
Standard Operating Procedure for R01 Sample Shipments from OAU to MSKCC

Version Date: 03/07/2024

POLICY:

Part of ARGO's mission is to ensure high-quality standards for management of clinical research protocols, processes, and systems and to ensure data quality adheres to relevant institutional and federal regulatory requirements and Good Clinical Practice (GCP) guidelines. All sites are responsible for ensuring adherence to the outlined protocol. If there are any questions, please contact MSKCC Clinical Research Manager: Cristina Olcese at OlceseC@mskcc.org or MSKCC Research Project Manager: Rivka Kahn at KahnR1@mskcc.org.

PROCEDURE:

The process for all R01 sample shipments is noted below:

- As soon as OAU and MSK decide to complete a sample shipment, GCDI RPM to email the OAU Research Team, MSK Research Team, and ARGO REDCap Team so that all process involved parties are aware.
- GCDI RPM to email MSK lab management to notify MSK -80 freezer space: (This must be at minimum one full week from shipment being sent).
 - Russell Holmes: holmesr3@mskcc.org
 - Tamara Torres: torrest@mskcc.org
 - CC GCDI Research Team
- GCDI RPM to Confirm Freezer storage space prior to shipment being sent:
 - Confirmed Freezer Space Location: _____
 - Confirmed by GCDI Research Staff Member Name: _____
 - Permission given by Name: _____
 - Confirmed on Date (M/D/Y): _____
- GCDI RPM to confirm GCDI team personnel on site at MSKCC can collect the shipment and place it in the confirmed freezer space upon arrival.
Communicate with Russell Holmes as well. Contacts:
 - Russell Holmes: holmesr3@mskcc.org



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- Once GCDI personnel is confirmed, GCDI RPM to confirm the correct MSKCC name and address for Delivery.
- GCDI RPM to confirm with Paul Zel (zelp@mskcc.org) that he will be able to return the Shipping container to the Sender.
- GCDI RPM to confirm with analysis recipient (Peter Ntiamoah: ntiamoap@mskcc.org) that this shipment time frame works.
- GCDI RPM to confirm a member of the GCDI Research team can go on site to cross check samples and Excel.
- Once all the above is confirmed, GCDI RPM to email the go ahead to OAU Research team to move to the next steps for sample shipment. Correct MSK address to be included in this email.
- OAU PM to notify all RAs at all sites to update the Biobank form. OAU PM to confirm this is all up to date.
- OAU RA to request Cases/Controls Excel from Matteo Di Bernardo.
- OAU RA receives samples from participating sites based on the above noted Cases/Controls Excel.
- OAU/Site RAs updates shipment information in Biobank form to OAU.
- Shipment is prepared at OAU and should match perfectly with the Cases/Controls Excel.
- Cases/Controls Excel is then sent to Matteo with any modification needed to sample labels.
- OAU to notify MSK team of date of planned shipment. Include ARGO REDCap team on this email.
- OAU to confirm with GCDI RPM the correct address for shipment to MSKCC.
- Please follow the below instructions for preparing the LN2 shipper (Princeton Cryo's model MVE):
 - The empty container should be pre-weighed. There is a recommended volume of liquid nitrogen that must be absorbed within the container to achieve the maximum time of frozen travel.
 - To prepare the shipper, especially when the container starts out warm, a small amount of liquid nitrogen is slowly added to reach the bottom of the neck tube. When bubbling stops, pour off the remaining liquid.



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- Refill the container and wait for the liquid nitrogen to be absorbed into the lining. Periodically check that the level of liquid is decreasing. This process cannot be rushed and may take several hours. If no liquid remains, repeat a refill.
- Weigh the container. There should be a minimum 16 lb. increase in weight to demonstrate the container is fully saturated/charged.
 - NOTE: To be acceptable for transportation, there can be no free-flowing liquid nitrogen in the charged container when fully inverted.
- Avoid making contact between the container plug and liquid nitrogen. It may cause the plug to shrink, compromise the container seal, and result in a premature loss of nitrogen over time.
- OAU to send the Shipping carrier and tracking number to MSK team. OAU to include the Shipment Excel in this email. (GCDI Research team to ensure Peter Ntiamoah and the ARGO REDCap team are on this email).
- Matteo re-imports Excel also with shipment status to MSK updated.
- Matteo generates shipment specific REDCap report.
- GCDI RPM to register the GCDI RPM and CRC's for Shipping notifications.
- GCDI RPM to email the tracking number to the GCDI research team and the personnel accepting the shipment.
- GCDI RPM to check the tracking number daily. Communicate with Shipping carrier and Team if there are any issues/delays with the shipment.
- Once shipment shows as arrived, GCDI RPM to communicate with the MSK GCDI personnel to confirm that the shipment has been received and placed in the correct freezer space.
- Confirm with the GCDI personnel that they have left the shipping container open to allow the container to air out, so no residue is left when the team is ready to send the shipping container back to Sender.
- Confirm with the GCDI personnel the exact location of the empty shipping container. Utilize Room Z439 for evaporation of the container.
- GCDI Research team to QA the shipment cryovials against the Excel document.
- If there are any discrepancies, GCDI Research team to review with OAU Research team.



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- Cases/Controls Excel is then sent to Matteo with any modifications needed to sample labels.
- Matteo re-imports excel with final modifications to sample labels.
- Shipment specific redcap report is automatically updated.
- GCDI Research staff to take a photo of where the samples are stored and email photo to GCDI research team and save in GCDI S folder.
- GCDI Research staff to email Paul Zel (zelp@mskcc.org). In the email, include:
 - Name, address, and telephone of Recipient
 - Name, address, and telephone of Sender
 - Note that our Nigerian collaborator is the owner of the container
 - Note the date that the shipper was emptied and request if he can bring his air monitoring device to be sure that there is no measurable residue in the shipping container.
 - Collect an estimate from Paul Zel on the cost of returning the shipping container.
- Once estimate is received from Paul Zel, email Cristina Olcese, GCDI CRM: (olceseC@mskcc.org) to confirm the Cost Center # for shipping costs.
- Email confirmed Cost Center # to Paul Zel.
- Collect Shipping carrier and Tracking number from Paul Zel.
- Email tracking number to the GCDI Research Team and the Nigerian team.
- Check tracking number daily. Communicate with Shipping carrier and Team if there are any issues/delays with the shipment.
- Once return shipment shows as arrived, communicate with the team in Nigeria that the container has been received.
- GCDI team to update R01 Samples Master Excel with a new tab for this shipment.
- GCDI Research team to notify Peter N. where the samples are in the Zuckerman lab.
- Peter N. picks up samples from Zuckerman lab.
- Peter N. sends the samples to PPBC (Precision Pathology Biobank).
- PPBC cuts and generates H&Es (takes 1-2 months).
- Pathologists review and determine which samples have enough tumor.



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- The samples that have enough tumor go back to PPBC to punch the tumor into conical tubes.
- Peter N. emails the list of all samples that did not have enough tumor to OAU (Include Matteo and Rivka on this email).
- Peter N. creates the list of Collaboration IDs that will go to CMO. The Collaboration ID = Sample Label in the Shipment Excel. **(This Collaboration ID is very important as this is our link to any clinical data).**
- Peter N. emails the list of Collaboration IDs to Matteo Di Bernardo and Rivka Kahn
- Matteo imports the Collaboration IDs into REDCap.
- Peter N. puts the information into CMO (including the Collaboration identifiers).
- CMO generates labels.
- Peter N. collects the labels from CMO and labels each tube, then matches each with the corresponding Buffy coats.
- Peter N. schedules drop off at CMO.
- Peter N. drops off at CMO, (takes about 1 month for CMO to send results).
- Results are then available in Cbio portal under project 05213 titled “CMO Merged Study for Principal Investigator (kinghamp).
 - Note: This project includes the CRC cases that were not part of the R01. To filter for the R01 samples, Filter the “Gene Panel” column for IMPACT 505.
- GCDI to email Matteo list of CBio portal IDs.
- Matteo to import CBio portal IDs into REDCap.
- Email contacts for this project:
 - Rivka Kahn, MSKCC RPM: kahnr1@mskcc.org
 - Naqiya Choonawala, MSKCC RPA: choonan@mskcc.org
 - Grace Fitzgerald, MSKCC CRC: fitzgeg1@mskcc.org
 - Ryan Foderor, MSKCC CRC: foderor@mskcc.org
 - Matteo Di Bernardo, REDCap Consultant: md3498@columbia.edu
 - Christopher Bamidele, REDCap Manager: bchristophersesan@gmail.com
 - Peter Ntiamoah, Surgical Pathology Manager: ntiamoap@mskcc.org



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- Israel Owoade, ARGO Program Manager: israeladeyemigmi@gmail.com
- Lawal Nafisat, ARGO Project Manager: olanafeesa@yahoo.com

Revision History

Revision #	Effective Date	Changes
1	3/Oct/2023	Steps in Process.
2	14/May/2024	Email Contacts
3	27/June/2024	Email Contacts
4	3/July/2024	LN2 Shipper Preparation Instructions added.