

Guide Notice Highlighting Harmonization and Data Sharing Expectations for Supplement and Revision Projects Addressing Social, Behavioral, Economic and Health Impacts of the COVID-19 Public Health Emergency

Key Dates

Release Date: May XX, 2020

Related Announcements

This notice relates to the following COVID-19 Public Health Emergency Notices of Special Interest for Administrative Supplements to Existing NIH Grants, Cooperative Agreements, and Urgent Competitive Revisions:

<https://grants.nih.gov/grants/guide/notice-files/NOT-AT-20-011.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-MD-20-019.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-AG-20-022.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-ES-20-020.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-AA-20-011.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-HG-20-030.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-GM-20-025.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-MH-20-047.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-097.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-DA-20-047.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-LM-20-010.html>

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-107.html>

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Purpose

NIH is issuing this Notice to highlight the need for and value of data harmonization and data sharing specifically in the context of urgent competitive revisions and administrative supplements producing data to investigate the social, behavioral, economic, and health impacts of the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.

Background

NIH has responded to the urgent need to address the COVID-19 Public Health Emergency by issuing numerous [Funding Opportunity Announcements specific to COVID-19](#) through urgent competitive revisions and administrative supplements. NIH recognizes that data harmonization and data sharing can increase the scientific impact of any individual study by facilitating collaborations, comparisons, and replications across studies. This Notice is issued to alert the research community of resources and guidance that will facilitate data harmonization and the development of robust data sharing plans.

Data Harmonization

The NIH is dedicated to advancing science by improving the yield and impact of its research portfolio. One way to accomplish this is to encourage investigators to use a common set of tools and resources to facilitate collection of common data elements (CDEs). NIH has worked with relevant communities to develop and provide access to tools and resources that can improve the consistency of data collection. NIH strongly encourages investigators collecting data in response to the COVID-19 Public Health Emergency to use these resources as they select instruments for their proposed studies. This is particularly important for efforts to rapidly assess the needs and impact of COVID-19 across different population groups, particularly vulnerable populations.

Investigators are encouraged to use existing well-validated and well-established instruments, but COVID-19 specific instruments have developed rapidly in response to the pandemic. To minimize the proliferation of “one-off” survey items, encourage comparisons across samples, and facilitate data integration and collaboration, a trans-NIH working group is making existing COVID-19 survey items and investigator contact information publicly available through two NIH-supported platforms: the NIH Public Health Emergency and Disaster Research Response (DR2) and the PhenX Toolkit. Researchers addressing COVID-19 questions, whether population-based or for clinical research, are strongly encouraged to consider these COVID-19 specific survey item repositories and select existing survey items or protocol modules currently being fielded if consensus based measures (e.g., <https://www.phenxtoolkit.org/collections/view/1>) are not available.

- The [NIH Public Health Emergency and Disaster Research Response \(DR2\)](#), has been established and hosted by the National Institute of Environmental Health Sciences (NIEHS) and the National Library of Medicine (NLM). This site includes COVID-19 related survey instruments and additional information such as the domains assessed, protocols, and a wide array of data collection tools and resources used in other public health emergencies and disasters.
- The [PhenX Toolkit](#) funded by the National Human Genome Research Institute (NHGRI) and [other NIH Institutes and Centers](#), hosts a collection of COVID-19 related item-module protocols drawn from the surveys listed in DR2. In addition, the PhenX Toolkit has a large collection of well-established and vetted phenotypic measurement protocols, including its newly released social determinants of health collections. These protocols are suitable for inclusion in COVID-19-related studies, enabling data harmonization across studies. The use of specific PhenX measures is expected by some NIH Institutes, Centers and Offices (ICOs). Applicants should follow ICO-specific guidance on the use of expected CDEs and should refer to the **Resources for Applicants** section below.

Recipients of awards under the cited notices are strongly encouraged to submit their COVID-19 specific instruments for inclusion into these resource sharing sites (see [Data Collection Tools & Resources Form for DR2 and PhenX Repositories](#)).

Data Sharing

Data collected as a result of NIH notices calling for urgent competitive revisions and administrative supplements to study the social, behavioral, economic, and health impacts of the COVID-19 Public Health Emergency are intended to be shared to support replication and maximize the research potential of investments. Therefore, NIH expects the following:

- Supplemental and Revision projects collecting data should use best practices in data sharing to accelerate the scientific community's ability to advance knowledge about the social, behavioral, economic and health impacts of COVID-19. As articulated in the [NIH Strategic Plan for Data Science](#), NIH seeks to leverage its role as a funding agency to encourage rapid, open sharing of data, and greater harmonization of scientific effort. Researchers are encouraged to ensure that the data resources that they produce meet the standard for being [FAIR—Findable, Accessible, Interoperable, and Reusable](#), and further elaborated upon by [FORCE 11](#). Some tools to help researchers in the digital cloud environment have also been generated by the [NIH Data Commons](#). In some instances, NIH ICOs have already established specific data sharing expectations for funded investigators and applicants should follow relevant IC-specific guidance (see **Resources for Applicants** below).
- NIH strongly encourages use of NIH-supported, domain-specific data repositories as a first choice for storing data and making it accessible (see [NLM Data Sharing Resources](#)). NIH requires researchers and publishers to make their COVID-19 publications immediately accessible in PubMed Central.
- Applicants who have established data sharing plans for the parent grant are encouraged to make any data collected through COVID-19-related supplements and revisions available through the same data archive, mechanism, or procedures.

Resources for Applicants

Resources on CDEs – ICO specific guidance on CDEs:

- **NIMH** - [NOT-MH-15-009 Data Harmonization for NIMH Human Subjects Research via the PhenX Toolkit](#) and [PhenX Mental Health Research Collections](#)
- **NINR** – CDEs at NINR (<https://www.ninr.nih.gov/researchandfunding/CDE-main>)

Resources on Data Sharing from Specific ICOs

- **NIMH** - [NOT-MH-15-012 Data Sharing Expectations for Clinical Research Funded by NIMH](#)
- **NIAAA** – [NOT-AA-19-020 Data-Sharing Policy for Human Subjects Grants Research](#)
- **NIA** - [Guidance on Sharing Data and other Resources](#)
- **NIDDK** - Some awardees may be required to provide protocols, data, or samples to the [NIDDK Central Repository](#). If you are required to provide materials you are encouraged to review the documents on the [NIDDK Central Repository website](#).

NIH Guidance on Data Sharing for studies not covered by the guidance listed under Resources on Data Sharing from Specific ICOs above, should follow the guidance below:

- For more information on data sharing, please view the following documents:
 - [NIH Office of Data Science Strategy](#)
 - [NIH Data Sharing Policy](#)

Inquiries

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