DEPARTMENT OF HEALTH & HUMAN SERVICES





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

DATE: August 14, 2019

TO: Office of Management and Budget (OMB)

Through: Reports Clearance Officer, DHHS¹

Mikia Currie, Project Clearance Chief, NIH ____ Melba Rojas, Project Clearance Liaison, NIMH

FROM: Gregory K. Farber, Ph.D.

National Institute of Mental Health (NIMH)

SUBJECT: National Institute of Mental Health Data Archive (NDA) Data Use Certification and

Data Submission Agreement (OMB Control #0925-0667, Expiration Date 11/30/2020)

This is a request for OMB to approve non-substantive changes to the National Institute of Mental Health Data Archive (NDA) Data Use Certification (DUC) and Data Submission Agreement (DSA) data collection instruments approved under OMB Control #0925-0667, Expiration Date: 11/30/2020.

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 DUC and DSA are data collection instruments completed by researchers submitting or requesting access to data stored in the multiple repositories that make up the NDA. Since the 2017 revision of the DUC and DSA there have been changes to the data repositories available within the NDA infrastructure. While the evolving nature of the NDA is clearly stated in the current Supporting Statement A on file with OMB, we are requesting approval of changes to language on the DUC and DSA that clearly describes the current NDA data infrastructure to NDA users. The changes to the DUC and DSA and described below.

<u>Updates to the DUC:</u>

- *NIMH Data Archive (NDA)* section
 - O In the first paragraph, replace the descriptions of each specific repository with a link directing users to the *About Us* area of the NDA website that contains a current list of repositories stored in the NDA data infrastructure.
- Data Use Terms and Conditions section
 - 8. Sharing of a NIMH Data Archive Study/Acknowledgements replace the "Acknowledgement Statements" for each repository stored in the NDA data infrastructure with a link directing users to the NDA Study Acknowledgements area of the NDA website that contains the required acknowledgement statement.

<u>Updates to the DSA:</u>

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- Data Submission Terms and Conditions section
 - **6. Data Accuracy** replace the specified submission cycle dates with a link to the *Sharing Regimen* area of the NDA website that describes deadlines for completing data quality control activities.
- NIMH Data Archive Submitter Information and Certifications section
 - O Add a **2. Data Repository** section with a link to the *About Us* area of the NDA website that contains a current list of repositories in the system to remind respondents of the repository options available within the NDA infrastructure. No additional information is collected from respondents in this section.
 - O Add a **4. Controlled Access dataset** section for respondents submitting data with consent-based data use limitations to remind them of Institutional Certification requirements.

These updates do 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 Use Certification (DUC)
- B. Revised clean copy of NDA Data Use Certification (DUC)
- C. Revised tracked changes copy of NDA Data Submission Agreement (DSA)
- D. Revised clean copy of NDA Data Submission Agreement (DSA)