Office of Data Science Strategy Concept Clearance FY2025

INITIATIVE TITLE: Enhancement and Management of Established Biomedical Data Repositories (DR) and Knowledgebases (KB)

INITIATIVE TYPE: Renew

ACTIVITY CODE: U24

OBJECTIVE(S):

Notice of Funding Opportunity (NOFO) to invite cooperative agreement (U24) applications for established biomedical data repositories or knowledgebases.

DESCRIPTION:

The purpose is to renew the Funding Opportunity supporting established biomedical data repositories and knowledgebases.

Repositories are defined as containing core data related to a particular system or systems that are available as a community resource and accept submission of relevant data from the community, validate, store, archive/preserve and distribute the data in compliance with the FAIR data principles. Knowledgebases are defined as data resources that collate, extract, organize, annotate, and link the growing body of information related to and relying on core datasets from one or more repositories, curate literature, and generate other forms of knowledge and distribute them in compliance with FAIR data principles.

The program supports data resources that demonstrate a sufficiently significant research usage and userbase to warrant NIH support. The program focuses on impact and methods used to engage research community(ies), demonstrate impact through citations, data, or information, and demonstrate coordination across a field or fields of study. For the purposes of this NOFO, established repositories and knowledgebases are defined as high-value data resources that are near or at optimal research community penetration and are a critical research resource as demonstrated by their usage, utility, and impact.

Based on programmatic input across NIH, including the NIH repository and knowledgebase working group, the reissue of this solicitation to focus on established data resources that continue to better address NIH Institute-specific mission priorities, life-cycle stages, and NIH goals for data resources and their sustainment. The broadly applicable results of this program align with the goals set forth in the NIH Strategic Plan for Data Science.

Key aspects of the solicitation include:

- **Scientific Significance:** The resource should be a key enabler of modern biomedical research with high significance and relevance to, and an explicit mission statement that describes the importance to the NIH domains of science.
- Community Needs and Engagement: The resource should demonstrate that there is sufficiently significant research usage and a userbase to warrant NIH support. Funded resources must demonstrate usage, utility, and scientific impact and openly share metrics.

- Quality of Data and Services and Efficiency of Operations: The resource should demonstrate
 adherence to the desirable characteristics of repositories and FAIR data principles. It should
 also use community standards for data and metadata, unique and persistent data identifiers,
 provenance of data, adequate infrastructure, and data storage. All applications must address
 resource development, project development, and transition planning.
- Governance and Stewardship: The resource should document processes for developing terms
 of use, including appropriate processes for data licenses and policies for responsible
 stewardship. Resources funded through this mechanism require an external advisory
 committee.

Application budgets are not limited but need to reflect the actual needs of the proposed project and require Institute approval. All applications with budgets above \$500K in direct costs/year require institute approval. Renewal applications are permitted.

IMPORTANCE:

Accessible, well-maintained, and efficiently operated data resources are critical enablers of modern biomedical research. Data resources, through good data management practices, are key to data and knowledge discovery, integration, and reuse, as outlined by the FAIR Data Principles (Findable, Accessible, Interoperable, and Reusable digital objects). In order to sustain a healthy and productive data resource ecosystem it is critical to ensure that each component: (a) delivers scientific impact to the communities that they serve; (b) employs and promotes good data management practices and efficient operation for quality and services; (c) engages with the user community and continuously address their needs; and (d) supports a process for data life-cycle analysis, long-term preservation, and responsible stewardship.

This NOFO is dedicated to supporting data resources (repositories or knowledgebases) that are expected to (a) adopt good data management practices as outlined by the FAIR Data Principles allowing resources to form a trans-NIH data ecosystem; (b) lower barriers for data sharing; (c) allow greater usage and utility of the data for research and discovery; (d) discourage development of resources under research grant mechanisms and to discourage use of research mechanism dollars for resources; and (e) incentivize efficiency of operations to allow longer term preservation of data and enable greater sustainability of resources. Hence the need for this important program to realize NIH's vision for a modernized biomedical data ecosystem per the goals outlined in NIH's strategic plan for data science.

HISTORY:

The funding opportunity announcements (<u>PAR-20-097</u> and <u>PAR-20-089</u>) were first launched in 2019 in partnership with ten NIH Institutes, Centers, and Offices (NIGMS, NHGRI, NINDS, NIMHD, NIEHS, NIDA, NIAID, NIAAA, NCI, and NHLBI) and were subsequently reissued in 2024 (<u>PAR-23-236</u> and <u>PAR-23-237</u>) together with seventeen Institutes, Centers, and Offices participating in the NOFO. NIH has funded 45 applications to date with a greater than 20% success rate. The applications have specific criteria to review data resources as opposed to research projects and hence are reviewed in a CSR special emphasis panel.

Based on the success of the program and support of the Scientific Data Council, ODSS requests concept clearance from the Councils of Councils to reissue this initiative with the proposed modifications.

CONCEPT CLEARANCE DATE: September 12, 2025