



MEMORANDUM

DATE: 13 December 2022

TO: IMPAACT Colleagues

FROM: IMPAACT Repository Advisory Group
Grace Aldrovandi, MD, IMPAACT Laboratory Center PI

SUBJECT: Disposition of PACTG/IMPAACT Specimens

On 10 July 2014, the IMPAACT Scientific Leadership Group provided guidance on specimens stored at IMPAACT sites, repositories, or testing laboratories. In that Memo, a group of 25 High Priority Studies were specified, and all non-remnant specimens from these studies were expected to be shipped to either the BRI or Fisher repositories.

The IMPAACT Management Oversight Group (MOG) has since reviewed studies deemed as “High Priority” and decided that all remaining specimens still located at study sites must be destroyed. The remaining samples currently being stored in the BRI and Fisher repositories will continue to be stored.

All remaining specimens located at study sites from the following studies need to be destroyed:

| | | | | | | |
|-----|------|-----|-----|--------|--------|-------|
| 076 | 219C | 316 | 356 | 390 | P1045 | P1060 |
| 152 | 288 | 338 | 377 | P1020A | P1053 | P1065 |
| 219 | 300 | 345 | 381 | P1025 | P1058 | P1083 |
| | | 351 | 382 | P1034 | P1058A | |

The network simply cannot afford to keep all of these specimens while continuing to collect and store many more from ongoing trials.

All samples at study sites from the protocols listed in this memorandum should be destroyed by 31 March 2023. The IMPAACT Management Oversight Group (MOG) will be informed of all sites not in compliance by this date.

The PI of the laboratory is responsible for ensuring that IMPAACT specimens are destroyed in accordance with all IMPAACT Network and institutional policies, any applicable local or country laws, and in a GCLP compliant manner. Laboratory staff will update LDMS to accurately reflect

that specimens were destroyed, including removing the specimens from the storage module, assigning the appropriate condition (e.g., DSR), and adding comments to document the date, responsible staff, and reason for specimen destruction.

Please contact the IMPAACT Laboratory Center and Specimen Archive group with any questions you may have: impaactqaqc@fstrf.org and specimen.archive@fstrf.org.

Questions specific to the LDMS should be addressed to User Support:

LDMS User Support

Web: <https://www.ldms.org/contact/>

Phone: (716) 834-0900 x7311

Email: ldmshelp@fstrf.org

Thank you all for your valuable contributions to PACTG/IMPAACT and for your cooperation in this process.

Appended: *Disposition of PACTG/IMPAACT Specimens* memo, dated 10 July 2014



MEMORANDUM

DATE: 10 July 2014

TO: IMPAACT Colleagues

FROM: Sharon Nachman, MD, IMPAACT Network Chair
James McIntyre, MD, IMPAACT Network Vice Chair
Grace Aldrovandi, MD, IMPAACT Laboratory Center PI
David Shapiro, PhD, IMPAACT Statistical and Data Management Center PI
Brooks Jackson, MD, MBA, LOC Grant PI

SUBJECT: Disposition of PACTG/IMPAACT Specimens

The IMPAACT Scientific Leadership Group (SLG) has carefully reviewed and considered inventory lists of specimens stored at IMPAACT sites as of 24 February 2014, including nearly one million specimens in freezers worldwide. We discussed how these might be used in future investigations and concluded that – with the exception of specimens from studies deemed as “high priority” and cerebrospinal fluid (CSF) specimens from all studies – all other specimens should be destroyed. The reasons for this difficult decision include:

- complexity of the informed consent/IRB/EC approval issues,
- uncertainty about specimen quality/viability, particularly those dating back several years,
- time and resources that would be required on the part of the Statistical and Data Management Center (SDMC) and others to respond to requests for possible specimen use, and
- costs associated with shipping and continued storage.

The network simply cannot afford to keep all of these specimens while continuing to collect and store many more from ongoing trials. The newer studies have clearer informed consent language regarding storage and future use than the older studies did, and more stringent quality control measures are in place to ensure sample integrity.

Many IMPAACT laboratories recently received spreadsheets from FSTRF listing the specimens in their freezers by protocol number, based on the Laboratory Data Management System (LDMS). Each laboratory will receive a listing of studies for which specimens should be destroyed per IMPAACT Specimen Destruction SOPs.

The remainder of this memorandum provides further instructions for laboratories not funded by either NIAID or NICHD for the new funding cycle (hereafter referred to as ‘**defunded**’ and for laboratories funded for the new funding cycle by either NIAID or NICHD (hereafter referred to as ‘**funded**’).

BOTH FUNDED AND DEFUNDED LABORATORIES

- Please send all samples from the studies designated as “high priority” on the list below to the BRI Repository or Fisher Repository as appropriate for your site. For previously NIAID-funded sites that are now funded by NICHD, all specimens collected under NIAID funding should be sent to BRI.
- Please destroy all testing remnants and derivative samples such as culture supernatants (including from high priority protocols). These remnants cannot be stored at the repositories.

DEFUNDED LABORATORIES

- PROMISE samples should be shipped to the appropriate repository. If your Institutional Review Board/Ethics Committee (IRB/EC) or drug regulatory authorities do not permit shipping to the repository, please contact impaact.centlab@fstrf.org to make alternative arrangements.
- Please send samples from all other ongoing studies to the appropriate repository.
- Please destroy the samples from all studies that are not on the “high priority” list below or currently ongoing.
- The samples to be shipped to the repository must be received by **1 November 2014**.

FUNDED LABORATORIES

- PROMISE 1077BF, 1077FF and P1084s samples should remain at your site until you are requested to ship them to a testing laboratory or to the repository; 1077HS specimens should continue to be shipped according to the current schedule, unless you are otherwise directed.
- Continue with current schedule of shipments for other ongoing studies, unless otherwise directed.
- Please destroy all samples from all studies that are not on the “high priority” list below or currently ongoing.

Thank you all for your valuable contributions to PACTG/IMPAACT and for your cooperation in this process. Please contact the IMPAACT Laboratory Center with any questions you may have: impaact.centlab@fstrf.org.

HIGH PRIORITY IMPAACT SPECIMENS

Non-remnant samples from the following studies should be sent to the Repository (BRI if collected with NIAID funding; Fisher if collected with NICHD funding) by funded and defunded sites.

1. Samples from the following High Priority Studies

| | | | | |
|----------|----------|---------------|----------|----------|
| ACTG 076 | ACTG 152 | ACTG 219/219C | ACTG 288 | ACTG 300 |
| ACTG 316 | ACTG 338 | ACTG 345 | ACTG 351 | ACTG 356 |
| ACTG 377 | ACTG 381 | ACTG 382 | ACTG 390 | P1020A |
| P1025 | P1034 | P1045 | P1053 | P1058 |
| P1058A | P1060* | P1065 | P1083 | |

* The IMPAACT Central Laboratory will contact P1060 sites with further instructions on which P1060 samples should be sent.

2. Samples from the PROMISE Studies

Defunded laboratories should send samples from the PROMISE studies (listed below) to the repository. If there are IRB/EC or Material Transfer Agreement (MTA) issues please contact impaact.centlab@fstrf.org.

IMPAACT 1077BF (1077BA, 1077BL, 1077BP, 1077BM)
IMPAACT 1077FF (1077FA, 1077FM)
IMPAACT 1077HS
IMPAACT P1084s

Note: As stated above, funded laboratories should retain 1077BF/FF and P1084s samples until requested to ship them to a testing laboratory or to the repository and continue shipping 1077HS specimens per the current schedule unless otherwise directed.

3. CSF Samples

CSF samples from any PACTG/IMPAACT study should be shipped to the repository, along with plasma/serum samples collected within one month of the CSF sample. FSTRF will work with sites to identify the appropriate aliquots and send listings of targeted specimens to ship. ***CSF samples that were not collected as part of ACTG/PACTG/IMPAACT studies will not be accepted at the repository.***

4. Samples from Ongoing Studies:

- Defunded laboratories should send samples from all ongoing studies to the repository.
- Funded sites should continue to follow the current schedule for shipment of specimens from ongoing studies.