



BRICS

Biomedical Research
Informatics Computing System

BRICS Seminar

Meta Study Updates

NIH Controlled-Access Data Repositories (CADRs) Status Update

Biomedical Research Informatics Computing System (BRICS)

January 14th, 2026



MTBI²



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Audio/Video	Please keep your microphone muted
Recording	<ul style="list-style-type: none">• Today's session will be recorded• Will be posted on the BRICS website: https://brics.cit.nih.gov/demo
Questions & Comments	<ul style="list-style-type: none">• We encourage your participation today• Please use the chat for questions & comments. The chat will be monitored throughout today's demo.• There will also be time after each speaker and at the end of the demo to ask live questions.

Agenda

Time	Topic	Speaker(s)
9:00 AM – 9:05AM	Introduction	Dr. Matthew McAuliffe
9:05 AM-9:35 AM	Meta Study Updates	Michelle Harris
9:35 AM-9:55 AM	NIH Controlled-Access Data Repositories (CADRs) - Review Security and Operational Updates	Priya Raju Narasingh
9:55 AM-10:00 AM	Closing Remarks	Dr. Matthew McAuliffe



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Meta Study Updates

Michelle Harris



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Meta Study Module Updates

Meta Study Overview

A Meta Study contains findings from other studies that could be used by researchers to conduct additional analysis. The information within the Meta Study can be used in publications and is accessi...

View Meta Studies

Column Visibility

#	TITLE	ORGANIZATION	META STUDY ID	PI	DATA TYPES	DATA CATEGORY	# SUBJECTS	PERMISSIONS	STATUS
1	Dissertation Proposal FITBIR Data Information	Clemson university	FITBIR-META-STUDY0000232	Samantha Kanny		Results		Admin	Draft
2	Finding Anatomical and Functional Imaging Markers for Post Traumatic Epilepsy	University of Southern California	FITBIR-META-STUDY0000221	Anand A Joshi		Results		Admin	Draft
3	FITBIR: Accelerating Synthesis is TBI Research Using Novel Methods	Oregon Health and Science University/Portland VA Healthcare System	FITBIR-META-STUDY0000223	Maya O'Neil		Other		Admin	Published
4	Imaging Biomarkers of Microstructure Relating to Cognitive Performance after Mild Traumatic Brain Injury	NYU	FITBIR-META-STUDY0000225	Yvonne Lui		Other; Results		Admin	Published
5	Implications of Race on Cognitive Post-Concussion Symptoms and Neurocognitive Performance	The University of Western Ontario	FITBIR-META-STUDY0000222	Anita Christie		Results; Saved Query		Admin	Draft
6	Leveraging FITBIR Data to Improve Clinical Practice of Severe TBI	The University of Texas Health Sciences Center	FITBIR-META-STUDY0000241	Jose Miguel Yamal			1787	Admin	Draft
7	NIH TOPNET UG3 Phase MRI Data for biomarker discover after rat controlled cortical impact injury	UCLA	FITBIR-META-STUDY0000227	Neil Harris		Raw Data		Admin	Draft
8	NIH TOPNET UH3 Phase MRI Data for biomarker discover after rat brain injury	Georgetown University	FITBIR-META-STUDY0000235	Mark Burns		Raw Data		Admin	Draft
9	Sex Differences in Mental Health Functioning Following Mild Traumatic Brain Injury	UCSD/VA San Diego	FITBIR-META-STUDY0000234	Amy Jak		Other; Results		Admin	Published
10	TBI Psychopathology and Sleep (TIPS)	University of Kansas	FITBIR-META-STUDY0000240	Nancy a Hamilton		Saved Query		Admin	Draft

- Changing the name from **Meta Study** to **Datastore** by the end of Feb 2026
- Allows management and storage of primary and secondary data from research studies
- Makes research data FAIR (Findable, Accessible, Interoperable, and Re-usable)



Meta Study Module Updates

The main use cases for the Meta Study are:

1. Meta Analysis

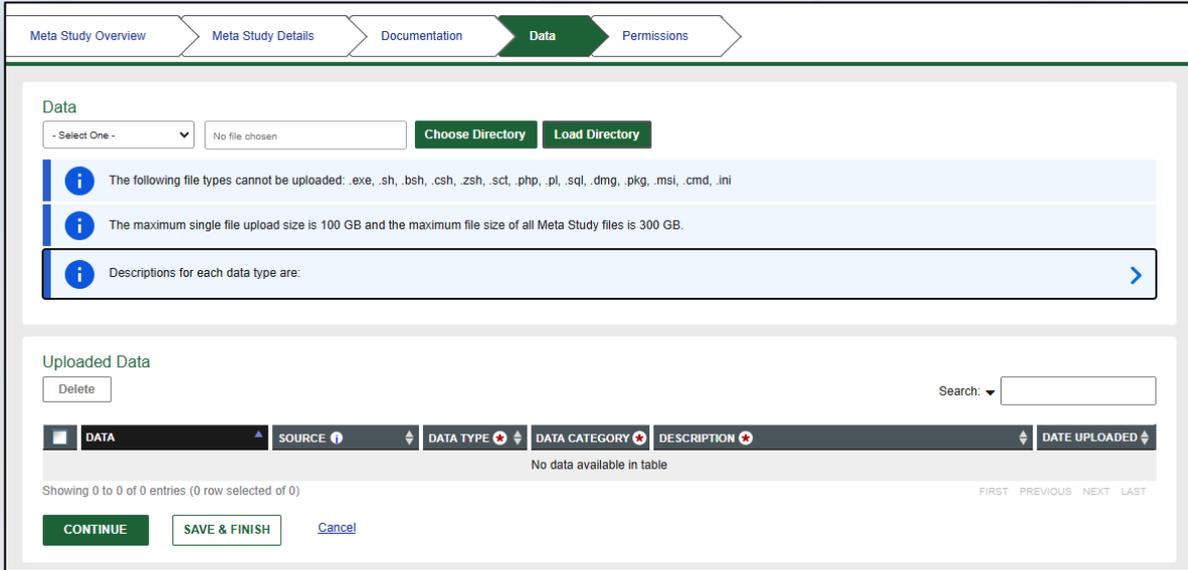
- Facilitates aggregation of data from different studies with BRICS Repository module for meta-analysis
- Accommodates upload(s) of data external to BRICS to be included in meta-analysis

2. Storage

- Facilitates storage of data from studies that do not have a requirement to upload data to the BRICS Repository module
- Supports NIH Data Management and Sharing Policy
- **NOTE:** Data stored inside of the file storage system will not be validated against CDEs or stored in the Data Repository module and it also will not be queryable under the Query Tool module



Meta Study Module Updates



The screenshot shows the 'Data' tab in the Meta Study Module. It includes a navigation bar with 'Meta Study Overview', 'Meta Study Details', 'Documentation', 'Data', and 'Permissions'. The 'Data' section has a dropdown menu set to '- Select One -', a 'No file chosen' status, and buttons for 'Choose Directory' and 'Load Directory'. Below this are three informational messages: one about disallowed file types (.exe, .sh, .bash, .csh, .zsh, .sct, .php, .pl, .sql, .dmg, .pkg, .msi, .cmd, .ini), one about file size limits (100 GB per file, 300 GB total), and one with a link to descriptions for each data type. The 'Uploaded Data' section features a 'Delete' button, a search field, and a table with columns: DATA, SOURCE, DATA TYPE, DATA CATEGORY, DESCRIPTION, and DATE UPLOADED. The table is currently empty, displaying 'No data available in table'. At the bottom, there are buttons for 'CONTINUE', 'SAVE & FINISH', and a 'Cancel' link.

- Not required to align data with CDEs
- Data can be uploaded directly in various file types
- File size limits:
 - Single file limit: 100 GB
 - Total file limit: 300 GB
- Admins can adjust file size limits as needed



Meta Study Module Updates

Resource	FITBIR
Title	FITBIR: Accelerating Synthesis in TBI Research Using Novel Methods
Meta Study ID	FITBIR-META-STUDY0000223
DOI	10.23718/FITBIR/1528491

- Data in Meta Study can be cited in publications using the generated DOI
- DOI will be in a DRAFT status until the study in the Meta Study is published at which point it will transition to a published state
- Office of Data Science Strategy (ODSS) contracts with DataCite to generate DOIs

Meta Study Module Updates

Newly Implemented Features

- Ability to data transfer with **Globus** – a platform for secure, high-speed data transfers
 - Facilitates connections between BRICS instances and Biowulf
- Allow users to request to archive or delete published data
- Ability to cancel pending requests to archive or delete published data



Uploaded Data

SELECT	DATA FILE NAME	SOURCE	DATA TYPE	DATA CATEGORY	DESCRIPTION	DATE UPLOADED	STATUS
<input type="checkbox"/>	Query Data 1	Query Tool	Query Data	Saved Query	This is a description that is 35 characters and will be... Edit Description	2023-07-11 08:45	Draft
<input type="checkbox"/>	File2.csv	External Edit Source	Biosample	Results	This is a description that is 35 characters and will be... Edit Description	2023-07-11 08:45	Deleted (pending)
<input type="checkbox"/>	Query Data 2	Query Tool	Query Data	Saved Query	Saved Query data Edit Description	2023-07-11 08:45	Deleted (pending)
<input type="checkbox"/>	File1.csv	External Edit Source	Clinical	Results	Description of clinical results data Edit Description	2023-07-11 08:45	Published

Dataset Actions

Change Status:



Demo



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Questions?





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Purpose

To provide an overview of **BRICS CADR implementation**, highlighting **release processes**, **compliance practices**, and **integration efforts** that ensure adherence to **NIH CADR standards**.

Agenda

- What is Controlled Access Data Repository (CADR)?
- BRICS Compliance with CADR Standards
- Documentation Summary
- CADR Phases & Timelines

Controlled Access Data Repository (CADR)

NIH is committed to ensuring that NIH controlled-access data are appropriately safeguarded. The NIH issued “Required Security and Operational Standards for NIH Controlled-Access Data Repositories,” [NOT-OD-25-159](#), to establish detailed security and operational standards for repositories that control access to human data including access management systems that meet the following criteria:

- Part of NIH Programs: Supported by intramural funding, cooperative agreements, contracts, or grants.
- Data Access & Storage: Provide long-term storage and controlled access for research data.
- Controlled Access Reviews: Manage access through prospective review of data requests.
- Federal Oversight: Use or partner with systems that employ federal staff to authorize access.

Repositories meeting these criteria are designated as NIH Controlled-Access Data Repositories (CADRs).

BRICS Compliance with CDR Guidelines

The **NIH CDR Guidebook** outlines required **security and operational standards** (NOT-OD-25-159) for all repositories managing NIH-controlled access data

Key Points

- Provides detailed **procedures** for meeting CDR compliance requirements.
- Defines the **roles and responsibilities** of all involved parties.
- Applies to both **NIH CDRs** and **associated access management systems**.
- Serves as the **primary reference** for ensuring repository adherence to NIH standards.

Reference

- The full **NIH CDR Guidebook** is available on the [NIH Official Website](https://brics.cit.nih.gov).

Documentation Summary

The BRICS team collaborated closely with Operations and respective Program teams to develop and finalize key documents required for CADR compliance.

Key Documents Delivered

- **DAC Charter** (Standardized Charter provided by NIH)
Defines the roles, responsibilities, and governance structure of the Data Access Committee.
- **NIH BRICS CADR SOP**
Standard Operating Procedure outlining the CADR process within the NIH BRICS framework.
- **Corrective Action Audit Workbook**
A structured tool to track and manage audit findings and corrective actions.



CADR Phases & Timelines

Phase 1 (April 2025):

- Received new rules regarding account eligibility:
 - Accounts not permitted for users with free email domains (from a predefined list)
 - Users from countries of concern are restricted
 - Certain companies or institutions are ineligible
 - Individuals appearing on specific restricted lists are not allowed
- Provided users with free email accounts the option to update their email address (managed by Operations)
- Deactivated the accounts of people who match those criteria
- Set rules during sign-up to, if the user matches the criteria, disallow account creation and lock the account
- Set up logging and a report dashboard for any requests that match these criteria

May 2025:

Implemented Security and Oversight Standards: Outlined within the Implementation Guide.

Submitted Corrective Action Plan Workbook: With Risk Mitigation Strategies for Any Controls Not Implemented.

Submitted Attestation Statement: Signed by Senior Official.

Phase 2 (Q4 2025):

Identity Enhancements

Increased identity verification requirements from our identity providers to require Identity Assurance Level 2 (government-ID backed ID verification)

BRICS Team partnered with RAS to ensure system compliance with **Identity Assurance Level 2 (IAL2)** or higher under the CADR initiative.



Phase 2 (Q4 2025):

- **Login.gov** upgraded to IAL2 standards:
 - Includes **facial recognition** and **photo ID + SSN verification**
 - Available **only to users within U.S. territories**
- Introduced **ID.me** as a new IAL2-compliant identity provider:
 - Supports **international and U.S. users**
 - Offers the same identity verification capabilities as Login.gov



Phase 2 (Q4 2025):

Enhanced Logging

Added significant additional logging throughout the system to report, for example:

The requested URL

Request originating IP Address

CADR Name and IC Name

Person's Name (Logged in user's Full Name)

Browser/Client information



BRICS Team has been working on implementing the NIH Controlled Access Data Repository (CADR) requirements from NIH Office of the Director (OCIO and OSP). These consist of both Technical/System Updates Policy and Procedure Updates.

CADR Requirements – Summary View of Group of Requirements (Threat Mitigation Requirements not included in the below table)	Responsible Party	Status for Current BRICS Instances	Time
Access is terminated for all users on the OCIO-provided list of prohibited users and institutions.	BRICS	Completed	April 2025
Data Access Committee (DAC) is chartered, established, and registered in NIH Registry. Standard Operating Procedures (SOPs) will be created.	IC with support from BRICS	Completed	July 2025
Identity verification will be performed for all data requesters and Signing Officials, following CADR guidelines.	BRICS	Completed	August 2025
Added additional logging throughout the system	BRICS	Completed	December 2025
All users will authenticate using Identity Assurance Level 2 (IAL2) security standards, via NIH RAS login.	BRICS	Completed	December 2025
ID.me will be introduced in as an additional identity provider for international users. Note: BRICS currently supports NIH PIV Card, DoD CAC card and Login.gov for RAS Login.	BRICS	Completed	December 2025
Standard Data Use Agreement (DUA) /Data Access Request (DAR) forms will be updated to include clauses required per the CADR guidelines.	IC with support from BRICS	In Progress	January 21 st , 2026



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Questions?

