

## Data and Resources Use Agreement Cloud Use Addendum

This Addendum is made and entered into as of the last date of signature by the Parties, by and between the National Institute of Diabetes and Digestive and Kidney Diseases (“NIDDK”), a component of the National Institutes of Health (“NIH”), and the Requesting Institution. This Addendum is intended for when an approved “Requestor” plans to use the NIDDK Central Repository (“NIDDK-CR”) analytics environment (“Analytics Workspace”) as their cloud computing solution to meet NIH Security Best Practices for Users of Controlled-Access Data. This Addendum sets all terms and conditions and rules of behavior for the use of the NIDDK-CR cloud computing environment in accordance with applicable NIH, NIDDK, and NIDDK-CR policies. The approved Requestor and Requesting Institution agree that all the terms and conditions of the NIDDK-CR Data and Resources Use Agreement (“DUA”) or other NIH Institutes, Centers, or Offices applicable Data Use Certification (“DUC”), apply as written unless otherwise noted below.

### Introduction:

According to NIH Policy [NOT-OD-25-159](#), Requestor and Requesting Institutions, who access data from NIH Controlled-Access Data Repositories (“CADR”), will be expected to adhere to the security standards outlined in the [NIH Security Best Practices for Users of Controlled-Access Data](#), as stipulated in new or renewed agreements, until project close-out or renewal. This Addendum is designed to align with the NIH Security Best Practices for Users of Controlled-Access Data, acknowledging that such guidance may be updated or clarified by NIH over time.

NIDDK Central Repository - Resources for Research (“NIDDK-CR R4R”) Analytics Workspace is a secure, cloud-based collaborative platform where researchers and data scientists can access a suite of integrated analytics tools and cloud computing resources. NIDDK-CR R4R Analytics Workspace promotes access to data, fostering collaboration in data science, data management, advanced analytics, and artificial intelligence (AI) innovation, supporting the discovery of data-driven biomedical insights. This Addendum governs the use of the NIDDK-CR R4R Analytics Workspace as a secure computing environment and does not cover or authorize the use of NIDDK-CR data in other computing environments, which may require separate approval and use agreements. The Analytics Workspace allows approved Requestors from participating NIH Institutes, Centers, and Offices, and their collaborators, to efficiently view, manipulate, combine, analyze, and summarize controlled-access data in a secure environment. NIDDK is providing the NIDDK-CR R4R Analytics Workspace as an alternative to the secondary research community to comply with NIH Policy NOT-OD-25-159.

NIDDK-CR R4R Analytics Workspace uses Amazon Web Services for data storage and computing, hosted and operated by NIDDK with technical support from contracted staff under federal contract (75N94021D00001/75N94021F00001). Requestors’ workbenches are created and managed by the Booz Allen Hamilton NIDDK-CR support team. NIDDK Authorizing Official has granted NIDDK-CR R4R and its Analytics Workspace a FISMA Moderate Authority to Operate (ATO), demonstrating that the system meets [NIH Security Best Practices for Users of Controlled-Access Data](#).

### Definitions:

**“Analysis Results Exports”**: Aggregate summary reports (e.g., aggregate, non-identifiable, consistent with applicable DUA/DUC publication and disclosure requirements) of analyses conducted within the Requestor’s workbench, provided by NIDDK-CR, after review, to an approved Requestor. Approval of exports remains at NIDDK-CR’s discretion.

**“Bring Your Own Data”**: Data from an NIH Controlled-Access Data Repository (CADR) that has been approved for access by the corresponding NIH Data Access Committee (DAC) to be analyzed in the Workbench, or Requestor/Requesting Institution-owned data that complies with NIH Security Standards, is free of identifiable information, and has been explicitly approved by NIDDK-CR DAC to be analyzed in combination with NIDDK-CR held controlled-access data. For the avoidance of doubt, approval by NIH CADR and/or DAC only authorizes use of the data for the approved research purpose, but it does not, by itself, authorize the ingestion or analysis within the NIDDK-CR R4R Analytics Workspace. Approval for workspace admission and data ingestion

remains at NIDDK's discretion and does not transfer data ownership, stewardship, or reuse rights of such data to NIDDK.

**“Data”:** Controlled-access data provided by NIH/NIDDK in limited data set format as defined in 45 CFR § 164.514(e)2 (do not contain direct identifiers, are sensitive, and must be protected), that may also be available from repositories other than NIDDK-CR, for example, dbGaP.

**“Materials”:** Include but are not limited to all data, specimens, products, analytes, metadata, documentation, code, analytic tools, methods, algorithms, workflows, results, summaries, analyses, or conclusions generated under the Research Project as a direct result from the use of NIH/NIDDK Resources.

**“Outcomes Report”:** Includes, but is not limited to, results, conclusions, significant findings, and any other information needed to describe or required to interpret the work performed under the Research Project within the Workbench. For artificial intelligence and machine learning modeling research, it includes information about the model (e.g., model settings and parameters, details and description of model building, cross-validation and testing, code, overall accuracy, specificity, sensitivity). An Outcomes Report supplements, but does not supersede, obligations of annual Progress Reporting.

**“Workbench”:** A secure, cloud-based collaborative analytics environment within the NIDDK-CR R4R Analytics Workspace that provides authorized users with access to computing resources, applications, and approved datasets for active data analysis. The Workbench supports temporary processing and computation of controlled-access data drawn from NIH or NIDDK-approved repositories and is not intended for long-term data storage or archiving.

#### **Terms and Conditions and Rules of Behavior:**

Use of the NIDDK-CR R4R Analytics Workspace satisfies the enhanced system-level technical security controls required under DUA/DUC for the analysis of controlled-access data. If the NIDDK-CR R4R Analytics Workspace serves as the secure computing environment for the Research Project, Requestors and Requesting Institutions are not required to implement NIST SP 800-171 or ISO/IEC 27001/27002 controls on their own systems unless they host, store, or process controlled-access data outside the NIDDK-CR environment. While use of the NIDDK-CR R4R Analytics Workspace satisfies system-level technical security controls for data processed within the environment, Requestors and Requesting Institutions remain responsible for meeting applicable user and institutional obligations under the [NIH Security Best Practices for Users of Controlled-Access Data](#).

1. Requestor agrees to disclose all individuals (i.e., name, position, role) who will collaborate or otherwise contribute to the conduct of the Research Project in a Workbench through the NIDDK-CR R4R Analytics Workspace. All listed individuals are considered Approved Users. All Approved Users agree to abide by the User Code of Conduct and all terms and conditions set forth in the DUA/DUC [ [DUA Reference](#) ], as well as this Addendum.
  - a. Requestor and Requesting Institution agree to remind all their Institution’s Approved Users that sharing of access credentials is strictly prohibited.
  - b. Each Approved User working in the Analytics Workspace must be a registered user of the NIDDK-CR R4R website under their own unique Institution email address.
  - c. Requestor and Requesting Institution agree that any misuse of the NIDDK-CR environment, including but not limited to User Code of Conduct violations, will lead to account suspension and may result in the Requesting Institution being barred from further access to NIDDK-CR resources.
2. The Requesting Institution shall ensure all Approved Users within their institutions comply with the security requirements contained within the User Code of Conduct, the DUA/DUC, and this Addendum. Requesting Institution agrees that:
  - a. Data must remain in the provided Workbench, and any review, analysis, manipulation, or modification of the Data will occur within this environment. Requestor and Approved Users will not download, copy, screen grab, screenshot, or otherwise extract Data from the NIDDK-CR provided Workbench.

- b. Entering NIDDK-CR controlled-access data into public generative AI tools violates DUA provisions. Requestors agree that the use of generative AI models outside the NIDDK-CR R4R Analytics Workspace is strictly prohibited, as is the use of any third-party tools, that transmit code outside the NIDDK-CR Workbench.
      - c. To promptly report any data incident consistent with the DUA/DUC, including any cloud-related security anomalies.
3. Requestor and the Requesting Institution agree that use of the NIDDK-CR R4R Analytics Workspace does not alter the terms of the DUA/DUC unless explicitly stated in this Addendum, and all prohibitions, requirements, and expectations remain in full effect per the effective date in the DUA/DUC, which must be renewed or closed out on an annual basis. If there are any conflicting terms and conditions between the DUA/DUC and this Addendum, then this Addendum will govern. For avoidance of doubt, nothing herein modifies the expiration date of the DUA/DUC. Requestor and Requesting Institution are responsible for ensuring that the referenced DUA/DUC is active; if the DUA/DUC expires or is no longer active, Requestor and Requesting Institution understand and acknowledge that access to the NIDDK-CR R4R Analytics Workspace will be paused until the DUA/DUC is renewed. If the DUA/DUC expiration exceeds ninety (90) days, closeout may be initiated as described below.
4. Subject to Article 8 of the NIDDK-CR DUA, “Research Progress Reporting and Dissemination of Research Results/Materials,” or similar “Research Use Reporting” term of the executed DUA/DUC, Requestor and Requesting Institution agree:
  - a. To submit an annual Progress Report to summarize the outcomes from the use of the Data. There are no modifications to reporting timelines or pre-publication clearance requirements due to the use of NIDDK-CR R4R Analytics Workspace.
  - b. To submit an Outcomes Report within 12 months of the completion of the Research Project. NIDDK-CR may post the Outcomes Report publicly on the NIDDK-CR R4R website.
  - c. Requestor agrees to submit requests for Analysis Results Exports or other egress requests at least thirty (30) days in advance to allow for sufficient time to generate and approve the egress of the exports. All publication, aggregation, and disclosure limitations described in the DUA/DUC remain fully applicable to any results exported or reported from the NIDDK-CR R4R Analytics Workspace.
5. Requestor and the Requesting Institution agree to follow closeout procedures, including data destruction/disposition, in accordance with Articles 5(f) and 7(b) of the NIDDK-CR DUA or similar closeout procedures of the executed DUC, as applicable and as amended below upon completion of the Research Project or within 30 days from reporting project closeout or prolonged period of inactivity:
  - a. The retention period for the NIDDK-CR R4R Analytics Workspace following the completion of the Research Project, for any review, analysis, manipulation, or modification of the Data within the provided Workbench necessary for policy, regulatory compliance, or publication verification, is three (3) years after the Research Project's completion. During this period, Approved Users may access the Workbench environment and request Analysis Results Exports. At the end of this period, NIDDK-CR R4R will delete the Workbench, and work conducted in the Workbench will no longer be retrievable. Requests for exceptions to retention or inactivity timelines may be considered on a case-by-case basis at NIDDK-CR's discretion, where required to meet regulatory, legal, or oversight obligations.
  - b. Requestor and Requesting Institution agree that Research Projects in the NIDDK-CR R4R Analytics Workbench with prolonged period of inactivity (greater than six (6) months) may be considered for closeout procedures in accordance with NIDDK-CR standard practice.
6. In accordance with Articles 3(d) and (e) of the NIDDK-CR DUA, or similar data combination terms of the executed DUC, the Requestor and Requesting Institution agree that Bring Your Own Data may only be ingested into the NIDDK-CR Analytics Workspace if explicitly approved for the specific Research Project. Requestor and Requesting Institution agree that no other data linkage or combination may be performed within the Workbench unless explicitly approved for the specific Research Project, including combination with other

previously approved NIDDK-CR datasets, derived AI embeddings, or model pre-training data.

7. Requestor and the Requesting Institution agree to cover costs associated with the creation and provision of individual Workbench environments, costs associated with data ingress and storage (Bring Your Own Data), compute (processing and analyses), egress (aggregate summary results exports), as well as costs associated with supplemental analytics support.
  - a. NIDDK-CR support staff may provide Requestor and Requesting Institution with complimentary routine troubleshooting support. Requestor and Requesting Institution agree that requests for technical or analytics support in excess of two hours may be subject to cost recovery following NIDDK-CR listed cost schedules.
  - b. The Requesting Institution shall ensure that estimated cloud costs and, if applicable, supplemental analytics support costs are paid in full within 15 days of invoicing. NIDDK-CR will provide an initial estimate of the upper and lower limit range for the cloud costs. Requestor and the Requesting Institution understand and acknowledge that actual costs may be higher or lower, and that underpayment will be billed to the Requestor and Requesting Institution.
  - c. Workbench will not be set up until DUA/DUC and this Addendum are fully executed and payment for the invoice is received by NIDDK-CR.

*Signatures on the next page*

**SIGNATURE of REQUESTOR**

Name of Requestor: \_\_\_\_\_

Signature of Requestor: \_\_\_\_\_

Date: \_\_\_\_\_

**SIGNATURE for REQUESTING INSTITUTION: LEGALLY AUTHORIZED ORGANIZATION REPRESENTATIVE**

Name of Requesting Institution: \_\_\_\_\_

Signature of Legally Authorized Official for Requesting Institution: \_\_\_\_\_

Name of Authorized Signatory: \_\_\_\_\_

Title of Authorized Signatory: \_\_\_\_\_

**NIDDK INFORMATION and AUTHORIZED SIGNATURE**

Program Official: \_\_\_\_\_

Name of Program Official: Rebecca M. Rodriguez, Ph.D.

Title of Program Official: Director, Repository Program

Authorized Signatory: \_\_\_\_\_

Name of Authorized Official: Carolyn Buller, Ph.D.

On Behalf of Charles Niebylski, Ph.D., J.D.

Title of Authorized Official: Director, Technology Advancement Office

Address: National Institute of Diabetes and Digestive and Kidney Diseases

31 Center Drive, Bethesda, MD 20892

**Any false or misleading statements made, presented, or submitted to the Government, including any relevant omissions, under this DUA and during the course of negotiation of this DUA are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§ 3801-3812 (civil liability) ([US Code Civil Liability](#)) and 18 U.S.C. § 1001 (criminal liability including fine(s) and/or imprisonment) ([US Code Criminal Liability](#)).**