NICHD Data and Specimen Hub:

N-DASH

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Maternal and Pediatric Infectious Disease Branch
Agenda

- NICHD Data and Specimen Hub (N-DASH) – UPDATE AND REVIEW OF ACTIVITIES
  - Implementation Phases
  - Policy and Governance
  - Technical View
  - Next Steps and future directions
  - Committee Membership
N-DASH will be a publically accessible online system that will enable sharing of data and specimens from completed NICHD-supported studies

- The Archive will:
  - Enable researchers to organize, store, and mine data from completed NICHD supported studies for secondary use
  - Allow users to annotate study data and artifacts, search for files using either metadata or indexed content, and request study files (and eventually biospecimens) for secondary use
  - House 8-10 NICHD studies ranging in data complexity when launched in June 2015
  - Follow an established governance structure that will comply with applicable federal and NIH policies, and ensure ongoing, high-level institutional oversight
  - Manage and adjust operations in accordance with NICHD’s Post-Study Data Archive Policy and procedures through the Archive Committee
Active and ongoing coordination between the Archiving Committee and the Technical Development Team is critical to ensuring the successful implementation of NICHD DASH

<table>
<thead>
<tr>
<th>Non-Technical Considerations (Committee)</th>
<th>Technical Considerations</th>
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</thead>
<tbody>
<tr>
<td>• Study Selection</td>
<td>• Functional/Business Requirements</td>
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<tr>
<td>• Organizational and Governance structure</td>
<td>• System Requirements</td>
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<tr>
<td>• Policies and Processes</td>
<td>• System Design</td>
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<td>• Stakeholder Management</td>
<td>• Architectural Design</td>
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<td>• Performance Management</td>
<td>• Data Design</td>
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<td>• Operational Risk Management</td>
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**Outputs:**

<table>
<thead>
<tr>
<th>Non-Technical Considerations (Committee)</th>
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<tbody>
<tr>
<td>• Study Portfolio</td>
<td>• Data Archive System with functionalities for the Researcher,</td>
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<tr>
<td>• Archive Policy, Governance &amp; Operational Processes</td>
<td>NICHD Leadership and Archive Administrator</td>
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[NIH Logo: Eunice Kennedy Shriver National Institute of Child Health and Human Development]
N-DASH is being developed and implemented in a phased manner with active engagement by the Archiving Committee.
The NICHD Data and Specimen Archiving Committee developed policy, instituted governance and operational processes for N-DASH.
NICHD DASH – Home Page

Browse the GPN Study
Get clinical data from the Genomic and Proteomic Network for Preterm Birth Research study
Learn More

Search for studies or specific study items such as audio files, biospecimens, data sets, documents, genomics, images and more.

Available Topics
- HIV/AIDS
- Infant Care and Infant Health
- Preconception Care and Prenatal Care
- Pregnancy
- Pregnancy Loss
- Preterm Labor and Birth

Browse Studies
- Genomic and Proteomic Network for Preterm Birth Research
- NISDI Pediatric cohort
- NISDI Pediatric Latin American Countries Epidemiologic Study
- NISDI Perinatal cohort
- NISDI Longitudinal Study in Latin American Countries
- LOI 2-018: The National Children's Study - Placenta Project

New to the Archive?
Learn about the data archive, view tutorials and download supporting documentation.
Researchers can only request data with the right documentation and approvals

1. **Add Data to Cart**
   - Requires the researcher to create an account in the Archive
   - Must provide contact and institution information

2. **Describe Research Purpose**
   - Data requests must be for research purposes
   - Requestor should provide: goals of the new study; how the requested data will be used to support the new study; and for some studies the researcher may need to provide the analysis plan

3. **Provide Request Documentation**
   - Signed Data Use Agreement – requires PI and Institutional Official signature
   - Institutional Certification of Use
   - Indication of IRB approval (if required)

4. **Approval**
   - The Archive Committee or a Study’s Steering Committee/PI will approve the request
   - Requestor must provide annual IRB updated documentation (if needed) and a summary report
   - Requestor must destroy the data at end of use agreement
Similarly for data to be housed in NICHD DASH, the submitting PI and Institution must comply with Archive policies

Complete Policy Compliance Checklist
• Requires the submitting PI state that the data comply with items such as HIPAA; 21 CFR (if required);

Provide Study Description
• Type of Study
• Key features

Describe Data Distribution Requirements
• Requirements for data distribution beyond what is already contained in the Archive Use Agreement

Submit Study Items
• Upload all required items to the Archive
• Items will be first in a staging area not available until approved

Annotate Study Items
• Categorization of the metadata for study item indexing

List Study Documents
• Institutional Certification
• Procedure Manuals, Code Books, Protocol, Data Dictionary, etc.

De-Identification Verification
• Submission will be subject to a de-identification verification process

Approval
• Archive Committee and Branch Chief must provide approval for the Study to be included

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Next Steps and Future Directions

- Launch in June
- Add new studies (aiming for 8-10 per year)
- Connectivity to the NICHD Biorepository
- Analytics Workbench
- Connectivity with external resources
- Data visualization
# Thank you to the Archive Committee

<table>
<thead>
<tr>
<th>Division/ Branch/ Center/Office</th>
<th>Members</th>
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<tbody>
<tr>
<td>Child Development and Behavior Branch (CDBB)</td>
<td>• James Griffin</td>
</tr>
<tr>
<td>Contraceptive Discovery and Development Branch (CDDB)</td>
<td>• Chon-Hwa Tsai-Morris</td>
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<tr>
<td>Developmental Biology and Structural Variation Branch (DBSVB)</td>
<td>• Mahua Mukhopadhyay</td>
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<tr>
<td>Fertility and Infertility Branch (FIB)</td>
<td>• Esther Eisenberg</td>
</tr>
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<td>Gynecologic Health and Disease Branch (GHDB)</td>
<td>• Susan Meikle</td>
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<td>Intellectual and Developmental Disabilities Branch (IDDB)</td>
<td>• Danuta Krotoski</td>
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<td>Maternal and Pediatric Infectious Disease Branch (MPIDB)</td>
<td>• Rohan Hazra</td>
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<td>Obstetric and Pediatric Pharmacology and Therapeutics Branch (OPPTB)</td>
<td>• Katerina Tsilou</td>
</tr>
<tr>
<td>Pediatric Growth and Nutrition Branch (PGNB)</td>
<td>• Gilman Grave</td>
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<td>Pediatric Trauma and Critical Illness Branch (PTCIB)</td>
<td>• Robert Tamburro</td>
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<td>Population Dynamics Branch (PDB)</td>
<td>• Regina Bures</td>
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<td>Pregnancy and Perinatology Branch (PPB)</td>
<td>• John Ilekis</td>
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<tr>
<td>Division of Intramural Research (DIR)</td>
<td>• Marian Willinger</td>
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<td>Division of Intramural Population Health Research (DIPHR)</td>
<td>• Jennifer Weck</td>
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<td>National Center for Medical Rehabilitation Research (NCMRR)</td>
<td>• Mary Ellen Michel</td>
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<td>Office of Extramural Policy (OEP)</td>
<td>• Eugene Hayunga</td>
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<tr>
<td>Office of Science Policy, Analysis and Communication (OSPAC)</td>
<td>• Jennifer Guimond</td>
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<tr>
<td>Information Resource &amp; Management Branch (IRMB) – Technical Lead</td>
<td>• Dave Songco, Archana Mohale, Booz Allen contract team</td>
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