



DATE: February 23, 2021

TO: Office of Management and Budget (OMB)  
Through: Reports Clearance Officer, Debbie Kramer, DHHS<sup>1</sup>  
Project Clearance Chief, Mikia Currie, NIH  
Project Clearance Liaison, Andrew Hooper, 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 (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 Data Archive (NDA) Data Use Certification (DUC) 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 DUC 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 DUC to improve the clarity of the data use terms and conditions. The changes to the DUC will not meaningfully alter the content, scope, or method of the information collection. The changes to the DUC are described below.

Updates to the DUC:

- *Introduction* section
  - Throughout this section, fully spell out the term “NIMH Data Archive.”
- *NIMH Data Archive (NDA)* section
  - In the third paragraph, add an extra example of derivative data, and rewrite the description of how changes in automation have impacted the concept of “identifiability.”
- *Data Use Terms and Conditions* section
  - **1. Non-transferability of Agreement** – fully spell out the term “NIMH Data Archive.”
  - **2. Data for Research Use** – precisely specify the location of the *Research Data Use Statement*.
  - **3. No Distribution of Data** – introduce the acronym “Institutional Review Board (IRB).”
  - **4. Collaboration with Shared Data** – fully spell out the term “NIMH Data Archive.”

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<sup>1</sup>Signature of Submitter

- o **5. No Re-identification of Subjects** – specify “the Recipient’s” instead of “your.”
  - o **6. Compliance with Applicable Human Subjects Protection and Institutional Requirements** – add details to further explain compliance with “applicable rules for the protection of human subjects.”
  - o **7. Additional Human Subjects Research Requirements** – replace “Institutional Review Board” with its acronym “IRB.”
  - o **9. Deletion of Data** – edit to clarify that this guidance refers specifically to data downloaded from the NIMH Data Archive.
  - o **12. Acknowledgements** – edit to specify how Digital Object Identifiers are created.
- *NIMH Data Archive Recipient Information and Certifications* section
    - o **2. Progress Report (For Renewal Requests Only)** – add the word “also” to clarify that the listed purposes of the Progress Report are not exclusive.
    - o **3. Research Data Use Statement** – rearrange for clarity; edit to reiterate that the terms and conditions apply to all listed data recipients; and edit to re-emphasize the terms and conditions relating to the storage and deletion of data.
    - o **6. Authorized Institutional Business Official** – fully spell out the term “Signing Official” and edit the URL to an NIH website that defines this term.
    - o **7. Signatures** – fully spell out the term “Institutional Business Official.”

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)