Standard Operating Procedure (SOP) for Shipping an Outbound Package

I. SCOPE AND PURPOSE

The Biospecimen Core Resource (BCR) ships a variety of outbound packages, including FedEx Padded Paks, Styrofoam insulated boxes, and liquid nitrogen dry vapor shippers (cryoports). Selecting the most appropriate shipment conditions and packaging is essential to ensure specimen integrity and compliance with regulations. This procedure applies to BCR Logistics laboratory personnel, though some steps may include or reference related procedures in Clinical Outreach, Histology, Virtual Microscopy, and the Molecular Genetics Laboratory (MGL) for shipment preparation.

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II. PROCEDURE

A. Safety Precautions

1. Liquid Nitrogen (LN_2) and dry ice can cause asphyxiation and severe burns. Always wear the appropriate personal protective equipment (PPE) required when working with these substances, including an impermeable lab coat, goggles, closed toe shoes, nitrile gloves, and thermal insulated gloves. A full face shield is required in lieu of goggles when working with LN_2.
   a. Refer to BPC-SAF-004 “Compressed Gases Hazards and Safety” for additional handling precautions.
2. Assume all samples are infectious. Refer to the following documents for guidance:
   a. BPC-SAF-011 “Microbiological Hazards and Safety”
   b. BPC-SAF-010 “Laboratory Exposure Plan”
   c. NCH IC-VII-1 “Exposure Control Plan for OSHA Blood-borne Pathogen”
3. If disposable items (such as packing material, shipping documents, or dry ice) become contaminated during this process, then they must be discarded in a biohazard bin.

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B. Quality Control

1. For quality control purposes use BCR-FRM-016 "Outbound Shipment Verification and Quality Control Form" to document all outgoing shipments.
2. All BCR personnel responsible for shipping must complete IATA/Saf-T-Pak Compliance Training before they can prepare, create, or handle a shipment. Trained employees must maintain this certification to continue to ship specimens.
3. Shipping addresses should be located using the calendar located on BCR SharePoint. A representative from Clinical Outreach or MGL will confirm this address as correct, or will provide the corrected shipping information. The address will be verified for typographical errors by an additional Logistics Tech, after an airbill has been generated, during the QC process.
4. Several monitors are in place to ensure adequate shipment tracking:
   a. The technician assigned to the shipping rotation is responsible for tracking packages to ensure timely delivery and to correct any issues or delays as quickly as possible. The technician checks the designated courier's website (e.g. FedEx) at the end of the work day in which they are shipped, and throughout the following work day(s) until a confirmation of delivery is received (via email or status on the website). **Any shipment that is experiencing unexpected delays requires immediate action from Logistics, including involving the Logistics Supervisor. The courier should be contacted for resolution and Clinical Outreach, as well as BCR leadership, should be notified.**
   b. When packages have been delivered to the recipient, they are proxy received in LabVantage (BCR-SOP-A001). A custom data audit tracks packages that have been created or shipped in LabVantage that have not been proxy received. These data audits are sent to the Program Director, Project Manager, Logistics Manager, and Logistics Supervisor.
   c. In the W230 Logistics Lab, a shipping whiteboard is used to track outstanding cryoports; this is updated daily. If a cryoport is not returned in an appropriate time frame (typically within 7 days), then Clinical Outreach should be notified to contact the site.

C. Ambient Temperature Shipments (e.g. slides, FFPE blocks)

1. Shipping Slides

a. If the slides to be shipped are not currently in Logistics' custody, then Virtual Microscopy (VM) will be notified. VM will pull the slides from storage and send them to Logistics, accompanied by a Custodial Domain Transfer (CDT) report that reflects this physical transfer in LabVantage (BCR-SOP-A001). Logistics will then verify the slides they received against this report before accepting slide custody in LabVantage.
b. Generate a shipping manifest from LabVantage (refer to BCR-SOP-A005, LabVantage User Manual).

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i. The manifest should contain the following information: site contact name and address, tracking number (once generated), total number of slides in the package, and the specimen/barcode information for all slides being shipped.
   (a) Note: When applicable, the BCR must act as an honest broker when distributing slides. No TSS identifiers can be present or viewable on slides or manifest distributed from the BCR to a different site.
ii. A copy of this manifest is emailed to the designated Clinical Outreach (CO) representative and shipment confirmation is requested.
iii. Once shipping address confirmation is received, an airbill can be created (see II.C.3. below). The tracking number is added to the shipping manifest, which is then saved on the BCR SharePoint (Shared documents > Logistics > Shipping Logs > Return of Slides) and an updated copy is emailed back to the CO Representative.
iv. A hard copy of the manifest is used by Logistics for QC purposes and will also be included in the outbound package.

c. Create a FedEx airbill (refer to section C.3. below)
d. A second Logistics technician must verify that the physical slides being shipped match those listed on the manifest created in II.C.1.b. Once verified, the technician signs and dates BCR-FRM-016 "Outbound Shipment Verification and QC".
e. Once verified, the glass slides can be placed into an appropriate slide case which is then taped shut and bubble wrapped to ensure safety during transit.
f. If size allows, place the shipping manifest and protected slides into a padded FedEx Pak, then close and seal it following the instructions on the outside of the Pak. Place the airbill pouch on the designated area on the front of the Pak. For larger packages, use an appropriately-sized cardboard box.
g. Complete the following in LabVantage (BCR-SOP-A005):
   i. Receive CDT and take custody of the slides.
   ii. Create a package for the shipment.
   iii. Place virtual slides into the LabVantage package.
   iv. "Ship" the package.
h. Physically take the package to the designated FedEx pick-up location for shipment. Track the package as specified in section II.B.4 above.

2. Shipping Formalin-Fixed Paraffin-Embedded (FFPE) Blocks

a. If the blocks to be shipped are not currently in Logistics' custody then Histology will be notified. Histology will pull the blocks from storage and send them to Logistics, accompanied by a Custodial Domain Transfer (CDT) report that reflects this physical transfer in LabVantage (BCR-SOP-A001). Logistics will then verify that the blocks they received against this report before accepting custody of them in LabVantage.
b. Create a shipping manifest as outlined above in II.C.1.b.
c. Create a FedEx airbill for FFPE blocks (refer to section C.3 below).
d. A second Logistics technician must verify, and initial BCR-FRM-016, that the physical blocks being shipped match those listed on the shipping manifest.

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e. Once verified the blocks can be placed into an appropriate container. During warmer months the blocks may be packaged with an ice pack to prevent melting of the paraffin.
f. If size allows, place the shipping manifest and blocks into a padded FedEx Pak, then close and seal it following the instructions on the outside of the Pak. Place the appropriate airbill pouch on the designated area on the front of the Pak. For larger packages use an appropriately sized cardboard box. For shipments requiring use of an ice pack during warmer months, use an appropriately sized insulated box.
g. Complete the following in LabVantage (BCR-SOP-A005):
   i. Receive CDT and take custody of the blocks.
   ii. Create a package for the shipment.
   iii. Place virtual blocks into the LabVantage package.
   iv. "Ship" the package.
h. Physically take the package to the designated FedEx pick-up location for shipment. Track the package as specified in section II.B.4 above.

3. Creating FedEx Airbills for slides or FFPE blocks

a. Log in to the FedEx website. Under the "Ship" header, select "Create a Shipment".
b. In the "To" section, enter the confirmed address and contact information.
c. In the "Package & Shipment Details" section, enter the following:
   i. Service Type: Standard or 2 Day shipping.
   ii. Package Type: Your Packaging or FedEx Pak (as applicable)
   iii. No. of Packages: 1
   iv. Weight: Weight of package (scale located in W230)
   v. Declared value:
      (a) Domestic shipments have a declared value of 0 USD
      (b) International shipments have a declared value of 10 USD
d. In the "Billing Details" section, enter the following:
   i. Bill transportation to: BCR-662
   ii. Your reference: Project, Receiving Site, and Sample Type.
e. In the "E-mail Notifications" section, expand the "Edit" link. Enter an email address for both the shipper and the receiver; then select "Tendered", "Exception" and "Delivery" in the "Notification type" column.
f. In the "Complete your Shipment" section, click "Ship".
g. Print the FedEx generated airbill.
h. For International Shipments:
   i. In the "Commodity Information" section select "Add new commodity". In the drop down menu under "Commodity", enter the following:
      (a) Commodity description
         (i) Slides: "This package contains # glass slides used for pathology. The slides are non-hazardous and are for research/analysis purposes only."
         (ii) Blocks: "This package contains # fixed blocks used for pathology. The samples are non-hazardous and are for research/analysis purposes only."

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(b) Unit of measure: pieces
(c) Quantity: 1
(d) Commodity weight: weight (from C.3.c.iv above)
(e) Customs value: 10 USD
(f) Country of manufacture: United States
(g) Shipment weight: same as commodity weight
(h) Total value: 10 USD

ii. Click "Add this commodity".
iii. In the "Customs Documentation" section, enter the following:
   (a) Select "Commercial Invoice"
   (b) Terms of sale: Free Carrier (FCA/FOB)
iv. In the "Complete your Shipment" section, click "Ship".
v. Print the Commercial Invoices and FedEx generated airbill.
vi. International shipments must also include three copies of the customs declaration letter found on Q-Pulse (BCR-TMP-003).
vii. Sign and place the Commercial Invoice and Customs Letter copies in a re-sealable airbill pouch along with the airbill.

4. Miscellaneous Ambient Packages

a. Follow all IATA/Saf-T-Pak guidelines and regulations for shipping.
b. Consult the Logistics Supervisor regarding packaging types and shipping rates.

D. Shipping on Dry Ice

1. Project guidelines (e.g. proteomics) and/or sample types (e.g. glass collection tubes) may require specimens to be shipped on dry ice in lieu of a cryoport. International dry ice shipments are not recommended. Contact the Logistics Supervisor for guidance if a dry ice package must be shipped outside the United States.
2. If the samples to be shipped are not currently in Logistics' custody then the department with custody will be notified. They will pull the samples from storage and send them to Logistics, accompanied by a Custodial Domain Transfer (CDT) report that reflects this physical transfer in LabVantage (BCR-SOP-A001). Logistics will then verify the samples they received against this report before accepting sample custody in LabVantage.
3. Generate a shipping manifest from LabVantage (refer to BCR-SOP-A005, LabVantage User Manual).
   a. The manifest should contain the following information: destination contact name and address, tracking number (once generated), total number of samples in the package, and the specimen/barcode information for all samples being shipped.
   b. A copy of this manifest is emailed to the designated CO Representative (and MGL representative if applicable) and shipment confirmation is requested.
   c. Once shipping address confirmation is received, an airbill can be created and the newly generated tracking number added to the manifest. The updated manifest is then saved on the BCR SharePoint (Shared documents > Logistics >Return Manifests) and a copy is emailed back to the Clinical Outreach representative.

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   d. A hard copy of the manifest is used by Logistics for QC purposes and will also be included in the outbound package.
4. A second Logistics technician must verify, and initial BCR-FRM-016 "Outbound Shipment Verification and QC", that the physical samples being shipped match those listed on the shipping manifest.
5. Place sample(s) in a Saf-T-Pak Biohazard bag with an absorbent sheet and seal completely. Place the sealed bag inside an insulated foam shipping container, working quickly to avoid thawing the sample(s). Using the shipping station scale, weigh and record the package weight prior to dry ice. Remove the sealed biohazard bag containing the samples and return to the cryocart or dry ice chest.
6. Fill the insulated container with enough dry ice to cover the bottom of the package. Place the sealed biohazard bag on top of this dry ice layer, then fill the rest of the box with dry ice.
   a. **Note: To ensure that samples remain frozen at all times, specimens must be completely buried in enough dry ice to still be covered upon arrival at the destination.
   b. A minimum of 4 pounds of dry ice must be used per package.
7. Weigh the full insulated container and subtract the weight of the insulated container and samples to calculate the weight of dry ice used.
8. **Never use tape to close the inner insulated container; dry ice must be allowed to ventilate as it evaporates to prevent an explosion.**
9. Place the insulated foam container into a secondary shipping cardboard box.
10. Place the shipping manifest in a plastic bag on the outside of the inner insulated foam shipping container, but inside the outer cardboard box.
11. Tape the secondary shipping cardboard box shut.
12. Fill out and attach a Dry Ice UN 1845 label to the package.
    a. **Note: Dry Ice UN 1845 labels require the shipper and recipient address to be durably marked on the package (in addition to the FedEx shipping label). The recipient address should be clearly marked and placed directly next to the dry ice label.
13. Create a FedEx Priority Overnight dry ice shipping label and air bill.
    a. Log in to the FedEx website, www.FedEx.com with assigned user name and password and go to "Create Shipment".
    b. In the "To" section, enter the confirmed address and contact information.
    c. In the "Package & Shipment Details" section, enter the following:
       i. Weight: Total weight of package (including the dry ice)
       ii. Declared value: 0 U.S. Dollars
       iii. Service Type: Priority Overnight
       iv. Package Type: Your Packaging
    d. In the "Billing Details" section, enter the following:
       i. Bill transportation to: BCR-662, FedEx Account # 491048662
       ii. Your reference: Project, Receiving Site, Dry Ice

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e. In the "Special Services" section, expand the "Edit" link. Select "Dry Ice" and enter the weight of the dry ice only in the "Total dry ice weight" field.
f. In the "E-mail Notifications" section, expand the "Edit" link. Enter an email address for the shipper and the receiver. For both, select "Tendered", "Exception" and "Delivery" in the "Notification type" column.
g. In the "Complete your Shipment" section, click "Ship".

14. Print the FedEx shipping label and place inside an airbill pouch attached to the package.
15. Complete the following in LabVantage (BCR-SOP-A005):
    a. Create a package for the shipment.
    b. Place virtual samples into the LabVantage package.
    c. "Ship" the package.
16. Physically take the package to the designated FedEx pick-up location for shipment. Track the package as specified in section II.B.4 above.

E. Outbound Cryoport Shipments

1. Clinical Outreach and Molecular should notify Logistics at least 24 hours prior to shipping. The BCR staff member requesting a cryoport is responsible for arranging and confirming the shipping date with the destination institution. For cryoports sent to TSSs, Clinical Outreach is responsible for confirming that the TSS meets all project requirements per BCR-SOP-C005 "Establishing New Tissue Source Sites and Communicating Project Requirements", and that all relevant shipping details are entered into the BCR SharePoint calendar prior to requesting a cryoport from Logistics.
2. **Charging Cryoports**:
    a. Place the cryoport beside the liquid nitrogen source and remove the data logger lid.
        i. If using the W230 fill station:
            (a) Connect the LN_2 Diffusion Stone to the fill station's LN_2 hose.
            (b) Place the stone end of the hose into the bottom of the cryoport and close the cryoport shell over the hose to subdue LN_2 splash.
            (c) Scan your Employee ID to activate the fill station and depress the green button to start the flow of LN_2.
            (d) Periodically lift the shell lid to visually check fill progress. Stop the LN_2 once it has reached the bottom of the cryoport neck and remove the hose.
            (e) Release the red button to stop the flow of LN_2.
        ii. If using a LN_2 dewar (when the fill station is unavailable):
            (a) Cryoports should be filled close to air vents to ensure that excess nitrogen is expediently removed from the area.
            (b) Secure the LN_2 transfer hose to the spout on the dewar labeled "liquid".
            (c) Place the Diffusion Stone end of the hose into the bottom of the cryoport and close the cryoport shell over the hose to subdue LN_2 splash.
            (d) Slowly turn open the liquid valve to begin filling the cryoport.
            (e) Periodically lift the shell lid to visually check fill progress. Stop the LN_2 once it has reached the bottom of the cryoport neck and remove the hose.
            (f) Turn valve in the opposite direction to shut off LN_2 flow.

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iii. Replace the data logger lid and label the cryoport shell with initials and the charge date.
iv. Allow the cryoport to properly charge (i.e. allow liquid nitrogen to fully saturate the absorbent material in the outer walls of the cryoport):
(a) If the cryoport is newly filled, the LN_2 must absorb for a minimum of 4 or up to 24 hours. The cryoport must then be refilled and the LN_2 absorbed for an additional 1-3 days.
(b) For all subsequent uses (i.e. when the cryoports is -80°C or colder from a previous use) of the cryoport, the LN_2 must absorb for 1-3 days to fully charge.
(c) Any deviations are noted on BCR-FRM-016 "Outbound Shipment Verification and QC".

3. Charged cryoports are prepared for shipment by pouring off the excess liquid nitrogen into an empty cryocart.
   a. Use the dated label on the cryoport shell to verify that an adequate charge time has elapsed (24 – 72 hours) and remove the data logger lid.
   b. With at least 2 technicians present, position the cryocart near the air vent and remove the lids. CAUTION – The cryocart must be positioned near the air vent during pour off. Do not prepare the cryoports when in close proximity to the O2 monitors as this may cause a centralized pocket of gaseous nitrogen to trigger a false low oxygen level alarm.
   c. Lift the cryoport using the top metal handle on the inner dewar, and position it over the cryocart until the flow of liquid nitrogen stops.
   d. Lower the cryoport to the ground, check for appropriate temperature probe length, and then replace the data logger lid.
4. Cryoports must maintain a temperature of -185°C or below to be shipped from the BCR. A one-hour temperature log is recorded using the data logger lid to confirm that the cryoport is holding temperature and functioning properly.
   a. To use the T-TEC Logger™ on an outbound cryoport:
      i. With the provided cable, connect the data-logger to the computer and open the T-TEC Logger™ tracking system program. Select Menu under USB-COM:4, then select Start Logger.
      ii. Enter: "Recipient, Cryoport #, Date, S" (S is for shipped) on Line 1 of the comments section.
      iii. Set the Logging Interval to 2 minutes for domestic and Canada shipments. Select 5 minutes for all international shipments.
      iv. Wait a minimum of 1 hour.
      v. Reconnect the data-logger to the computer and open T-TEC Logger™ software. Under Menu select Stop Logger.
      vi. Under Menu select Download Data. Save the pdf to the Shared Drive (RESQualman G Drive > BCR > BCR Cryoport Data > Year > Month) using the "Recipient, Cryoport #, Date, S" naming format. Once saved, open and view the temperature graph to ensure that the probe is working properly.

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vii. If the cryoport and logger are functioning properly, then restart the logger following the steps above but substituting the "S" for shipped with an "R" for received in the T-TEC™ comments section.

b. To Use the Libero™ Data Logger on an outbound cryoport:

i. Remove the data-logger USB from its bracket and simultaneously press the Transit and Arrived buttons until the screen says "Conf" (configure). Insert the logger into a USB port on the W230 shipping computer and open the Libero™ Configuration Utility program, selecting either the gear icon or Device > Configuration.

ii. In the left hand column, select Description and enter: "Recipient, Cryoport #, Date, S". Enter the same for the .pdf file name. **Note: This field has a character limit; the file name may need to be shortened.

iii. In the left hand column, select Logging and set the interval length to 2 minute for domestic shipments and Canada, and 5 minutes for international shipments. Maintain all other default start options and select "Apply".

iv. Remove the USB and replace the logger in the cryoport bracket. Depress the Transit button on the logger until the temperature displays.

v. After one hour, stop the logger by holding the Arrived button until the screen display changes from "Transit" to "Arrived". Remove the logger from the bracket and insert into the USB computer port.

vi. Open the .pdf to view the temperature graph and ensure that the probe is working properly. Save the file to the Shared Drive using the "Recipient, Cryoport #, Date, S" naming format.

vii. If the cryoport and logger are functioning properly, restart the logger following the steps above but substituting the "S" for shipped with an "R" for received in the Libero™ Configuration Utility "Description" section.

c. If the cryoport is not holding an acceptable temperature and the data logger is the suspected issue, then the one-hour test is repeated using a new logger.

d. If a temperature of -185°C or below was not maintained for at least one hour, then the cryoport CANNOT be used to ship, and a note is entered on the Cryoport and Data Logger Incident spreadsheet on the BCR SharePoint (REX/BPC/TCGA-BCR > Shared Documents > Logistics > Cryoport and Logger Issues). If the cryoport is suspected to be malfunctioning, then it is taken to Biomedical Engineering and another cryoport is selected for the shipment. The one hour temperature test is repeated on the new cryoport.

5. Returning specimens to sites:

a. If not provided by the CO representative, generate a shipping manifest from LabVantage (refer to BCR-SOP-A005, LabVantage User Manual).

i. A copy of this manifest is emailed to the designated Clinical Outreach (CO) representative and shipment confirmation is requested.

ii. Once shipping address confirmation is received, an airbill can be created, and the newly generated tracking number added to the manifest. The updated manifest is saved on the BCR SharePoint (Shared documents > Logistics >

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Shipping Logs > Return of Specimens) and a copy is emailed back to the CO representative.

iii. A hard copy of the manifest is used by Logistics for QC purposes and will also be included in the outbound package.

b. Pull specimens from freezer and place in a properly filled cryocart.

c. After the manifest has been confirmed by the CO representative, two technicians must verify that the specimens pulled match what is on the manifest.

d. Place samples into 9x9 specimen boxes and load them into a cryoport rack. Then insert the rack into the prepared outbound cryoport.

6. **Creating FedEx airbills for cryoports**:

a. Domestic Shipments

i. Go to "Ship" > "Create Shipment".

ii. In the "To" section, enter the address and contact information. Verify address and contact information from Clinical Outreach Coordinator before shipping a package (refer to BCR-SOP-C030 Customer Relationship Management (CRM) Software in Clinical Outreach).

iii. In the "Package & Shipment Details" section, enter the following:

(a) Weight: 51 lbs.
(b) Declared value: 2000 U.S. Dollars
(c) Service Type: Priority Overnight
(d) Package Type: Your Packaging

iv. In the "Billing Details" section, enter the following:

(a) Bill transportation to: BCR-662, FedEx Account # 491048662
(b) Your reference: Project, Destination, Outbound Cryoport

v. In the "E-mail Notifications" section, expand the "Edit" link. Enter an email address for the shipper and the receiver. For both, select "Tendered", "Exception" and "Delivery".

vi. In the "Complete your Shipment" section, click "Ship" then print the receipt and airbill.

vii. Create an inbound airbill following the steps outlined above ensuring that the BCR address is used for the destination and your reference: Project, Site, Inbound Cryoport.

b. International Shipments

i. Go to "Ship" > "Create Shipment".

ii. In the "To" section, first select the "Country/Location" to which you are shipping. Then enter the address and contact information. Always verify the address and contact information from Clinical Outreach Coordinator before shipping a package, if applicable (refer to BCR-SOP-C030, "Customer Relationship Management (CRM) Software in Clinical Outreach").

iii. In the "Package & Shipment Details" section, enter the following:

(a) Weight: 51 lbs.
(b) Declared value: $25
(c) Service Type: International Priority

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(d) Package Type: Your Packaging
(e) Package contents: Products/Commodities
(f) Total customs value: $25.00 USD.

iv. In the "Billing Details" section, enter the following:
(a) Bill transportation to: BCR-662, FedEx Account # 491048662
(b) Bill duties/taxes/fees to: BCR-662, FedEx Account # 491048662
(c) Your reference: Project, Destination, Outbound Cryoport

v. In the "E-mail Notifications" section, expand the "Edit" link. Enter an email address for the shipper and the recipient. For both, select "Tendered", "Exception" and "Delivery" in the "Notification type" column.

vi. Select "Continue Your Shipment".

vii. In the "Commodity Information" section, select "Add new commodity" in the drop down menu, under "Commodity", enter the following:
(a) <u>If</u> the cryoport is empty: This package is an empty dry vapor shipper. The package contains an aluminum dewar inside of a plastic shell.
(b) If samples are being shipped: This is a dry shipper that contains n# sample(s) of n# human exempt samples. These samples are non-infectious and non-hazardous, for research/analysis purposes only
(c) If analyte plates are being shipped: "This is a dry shipper that contains n# plate(s) of n# human genomic DNA/RNA samples. These samples are non-infectious and non-hazardous, for research/analysis purposes only."
(d) Unit of measure: pieces
(e) Quantity: 1
(f) Commodity weight: 51 lbs.
(g) Customs value: $25
(h) Country of manufacture: United States
(i) Shipment weight: 51 lbs.
(j) Total carriage value: Same value entered in steps II. C. 4.f.
(k) Click "Add this commodity".

viii. In the "Customs Documentation" section, enter the following:

ix. Select "Commercial Invoice"

x. Terms of sale: Free Carrier (FCA/FOB)

xi. Click "Ship".

xii. Print receipt, commercial invoice, and airbill. Sign all 3 invoice copies that automatically print for international shipments.

xiii. Complete an international customs letter (SharePoint>Logistics Forms> Shipping Documents> International Customs Letter)
(a) Select ONE of the following on the letter and delete the other.
(i) This package is an empty dry vapor shipper. The package contains an aluminum dewar inside of a plastic shell.
(ii) This is a vapor shipper that has no restrictions or regulations. It contains n# plate(s) of _ human genomic RNA samples. These

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samples are non-infectious and non-hazardous, for research/analysis purposes only.

(b) Print and sign 4 copies of the international customs letter on Nationwide Children's Hospital letter head.

(c) Consult with Logistics Supervisor to determine if additional customs documentation is needed.

xiv. International sites must generate their own return airbill to ensure all appropriate customs paperwork is completed. The BCR FedEx account number is provided to these sites for this purpose.

7. **Preparing for Shipment**:
   a. The cryoport lid must be securely labeled with the destination contact name, street address, and telephone number.
   b. The outbound shipping label (and commercial invoice, if applicable) is placed in an airbill pouch attached to an airbill tie-on tag. The tie-on tag must be securely attached to a handle on the outer shell of the cryoport with a zip tie. See Figure 1.
   c. The following items are placed into a 9x12 inch plastic bag:
      i. The return shipping label and tie-on tag for domestic sites; or an empty airbill pouch and tie-on tag for international sites.
      ii. Completed BCR-FRM-011 "Cryoport Temperature Log"
      iii. Return Address Form (with FedEx account # for international sites)
      iv. Exempt Human Specimen sticker if the returning cryoport will contain human specimens.
      v. 8 Cable Ties
      vi. For analyte shipments, also include the 96-well plate sample information form(s) and matrix well plate data form(s) provided by MGL.
   d. Tape the 9x12 bag to the inner lid of the cryoport shell using packing tape.
   e. The 9x9 specimen boxes are placed into a cryoport rack which may be pre-chilled in a cryocart before shipping (recommended to more rapidly achieve the required shipping temperature rebound). The specimen boxes will be shipped empty for sample collections, will contain specimens for sample returns, or will contain matrix well plates for analyte shipments.
   f. The cryoport temperature probe must remain exposed, not retracted into the Styrofoam portion of the lid.
   g. The Libero™ data loggers must be secured to in their bracket with a red zip tie. See Figure 2.
   h. The cryoport shell lid is closed and the locking mechanism fastened with two cable ties, which must be place through the locking mechanism per Figure 3.
8. Complete the following in LabVantage (BCR-SOP-A005):
   a. Create a package for the shipment.
   b. Place virtual samples into the LabVantage package if applicable.
   c. "Ship" the package.
9. Complete the appropriate information on BCR-FRM-016.

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Standard Operating Procedure (SOP) for Shipping an Outbound Package

a. The tracking numbers are e-mailed to the BCR Logistics group for verification. Once verified they are e-mailed out to the relevant BCR departments.
b. Two Logistics technicians must review and initial that the shipment information is correct. For Molecular analyte shipments the Plate ID section is filled in and reviewed by one Logistics technician and one Molecular technician.

10. Add the following information for all cryoport shipments to the whiteboard before taking an outbound cryoport to the dock: ship date, destination, estimated arrival date, comments, tracking number, and shipper initials.
11. Physically take the cryoport to the designated FedEx pick-up location for shipment. Track the package as specified in section II.B.4 above.

F. Documentation and Shipment Tracking

1. The technician on the shipping rotation will check the FedEx site during the workday as well as at least once daily after shipment to ensure that there are no delays or issues with the shipments.
   a. If a shipment is delayed, then notify the appropriate Clinical Outreach representative and the Logistics Supervisor.
2. Upon confirmation of receipt (via automated email from FedEx or a "Delivered" status on the FedEx website), the package is proxy received in LabVantage (refer to A005) and the whiteboard is updated with the site received date.
3. All outstanding cryoport shipments on the whiteboard are reviewed. If the return shipment is overdue (7 or more days past the original ship date), then notify the appropriate Clinical Outreach representative. Cryoport shipments are removed from the whiteboard only when they have been returned to the BCR.

II. REFERENCES

None

II. COMPREHENSIVE REVISION HISTORY

A. Version 1, effective date **8/16/2016**- New

1. Combined SOP BCR L007, L010, the returning portion of L013, L019, and the outbound section of L022
2. Changed all titles in Clinical Outreach to Clinical Outreach Representative

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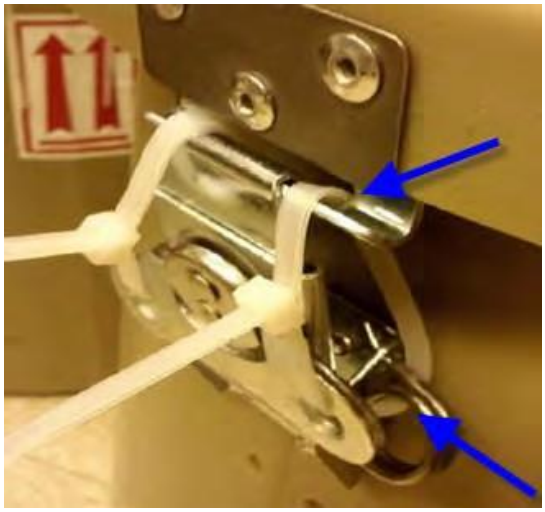
Standard Operating Procedure (SOP) for Shipping an Outbound Package

Figure 1

Figure 2

Figure 3



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Standard Operating Procedure (SOP) for Shipping an Outbound Package

Signatures

Approved By: **Signature on file** **Date:** **Date on file**

Julie M. Gastier-Foster, Ph.D., FACMG, Principal Investigator

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