acinar” tissue, although it contains other types of pancreatic tissue, often including imbedded islets, ductal tissue, and blood vessel fragments.

MATERIALS

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NAME	CATALOG #	VENDOR
Human AB Serum (ABS) HI	100-512; Heat Inactivated	Gemini Bioproducts
PIM(G)® (5 mL Glutamine/Glutathione)	PIM(G)®	Prodo Laboratories, Inc
PIM(T)®	PIM(T)®	Prodo Laboratories, Inc
Corning™ Ciprofloxacin Hydrochloride	MT61277RG (Corning™ 61277RG)	Fisher Scientific
MP Biomedicals™ Ciprofloxacin Hydrochloride or equivalent	MP219902005	Fisher Scientific
Corning™ Hanks Balanced Salt Solutions (HBSS) or equivalent	MT21020CM	Fisher Scientific
Sigma T9128-Trypsin Inhibitor from Glycine max (soybean)	501784544	Fisher Scientific

MATERIALS TEXT

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

Uline S-5045

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

Long-Term Storage Cryogenic Tubes or equivalent
Cryogenic Tubes - 5 mL

Thermo Scientific™ Nalgene™ 03-337-7H

Sterile, externally threaded Thermo Scientific™ Nalgene™ General Long-Term Storage Cryogenic Tubes, ideal for research and general lab storage.

EQUIPMENT

NAME	CATALOG #	VENDOR
Laser Labels	S-5045	Uline
Long-Term Storage Cryogenic Tubes or equivalent	03-337-7H	

SAFETY WARNINGS

Please see attached SDS (Safety Data Sheet) for hazards and safety warnings.

Corning Ciprofloxacin Hydrochloride Corning Cipro SDS-2014Jul22.pdf

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Precautionary statements:

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

MP Biomedical Ciprofloxacin MP_MSDS_199020_USA_EN.pdf

First-aid measures
General information: No special measures required.

- After inhalation: Supply fresh air; consult doctor in case of complaints.
- After skin contact: Generally the product does not irritate the skin.
- After eye contact: Rinse opened eye for several minutes under running water.
- After swallowing: If symptoms persist consult doctor.
- Most important symptoms and effects, both acute and delayed. No further relevant information available.

GemCell™ U.S. Origin Human Serum AB GemCell Human Serum AB.pdf

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

- Biohazard contains human source material. Handle as though capable of transmitting infectious agents.
- Toxicity: Not Established.

Target Organs/Systems: Product could possibly irritate the skin, eyes and respiratory system. Do not ingest this product.

Trypsin inhibitor, from Glycine max (soybean) - lyophilized powder - Sigma T9128 Trypsin MSDSAction.pdf

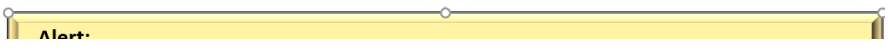
Personal precautions, protective equipment and emergency procedures

- Avoid dust formation. Avoid breathing vapours, mist or gas.

Personal protective equipment

- **Eye/face protection**
  Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).
- **Skin protection**
  Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands.
- **Body Protection**
  Choose body protection in relation to its type, to the concentration and amount of dangerous substances, and to the specific work-place., The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.
- **Respiratory protection**
  Respiratory protection is not required. Where protection from nuisance levels of dusts are desired, use type N95 (US) or type P1 (EN 143) dust masks. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or CEN (EU).

Carefully place cryogenic tubes in a liquid nitrogen bath taking all safety precautions to protect you from being burned by liquid nitrogen (mask, gloves, tongs, and apron).



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Alert:

Cryogenic vials are intended for placement only in the **vapor** phase of liquid nitrogen and should **not** be used for storage in the liquid phase of liquid nitrogen. Immersion of the vials in the liquid phase could result in penetration of the liquefied gas into the vial, resulting in rapid vaporization of the liquid upon removal and possible explosion or leakage from the vial/closure perimeter.

To prevent cryogenic vials from exploding, never overfill liquid nitrogen storage units. Always examine vials before use to ensure no visible defects around the closure rims. Always use full face shields, heavy safety gloves and laboratory protective apparel when removing vials from cryogenic storage. Always permit vials to warm slowly in a biological safety cabinet. Never reuse cryogenic vials.

BEFORE STARTING

References:

- Prodo Labs, Inc. Protocols and Website: https://prodolabs.com/protocols/
  Media-Preparation-and-Use-Instructions-1.pdf
- Scharp DW, Arulmoli J, Morgan K, Sunshine H, Hao E: Advances in Human Islet Processing: Manufacturing Steps to Achieve Predictable Islet Outcomes from Research Pancreases. OBM Transplantation 2019 Feb, Volume 3, Issue 1(Current Advancement of Islet Cell Transplantation in the Treatment of Diabetes Mellitus).

Preparation of Supplies and Reagents

1 The IIDP will provide each center with the following supplies necessary for islet culture:

- Gemini Human AB Serum (ABS)-Heat Inactivated (HI)
- PIM(G)®
- PIM(T)®
- Ciprofloxacin Hydrochloride. Either MP Biomedicals™ MP219902005 or Corning™ MT61277RG (61277RF is available in 1 gm bottles and 61277RG in 5 gm bottles. Due to the relatively short shelf life (12-18 months), usually 1 gm bottles will be ordered).
- Sigma T9128 Trypsin Inhibitor from Glycine max (soybean) – lyophilized powder
- 5 mL Cryogenic tubes for freezing

2 **Laboratory Supplies:**

The following supplies are necessary for the preparation of NIPT prior to flash freezing for distribution:

- Islet preparation and distribution
- Hanks Buffered Salt Solution (HBSS) – no additives.
  (Note: Either HBSS with or without Calcium, Magnesium, and phenol red can be used)
- 15 mL, 50 mL, or 250 mL conical tubes (depending on final volume of islet prep)
- Wide mouth pipettes and pipettor
- Sampling wide-bore pipette tip and pipettor (Gilson or Drummond)

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- Routine lab supplies for transferring, media changing and counting islets
- Thermo Scientific™ Nalgene™ General Long-Term Storage Cryogenic Tubes Self- Standing with Round Bottom (Product #03-337-7H) (*This brand and style of cryogenic tubes are recommended but not mandatory)*

Alert:
Cryogenic vials are intended for placement only in the **vapor** phase of liquid nitrogen and should **not** be used for storage in the liquid phase of liquid nitrogen. Immersion of the vials in the liquid phase could result in penetration of the liquefied gas into the vial, resulting in rapid vaporization of the liquid upon removal and possible explosion or leakage from the vial/closure perimeter.

To prevent cryogenic vials from exploding, never overfill liquid nitrogen storage units. Always examine vials before use to ensure no visible defects around the closure rims. Always use full face shields, heavy safety gloves and laboratory protective apparel when removing vials from cryogenic storage. Always permit vials to warm slowly in a biological safety cabinet. Never reuse cryogenic vials.

- Cryogenic markers or pencils for tube labeling
- Centrifuge with capabilities of spinning the appropriate sized conicals and the 5 mL cryogenic vials at **1000 rpm 00:02:00**
- Sterile pipettes, pipettors, and other appropriate sterile labware for manipulation of tissue preparations
- IIDP Frozen Box Labels from IIDP template
- Flash Frozen Tissue Shipment Forms
- FedEx Shipping Form
- Liquid nitrogen and appropriate vessels and equipment for safely freezing the NIPT
- Liquid nitrogen storage tanks or **-80 °C** or **-135 °C** freezer
- Appropriately sized Styrofoam shipping boxes and adequate dry ice (at least 5 lbs).

Procedures

3 Receipt of Supplies:

The majority of supplies should be stored in appropriate dry, temperature-controlled environments (room temperature **-20 °C** to **28 °C**).

- The Prodo Labs PIM(T) should be stored, in the dark, between **2 °C** and **8 °C** upon receipt but is stable at room temperature.
- The Gemini Human AB serum and the PIM(G) vials should be stored at **-5 °C** to **-20 °C** in the dark.
- The T9128 Trypsin Inhibitor from Glycine max (soybean) – lyophilized powder should be stored between **2 °C** and **8 °C** upon receipt.

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- The Ciprofloxacin should be stored as indicated by manufacturer (Corning at room temperature OR MP Biomedicals at 4°C). Aliquots of Ciprofloxin can be prepared prior to the isolation. Prepare the Ciprofloxacin according to the directions in the table. Filter sterilized suspension aliquots should be stored at **-5 °C** to **-20 °C**

Preparation of Ciprofloxacin, Media and Trypsin Inhibitor

4 *Preparation of Ciprofloxacin:*

Aliquots of Ciprofloxacin can be prepared prior to the isolation. Prepare the Ciprofloxacin according to the directions in the table. Filter sterilized suspension aliquots should be stored at **-20 °C** .

Pre-Preparation of Ciprofloxacin Powder for Addition to Media

- Remove 0.5 gm (500 mg) of ciprofloxacin hydrochloride from the bottle and QS to 50 mL with distilled water. This will give a stock concentration of 10 mg/mL
- Mix with a stir bar and stirring plate until totally dissolved.
- Filter sterilize the solution using a 0.2µM filter.
- Aliquot into sterile tubes, 5 mL samples, label as stock solution, and freeze at -20° for later use.
- The expiration date of the solution is indicated on the Certificate of Analysis and/or the bottle. Document expiration date as date of CoA.
- Diluted solution is good for 1 year frozen (if less than CoA expiration date) and 1 month thawed.

Record Cipro preparation on ***Attachment 1: Solutions Preparation Sheet***, of this SOP.

Attachment 1-Solutions preparation Sheets.docx

5 Preparation of PIM(T) Media:

- Prepare one 500 mL bottle of PIM(T) media prior to the isolation
- Thaw and add 5 mL of PIM(G)
- Thaw and add 12.5 mL of AB serum (2.5% v/v)
- Thaw and add 0.5 mL of prepared ciprofloxacin sterile aliquot
- Once all additives have been added to the bottle of PIM(T), it is now referred to as PIM(T) complete.

Record media preparation on ***Attachment 1: Solutions Preparation Sheet***, of this SOP.

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6 The T9128 Trypsin Inhibitor from Glycine max (soybean) – lyophilized powder should be stored between 2 °C and 8 °C . ***Aliquots of Trypsin inhibitor can be prepared prior to the isolation.*** Prepare the Trypsin inhibitor according to the directions in the table. Filter sterilized suspension aliquots should be stored at -20 °C .

Pre-Preparation of Trypsin inhibitor for Addition to Media:

- Weigh 1 gm (1000mg) of Trypsin inhibitor from the bottle and QS to 100mL with serum free PIM-T (no additives). This will give a stock concentration of 10mg/ml.
- Mix with a stir bar and stirring plate until totally dissolved.
- Allow to stand on ice at least 30 min before filter sterilizing.
- Filter sterilize the solution using a 0.2µM filter.
- Aliquot into sterile tubes, 5 mL samples, label as stock solution, and freeze at -20º for later use.
- Stock solution is stable at -20C◦.
- Inhibitor must be added fresh to the medium before culture or shipment.

Record Trypsin preparation on ***Attachment 1: Solutions Preparation Sheet***, of this SOP.

Begin NIPT (Acinar) Broadcast

7 Begin Acinar broadcast on IIDP Secure Access Center Website as soon as the islet isolation is confirmed.

8 Enter donor and isolation information on IIDP secure website under Quick Acinar Broadcast. Complete Donor Information Form and Processing and Distribution of Acinar Tissue Form.

9 Donor Information Form is same as for islets and all entered information will be auto-populated to the subsequent Islet Broadcast.

10 Relevant information entered on the Processing and Distribution of Acinar Tissue Form will be auto-populated to the Islet Broadcast.

11 Complete information regarding NIPT will be available as freshly isolated *(**Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue** SOP)* and/or flash frozen (current SOP).

12 Complete the broadcast records and proceed to Broadcast.

Note: The Broadcast Deadline should be set for the approximate time of when the purification will be completed so that the total amount of accepted tissue will be known prior to when the NIPT tissue is to be prepared. Freshly isolated NIPT should be sent out on the day of the isolation or at the next available FedEx

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pickup, within 24 hours of isolation ***(Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue SOP).*** *This will limit freshly isolated NIPT broadcasts to Sunday evenings through Thursdays (or Fridays if investigators will accept Saturday deliveries).The NIPT Broadcasts are done prior to the Islet Broadcasts.*

13 Set your NIPT Broadcast Deadline to the assumed time when the purification will be completed. This will ensure that the NIPT tissue will have minimum holding time prior to freezing the requested NIPT or packaging of the freshly isolated samples. *(See* ***Collection, Packaging and Cold Shipping of Fresh Non-Islet Pancreatic (Acinar) Tissue SOP****)*

14 When Deadline of Broadcast is met, an automated email will be sent to center asking to View Acinar Offers and to confirm the shipment or cancellation of each request.

Collection of NIPT for Transport

15 The NIPT, the tissue remaining in the COBE purification bag, should be transferred under sterile conditions, into two 250 mL conical tubes, as soon as feasible during the islet isolation process. Top with Hanks Buffered Salt Solution (HBSS), cap, invert to mix and dilute Ficoll, and centrifuge at **180 x g, 4°C 00:02:00**

16 Obtain PIM-T Complete prepared in Step 5.

17 Obtain the T9128 Trypsin Inhibitor from Glycine max (soybean) – lyophilized powder from Step 6. Thaw aliquot.

18 Once deadline has been reached and final amounts of accepted **FRESH and FROZEN NIPT** is confirmed, calculate the amount of PIM-T needed. Complete that which is needed for all shipments. Add 1 mL of **Trypsin Inhibitor stock (Attachment 1)** to each 100 mL of PIM-T Complete for NIPT shipping (~150mL of media/1mL NIPT total requested). This will give a final working concentration of 100 µg/mL of Trypsin inhibitor in the media. Resuspend only the amount of NIPT tissue needed to complete the requests in 10x the volume of PIM-T Complete plus inhibitor.
Example: If there is one request for 1.5 mL, only resuspend 1.5 mL of NIPT in 15 mL of PIM-T Complete plus inhibitor. This will save on the cost of the inhibitor and media.

19 If the deadline has not yet been reached and the total amounts of NIPT accepted is not yet known, suspend up to 20 mL of pellet to 10 times the pellet volume with PIM-T Complete plus inhibitor (200mL). Lay conical of the NIPT suspension on its side at 4°C to avoid pelleting of NIPT while waiting to confirm acinar shipments. *Note: As the NIPT program expands more tissue may be held as recipient requests increase.*

20

Note: Once inhibitor is added to the PIM-T Complete, it must be used on the day of addition.

Preparation of Flash Frozen NIPT

21 As investigator's requests are determined through the broadcast system for Flash Frozen NIPT, prepare appropriate amounts of tissue into proper sized consolidation vessels for reezing from the diluted samples in steps 18 or 19 above. Label each conical for identification during transfer. Label corresponding 5mL cryogenic tube with RRID #, date,

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amount of requested NIPT tissue and recipient name and hold until ready for final transfer.

- For 0.5 – 1.0 mL of requested NIPT pelleted tissue, add 5 - 10 mL of NIPT suspension to 15 mL conical.
- For 1.1 – 2.0 mL of requested NIPT pelleted tissue, add 11-20 mL of NIPT suspension to 50 mL conical.
- For 2.1 – 3.0 mL of requested NIPT pelleted tissue, add 21-30 mL of NIPT suspension to 50 mL conical.
- For 3.1 – 4.0 mL of requested NIPT pelleted tissue, add 31-40 mL of NIPT suspension to 50 mL conical.

22 Centrifuge all samples at **180 x g, 4°C 00:02:00** to pellet the acinar tissue. Remove the supernatant and wash the tissue with HBSS without serum by topping each conical with appropriate amount of HBSS. This will remove the serum (protein) from the acinar tissue. Resuspend tissue. Repeat the centrifugation **180 x g, 4°C 00:02:00**

23 Remove supernatant. Wet pipet and transfer each pellet to corresponding labeled 5 mL cryogenic tube, rinsing original tube with HBBS without serum to ensure all tissue is transferred. Centrifuge cryogenic tubes at **180 x g, 4°C 00:02:00** to pellet the acinar tissue. Remove all supernatant to ensure a dry, serum-free pellet.

24 Freeze pellet by placing tube in liquid nitrogen per your center's protocol.

Carefully place cryogenic tubes in a liquid nitrogen bath taking all safety precautions to protect you from being burned by liquid nitrogen (mask, gloves, tongs, and apron).

Safely transfer the vials into a labeled container and store in a **-80 °C** or **-135 °C** freezer or in the vapor phase of a liquid nitrogen storage tank until shipment.

Completing the Distribution Records

25 The shipping center will enter the NIPT to be shipped (Confirm Recipient screen) and will enter FedEx tracking numbers Broadcast 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 FedEx system and free up time for the centers and the IIDP. The investigators will have the FedEx tracking numbers listed in their History of Acinar Tissue Offers table.

Note: If the investigator has picked up the NIPT at the distributing center then the center should check "Yes" in the "Direct Pickup" column and "Yes" under "NIPT Shipped?" once they are picked up.

26 Once a recipient is confirmed, click on the "Print Tissue Shipment Forms" and include the appropriate form with each shipment.

Note: The center must click on the Print Tissue Shipment Form (TSF) in order to complete the distribution process and trigger the email distribution.

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NIPT should be maintained below **-80 °C** until ready for shipment.

A completed Flash Frozen Tissue Shipment Form should accompany each sample shipment. Approximately five pounds of dry ice should fill a small, thick Styrofoam shipping box. Multiple tubes of NIPT can be sent in a single box as necessary to satisfy the number of requested NIPT. The tubes should be placed in the middle of the dry ice. The IIDP Frozen Sample Labels should be placed on two sides of the box and the dry ice regulation label should be completed before shipping.

28 Samples should be sent priority overnight shipping by FedEx with appropriate boxes checked on the FedEx form for dry ice shipments. (*No materials will be returned by the investigators.)*

29 User Feed Back Forms should be completed online by the investigators.

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