

ACTG/IMPAACT BRI Specimen Repository: The “IDEA GENERATOR”

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for the Repository Advisory Group and the four-point-four million
pedigreed protocol specimens that reside in our joint BRI
biorepository

Background

- The AIDS Clinical Trial Networks have pedigreed clinical trial specimens suitable for studying HIV-1 antiretroviral drug resistance questions
 - ACTG/IMPAACT Biomedical Research Institute (BRI) biorepository
 - Access is available for both Network and non-network investigators using two user-initiated search utilities
 - Frontier Science Foundation (FSTRF) provides data management
 - Repository Advisory Group (RAG) provides oversight
 - The HIV-1 prevention trial Networks (HPTN, MTN and HVTN) provide specimen access through ancillary study concept proposals
 - Other considerations are required to access HIV-2 specimens

BRI Specimen Access

- Two mechanisms are available
 - **Specimen Inventory Report Utility** for ACTG/IMPAACT Network Investigators
 - **Specimen Repository Website** for both Network and non-Network investigators

Specimen Inventory Report Utility

Available to ACTG/IMPAACT Investigators and their collaborators

Slides provided by Marlene Cooper, M.S.

Specimen Inventory Report Utility

- Provide investigators with real-time access to ALL specimen inventory information for feasibility assessments and inventory checks
- SPECIMEN COUNT (04/13/16)
 - ACTG 4.3×10^6
 - IMPAACT 5.6×10^5
- Reports display aliquot counts in summary or aggregate format
- PID specific listings or more complex queries involving clinical or lab endpoints will still be vetted first by SDMC staff

Specimen Inventory Report Utility Options

- Requires FSTRF portal user name and password
- Available for ACTG and IMPAACT investigators
- User can define protocol, visit values, specimen types, and lab categories to generate summaries
- Multiple report options to display and sort the summary counts by lab, visit, specimen type and number of patients
- Report available in Excel or PDF format

Specimen Inventory Report Utility Details

- Study participants who have de-consented to use of stored specimens for future research are not included in the reports
- Report can be filtered to only display specimens at Processing Laboratories or Biorepository
- Testing remnants are not included

Initial Report Criteria


Specimen Inventory Report

ACTG

This utility is used to generate report which would display aliquot counts in summary/aggregate format. Patients that have deconsented to the use of stored specimens for future non-protocol defined testing are excluded from the report.

* Required field

Report Criteria
* Study:
Lab:
Visit:
Only include specimens for which storage locations were assigned in LDMS:
 YES
 NO

Specimens
Is alternative tube type acceptable?
 Yes  Option appears when SST or NON additive type selected
 No
Primary type:
Additive type:
Derivative type:
Sub Additive/Derivative type:

Specimens selected:

#	Primary	Additive	Derivative	Sub Additive/Derivative	Delete
1	BLD	SST	SER		<input type="checkbox"/>

Secondary Report Criteria

Specimen Inventory Report

Selected Values

Study: A5175
Lab: Processing Lab
Only include specimens for which storage locations were assigned in LDMS: NO
Is alternative tube type acceptable? YES

Specimens Selected:

#	Primary	Additive	Derivative	Sub Additive/Derivative
1	BLD	SST	SER	

- * Report options:
- Display counts by Derivative and labid
 - Display counts by Derivative, labid and visit
 - Display counts by Derivative, visit and PID

- Report format
- PDF
 - Excel

Submit

Reset

Report Output Example

[Link to LDMS codes appendix](#)



[LDMS Codes](#) FSTRF

Specimen Inventory Report

Study A5001

Lab ID: Processing Lab

Visit details: All

Only include specimens for which storage locations were assigned in LDMS: No

Specimens selected: Primary=BLD , Derivative=CEL

Alternate tube type acceptable: N/A

Mother/Child criteria: N/A

Report format: pdf

Report options: Aggregate count by Derivative and Labid

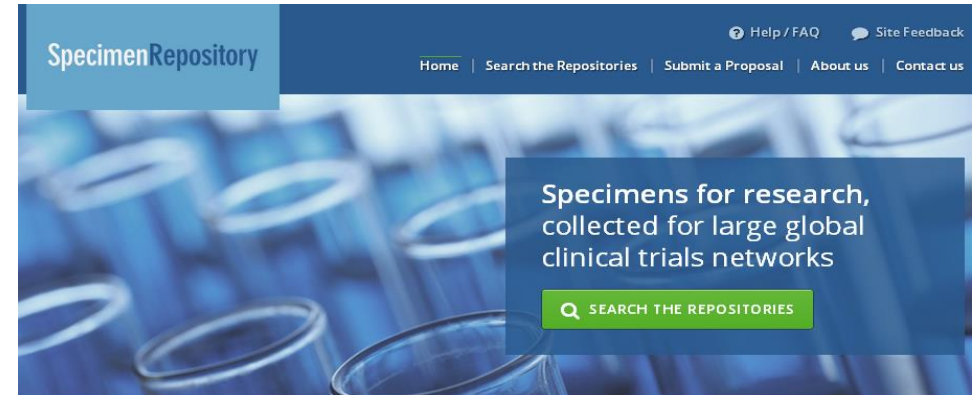
<u>Derivative</u>	<u>Labid</u>	<u>Lab Name</u>	<u>Aliquot Count</u>
CEL	1	Partners AIDS Research Center	1,037
CEL	2	Beth Isreal Deaconess Medical Center	67
CEL	6	Stanford University	797
CEL	7	UCLA CARE Center	1,290
CEL	8	University of California at San Diego	1,201
CEL	9	ARI/UCSF Laboratory of Clinical Virology	93
CEL	11	University of Miami	56
CEL	12	University of Pittsburgh	302
CEL	15	Retrovirus Laboratory University of Washington	102
CEL	17	Duke University	6
CEL	21	NYU/Bellevue Hospital Medical Center	278
CEL	22	New Jersey Medical School	8
CEL	23	Ohio State Medical Center	4
CEL	24	University of Cincinnati Retrovirology Reference Laboratory	26
CEL	28	University California at San Diego AVRC	22
CEL	29	Rush University Medical Center	11
CEL	31	Washington University	71

Specimen Repository Website

Access available to both Network and non-
Network investigators

The Website

- Interactive tool for viewing aggregate specimen counts based on search criteria
- **Limited to data from protocols that have been closed for > 5 years (~2.5 x 10⁶ specimens)**
- Displays information about studies in search results
- Provides information and links about the New Work Concept Sheet (NWCS) process



The specimen repositories are a collaboration between the ACTG and IMPAACT clinical trial networks to make the large body of specimens collected for HIV research available to investigators.

ACTG (The AIDS Clinical Trials Group) and IMPAACT (The International Maternal Pediatric Adolescent AIDS Clinical Trials) are two large global efforts studying HIV and related infections.

The specimens stored at the repositories were initially collected for specific studies that have concluded, and are now available to investigators conducting new research.

Using this website

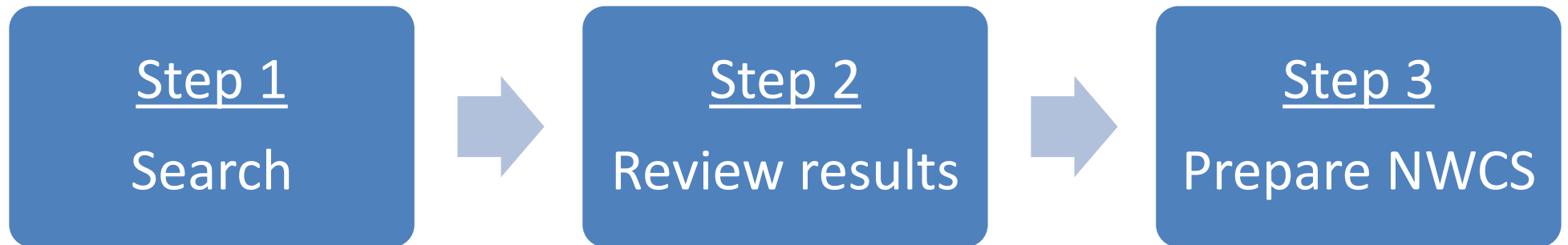
You can use the interactive search tool on this website to learn about the types of specimens available at the repositories. After completing a search, you can see the number of specimens and unique participants available, information about the studies for which they were collected, and what research was published for those studies. The search tool will also provide you with a report that lists your specimens of interest. You can then use this report to help write your research proposal to the network.

 [START SEARCHING](#)

What's in the repositories?		
	ACTG	IMPAACT
Specimens	1328464	304780
Protocols	196	17
Types of specimens	19	9
Cryopreserved PBMCs	260576	97932
Plasma	881257	195289
Serum	146090	10734



User Workflow



Step 1: Search

- Two ways to search
 - By study number
 - Define search criteria
- Types of criteria
 - Specimen characteristics
 - Study characteristics
 - Participant characteristics

General Information

Study code *(optional)*

You can choose one or more studies from this list

Are you interested in using specimens for human genomic testing?

Yes

No

Materials

Material type

Blood-based

Cord Blood

LeukoPak

PAXgene Blood

Plasma

[+ Study Characteristics](#)

[+ Participant Information](#)

Other Options

*If you need to search the repository with options that are not shown here, please **contact us** to request a custom search.*

SUBMIT SEARCH

RESET FORM ↻

Step 1: Search (Example)

- Viable PBMCs
- Female participants
- Baseline samples

PBMC viable [?](#)



What type of pbmc viable specimens are you looking for?

EDTA

Acid Citrate Dextrose

Heparin

Sodium Citrate

Other

Sex

This is the participant's biological sex at the time of birth.

Male

Female

No preference

Study weeks











Baseline

Post-baseline

No preference

Step 2: Review Results

- Results grouped by study and material type
- Shows number of unique participants and specimens
- Hover over study for details about it

Study	Material Type	Unique Participants	Specimens
IMPAACT P 1053 	PBMC viable (Acid Citrate Dextrose)	2	4
IMPAACT P 1053 	PBMC viable (EDTA)	3	9
IMPAACT P 1034 	PBMC viable (Acid Citrate Dextrose)	10	44
IMPAACT P 1034 	PBMC viable (EDTA)	2	3
IMPAACT 390 	PBMC viable (Acid Citrate Dextrose)	1	5
IMPAACT 390 	PBMC viable (EDTA)	19	158
IMPAACT 382 	PBMC viable (Acid Citrate Dextrose)	17	33
IMPAACT 382 	PBMC viable (EDTA)	8	28
IMPAACT 381 	PBMC viable (Acid Citrate Dextrose)	58	293
IMPAACT 381 	PBMC viable (EDTA)	15	38
Total: 109 studies	1 Material Types	4,668 Participants	18,315 Specimens

Step 2: Review Results




Details for a study

- Objectives
- Regimen
- Study Location
- Link to Schedule of Events (PDF)
- Links to Published Articles

381: Establishment and Maintenance of Long-Term Undetectable plasma hiv-1 rna: correlation with immunologic reconstitution and viral dynamics

Objectives: To determine if, controlling for baseline viral load, there is a positive correlation between the baseline immunologic status and the virologic and immunologic response to HAART at 1, 2, and 3 years after initiation of treatment.

Regimen: HAART, including either protease inhibitor or EFV

Study Location	US
Schedule of Events	The SOE may be downloaded here  (PDF format)
Journal articles	<p>Immune reconstitution and predictors of virologic failure in adolescents infected through risk behaviors and initiating HAART: week 60 results from the PACTG 381 cohort </p> <p>Rudy BJ, Lindsey JC, Flynn PM, Bosch RJ, Wilson CM, Hughes ME, Douglas SD; Pediatric Aids Clinical Trials Group 381 Study Team AIDS Res Hum Retroviruses 2006 Vol. 22 (3) 213-21 PubMed ID: 16545007</p> <p>Virologic and immunologic outcomes after 24 weeks in HIV-1 infected adolescents on highly active antiretroviral therapy </p> <p>Flynn PM, Rudy BJ, Douglas SD, Lathey J, Spector SA, Martinez J, Silio M, Belzer M, Friedman L, D'Angelo L, McNamara J, Hodge J, Hughes MD, Lindsey JC; Pediatric AIDS Clinical Trial Group 381 Study Team JID 2004 Vol. 190 (2) 271-9 PubMed ID: 15216461</p>

Step 2: Review Results

- Three ways to save results
 - Print
 - Download PDF
 - Save link
- Links to search results will reflect current data since the specimen database is refreshed weekly

PRINT THIS REPORT DOWNLOAD REPORT LINK TO THIS REPORT

Your search

Material types: PBMC viable (Acid Citrate Dextrose, EDTA, Heparin, Other, Sodium Citrate);
HIV treatment status: Infected
Hepatitis C virus infection status: Infected
Participant sex: Male
More ▾

<< EDIT SEARCH CRITERIA

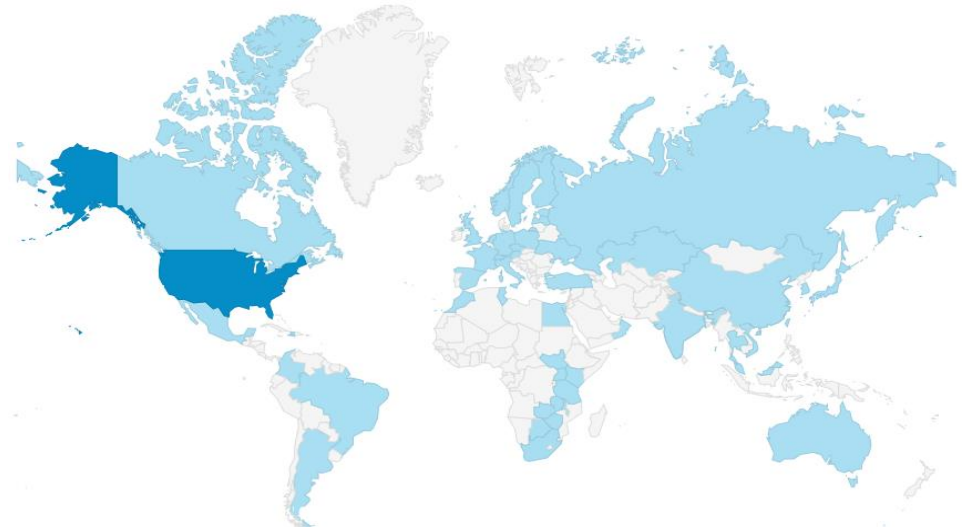
Need to run a more customized search? [Get in touch >>](#)

Step 3: Prepare NWCS

- Website provides brief explanation of the NWCS process
- Links to network specific webpages to walk the user through the submission process
- FAQ page provides additional information

Website Usage (April 2015-March 2016)

- 6,121 sessions
- 4,788 unique visitors
- Users from over 105 different countries
- 17,528 page views
- 2.86 average pages per session
- 66.9% bounce rate



Repository Website Milestones

- ACTG/IMPAACT Repository Website version 1.0 released to the public on April 29th, 2015
- Two subsequent updates (v1.1.0 and v1.2.0)
- The DMC continues to maintain and update the database used by the website, which contains LDMS specimen inventory data, clinical data, lab results, protocol information, and publication data.
- This work involves receiving and processing monthly data feeds from the networks, following up on data validation issues, adding new studies to the system as they become approved, and general database and hardware maintenance activities.

ACTG Update

- A question was added to the NWCS template in July 2015 asking whether the Repository website was used.
- Since July, there have been 8 NWCS submissions/revisions, of those 1 indicated they used the website, 7 did not.
- The total number of NWCS processed in 2015 was 25, which is up from only 15 processed in 2014.

IMPAACT Update

- The NWCS form was revised in August 2015 to ask whether the Repository website was used, and the website was used for three of the five NWCS proposals received since then.
- There were a total of 5 NWCS proposals received in 2015 as compared to only two in 2014.
- In addition, IMPAACT issued a solicitation for Early Career Investigator Awards last March, and the solicitation specifically encouraged use of the repository web tool (although this wasn't formally tracked).

Additional information

- Contact “Us link” provides a mechanism to request additional assistance for more complex queries
- To facilitate specimen access, a funding opportunity application (DAIDS supplemental) is in preparation for release this spring

Thank You

- ACTG, SSS and FSTRF
- IMPAACT and FHI360
- NIAID/DAIDS
- NICHD
- Biomedical Research Institute (BRI)
- Fisher BioServices
- Emerson Media

