



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Institute of Mental Health
6001 Executive Boulevard
Bethesda, Maryland 20892

DATE: October 15, 2021

TO: Office of Management and Budget (OMB)
Through: Reports Clearance Officer, Debbie Kramer, DHHS¹
Project Clearance Chief, Mikia Currie, NIH
Project Clearance Liaison, Andrew Hooper, NIMH

FROM: Theresa Smith
National Institute of Mental Health (NIMH)

SUBJECT: National Institute of Mental Health Data Archive Data Submission Agreement (OMB Control #0925-0667, Expiration Date 01/31/2024)

This is a request for OMB to approve non-substantive changes to the National Institute of Mental Health (NIMH) Data Archive (NDA) Data Submission Agreement (DSA) data collection instrument approved under OMB Control #0925-0667, Expiration Date: 01/31/2024.

The NDA is an infrastructure for sharing human subjects research data and tools, comprised of multiple data repositories covering several research domains, to further collaboration and scientific discovery. The DSA is a data collection instrument completed by researchers requesting access to data stored in the multiple repositories that make up the NDA. We are requesting approval of minor changes to language on the DSA to clarify guidance on complying with institutional requirements. The changes to the DSA will not meaningfully alter the content, scope, or method of the information collection. The changes to the DSA are described below.

Updates to the DSA:

- *Appropriate Consent and Compliance with Institutional Requirements* section
 - In the first paragraph, add “and/or with the approval of the Institutional Review Board” to the end of the first sentence, “Submitter acknowledges that data are submitted to the NIMH Data Archive in accordance with informed consent of research participants.”

This update does not change the respondent time and cost burden estimates in section A.12 of the Supporting Statement A currently on file with OMB.

Attachments:

- A. Revised tracked changes copy of NDA Data Submission Agreement
- B. Revised clean copy of NDA Data Submission Agreement

¹You full consideration is appreciated.