NIDDK-CR Data Science and Meet the Expert Webinar Series

National Institute of Diabetes and Digestive and Kidney Diseases

Central Repository



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About the Series

- Aims to accelerate data science and AI-driven biomedical research by fostering collaboration between biomedical researchers and experts in the field
- Monthly webinar held on the **last Thursday of each month***

Upcoming Webinars

- Tools for whole-slide imaging pathomics
- Fusion Tool Demo

Learn more about the webinar series, register for future webinars, and access past webinars materials and recordings

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Data Science Centric Challenge Series

Goals of NIDDK-CR Data-science centric challenge series

- Develop tools, approaches, models and/or methods to increase data interoperability and usability for artificial intelligence (AI) and machine learning (ML) applications
- Augment and enhance existing data for future secondary research, including data-driven discovery by AI/ML researchers
- Discover innovative approaches to enhance the utility of datasets for AI/ML applications

Visit our website for more information on our data-centric movement and to learn more about our past data-challenges

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The Analytics Workbench V1.0

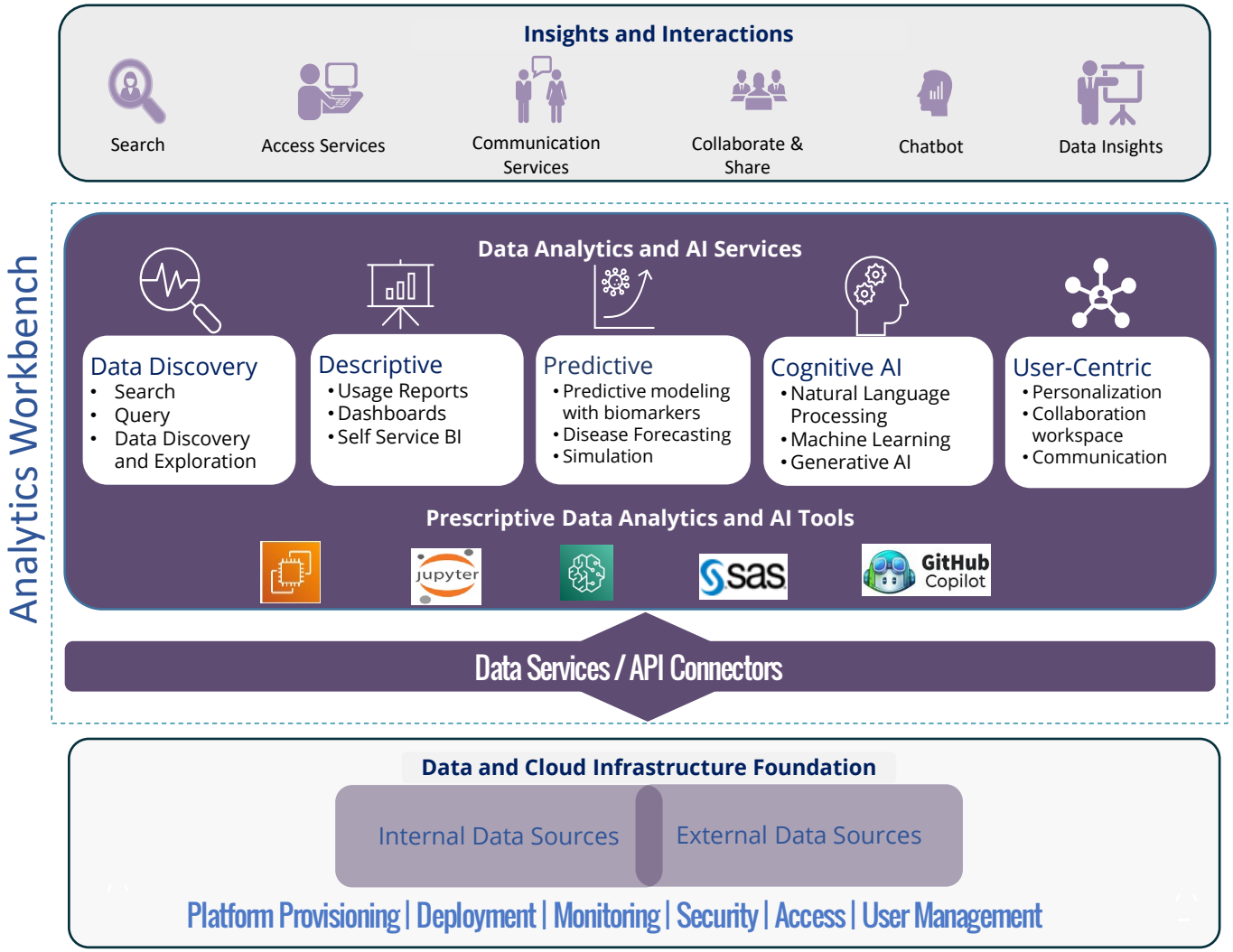
Streamlining *end-to-end data science lifecycle and discovery of data-driven biomedical insights.*

Innovation and ease of use

A cloud-based analytics environment where researchers and data scientists can access a suite of integrated analytics tools and cloud computing resources to participate in data challenges and AI innovation.

Expected Benefits of Analytics Workbench:

- **Promote Collaboration**
- **Support AI Innovation**
- **Minimize Data Movement**
- **Improve User Experience**
- **Discover Data Insights**
- **Advance NIDDK Research Mission**



Analytics Workbench is integrated with the *NIDDK-CR R4R Platform* and *Challenge Management Platform* offerings. More information at https://repository.niddk.nih.gov/home

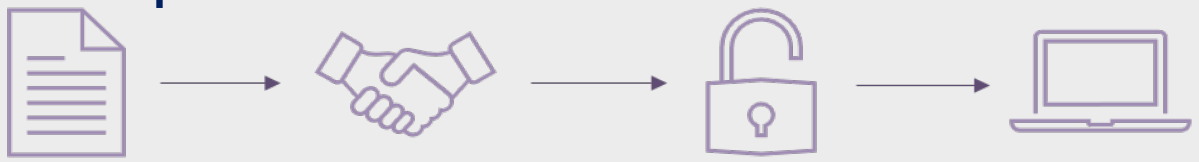
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Co-Analysis Pilot

A streamlined, joint access pathway unlocking cross-repository data science across metabolic, renal, digestive, and aging research

How the pilot works:



Submit one request → **Single joint DAC review** → **Access both repositories** → **Analyze in secure Workbench**

Cross-Repository Study Collections:

NIDDK CR

LookAHEAD; DPP; DPPOS; DCCT; EDIC; CRIC

NIA AgingResearchBiobank

LIFE; ENERGISE; SWAN; CALERIE; ASPREE; MOST; SOF; STRIDE; Testosterone Trials

- Larger, more diverse combined cohorts; greater statistical power and generalizability
- Well-characterized, longitudinal phenotyping linked to specimens across midlife–older age
- Enables novel cross-domain questions

Built for Co-Analysis, Not Just Co-Access

- Approved investigators can analyze data from both repositories together inside the secure NIDDK CR R4R Analytics Workbench, ***supporting integrated modeling, feature extraction, and AI/ML-driven pattern discovery without moving data out of a compliant environment.***

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Meet the Experts

Cheryl Jacobs is the Assistant Director for Genomics and Data Access from NIH Office of Science Policy. She has over 10 years' experience working on and leading evidence-based policies to support the broad and responsible sharing of controlled-access data. She brings extensive knowledge of research participant protections and facilitating access to sensitive biomedical research data.



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Meet the Experts

Kylie Snow, MPH, is a Health Scientist at Booz Allen Hamilton. She currently supports NIDDK Central Repository as a Data Manager, supporting investigators through all steps of the data and specimen request process and facilitating communications between requestors, Data Coordinating Centers, biorepositories, and NIDDK staff. Prior to her time at Booz Allen Hamilton, she worked at the Emory University School of Medicine Health Services Research Center, where she researched county-level determinants of end-stage kidney disease mortality. Ms. Snow completed her Master of Public Health in Epidemiology at Emory University Rollins School of Public Health.



Booz Allen Hamilton Internal

National Institutes of Health

NIDDK-CR Webinar and Office Hours Series

Securing NIH Controlled Access Data

Cheryl Jacobs, PhD
Assistant Director for Genomics and Data Access, Division of Scientific Data Sharing Policy
Office of Science Policy
National Institutes of Health

September 24, 2026

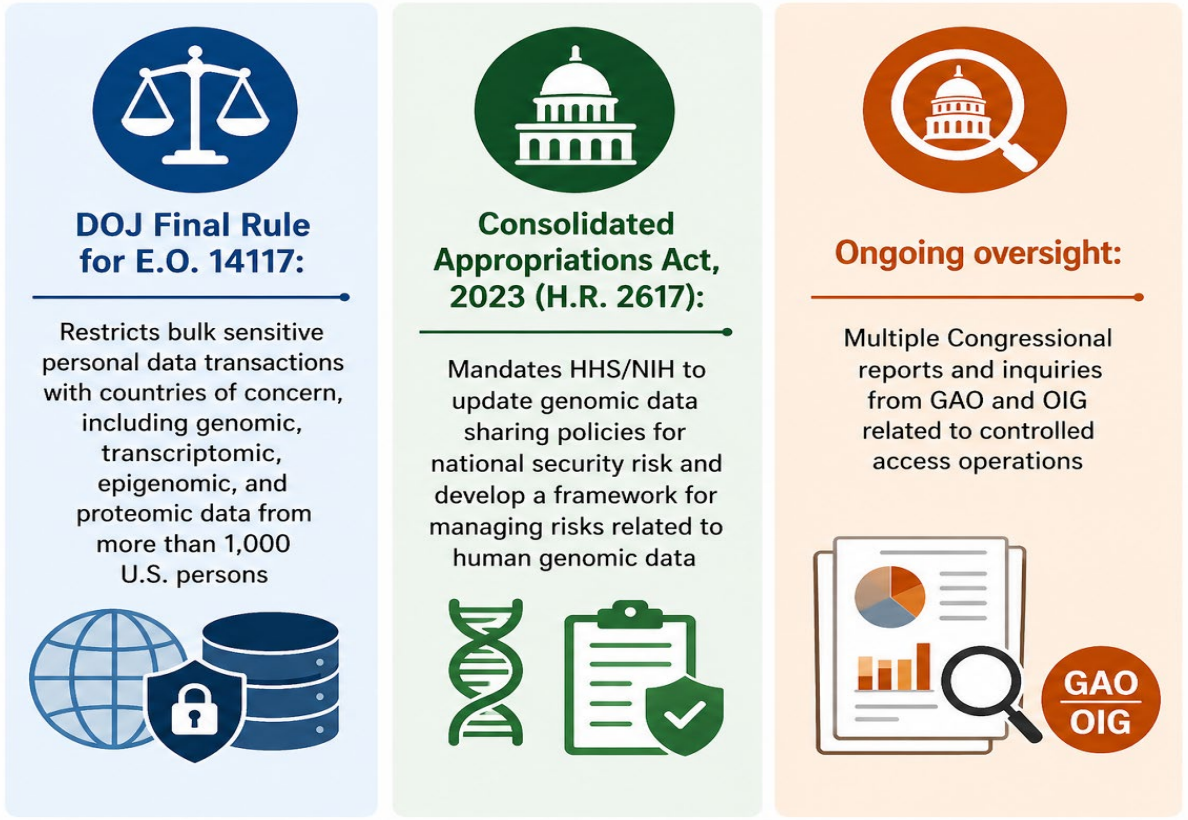
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Agenda

- Criteria for NIH Controlled-Access Data Repositories
- NIH Controlled-Access Data Repository Requirements
- Expectations for How NIH Controlled-Access Data Repositories and Users Can Satisfy Requirements

Evolving Controlled Access Landscape

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- External Policy and Oversight Drivers
  - National security directives
  - Congressional interest in NIH controlled access
- No unified framework for NIH repositories that control access

NIH Controlled-Access Data Repository Criteria

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- NIH maintains a publicly available list of NIH CADRs

Enhancing NIH CADR Data Access Processes

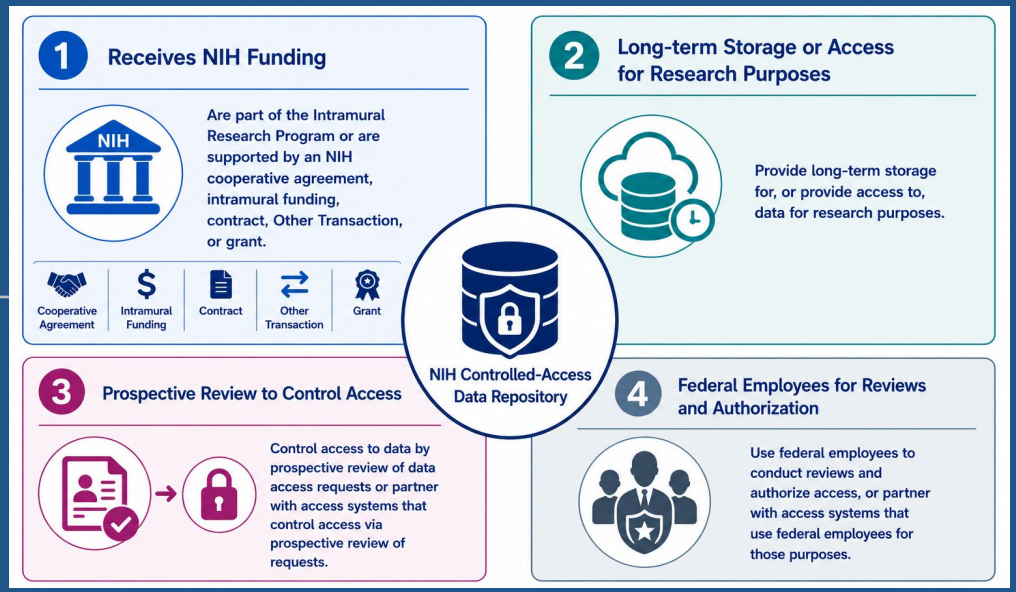
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- Security and Operational Standards for NIH Controlled-Access Data Repositories (NOT-OD-25-159):
  - Strengthen protections for the privacy and autonomy of research participants
  - Harmonize submission and access processes across NIH CADRs
  - Establish clear security requirements for NIH CADRs and users
  - Sets standards for public transparency

CATEGORY	DESCRIPTION
Laws and Policies	Documentation of adherence to relevant laws and policies
Data Access	Standard processes for reviewing and granting access to controlled data
Data Submission	Standard processes for submitting data to NIH CADRs
Security and Transparency	Security standards for NIH CADRs and users of NIH CADR data; public transparency requirements

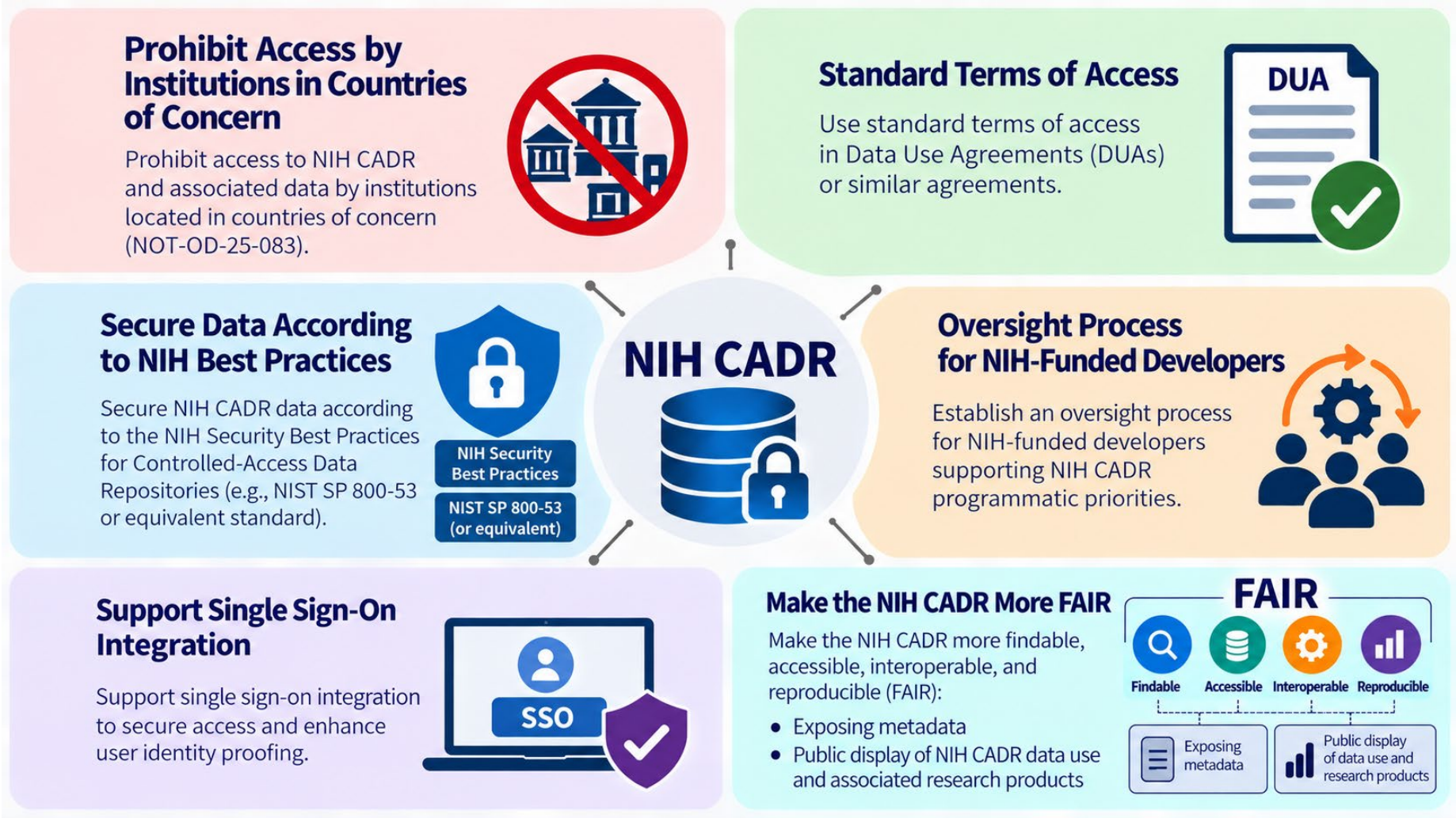
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NIH CADR Requirements for CADRs



Enhanced Security and Harmonized Standards for NIH CADRs

National Institutes of Health



This is not conclusive of CADR Requirements. For more information, see [NIH CADR Guidebook]

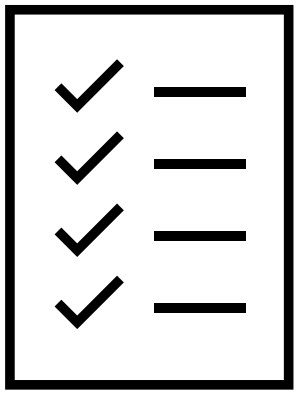
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NIH CADR Requirements for Users of CADR data



Standard Processes for User Access to NIH CADR Data

- Appropriate credentials to submit a request
  - Permanent employee of their institution at a level equivalent to, but not limited to, that of an academic professor or senior researcher (this excludes trainees; lab employees)
  - Uses an institutional or corporation email address
  - Has direct oversight of staff
  - Accountable for ensuring terms of access followed by staff
  - Only occupy role one role on the request (e.g., either as a user or Institutional Signing Official)
- Requests reviewed by an NIH Data Access Committee (DAC)
- Annual access with reporting requirements
- Enhanced authentication and security standards



For more information, see NIH CADR Guidebook

Securing Data According to NIH Security Best Practices

National Institutes of Health

- **All new and renewing data access requests must meet** the NIH Security Best Practices for Users of Controlled-Access Data. Investigators and their institutions:
  - Attest that the **system storing controlled-access data** is compliant with NIST SP 800-171.
  - Attest to the equivalent ISO/IEC 27001/27002 standard if they are a Non-U.S.
  - If using a third-party IT system or Cloud Service Provider **for data analysis or storage,** provide an attestation that the third-party system is compliant with NIST SP 800-171.

- No independent audit is required; **self-assessment is sufficient.**

NIH Accepts POA&Ms As Compliant With Security Controls

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NIH has a path forward for users that cannot meet NIST SP 800-171

- Users will be considered compliant if they:
  - They assess their security posture against NIST SP 800-171 or the equivalent ISO/IEC 27001/27002 standards
  - To the extent possible, update their security to align with NIST SP 800-171
  - Develop **Plans of Action and Milestones (POA&Ms)** to address areas requiring further risk mitigation

For more information, see NIH Security Best Practices for Users of Controlled-Access Data

Enhanced Identity and Authentication Assurance

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- Users will experience authentication at Authenticator Assurance Level 2 (AAL2) and Identity-proofing at Identity Assurance Level 2 (IAL2)
- This means users will be expected to provide additional documentation to verify their identity when accessing controlled data from an NIH CADR



For more information, see NIH CADR Guidebook

Example of User Provided Documentation to Verify Identity

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Users who log in to NIH CADRs will need to confirm identity by completing the identity proofing process at IAL2 through identity providers such as Login.gov or ID.me

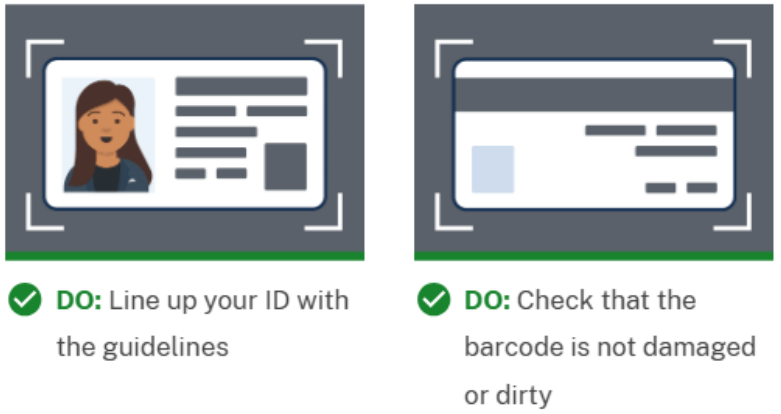
Step 1. Take a Photo of my ID:

- U.S. Drivers license, State ID, or Passport Book

Step 2. Take a selfie; or verify your identity in-person at any United States Post Office near you

Step 3. Enter your Social Security Number (SSN)

Step 4. Enter one-time code sent to your phone



IAL2 identity proofing steps may vary depending on the NIH CADR

Summary

- NIH has harmonized and standardized NIH CADR data access process
  - Impacts NIH CADRs and users of CADR data
- Enhanced security controls for the protection of CADR data
  - NIH CADRs are expected to secure data according to NIST SP 800-53 or equivalent controls
  - Users are expected to secure data according to NIST SP 800-171 or equivalent controls
- Strengthen protections for the privacy and autonomy of research participants
- NIH has provided resources to support user implementation of these requirements
  - 2026 Community Days: Securing NIH Controlled-Access Data
  - Guidance for Researchers and IT about NIST SP 800-171 controls
    - Scroll to Resources at the bottom of the page
  - FAQs about NIH Security Best Practices
- Questions? Email SciencePolicy@nih.gov

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Office Hours

September 24, 2026



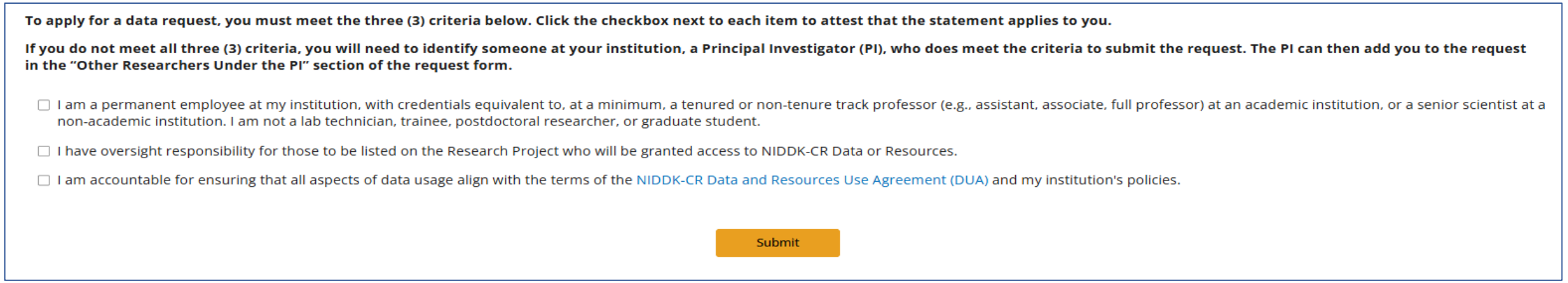
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Who can submit requests for resources from NIDDK-CR?

- Resources are available to qualified researchers via the request process in NIDDK-CR
- To create an account, requestors must authenticate with RAS IAL2 using an **institutional email address**; personal emails are not permitted
- Requestors (e.g., Principal investigators) must be a **permanent employee of the requesting institution** with **oversight responsibility**
- Requestors must have an **authorized institutional signatory official** to execute a legally binding agreement with NIDDK

Example Attestation Modal to Begin a Request:



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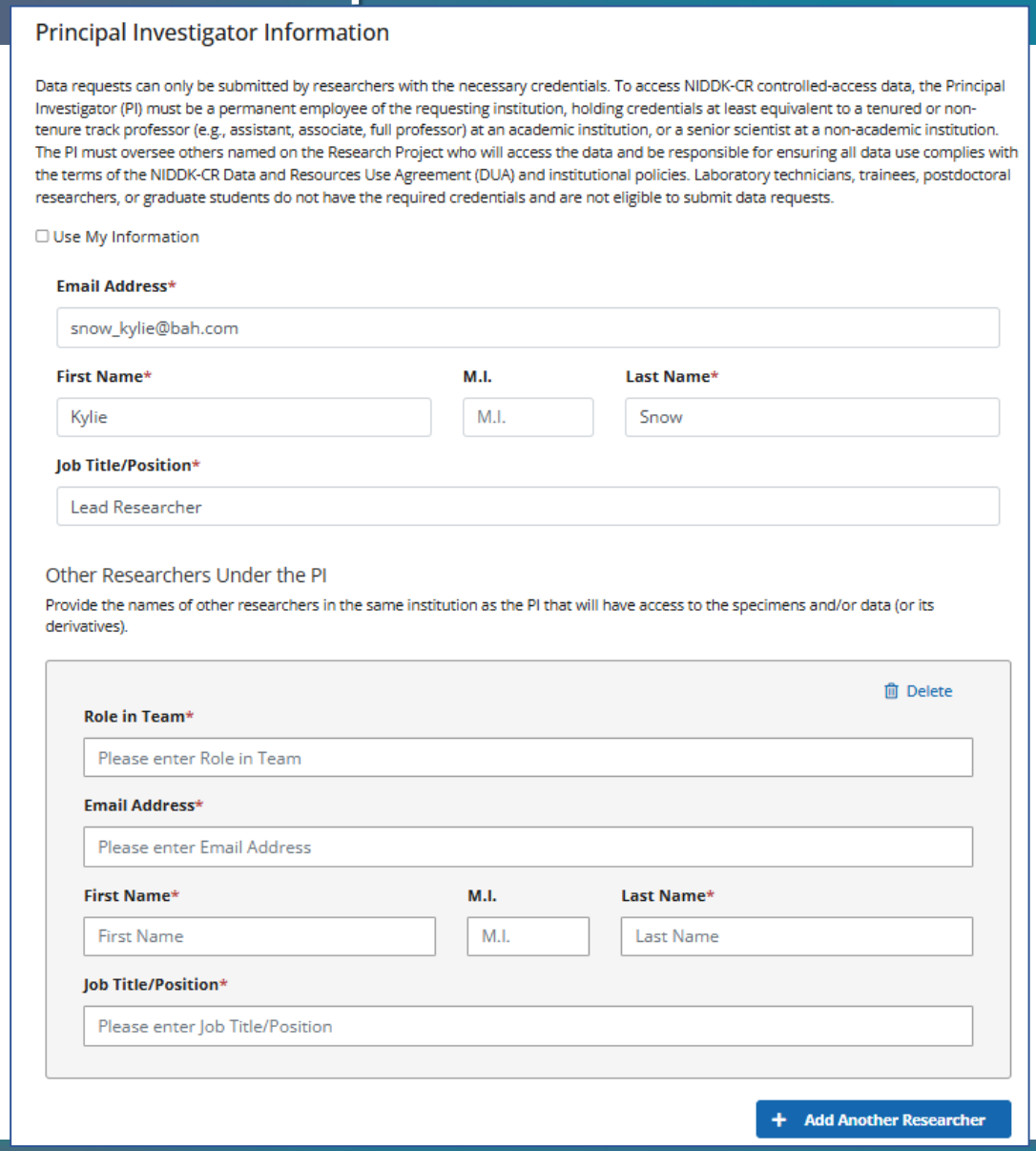
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What if I do not meet the Principal Investigator (PI) requirements to request resources?

- If you do not meet the PI requirements, you must **identify a PI at your institution** who meets the criteria in order to submit a request for resources
- The PI can add you and other team members in the “Other Researchers Under the PI” section of the request form



Note: Requestors from countries of concern are unable and prohibited from requesting access to resources

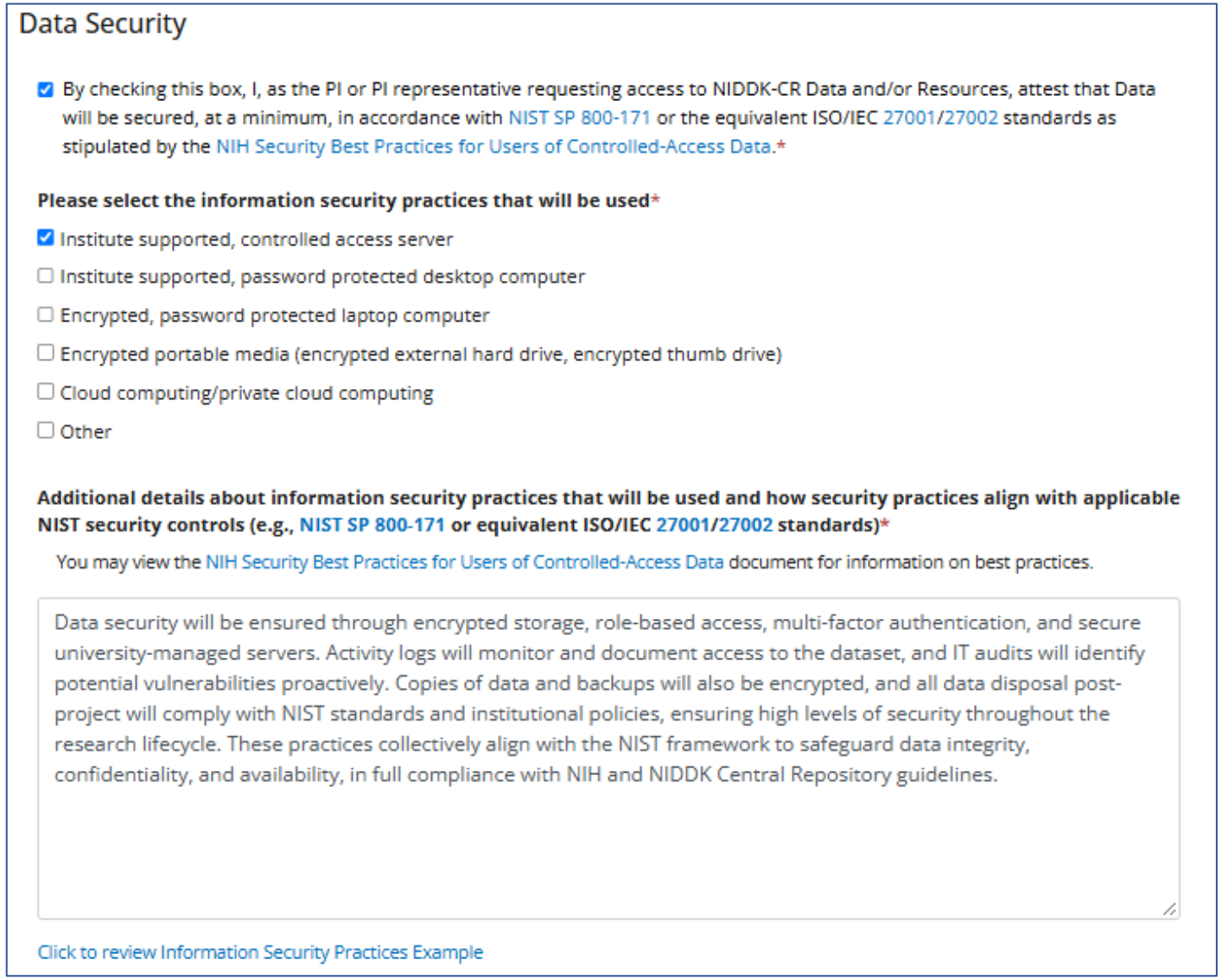


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What security requirements are required to access data from NIDDK-CR?

- Requestors and their Requesting Institutions are required to attest to implementation of applicable **NIST security controls**
- For example, NIST SP 800-171 or equivalent ISO/IEC 27001/27002 standards, as stipulated by the NIH Security Best Practices for Users of Controlled-Access Data



Data Security

☑ By checking this box, I, as the PI or PI representative requesting access to NIDDK-CR Data and/or Resources, attest that Data will be secured, at a minimum, in accordance with NIST SP 800-171 or the equivalent ISO/IEC 27001/27002 standards as stipulated by the NIH Security Best Practices for Users of Controlled-Access Data.*

Please select the information security practices that will be used*

☑ Institute supported, controlled access server

☐ Institute supported, password protected desktop computer

☐ Encrypted, password protected laptop computer

☐ Encrypted portable media (encrypted external hard drive, encrypted thumb drive)

☐ Cloud computing/private cloud computing

☐ Other

Additional details about information security practices that will be used and how security practices align with applicable NIST security controls (e.g., NIST SP 800-171 or equivalent ISO/IEC 27001/27002 standards)*

You may view the NIH Security Best Practices for Users of Controlled-Access Data document for information on best practices.

Data security will be ensured through encrypted storage, role-based access, multi-factor authentication, and secure university-managed servers. Activity logs will monitor and document access to the dataset, and IT audits will identify potential vulnerabilities proactively. Copies of data and backups will also be encrypted, and all data disposal post-project will comply with NIST standards and institutional policies, ensuring high levels of security throughout the research lifecycle. These practices collectively align with the NIST framework to safeguard data integrity, confidentiality, and availability, in full compliance with NIH and NIDDK Central Repository guidelines.

Click to review Information Security Practices Example

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What if my institution has not implemented NIST SP 800-171 or equivalent security controls?

- For institutions that are unable to meet the required security controls, NIDDK-CR can provide a secure cloud-based **NIDDK-CR Analytics Workbench**
  - NIDDK-CR Workbench currently has AWS SageMaker Studio (JupyterLab, R, Python, and more)
  - Analyze data without downloading to local environment
  - Workbench cost estimates are provided during the workbench request process; **Credits** are available to help cover workbench usage costs

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I already have an approved NIDDK-CR request. How do these requirements affect previous requests?

- To renew or close out a request, you must submit an **Annual Progress Report**
- If renewing your request, NIDDK-CR support team will review your request to ensure compliance with current policies and you may need to:
  - Update the **Data Security** section to confirm alignment with NIH security requirements
  - Update the public-facing **Research Use Statement** section to describe how your project aligns with the permitted uses for the requested study resources
  - Complete other new required fields in your request form
- If closing out your request (e.g., NIDDK-CR resources are deleted/destroyed or NIDDK-CR Workbench terminated), a Certificate of Destruction/Disposition will be sent to your authorized institutional signatory official for signature

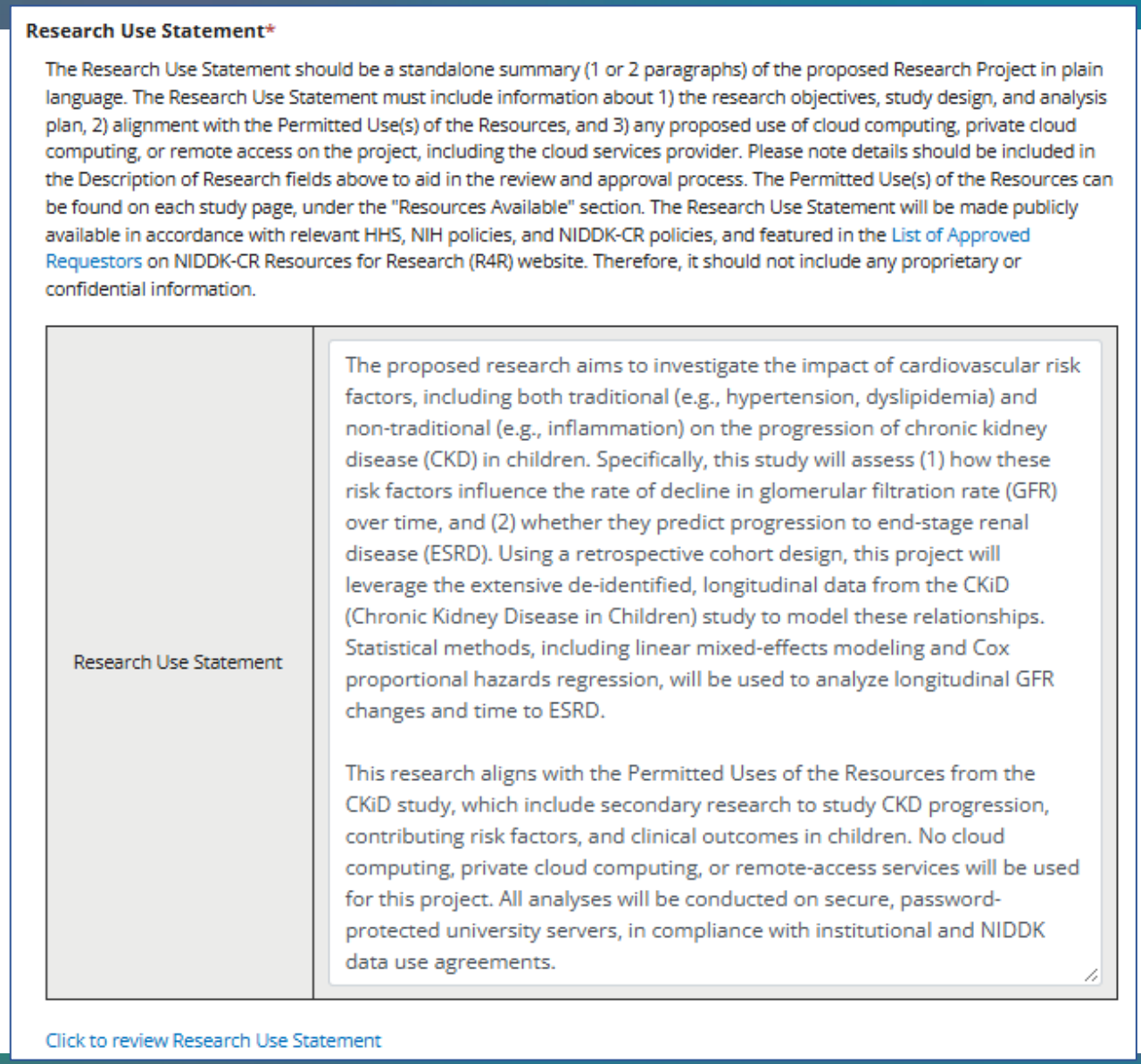
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What is a Research Use Statement and what should I include?

The Research Use Statement in NIDDK-CR requests:

- Is a standalone summary of the proposed Research Project in plain language
- Includes the research objectives, study design, and analysis plan
- Specifically mentions the alignment with the Permitted Uses of the Resources
- Includes any proposed use of cloud computing or remote access (or NIDDK-CR Workbench)
- Is publicly available on the NIDDK-CR website under the “List of Approved Requestors” page



Research Use Statement*

The Research Use Statement should be a standalone summary (1 or 2 paragraphs) of the proposed Research Project in plain language. The Research Use Statement must include information about 1) the research objectives, study design, and analysis plan, 2) alignment with the Permitted Use(s) of the Resources, and 3) any proposed use of cloud computing, private cloud computing, or remote access on the project, including the cloud services provider. Please note details should be included in the Description of Research fields above to aid in the review and approval process. The Permitted Use(s) of the Resources can be found on each study page, under the "Resources Available" section. The Research Use Statement will be made publicly available in accordance with relevant HHS, NIH policies, and NIDDK-CR policies, and featured in the List of Approved Requestors on NIDDK-CR Resources for Research (R4R) website. Therefore, it should not include any proprietary or confidential information.

Research Use Statement	The proposed research aims to investigate the impact of cardiovascular risk factors, including both traditional (e.g., hypertension, dyslipidemia) and non-traditional (e.g., inflammation) on the progression of chronic kidney disease (CKD) in children. Specifically, this study will assess (1) how these risk factors influence the rate of decline in glomerular filtration rate (GFR) over time, and (2) whether they predict progression to end-stage renal disease (ESRD). Using a retrospective cohort design, this project will leverage the extensive de-identified, longitudinal data from the CKiD (Chronic Kidney Disease in Children) study to model these relationships. Statistical methods, including linear mixed-effects modeling and Cox proportional hazards regression, will be used to analyze longitudinal GFR changes and time to ESRD. This research aligns with the Permitted Uses of the Resources from the CKiD study, which include secondary research to study CKD progression, contributing risk factors, and clinical outcomes in children. No cloud computing, private cloud computing, or remote-access services will be used for this project. All analyses will be conducted on secure, password-protected university servers, in compliance with institutional and NIDDK data use agreements.

Click to review Research Use Statement

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Where can I find the permitted uses of the resources?

Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI)

Network: Acute Kidney Injury Network (AKI)

Login to Start a Request

Home › Studies › Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury

Citation
Chinchilli, Vernon (2022). Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI) (Version 2) [Dataset] NIDDK Central Repository. https://doi.org/10.58020/js2k-9d54

Data Availability Statement
Data from Assessment, Serial Evaluation, and Subsequent Sequelae in Acute Kidney Injury (ASSESS-AKI) [(Version 2) https://doi.org/10.58020/js2k-9d54] reported here are available for request at the NIDDK Central Repository (NIDDK-CR) website, Resources for Research (R4R), https://repository.niddk.nih.gov/.

Acknowledgement Statement
The ASSESS-AKI study was conducted by the study investigators and supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK). The resources from the ASSESS-AKI (https://doi.org/10.58020/js2k-9d54) study reported here were supplied by NIDDK Central Repository (NIDDK-CR) and are available for request at https://repository.niddk.nih.gov. This manuscript was not prepared under the auspices of the ASSESS-AKI study and does not necessarily reflect the opinions or views of the ASSESS-AKI study, NIDDK-CR, or NIDDK.

Data Package Version
Version 2 (Updated on: Feb 03, 2022)

Resource Availability
- Data Available for Request
- Specimens Available for Request

Resource Use Information
- Permitted Use(s) of the Resources
- Certificate of Confidentiality

Publications
Explore publications resulting from the use of study resources

View publications (27)

Permitted uses are available on a study's overview page; clicking on the hyperlink will navigate you down the page to see the study's permitted uses of the resources

Resources Available

Permitted Use(s) of the Resources

- Use is allowed only for the specified disease(s), disorder(s), condition(s), or research area(s): Kidney Disorder

Certificate of Confidentiality

- This NIDDK-funded study is covered by a Certificate of Confidentiality. More information on what this means to Requestors is available in the NIH FAQ.

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Resources

For additional information, please see the following resources:

- NIDDK-CR Frequently Asked Questions
- NIDDK-CR General Information
- NIDDK-CR For Requestors
- NIDDK-CR Past Webinars
- NIDDK-CR Office Hours on RAS Recording
- NIST for Researchers Video