Protocol for Investigator Requests for PHACS Biospecimens

1. Purpose

This protocol establishes the standardized process for investigators requesting biospecimens from the PHACS network while the NICHD Data and Specimen Hub (DASH) remains unavailable for specimen dissemination as it transitions to BRICS platform. The process described ensures responsible stewardship of biospecimens while maintaining scientific integrity, participant protection, regulatory compliance, and complete chain-of-custody documentation.

Frontier Science will serve as the administrative specimen coordination hub, will manage specimen inventory through the Laboratory Data Management System (LDMS), coordinate requests and approvals, ensure required MTAs are in place by working closely with the Harvard T. H. Chan School of Public Health (HSPH), and authorize specimen releases until DASH becomes available. The Repository at Fisher Bioservices will maintain physical custody of specimens and perform retrieval, packaging, and shipment.

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2. Scope

This procedure applies to grantees requesting biospecimens from past PHACS studies deposited to NICHD DASH (AMP, AMP Up, AMP Up Lite, SMARTT, TERBO BRAIN) and PHACS-affiliated studies (HOPE).

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3. Terminology

Term	Definition
AMP	Adolescent Master Protocol
AMP Up	Adolescent Master Protocol for Participants 18 Years of Age and Older
AMP Up Lite	Adolescent Master Protocol for Participants 18 Years of Age and Older - Lite
BRICS	Biomedical Research Informatics Computing System
Central Repository	Specimen repository located at Fisher Bioservices
DASH	Data and Specimen Hub
Data Center	Data center located at Frontier Science
FS	Frontier Science Foundation
HOPE	Health Outcomes around Pregnancy and Exposure to HIV/ARVs
HSPH	Harvard T. H. Chan School of Public Health

Term	Definition
IRB	Institutional Review Board
LDMS	Laboratory Data Management System
MTA	Material Transfer Agreement
NICHD	National Institute of Child Health and Human Development
PHACS	Pediatric HIV/AIDS Cohort Study
SMARTT	Surveillance Monitoring for ART Toxicities
Specimen request form	Online form for requesting the release of specimens from the Central Repository
TERBO BRAIN	Trajectories of Emotional Regulation and Behavior Outcomes and Related Brain Regions and Intrinsic Networks

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4. Roles and Responsibilities

Investigator

The requesting investigator is responsible for:

- Developing the scientific proposal
- Completing the specimen request form
- Identifying requested specimen types, volumes, and quantities
- Working with Frontier Science, which will prepare the specimen inventory request

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Data Center @ Frontier Science

The Data Center is responsible for:

- Serving as the primary point of contact
- Performing administrative review of the specimen request
- Assembling an LDMS specimen inventory list
- Ensuring necessary agreements are in place (MTAs)
- Preparing specimen release authorizations
- Coordinating with the Central Repository
- Maintaining complete documentation

The Central Repository is responsible for:

- Maintaining physical custody of specimens
- Confirming specimen availability
- Retrieving requested specimens
- Performing quality verification
- Packaging specimens and relabeling per the DASH standard procedures
- Shipping specimens
- Maintaining chain-of-custody documentation
- Maintaining and updating specimen inventory availability in LDMS (LDMS #243 database)
- Communicating with Frontier Science when the specimen request has been completed

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5. Procedure

Step 1. Feasibility Assessment

Investigators are encouraged to consult with the Data Center @ Frontier Science before preparing a formal request.

Consultation may include:

- Available specimen types and volumes
- Estimated specimen counts
- Collection timepoints
- Requested specimen list
- Requested clinical data elements
- IRB approval or exemption
- Funding for specimen shipment
- Biosafety approvals (if applicable)

Step 2. Administrative Review

The Data Center @ Frontier Science reviews the online specimen request form for completeness.

Administrative review includes verification of:

- Completeness of submission
- Necessary approvals

- Invoice number for Repository billing
- Funding in place for specimen shipment
- Consent restrictions, if any

Incomplete requests are returned for revision.

Step 3. LDMS Feasibility Assessment

The Data Center @ Frontier Science performs an inventory assessment using the LDMS database.

Assessment includes:

- Available specimens
- Specimen type
- Collection visit
- Aliquot availability
- Volume
- Storage location
- Storage conditions
- Freeze/thaw history
- Remaining inventory after proposed release

A feasibility report is prepared.

Step 4. Material Transfer Agreements (MTAs)

Following approval, the Data Center @ Frontier Science ensures appropriate agreements are in place working closely with HSPH.

An MTA is required whenever biospecimens are transferred to a recipient institution from the Central Repository in the absence of a negotiated subaward to that institution which specifies conduct of assays on PHACS or HOPE specimens as part of its scope of work.

The MTA should define the following:

- Approved research purpose
- Ownership of specimens
- Restrictions on redistribution
- Storage requirements
- Security requirements
- Intellectual property provisions

- Publication requirements
- Acknowledgment requirements
- Requirements for destruction or return of unused specimens
- Reporting of final specimen disposition

The MTA must be fully executed before specimen shipment.

Step 5. Final Release Authorization

Before authorizing specimen release, the Data Center verifies that:

- NICHD approval has been obtained
- IRB approval remains current, if required
- MTA has been fully executed, if required
- Funding for specimen shipment is in place
- Shipping requirements have been confirmed

The Data Center assigns a Request Tracking Number and issues written authorization to the Central Repository.

No specimens or associated data will be released until all required approvals and agreements have been completed.

Step 6. Repository Fulfillment

Upon receipt of release authorization, the Central Repository:

- Confirms physical inventory
- Retrieves specimens
- Performs quality verification
- Documents chain of custody
- Packages specimens according to applicable shipping regulations
- Ships specimens
- Invoices for shipping costs
- Provides shipment confirmation and tracking information to the Data Center

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Step 7. LDMS Records

Following shipment, the Central Repository updates their LDMS to reflect:

- Requested specimens were shipped
- Send LDMS generated report to FS
- Any changes to remaining inventory

Other documentation is also created and stored:

- Shipment tracking number
- Recipient institution
- Request identifier
- Associated study
- Final specimen disposition

Step 8. Post-Distribution Responsibilities

Recipients agree to:

- Use de-identified specimens only for approved research
- Maintain participant confidentiality
- Not redistribute specimens or data without written approval
- Report destruction, exhaustion, or return of specimens as required

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6. Expected Timeline

Activity	Target Timeline
Administrative Review	2 business days
LDMS Feasibility Assessment	3 business days
MTA Execution	Variable (typically 1–4 months)
Final Authorization	2 business days
Repository Fulfillment	5–15 business days

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7. Documentation Maintained by the Data Center

The Data Center maintains:

- Request form with NICHD approval in lieu of DASH approval
- NICHD approval in lieu of DASH

- LDMS feasibility report
- Inventory listing
- MTA correspondence
- Repository release communication
- Chain-of-custody records

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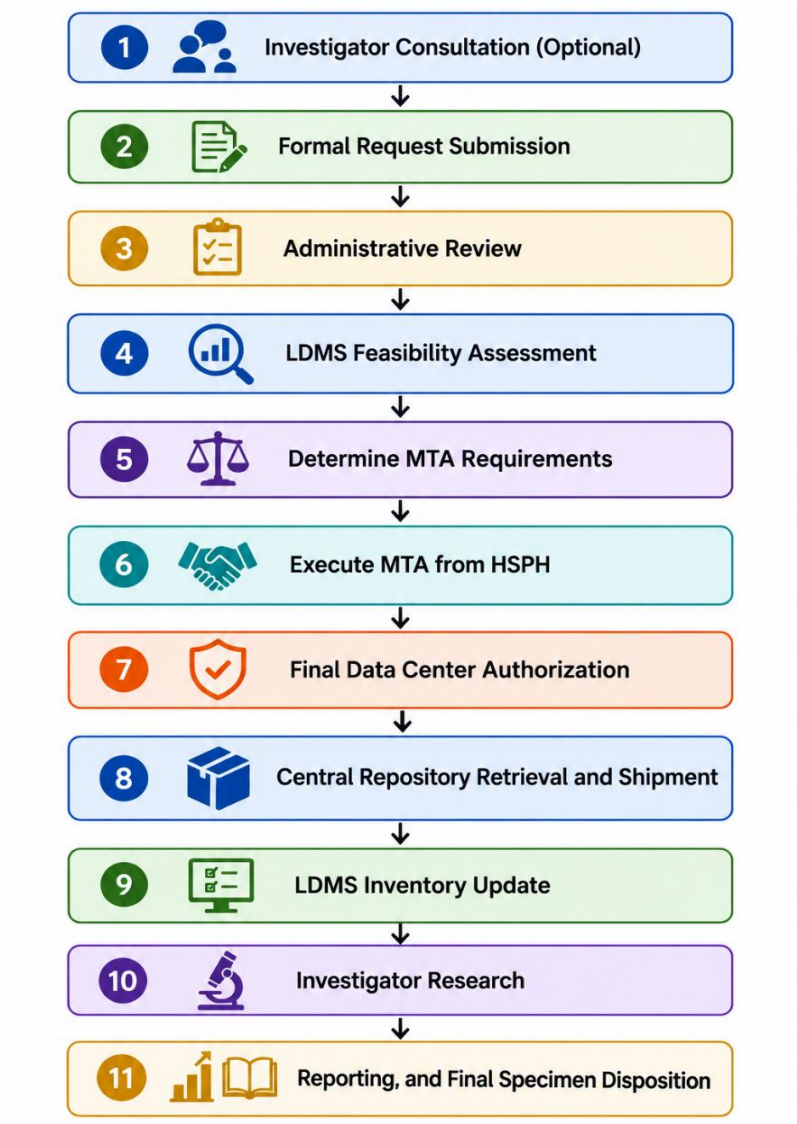
8. Process Flow



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9. Contacts

LDMS Related Questions

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Additional Questions

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