



MEMORANDUM

DATE: 24 April 2024
TO: IMPAACT Colleagues
FROM: Grace Aldrovandi, MD, Principal Investigator, IMPAACT Laboratory Center and Sharon Nachman, MD, IMPAACT Network Chair
SUBJECT: IMPAACT Specimen Shipping Plan – **Applies to NIAID SITES ONLY**

The purpose of this memorandum is to provide information regarding the implementation of new IMPAACT shipping procedures. These procedures aim to establish intermediary repository storage, ensuring optimal specimen integrity.

Designated Repositories

- For studies collecting samples destined for an end testing laboratory in the United States: samples will be shipped to the Biomedical Research Institute (BRI) Repository (Lab #999).
- For studies collecting samples destined for an end testing laboratory in Africa: samples will be shipped to the BARC-SA Biobank (Lab #481) in Johannesburg.
- Note: samples will not be shipped to the applicable repository if they are requested sooner for direct shipment to an end testing laboratory.

Shipment Considerations

- Shipments will occur on a quarterly basis (every three months).
- To avoid disruptions during the December-January holiday period, shipping will occur:
 - FEB >> MAY >> AUG >> NOV
- US and international labs will ship to BRI or BARC any time during the designated month (IMPAACT labs will not be assigned to a specific week in the month to ship).
- Protocol-specific Specimen Request Lists will not be sent for these shipments by the IMPAACT laboratory data managers (LDMs); however, laboratories may receive data queries for overdue shipments when specimens are not shipped on time according to the LPC.
- Samples from multiple IMPAACT studies may be included in a shipment – leaving the required empty slot between studies in the shipping box (2” 9x9 box).
 - **Important:** IMPAACT and ACTG samples must not be mixed in the same shipment.
- Sites will continue to follow specimen shipment guidance in IMPAACT MOP Section 17.

Exception for Viable PBMCs



- Due to the need to ship viable PBMCs using dry shippers (LN2) which are in limited supply, these shipments will occur every six months (in May and November).
- If the lab does not have its own shippers, BRI may loan shippers for this purpose.
- Staggered shipments within the month may be necessary to effectively manage demand and supply of the LN2 shippers.
- BRI does NOT loan more than two dry shippers per lab at any given time.
- Any borrowed BRI shippers MUST be put to use upon receipt and sent promptly to BRI.
- Dry shippers can hold four boxes (4x81 samples each = 324 vials).

Material Transfer Agreements (MTAs), Specimen Transfer Agreements (STAs) and Permits

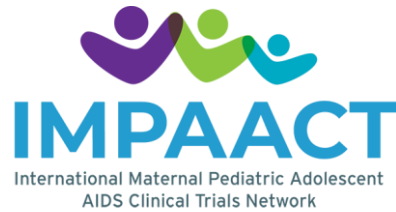
- Prior to initiating any shipments, MTAs must be established between the sites and BRI, along with any required permits.
- MTAs between the sites and the BARC-SA Biobank must also be executed if required and permits obtained if needed.
- MTAs with BRI or BARC must allow the applicable repository to transfer stored samples to a third party with the understanding that either the original Repository MTA would need to be amended OR there would need to be an additional/subsequent MTA with the end testing lab once that lab is designated by the protocol team.
- Reminder – all MTA communications should include the IMPAACT MTA email alias to allow for tracking of the documents (impaactMTA@fstrf.org).

Flexibility and Protocol-Specific Approaches

- There will need to be flexibility and considerations on a protocol-by-protocol basis.
- It is acknowledged that some sites are not permitted to ship samples to a Repository but only directly to an end testing lab per their MTA/STA.
- Shipments to the repositories may be delayed, or not occur, under the following circumstances:
 - specimens that will not be stored long-term (for example, those with real-time testing).
 - for studies with limited follow-up visits or limited samples collected, the frequency of shipments will vary based on other opportunistic shipments. If samples are not otherwise being shipped every three months, samples will be shipped every six months (a mandatory shipment).

Communication and Coordination

- Each protocol team will inform the participating sites and labs when shipments will start for each protocol, and exactly what specimens will be sent to BRI and/or BARC-SA Biobank.
- Lab Processing Charts (LPCs) will be updated accordingly for each protocol.



Please note this shipping plan is to be implemented by NIAID sites/labs only. Any changes to NICHD site/lab shipping procedures will be communicated to those sites by Westat.

Any questions should be directed to the IMPAACT Laboratory Center (impaact.qaqc@fstrf.org).

Your participation in IMPAACT studies is deeply appreciated.

Thank you