

National Institute of Allergy and Infectious Diseases
Data Use Agreement
NIAID Clinical Trials Data Repository

National Institute of Allergy and Infectious Diseases (NIAID) Data Use Agreement (DUA) outlines the terms of use for controlled-access dataset(s) from NIAID supported clinical trials maintained in the NIAID Clinical Trials Data Repository, Accessclinicaldata@NIAID, supported and managed by NIAID. This DUA is between the NIAID, a component of the National Institutes of Health (NIH), and **INSTITUTION_NAME** (“**Accessing Institution**”), on behalf of **USER_NAME** (“**Approved User**”), and will become effective on the date of the last signature below to this DUA.

NIAID has established this data platform for securely storing and sharing controlled-access human clinical trials data from NIAID supported clinical trials for COVID-19 and other infectious diseases for research purposes and has been built to protect participant privacy and data security. De-identified individual participant-level data from clinical trials will be made available to Approved Users only through controlled-access, and Accessing Institution must agree to the terms of data access and permitted uses of the data and execute this DUA as established with signatures from Approved User, Accessing Institution, and NIAID, prior to access to the approved dataset. Failure to comply with the terms of this agreement at any time may result in revocation of data access.

TERMS OF ACCESS

1. Definitions

- (a) **Accessclinicaldata@NIAID** is a NIAID managed cloud-based data repository to store, share, and access clinical trials data from NIAID sponsored clinical trials for research purposes.
- (b) **Accessing Institution** is the institution, entity, or organization that will be signatory of this agreement and the responsible party for the conduct of its User(s) approved to access Data under this agreement.
- (c) **Approved User** is an individual who has submitted a Data Access Request that has been reviewed and approved and authorized by NIAID to access the specific clinical trial dataset(s).
- (d) **Data** are the specific clinical trial dataset(s) available for access by the research community and are de-identified data, which is individual participant-level data that is health information collected for the clinical trial that has been stripped of all protected health identifiers as defined by HIPAA that can be used to identify the participant.
- (e) **Data Access Request (DAR)** is a NIAID document that the requestor is required to complete and submit to NIAID for review and approval prior to accessing clinical data in the NIAID Clinical Trials Data Repository, Accessclinicaldata@NIAID. Attachment A provides a blank DAR form.
- (f) **Data Use Agreement (DUA)** is this NIAID agreement that Approved User and Accessing Institution agree to and sign that outlines the terms of data use for the dataset approved and authorized by NIAID. This DUA will also be signed by an authorized NIAID official.
- (g) **Research Project** is the research project described in the Research Use Statement of the DAR and approved by NIAID.

2. Access to specific clinical trial dataset(s) is through a DAR submitted by a user for each Research Project to NIAID for review and approval to the user and those named in the DAR; that user shall become the only Approved User of the requested dataset(s) under that DAR and this DUA. Any collaborators not named in the DAR or at a different institution must submit an independent DAR using the same project title and Research Project and a DUA specific to that user and institution must be executed.

3. Approved User and Accessing Institution agree to:

- (a) Retain control of and agree not to distribute to any entity or individual not listed in the DAR, controlled-access clinical trial dataset(s) or any data derivatives obtained through the approval of the DAR. The approved DUA is not transferrable to another user or institution. For avoidance of doubt, controlled-access clinical trial dataset(s) or any data derivatives may not be distributed to any entity or individual not listed in the DAR even if that entity or individual is under the direct supervision of Approved User.
- (b) Keep Data secure and confidential at all times and adhere to all data security practices, safeguard Data and protect participants' privacy, and adhere to the terms of use defined in this Agreement and Accessing Institution's IT security requirements and policies to prevent unauthorized use of or access to data including completing appropriate training related to data security and privacy.
- (c) Obtain the appropriate regulatory or ethical approvals for the Research Project and use of the approved dataset, including, if applicable, approval of an Institutional Review Board, subject to applicable laws and regulations and institutional policy and in compliance with all applicable national, tribal, and state, local laws, regulations and policies as well as training in human subjects research protection for the duration of the DUA to manage and secure human clinical trial data and protecting participant privacy.
- (d) Comply with the Certificate of Confidentiality protecting Accessclinicaldata@NIAID. Data residing in Accessclinicaldata@NIAID is protected by a Certificate of Confidentiality pursuant to section 301(d) of the Public Health Service Act. The Certificate of Confidentiality prohibits disclosure, including in any federal, state, or local criminal, civil, administrative, legislative, or other proceeding, of identifiable, sensitive information collected or used during research unless disclosure is made pursuant to a statutory exception. The Certificate of Confidentiality also protects all copies of Data from the Accessclinicaldata@NIAID in perpetuity as explained in the NIH Policy for Issuing Certificates of Confidentiality (<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-17-109.html>).
- (e) Use the approved dataset(s) solely as described in the approved DAR. New uses of these Data outside those described and approved in the DAR will require submission of a new DAR by Approved User; modifications to the Research Project will require a new DAR.
- (f) Not use the Data for any purposes inconsistent with any data use limitations.
- (g) Not sell, rent, lease, loan or otherwise give access to the Data to any individual at any point in time for any purpose the controlled-access datasets obtained through the attached DAR and any data derivatives of controlled-access datasets, in whole or in part unless approved by NIAID. If Accessing Institution is required by law or legal process to use or disclose the Data, Accessing Institution will promptly notify NIAID to the extent allowed by law, prior to such use or disclosure and will disclose the least possible amount of Data necessary to fulfill Accessing Institution's legal obligations.

- (h) Not use the approved datasets, either alone or in concert with any other information or datasets, for any of the following purposes.
 - i. Identifying or contacting individual participants or their living relatives from whom Data was collected unless required by law to maintain public health and safety, or generating information (e.g., facial images or comparable representations) that could allow the identities of research participants to be readily ascertained.
 - ii. Any diagnostic, prognostic, or treatment purpose. Although an approved dataset cannot be used for a clinical diagnosis or treatment of an individual patient, this does not prohibit use of an approved dataset to support the development of diagnostic, prognostic, or therapeutic purposes.
 - iii. Any commercial purpose, including selling, commercial screening, or transferring Human Data to a third party for commercial purposes. "Commercial purpose" does not include using an approved dataset to develop commercial products or services as diagnostics or therapeutics interventions.
- (i) Agree to notify NIAID if Approved User leaves Accessing Institution. Approved User is required to submit a new DAR from the new Accessing Institution that must be reviewed and approved by NIAID and a new DUA is required to be executed and signed by NIAID, the new Accessing Institution, and Approved User.
- (j) Agree to notify the NIAID of any unauthorized data sharing, breaches of data security, or inadvertent data releases (including discovery that data obtained from NIAID have been incompletely de-identified), that may compromise data confidentiality within 24 hours of when the incident is identified. As permitted by law, notifications should include any known information regarding the incident and a general description of the activities or process in place to define and remediate the situation fully.
 - i. Within 3 business days of the NIAID notification, Approved User agrees to submit to the NIAID a detailed written report including the date and nature of the event, actions taken or to be taken to remediate the issue(s), and plans or processes developed to prevent further problems, including specific information on timelines anticipated for action.
 - ii. Approved User agrees to provide documentation verifying that the remediation plans have been implemented.
 - iii. Unauthorized data sharing incident may result in further compliance measures affecting Approved User and result in termination or suspension of the DUA and access to the approved clinical trial dataset(s). NIAID, NIH, or another entity designated by NIH may, as permitted by law, also investigate any data security incident or policy violation.
 - 1) Approved User agrees to support such investigations and provide information, within the limits of applicable local, state, tribal, and federal laws and regulations.
 - 2) Approved User agrees to work with the NIAID and NIH to assure that plans and procedures that are developed to address identified problems are mutually acceptable and consistent with applicable law.
- (k) Acknowledges that the NIAID may terminate the approved request including this Agreement and immediately revoke or suspend access to all controlled-access datasets if the Approved User and/or Accessing Institution is found to be no longer in compliance-with the terms of access.

4. Dissemination of Research Findings and Acknowledgement of Controlled-Access Datasets

- (a) It is NIAID's intent to promote the dissemination of research findings from use of controlled-access clinical trial dataset(s) subject as widely as possible through scientific publication or other appropriate public dissemination mechanisms. Approved User is strongly encouraged to publish their results in peer-reviewed journals, open access journals, and to present research findings at scientific meetings.
- (b) Approved User agrees to acknowledge the NIAID Clinical Trials Data Repository, Accessclinicaldata@NIAID, in all oral and written presentations, disclosures, and publications resulting from any analyses of Data obtained through the NIAID.

5. Research Use Reporting

- (a) Approved User and Accessing Institution agree to provide a Progress Update at the expiration of the one (1) year data access period.
- (b) If Approved User seeks renewal of the data access period for an additional year, Approved User must submit a new DAR and agree and sign a new DUA for review and approval by NIAID.

6. Governing Law, Inventions, Non-Endorsement, No Warranties, Indemnification, and Liability

- (a) This DUA will be construed in accordance with United States Federal law as applied by the Federal courts in the District of Columbia.
- (b) Accessing Institution, Approved User, and other individuals listed in the DAR are free to pursue patent protection on any inventions or discoveries developed through their approved use of the Data.
- (c) Neither Accessing Institution nor Approved User shall claim, infer, or imply endorsement by NIAID or any component of the United States Government, of the Research Project, the entity or personnel conducting the research, or any resulting commercial product(s).
- (d) Data delivered pursuant to this DUA is understood to be experimental in nature. Approved User and Accessing Institution acknowledge that although all reasonable efforts have been taken to ensure the accuracy and reliability of Accessclinicaldata@NIAID Data obtained through the attached DAR, NIAID, NIH, and all contributors to these datasets do not and cannot warrant the results that may be obtained by using any Data included therein. NIAID, NIH, and all contributors to these datasets make no representations and extend no expressed or implied warranties of any kind, including warranties of merchantability, quality, or fitness for a particular purpose, or that the use of Data will not infringe any patent or other proprietary rights.
- (e) No indemnification for any loss, claim, damage, or liability is intended or provided by any party under this agreement. Each party shall be liable for any loss, claim, damage, or liability that said party incurs as a result of its activities under this agreement, except that NIAID, as an agency of the United States, may be liable only to the extent provided under the Federal Tort Claims Act, 28 USC 2671 *et seq.*

7. Termination and Data Destruction

- (a) Upon Research Project close-out, Approved User agrees to destroy all copies, versions, and data derivatives of the dataset(s) retrieved from Accessclinicaldata@NIAID on both local servers and hardware, and if cloud computing was used, delete the data and cloud images from cloud

computing provider storage, virtual and physical machines, databases, and random access archives.

- (b) Data retained to comply with any institutional policies (e.g., scientific data retention policy), law, and scientific transparency expectations for disseminated research results, and/or journal policies for the purpose of supporting the findings (e.g., validation) resulting from the research described in the DAR will be considered to be part of the approved Research Project. The NIAID DUA terms of agreement will remain effective prior to Research Project close-out, including for any time that the Data are retained for validation purposes.

8. Effective Date and Term:

- (a) The effective date of this DUA shall be the receipt by NIAID of a completed DUA with the appropriate signatures.
- (b) Access is granted for a period of **one (1) year**, with the option to renew access with a new DAR and DUA or to close-out the Research Project at the end of that year.

Signatures Begin on the Next Page

Signature Page

ACKNOWLEDGEMENT OF APPROVED USER:

NAME
TITLE

Date

FOR ACCESSING_INSTITUTION_NAME (ACCESSING INSTITUTION):

NAME
TITLE

Date

Mailing Address for Notices:

OFFICE_NAME
ADDRESS
ADDRESS
CITY, ST 12345-6789

Tel: 121-987-6543 / Fax: 121-987-3456

FOR NIAID:

Reed Shabman
Acting Director, Office of Data Science and Emerging Technologies

Date

Mailing Address for Notices:

NIH/NIAID 5601 Fishers Lanes
Rockville, MD 20892-9805

ACCESSING_INSTITUTION
APPROVED_USER

Attachment A

Accessclinicaldata@NIAID NIAID Data Access Request Form

- *To access data, a Data Access Request (DAR) is required to be submitted to NIAID by the requestor using this electronic DAR form as part of the request access process found on the **Accessclinicaldata@NIAID** data platform and will be reviewed by the NIAID Clinical Trials Data Access Committee.*
- *Upon approval of the DAR by NIAID and prior to accessing the data set, the primary requestor and their institution will be notified and required to agree to and sign a NIAID Data Use Agreement (DUA) found on the **Accessclinicaldata@NIAID** data platform that outlines the terms of the use of the data.*

*** required**

Requestor's Information

*First Name, Middle Name, *Last Name

*Email Address

ORCID ID

*Address

*Degree

*Position/Title

*Department/Branch

*Institution

Requestor's Institutional Signing Official Information

*First Name, Middle Name, *Last Name

*Email Address

*Phone Number

*Address

*Position/Title

*Department/Branch

*Institution

Additional Internal Staff and Collaborators' Information

Will additional internal staff or collaborators have access to the data?*

If yes, it is required that primary requestor provides the information below for any internal staff and collaborators at your institution who will have access to the approved data sets; Data Users outside of your institution will be required to submit a separate DAR for review and approval and approved user and their institution will be required to sign a separate DUA.

ACCESSING_INSTITUTION
APPROVED_USER

*Full name, *Email Address, *Degree, *Position/Title, *Department, Institution

Data Request*

NIAID Adaptive COVID-19 Treatment Trial (ACTT)

Research Use Statement (limit to 3500 characters)*

The Research Use Statement should include the following:

- *Research Project Title*
- *Objectives of the proposed research project*
- *Study design*
- *Describe how requested dataset is consistent with the objectives of the proposed research project*
- *Analysis plan*