

above), researchers are encouraged to select a data repository that is appropriate for the data generated from the research project and is in accordance with the desired characteristics, taking into consideration the following guidance:

A. Primary consideration should be given to data repositories that are discipline or data-type specific to support effective data discovery and reuse. NIH makes a list of such data repositories available (see https://www.nlm.nih.gov/NIHbmic/domain_specific_repositories.html).

B. If no appropriate discipline or data-type specific repository is available, researchers should consider a variety of other potentially suitable data sharing options:

i. Small datasets (up to 2 GB in size) may be included as supplementary material to accompany articles submitted to PubMed Central (see <https://www.ncbi.nlm.nih.gov/pmc/about/guidelines/#suppm>).

ii. Data repositories, including generalist repositories (see https://www.nlm.nih.gov/NIHbmic/generalist_repositories.html) or institutional repositories, that make data available to the larger research community, institutions, or the broader public.

iii. Large datasets may benefit from cloud-based data repositories for data access, preservation, and sharing.

I. Desirable Characteristics for All Data Repositories

The characteristics in this section are relevant to all repositories that manage and share data resulting from Federally funded research:

A. *Unique Persistent Identifiers*: Assigns datasets a citable, unique persistent identifier (PID), such as a digital object identifier (DOI) or accession number, to support data discovery, reporting (e.g., of research progress), and research assessment (e.g., identifying the outputs of federally funded research). The unique PID points to a persistent landing page that remains accessible even if the dataset is de-accessioned or no longer available.

B. *Long-Term Sustainability*: Has a plan for long-term management of data, including maintaining integrity, authenticity, and availability of datasets; building on a stable technical infrastructure and funding plans; and having contingency plans to ensure data are available and maintained during and after unforeseen events.

C. *Metadata*: Ensures datasets are accompanied by metadata to enable discovery, reuse, and citation of datasets, using schema that are appropriate to, and ideally widely used

across, the community(ies) the repository serves. Domain-specific repositories would generally have more detailed metadata than generalist repositories.

D. *Curation and Quality Assurance*: Provides, or has a mechanism for others to provide, expert curation and quality assurance to improve the accuracy and integrity of datasets and metadata.

E. *Free and Easy Access*: Provides broad, equitable, and maximally open access to datasets and their metadata free of charge in a timely manner after submission, consistent with legal and ethical limits required to maintain privacy and confidentiality, Tribal sovereignty, and protection of other sensitive data.

F. *Broad and Measured Reuse*: Makes datasets and their metadata available with broadest possible terms of reuse; and provides the ability to measure attribution, citation, and reuse of data (e.g., through assignment of adequate metadata, unique PIDs).

G. *Clear Use Guidance*: Provides accompanying documentation describing terms of dataset access and use (e.g., particular licenses, need for approval by a data use committee).

H. *Security and Integrity*: Has documented measures in place to meet generally accepted criteria for preventing unauthorized access to, modification of, or release of data, with levels of security that are appropriate to the sensitivity of data.

I. *Confidentiality*: Has documented capabilities for ensuring that administrative, technical, and physical safeguards are employed to comply with applicable confidentiality, risk management, and continuous monitoring requirements for sensitive data.

J. *Common Format*: Allows datasets and metadata downloaded, accessed, or exported from the repository to be in widely used, preferably non-proprietary, formats consistent with those used in the community(ies) the repository serves.

K. *Provenance*: Has mechanisms in place to record the origin, chain of custody, and any modifications to submitted datasets and metadata.

L. *Retention Policy*: Provides documentation on policies for data retention within the repository.

II. Additional Considerations for Repositories Storing Human Data (even if de-identified)

The additional characteristics outlined in this section are intended for repositories storing human data, which are also expected to exhibit the characteristics outlined in Section I,

particularly with respect to confidentiality, security, and integrity. These characteristics also apply to repositories that store only de-identified human data, as preventing re-identification is often not possible, thus requiring additional considerations to protect privacy and security.

A. *Fidelity to Consent*: Employs documented procedures to restrict dataset access and use to those that are consistent with participant consent (such as for use only within the context of research on a specific disease or condition) and changes in consent.

B. *Restricted Use Compliant*: Employs documented procedures to communicate and enforce data use restrictions, such as preventing reidentification or redistribution to unauthorized users.

C. *Privacy*: Implements and provides documentation of appropriate approaches (e.g., tiered access, credentialing of data users, security safeguards against potential breaches) to protect human subjects' data from inappropriate access.

D. *Plan for Breach*: Has security measures that include a response plan for detected data breaches.

E. *Download Control*: Controls and audits access to and download of datasets (if download is permitted).

F. *Violations*: Has procedures for addressing violations of terms-of-use by users and data mismanagement by the repository.

G. *Request Review*: Makes use of an established and transparent process for reviewing data access requests.

Dated: October 19, 2020.

Lawrence A. Tabak,
Principal Deputy Director, National Institutes of Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Neurological Disorders and Stroke; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial

property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NST-1 Additional Review.

Date: December 3, 2020.

Time: 1:00 p.m. to 5:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Neuroscience Center, 6001 Executive Boulevard, Rockville, MD 20852 (Virtual Meeting).

Contact Person: William C. Benzing, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS, NIH, NSC, 6001 Executive Blvd., Suite 3204, MSC 9529, Bethesda, MD 20892-9529, (301) 496-0660, benzingw@mail.nih.gov.

Name of Committee: National Institute of Neurological Disorders and Stroke Special Emphasis Panel; NINDS Research Education R25.

Date: December 11, 2020.

Time: 10:00 a.m. to 1:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NSC Building, 6001 Executive Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Delany Torres, Ph.D., Scientific Review Officer, Scientific Review Branch, Division of Extramural Activities, NINDS, Neuroscience Center Building (NSC), 6001 Executive Blvd., Suite 3208, Bethesda, MD 20892, delany.torressalazar@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.853, Clinical Research Related to Neurological Disorders; 93.854, Biological Basis Research in the Neurosciences, National Institutes of Health, HHS)

Dated: October 26, 2020.

Tyeshia M. Roberson,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and

the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Heart, Lung, and Blood Initial Review Group; Heart, Lung, and Blood Program Project Review Committee.

Date: December 2, 2020.

Time: 10:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6705 Rockledge Drive, Bethesda, MD 20814 (Virtual Meeting).

Contact Person: Melissa H Nagelin, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, 6705 Rockledge Drive, Room 208-R, Bethesda, MD 20892, 301-827-7951, nagelinmh2@nhlbi.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 27, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; NHLBI SBIR Phase IIB Small Market and Bridge Awards.

Date: December 2, 2020.

Time: 10:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20814, (Virtual Meeting).

Contact Person: Susan Wohler Sunnarborg, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 208-Z, Bethesda, MD 20892, (301) 827-7987, susan.sunnarborg@nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; CATALYZE: ENABLING TECHNOLOGIES.

Date: December 2, 2020.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20814, (Virtual Meeting).

Contact Person: Kristin Goltry, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209-B, Bethesda, MD 20892, (301) 435-0297, goltrykl@mail.nih.gov.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; CATALYZE: PRODUCT DEFINITION.

Date: December 3, 2020.

Time: 11:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Rockledge I, 6705 Rockledge Drive, Bethesda, MD 20814, (Virtual Meeting).

Contact Person: Kristin Goltry, Ph.D., Scientific Review Officer, Office of Scientific Review/DERA, National Heart, Lung, and Blood Institute, National Institutes of Health, 6705 Rockledge Drive, Room 209-B, Bethesda, MD 20892, (301) 435-0297, goltrykl@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases and Resources Research, National Institutes of Health, HHS)

Dated: October 27, 2020.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting.