Glossary of NICHD DASH Terms

This Glossary provides a list of terms and associated definitions commonly used across the *Eunice Kennedy Shriver* National Institute of Child Health and Human Development (NICHD) Data and Specimen Hub (DASH).

The DASH Glossary supplements the <u>DASH Policy</u> and the <u>DASH Frequently Asked</u> <u>Questions</u>. Please refer to the <u>DASH Site Map</u> to learn how to navigate to a specific function, and to the <u>DASH Tutorial</u> for step-by-step instructions on how to use all available DASH functionalities.

Α

- Affiliates: Members of a research team from the same institution as the Recipient (study PI), who is requesting access to DASH data or biospecimens to carry out a secondary study. Affiliates must be registered in DASH. [Please see the DASH Data Use Agreement on the Request Resources page for additional details.]
- Associates: Members of a research team from a different institution as the Recipient (study PI), who is requesting access to DASH data or biospecimens to carry out a secondary study. Associates are not required to register in DASH. [Please see the DASH Data Use Agreement on the <u>Request Resources page</u> for additional details.]
- Authorized Organization Representative (AOR): The individual, named by the applicant organization, who is authorized to act for the applicant and to assume the obligations imposed by the Federal laws, regulations, requirements, and conditions that apply to grant applications or grant awards. The AOR is also referred to as the Institutional Business Official in some cases. This person must have authority to enter into agreements on behalf of your institution. [Please see the NIH Grants Glossary page for additional details.]

В

- Biospecimen: Biological specimens and/or derivatives collected from human participants in research studies that are available through DASH. Biospecimens are subject to release to the Recipient, according to the criteria laid out in the NICHD DASH Policy, which includes the execution of a NICHD DASH Material Transfer Agreement, approval by the NICHD DASH Biospecimen Access Committee, and, if applicable, by study-specific entities. Examples of biospecimens include urine, blood, tissue, cells, DNA, RNA, environmental samples, and other biological specimen types. Navigate to the Explore Biospecimens page to view a listing of biospecimens available from studies stored in DASH.
- **Biospecimen Access Committee:** A subset of the NICHD DASH Committee who is responsible for the review and approval of biospecimen requests in DASH.

- Biospecimen Catalog: Information about biospecimens (such as type, amount available, participant age, etc.) from a particular study that are available for request through DASH.
- Biospecimen Letter of Availability: Letter provided by DASH to investigators who do not
 yet have funding to conduct research using biospecimens from DASH but are interested
 in applying for funding (proof of funding is required to obtain biospecimens from DASH
 for secondary research). DASH can provide the letter of biospecimen availability after
 you complete your biospecimen request in DASH.
- Biospecimen Request: The process in DASH to request biospecimens, which includes
 completing the online Biospecimen Request Form, uploading the Biospecimen Request
 Form signed by the Requester, Material Transfer Agreement signed by the Recipient and
 the Authorized Organization Representative (AOR), proof of funding for obtaining the
 biospecimens, and Institutional Review Board (IRB) approval (if required for the
 requested biospecimens). You must be registered in DASH to request biospecimens.
 Refer to the Request Biospecimens Tutorial for step-by-step instructions on how to
 submit a biospecimen request.
- **Biospecimen Request Form:** Online form completed by the Requester during the biospecimen request process in DASH.

C

- Cart-Level Approval: During the data request process, when you add study items
 (datasets and documents) to your Cart, a pop-up window will appear to indicate what
 type of access the study allows. Cart-level approval indicates that, once approved, you
 will only have access to the individual dataset and document files you added to your cart
 and requested from DASH (see also Study-Level Approval).
- Cataloging: The process of submitting essential information about an existing study or
 data collection stored in a publicly accessible repository external to DASH. DASH users
 can search for cataloged studies or data collections in DASH and will be directed to the
 external site to access data or additional information. Please refer to the <u>Catalog Study</u>
 Tutorial for more information on cataloging studies in DASH.
- **Collaborators:** Members of a research team from a different institution as the Recipient (study PI), who are working collaboratively on the same research plan under the supervision of other Principal Investigators. Collaborators are required to submit a separate Data Request Form and sign a separate Data Use Agreement with NICHD.
- Curator: Individual/s from the DASH Support Team who assists data/biospecimen
 catalog submissions to DASH, including answering user questions, providing guidance on
 data/biospecimen catalog de-identification, reviewing and approving study and
 biospecimen catalog submissions, etc. Please contact the NICHD DASH Administrator at
 SupportDASH@mail.nih.gov to contact DASH curators.

- **Data Access Committee:** A subset of the NICHD DASH Committee who is responsible for the review and approval of data requests in DASH.
- Data Collections: Data stored external to DASH in NICHD-funded resources that are
 available for secondary use. Data collections are cataloged in DASH, meaning DASH will
 provide essential information about these collections and DASH users will be directed to
 the external resource to access data and other information. Examples of data collections
 include, but are not limited to, other NICHD-funded projects, data repositories, patient
 registries, and other resources that are not considered research studies (see also Study).

These resources are featured in the <u>Data Collections Explorer</u>, which includes direct links to navigate to the collections outside of DASH.

- Data Preparation Tool (DPT): A desktop tool that is downloaded from DASH and
 installed on the data submitter's computer in order to submit studies to DASH. It is used
 to organize study items (e.g., datasets, documents, and information about
 biospecimens) associated with the study and allows the submitter to annotate these
 items prior to uploading them into DASH, either for a new study submission or to add
 more items (files) to an existing study.
- Data Request: The process in DASH to request data, which includes completing the
 online Data Request Form, uploading the Data Request Form signed by the Requester,
 Data Use Agreement signed by the Data Recipient and the Authorized Organization
 Representative (AOR), and obtaining Institutional Review Board (IRB) approval, if
 required for the requested study data. You must be registered in DASH to request data.
 Refer to the Request Data Tutorial for step-by-step instructions on how to submit a data
 request.
- Data Request Form: Online form completed by the Requester during the data request process in DASH.
- Data Use Agreement: Formal agreement executed between NICHD and the Recipient's Institution, defining the terms and conditions under which study data obtained from DASH can be used for secondary research.
- Datasets: Individual-level data files generated from research studies. DASH studies
 typically have more than one dataset, which may pertain to demographics, adverse
 events, medications, and other information gathered from study participants. Navigate
 to the Explore Datasets page to view a listing of individual datasets available from
 studies stored in DASH.
- Documents: Documentation associated with research studies stored in DASH and made available for secondary use. DASH studies typically have multiple documents, which may include study protocols, manual of operations, case report forms/data collection instruments, codebooks, de-identification methodology, and other documentation pertinent to the interpretation of shared data in DASH. Navigate to the Explore

<u>Documents</u> page to view a listing of individual documents available from studies stored in DASH.

Ε

- Environmental Samples: Specimens collected from the study participant's environment
 as part of the research study protocol, such as water, dust, and other samples from the
 participant's home dwelling. Environmental samples are available from the <u>National</u>
 Children's Study in DASH, which can be accessed from the <u>Explore Biospecimens</u> page.
- Explore Biospecimens: Located on the top navigation bar of the DASH homepage, the Explore Biospecimens page contains a list of biospecimens available from select studies stored in DASH. You can use biospecimen/study filters to identify desired samples and add them to your Cart to request.
- Explore Data Collections: Located on the top navigation bar of the DASH homepage (Explore Data → Data Collections), the Explore Data Collections page contains a list of other NICHD-funded data collections and resources that have data available for secondary use (see also Data Collections).
- Explore Datasets: Located on the top navigation bar of the DASH homepage (Explore Data → Datasets), the Explore Datasets page contains a list of all datasets available from studies stored in DASH. You can use dataset/study filters to identify desired datasets and add them to your Cart to request.
- Explore Documents: Located on the top navigation bar of the DASH homepage (Explore Data → Documents), the Explore Documents page contains a list of all documents available from studies stored in DASH. You can use document/study filters to identify desired documents and add them to your Cart to request.
- Explore Studies: Located on the top navigation bar of the DASH homepage (Explore Data → Studies), the Explore Studies page contains a list of all research studies stored in DASH that are available for secondary use.

l

- Inbox: A folder in the Workspace (see also Workspace) available to all registered DASH users. After your data request is approved, the study items (datasets, documents, etc.) that you requested access for will be moved to your Inbox. From your Inbox, you can download these items. Please refer to the Workspace Tutorial for instructions on accessing data after your request has been approved.
- Institutional Certification: A certification provided by the data/biospecimen catalog
 submitting institution attesting that an IRB or equivalent Privacy Board has determined
 that sharing of data/biospecimens via DASH is consistent with the informed consent for
 the study and that the identities of research participants will not be disclosed to NICHD.
 Data or biospecimen catalog submitters must use the Institutional Certification for Data
 or Biospecimen Catalog submissions provided on the <u>Submission Resources</u> page in
 DASH.

M

- Material Transfer Agreement: Formal agreement executed between NICHD and the Recipient Institution defining the terms and conditions under which specimens obtained through DASH can be used for secondary research.
- My Cart: A user space in DASH similar to a shopping cart on other websites where items of interest (e.g., datasets, biospecimens) can be added for proceeding with request and obtaining access for secondary research.

Ν

NICHD DASH Administrator: The DASH representative who interfaces with users to
provide support and manages study submissions and data/biospecimen requests. For all
DASH-related inquiries, please contact the DASH Administrator at
SupportDASH@mail.nih.gov.

R

- Recipient: The lead individual who receives access to the data/biospecimens on behalf
 of the Recipient Institution. The Recipient may share access to data/biospecimens only
 with individuals who are listed in the Data Use Agreement/Material Transfer Agreement
 respectively.
- Recipient Institution: An institution (e.g., a non-profit or for-profit organization or corporation) which is the employer of the Recipient. The Recipient Institution must execute the Data Use Agreement (DUA) or Material Transfer Agreement (MTA) with NICHD for data or biospecimens respectively, abide by the terms and conditions of the executed DUA/MTA, and assume responsibility for the compliance of the Recipient, Requester, and other individuals with access to the data or biospecimens, as detailed in the respective agreement.
- Requester: The individual submitting the data or biospecimen request online in the DASH system. The Requester may or may not be the same individual as the Recipient of the data or biospecimens (for example, the Requester may be a study co-investigator or research assistant, and the Recipient may be the Principal Investigator). If not the same individual as the Recipient, the Requester must be from the same institution as the Recipient and must be delegated by the Recipient to submit the data or biospecimen request online in the DASH system. The Requester is permitted to obtain data or biospecimens on behalf of the Recipient from DASH.
- **Research Plan:** Description of the proposed research that serves as the basis for the data or biospecimen access request in DASH. The Research Plan must include the title of the Research Project and description of the research need (i.e., study aims/goals, hypothesis that will be tested, methodology to be used, and the expected outcomes).

S

• **Secondary Research:** A new study using existing data or biospecimens for exploring new hypothesis, analysis, or investigation of a research topic.

- **Site Map:** A graphical representation of the DASH website organization and workflow. The <u>Site Map</u> is accessible from the DASH homepage and is also available under the "Resources" tab.
- Study: A research protocol (including interventional and observational research) or set
 of experiments designed to investigate a research question and/or evaluate biomedical
 or health-related outcomes. Studies available through DASH include NIH defined clinical
 trials and other types of clinical research funded by NICHD. Navigate to the ExploreStudies page to view all studies available through DASH.
- Study-Level Approval: During the data request process, when you add study items
 (datasets and documents) to your Cart, a pop-up window will appear to indicate what
 type of access the study allows. Study-level approval indicates that, once approved, you
 will have access to all dataset and document files available from the study, and not just
 the items you added to your cart and requested from DASH (see also Cart-Level
 Approval).
- Study Overview Page: A page in DASH that is unique to each study describing detailed information about the study, including study timeline, study schema, study population, and study items available (e.g., datasets, documents, biospecimens). From the ExploreStudies page, you can click on the study title to access the corresponding study overview page.
- **Submission:** Process by which NICHD-funded investigators (extramural and intramural) can submit their studies to DASH to be made available to DASH users for secondary research. Please refer to the <u>Submit Study Tutorial</u> for step-by-step instructions on how to submit your study to DASH.
- **Submitter:** Individual who has submitted study data and/or a biospecimen catalog with information about biospecimens that are available for request through DASH.

W

Workspace: A functional space where DASH users who have been approved for data or biospecimens can view their requests, download approved data files and their Data Use Agreement (DUA) or Material Transfer Agreement (MTA), and modify Affiliates or Associates (only for data) listed on the DUA or MTA. The Workspace has three sections: Inbox (see definition above), Data Requests, and Biospecimen Requests. The "Data Requests" and "Biospecimen Requests" sections are similar to virtual filing cabinets where all approved study items and executed DUAs/MTAs are stored. Please refer to the Workspace Tutorial for instructions on accessing data or biospecimen information after your request has been approved.