



BRICS

THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK

Chapter

5

Data Repository



CHAPTER 5 – DATA REPOSITORY

The **Data Repository** is the central hub of the BRICS system, providing functionality to manage study information, and contribute, upload, and store the research data associated with each study.

The Data Repository module is closely related to the Data Dictionary module which provides long term repository for research data.

5.1 OBJECTIVE

The **Data Repository Tool** provides useful features for:

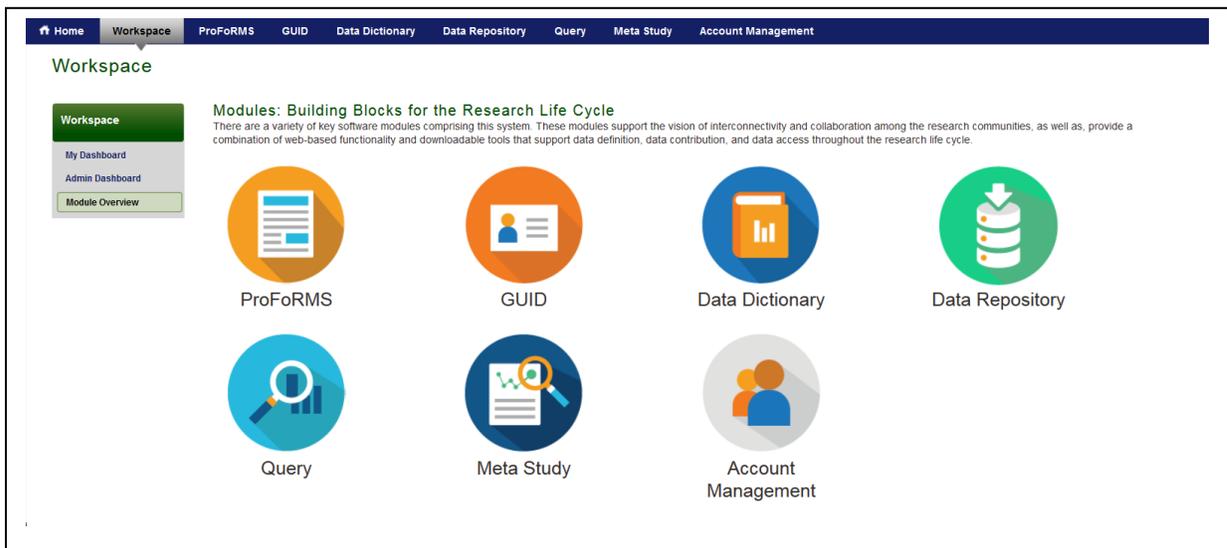
- ❖ Manage Studies
 - View Studies
 - Create a Study
 - Edit a Study
 - Submit Request to Approve Data Document
 - Add Form Structure
 - Search Studies
- ❖ Other Tools: Submission Tools, MIPAV Tool, and Download Tool (See [Chapter 9 MIPAV](#), [Chapter 10 Data Validation](#), and [Chapter 11 Download Tool](#)) are located within the Data Repository module. Please refer to the above-referenced chapters for additional information.

5.2 MODULE NAVIGATION

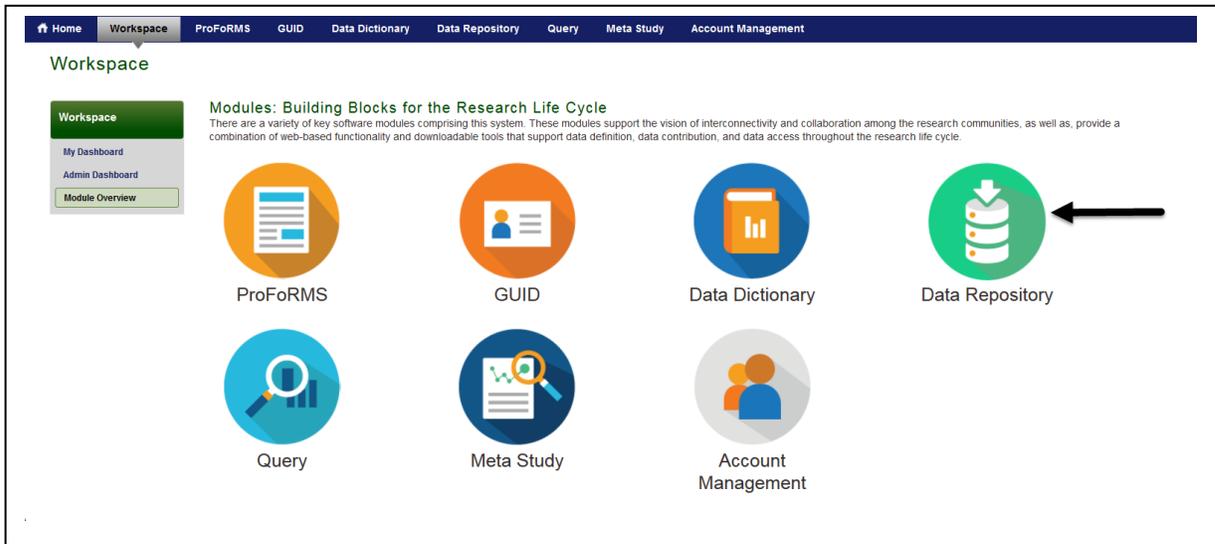
The **Data Repository** module (including sub-modules) are available within the BRICS Workspace

To Access the Data Repository Module: Perform the following actions:

1. Login to the system.
2. Navigate to the Workspace landing page



3. Click the **Data Repository** module icon



ICON KEY

 Notes

 Important
Information

Things to Note:

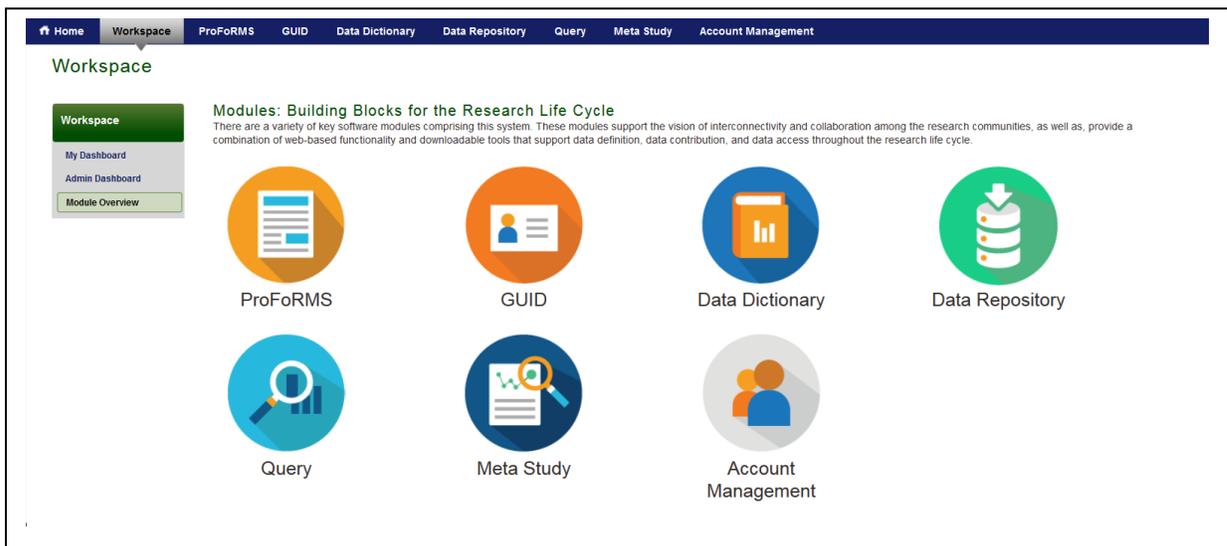
-  The best user experience with navigating through the Data Repository module is with the latest Firefox browser
-  Java Runtime Environment (JRE) version 8 or higher is required. [Check](#) your version of Java.

5.2.1 View Studies

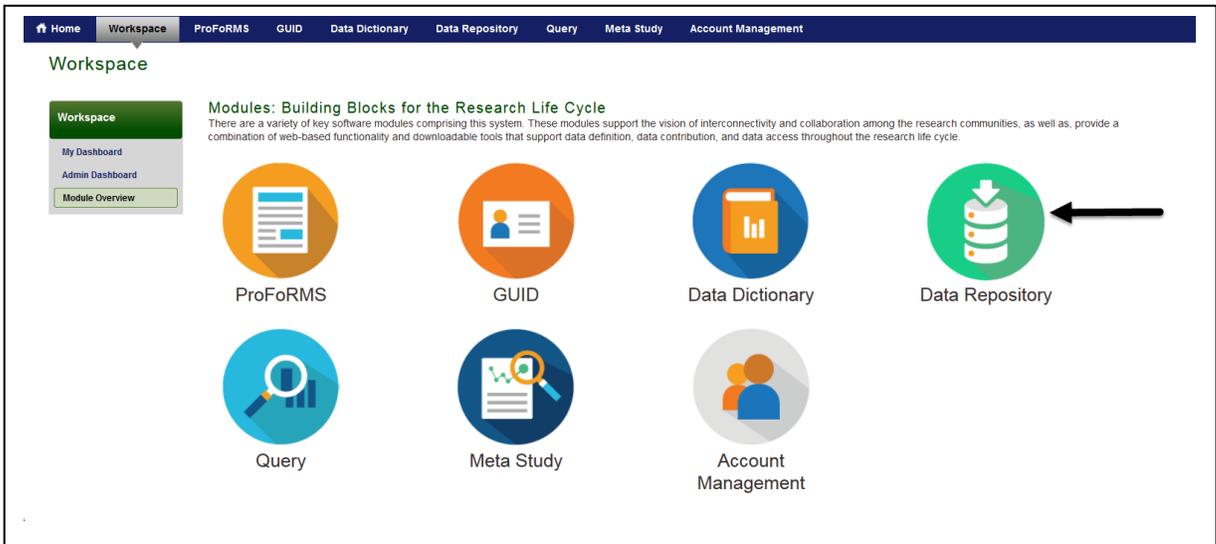
The **View Studies** lists the studies that the user has permission to view. The filters provided within the View Studies list allows users to filter the list by **Ownership**, **Data Submission Status**, and **Data Type**. The search capability allows users to search by: **Study Title**, **Organization**, **Study ID**, **Principle Investigator (PI)**, **Funding Source**, and by the **Permission type** that the user holds for that particular study (Owner, Admin, Read, or Write).

To View Studies in Data Repository: Perform the following actions:

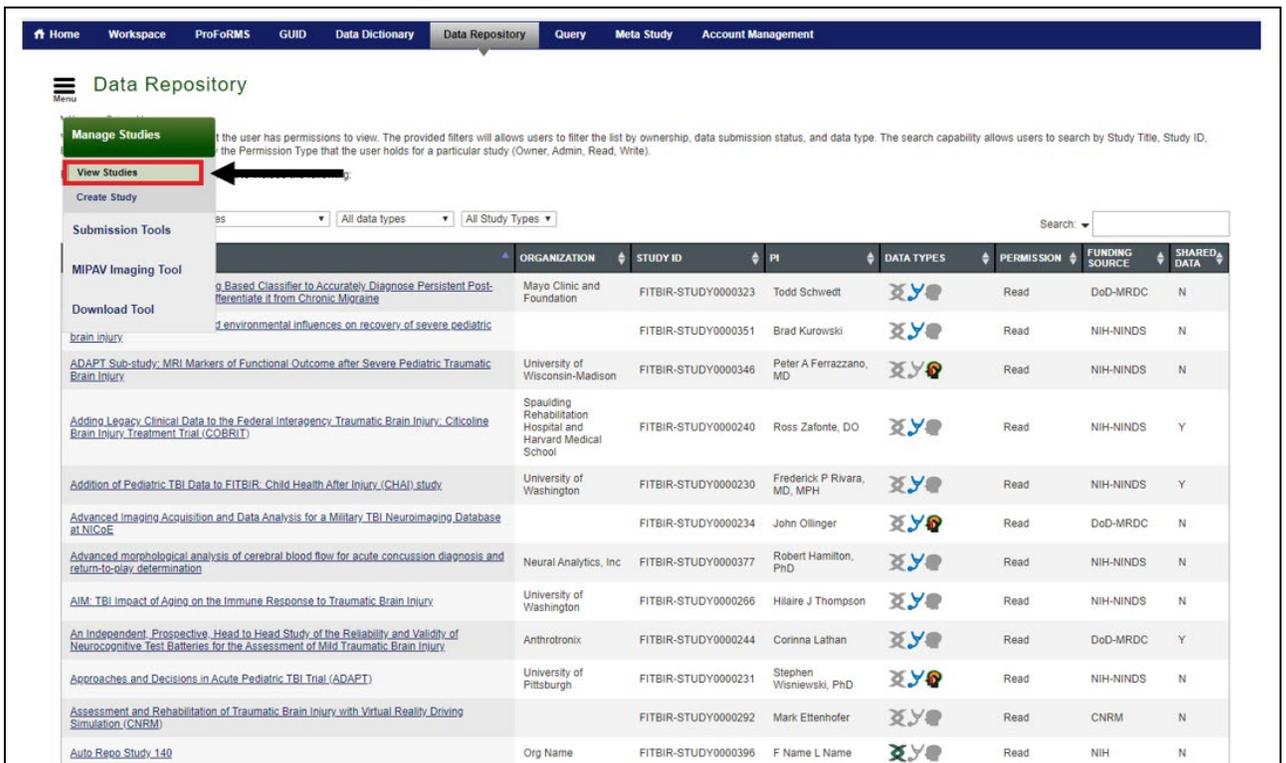
1. Login to the system.
2. Navigate to the Workspace landing page.



3. Click the **Data Repository** module icon.



4. Click the  **Menu** on the left-side tool bar to select the View Studies. **Note:** By default, the system brings you to the View Studies from the Workspace landing page. Results are shown in a tabular format to include the following:



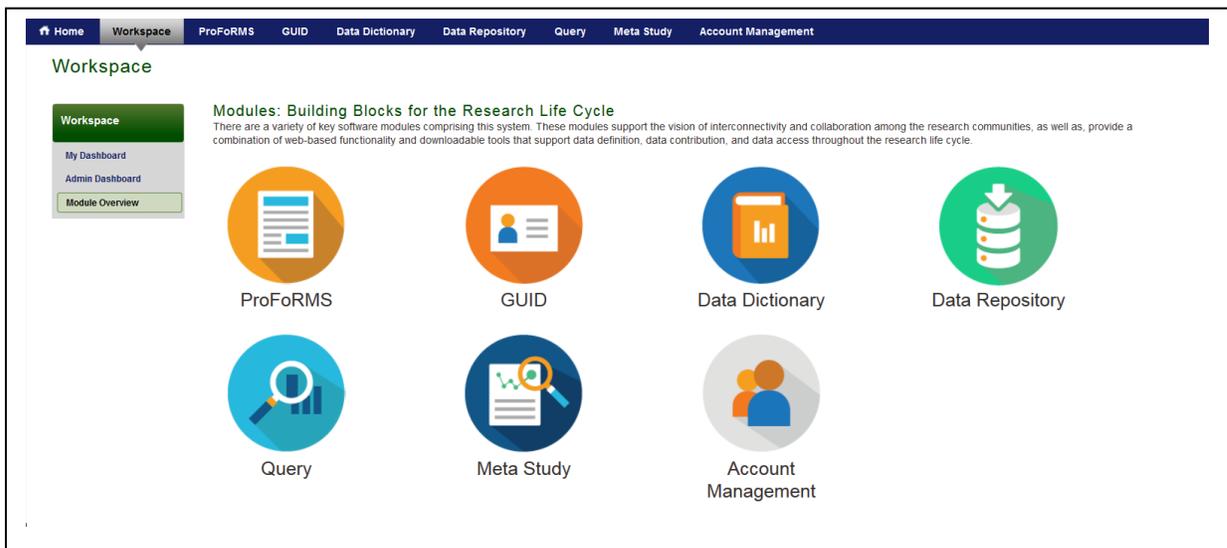
| | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE | SHARED DATA |
|--|--|---------------------|-----------------------------|------------|------------|----------------|-------------|
| MIPAV Imaging Tool | Mayo Clinic and Foundation | FITBIR-STUDY0000323 | Todd Schwedt | | Read | DoD-MRDC | N |
| Download Tool | | FITBIR-STUDY0000351 | Brad Kurowski | | Read | NIH-NINDS | N |
| ADAPT Sub-study: MRI Markers of Functional Outcome after Severe Pediatric Traumatic Brain Injury | University of Wisconsin-Madison | FITBIR-STUDY0000346 | Peter A Ferrazzano, MD | | Read | NIH-NINDS | N |
| Adding Legacy Clinical Data to the Federal Interagency Traumatic Brain Injury, Citicoline Brain Injury Treatment Trial (COBRIT) | Spaulding Rehabilitation Hospital and Harvard Medical School | FITBIR-STUDY0000240 | Ross Zafonte, DO | | Read | NIH-NINDS | Y |
| Addition of Pediatric TBI Data to FITBIR Child Health After Injury (CHAI) study | University of Washington | FITBIR-STUDY0000230 | Frederick P Rivara, MD, MPH | | Read | NIH-NINDS | Y |
| Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database at NlCoE | | FITBIR-STUDY0000234 | John Ollinger | | Read | DoD-MRDC | N |
| Advanced morphological analysis of cerebral blood flow for acute concussion diagnosis and return-to-play determination | Neural Analytics, Inc | FITBIR-STUDY0000377 | Robert Hamilton, PhD | | Read | NIH-NINDS | N |
| AIM: TBI Impact of Aging on the Immune Response to Traumatic Brain Injury | University of Washington | FITBIR-STUDY0000266 | Hilaire J Thompson | | Read | NIH-NINDS | N |
| An Independent, Prospective, Head-to-Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury | Anthrotronix | FITBIR-STUDY0000244 | Corinna Lathan | | Read | DoD-MRDC | Y |
| Approaches and Decisions in Acute Pediatric TBI Trial (ADAPT) | University of Pittsburgh | FITBIR-STUDY0000231 | Stephen Wisniewski, PhD | | Read | NIH-NINDS | N |
| Assessment and Rehabilitation of Traumatic Brain Injury with Virtual Reality Driving Simulation (CNRM) | | FITBIR-STUDY0000292 | Mark Ettenhofer | | Read | CNRM | N |
| Auto Repo Study_140 | Org Name | FITBIR-STUDY0000396 | F Name L Name | | Read | NIH | N |

5.2.2 Edit Studies

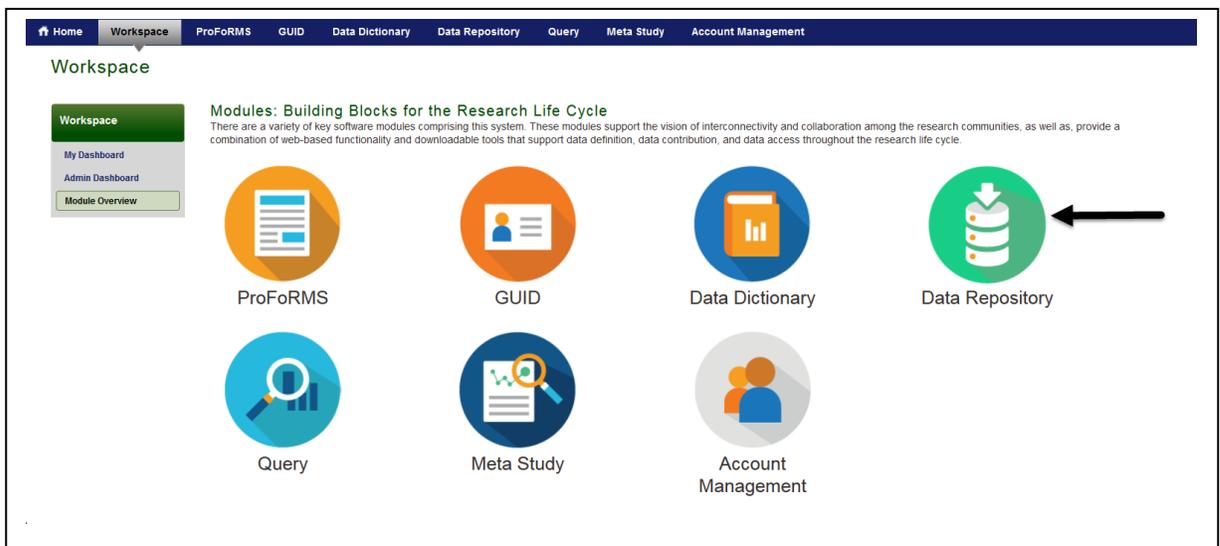
The **Edit Studies** function allows the user to edit studies that the user has permissions to edit.

To Edit Studies in Data Repository: **Perform the following actions:**

1. Login to the system.
2. Navigate to the Workspace landing page.



3. Click the **Data Repository** module icon.



- By default, the system brings you to the View Studies from the Workspace landing page. From the Data Repository View Studies list page, select the study you like to edit by clicking on the study link as shown below:

Home Workspace ProFORMS GUID Data Dictionary Data Repository Query Meta Study Account Management

Data Repository

View Studies

View Studies lists the studies that the user has permissions to view. The provided filters will allow users to filter the list by ownership, data submission status, and data type. The search capability allows users to search by Study Title, Study ID, Principle Investigator (PI), and by the Permission Type that the user holds for a particular study (Owner, Admin, Read, Write).

Results are shown in a tabular format to include the following:

Ownership: all | All studies | All data types | All Study Types | Search

| TITLE | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE | SHARED DATA |
|--|--|--------------------|------------------------------|------------|------------|----------------|-------------|
| A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine | Foundation | FITBR-STUDY0000323 | Todd Schwedt | | Read | DoD-MRDC | N |
| ADAPT Sub-study: Genetic and environmental influences on recovery of severe pediatric brain injury | | FITBR-STUDY0000351 | Brad Kurovski | | Read | NIH-NINDS | N |
| ADAPT Sub-study: MRI Markers of Functional Outcome after Severe Pediatric Traumatic Brain Injury | University of Wisconsin-Madison | FITBR-STUDY0000346 | Peter A. Ferrazzano, MD | | Read | NIH-NINDS | N |
| Adding Legacy Clinical Data to the Federal Interagency Traumatic Brain Injury, Cocaine Brain Injury Treatment Trial (COBRIT) | Spaulding Rehabilitation Hospital and Harvard Medical School | FITBR-STUDY0000240 | Ross Zafonte, DO | | Read | NIH-NINDS | Y |
| Addition of Pediatric TBI Data to FITBR: Child Health After Injury / CHAI study | University of Washington | FITBR-STUDY0000230 | Frederick P. Rivara, MD, MPH | | Read | NIH-NINDS | Y |
| Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database at NIDCD | | FITBR-STUDY0000234 | John Olinger | | Read | DoD-MRDC | N |
| Advanced morphological analysis of cerebral blood flow for acute concussion diagnosis and risk-to-rew determination | Neural Analytics, Inc | FITBR-STUDY0000377 | Robert Hamilton, PhD | | Read | NIH-NINDS | N |
| AIM: TBI Impact of Aged on the Immune Response to Traumatic Brain Injury | University of Washington | FITBR-STUDY0000256 | Hilane J. Thompson | | Read | NIH-NINDS | N |
| An Independent, Prospective, Head-to-Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury | Anthrotronix | FITBR-STUDY0000244 | Corinna Lathan | | Read | DoD-MRDC | Y |
| Approaches and Decisions in Acute Pediatric TBI Trial (ADAPT) | University of Pittsburgh | FITBR-STUDY0000231 | Stephen Wisniewski, PhD | | Read | NIH-NINDS | N |
| Assessment and Rehabilitation of Traumatic Brain Injury with Virtual Reality-Driven Simulation (CNRM) | | FITBR-STUDY0000292 | Mark Eitenhofer | | Read | CNRM | N |
| Automated Comprehensive Evaluation of Mild Traumatic Brain Injury Visual Dysfunction | WOMACK ARMY MEDICAL CENTER | FITBR-STUDY0000326 | Jose E. Capo-Agorta | | Read | DoD-MRDC | Y |
| Biomarker-Driven Development of Experimental Therapeutics for Traumatic Brain Injury (CNRM) | National Institutes of Health Clinical Center (CC) | FITBR-STUDY0000272 | Jessica Gil | | Read | CNRM | Y |
| Biomechanical Basis of Pediatric mTBI Due to Sports-Related Concussion | Virginia Polytechnic Institute and State University | FITBR-STUDY0000274 | Stefan Duma, PhD | | Read | NIH-NINDS | N |
| Blood Biomarker Profile of TBI-Associated Cognitive Impairment Among Old and Young Veterans | University of California, San Francisco | FITBR-STUDY0000334 | Kristine Yaffe, M.D. | | Read | DoD-MRDC | N |

5. The Study Overview page appears. Click the **Edit** button.

Home
Workspace
ProFoRMS
GUID
Data Dictionary
Data Repository
Query
Meta Study
Account Management

Data Repository

[View Studies](#) - A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Study: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Study Overview:

Title: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Study ID: FITBIR-STUDY0000323

Study ID Source: BRICS System Generated

Study DOI:

Study DOI Source:

Visibility: Public

Recruitment Status: Recruiting

Study Type: Other

Study URL:

Therapeutic Agents:

Therapy Types:

Therapeutic Targets:

Model Names:

Model Types:

Abstract: Traumatic brain injury (TBI) and post-traumatic headache (PTH) are common conditions that exert substantial impacts in the military and in the civilian population. TBI is a signature injury of U.S. Soldiers during modern warfare with 20% of Operation Enduring Freedom and Operation Iraqi Freedom Veterans having experienced TBI, 75% of which are mild TBI (mTBI). In addition, approximately 1.7 million American civilians seek medical attention each year for TBI and there are 1.5-3.3 million sports-related mTBIs annually. Headache is the most common symptom following mTBI, with estimates of headache prevalence following mTBI as high as 90%. PTH is often persistent (i.e., endures for >3 months following the injury), with about 66% of people with mTBI reporting continued headaches at 3 months post-injury.

Study Aims:

Start Date: 2015-09-15

End Date: 2018-09-14

Duration: 1095 days

Primary Funding Source: DoD-MRDC

Estimated Number of Subjects:

Study Research Management:

| TITLE | FULL NAME | E-MAIL | ORGANIZATION |
|--------------------------------|-----------|-------------------|----------------------------|
| Primary Principal Investigator | John doe | john.doe@mayo.edu | Mayo Clinic and Foundation |

Showing 1 to 1 of 1 entries First Previous 1 Next Last

Study Site:

| SITE NAME | ADDRESS | CITY | STATE | COUNTRY | PHONE NUMBER |
|--------------------------------------|------------------------|------------|-------|--------------------------|--------------|
| Mayo Clinic and Foundation (Primary) | 13400 E Shea Boulevard | Scottsdale | AZ | United States of America | |

Showing 1 to 1 of 1 entries First Previous 1 Next Last

Administrative Files

Listed below are the administrative files that have been uploaded for your study.

| NAME | TYPE | DESCRIPTION | DATE UPLOADED |
|-------------------------------|--------------------------|--------------------------|------------------|
| FITBIR_Submission_Request.pdf | Data Submission Document | Data Submission Document | 2016-04-27 00:00 |

Showing 1 to 1 of 1 entries First Previous 1 Next Last

Dataset Submissions

Show shared & private

| DATA SET ID | NAME | SUBMISSION DATE | TYPE | STATUS | # OF REC |
|---------------------------|------|-----------------|------|--------|----------|
| No matching records found | | | | | |

Showing 0 to 0 of 0 entries (filtered from 21 total entries) First Previous Next Last

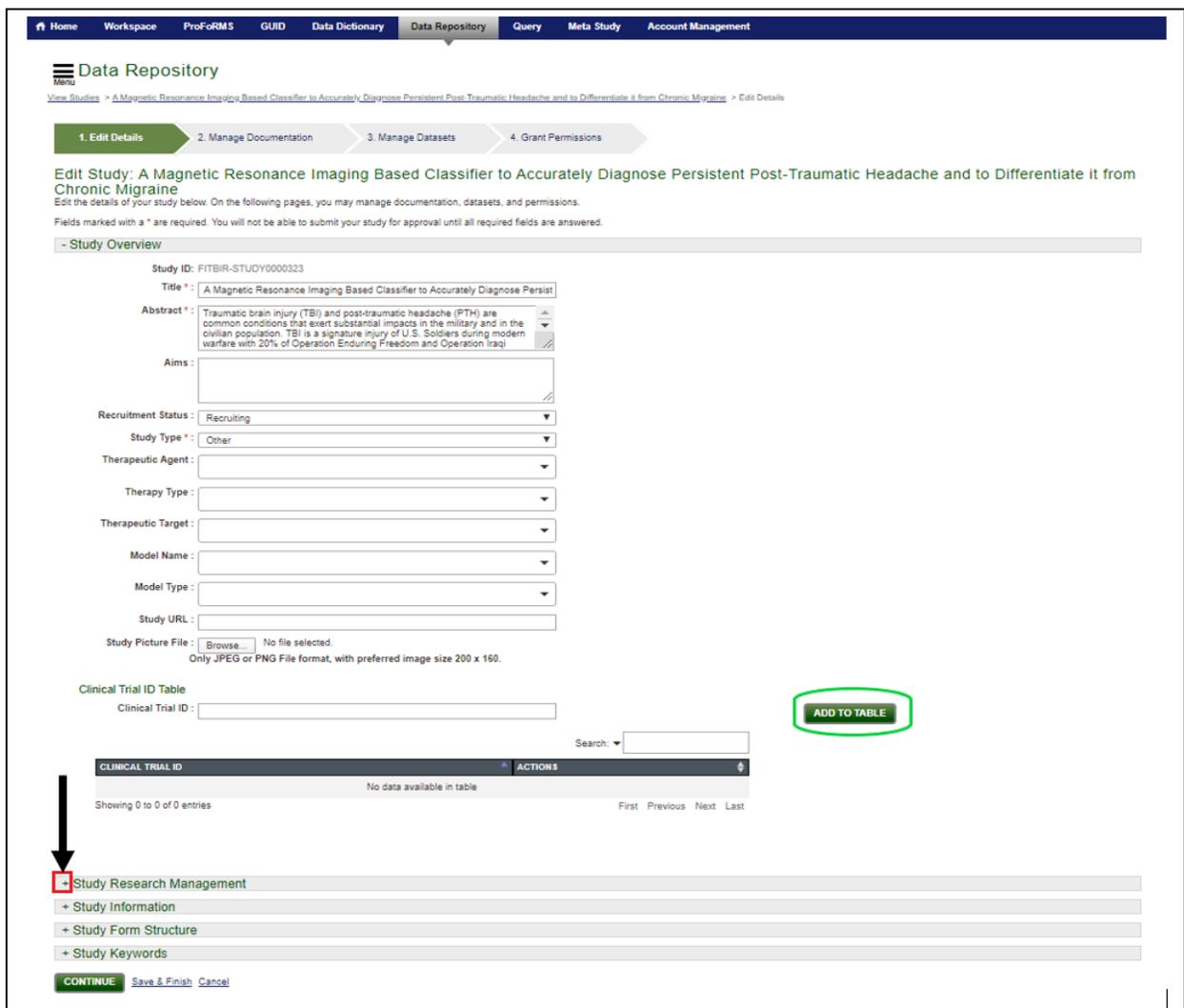
Data Access Report

Time Filter: all Download

| DATA SET ID | NAME | STATUS | USER NAME | DATE | # OF REC | DOWNLOAD LOC. |
|-------------|------|----------|-----------|------------------|----------|-----------------|
| 2042 | | Archived | | 2017-06-13 15:41 | 64 | Data Repository |

6. Edit the details of your study as shown below. Clicking on the **[+]** expansion icon expands the various section (**Study Research Management**, **Study Information**, **Study Form Structure**, and **Study Keywords**) for additional study details.

On the following pages, you may manage **documentation**, **datasets**, and **permissions**. **Note:** Fields marked with an asterisk * are required. You will not be able to submit your study for approval until all required fields are answered.



Home Workspace ProfORMS GUID Data Dictionary Data Repository Query Meta Study Account Management

Data Repository

View Studies > A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine > Edit Details

1. Edit Details 2. Manage Documentation 3. Manage Datasets 4. Grant Permissions

Edit Study: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine
 Edit the details of your study below. On the following pages, you may manage documentation, datasets, and permissions.
 Fields marked with a * are required. You will not be able to submit your study for approval until all required fields are answered.

- Study Overview

Study ID: FITBIR-STUDY0000323

Title *: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Abstract *: Traumatic brain injury (TBI) and post-traumatic headache (PTH) are common conditions that exert substantial impacts in the military and in the civilian population. TBI is a signature injury of U.S. Soldiers during modern warfare with 20% of Operation Enduring Freedom and Operation Iraq

Aims:

Recruitment Status: Recruiting

Study Type *: Other

Therapeutic Agent:

Therapy Type:

Therapeutic Target:

Model Name:

Model Type:

Study URL:

Study Picture File: No file selected.
 Only JPEG or PNG File format, with preferred image size 200 x 160.

Clinical Trial ID Table

Clinical Trial ID:

Search:

ADD TO TABLE

| CLINICAL TRIAL ID | ACTIONS |
|----------------------------|---------|
| No data available in table | |

Showing 0 to 0 of 0 entries First Previous Next Last

- Study Research Management

+ Study Information

+ Study Form Structure

+ Study Keywords

CONTINUE Save & Finish Cancel

7. Click the **Continue** button when complete.

Home Workspace ProFoRMS GUID Data Dictionary **Data Repository** Query Meta Study Account Management

Data Repository

View Studies > A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine > Edit Details

1. Edit Details 2. Manage Documentation 3. Manage Datasets 4. Grant Permissions

Edit Study: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Edit the details of your study below. On the following pages, you may manage documentation, datasets, and permissions.

Fields marked with a * are required. You will not be able to submit your study for approval until all required fields are answered.

- Study Overview

Study ID: FITBIR-STUDY0000323

Title *:

Abstract *:

Aims:

Recruitment Status:

Study Type *:

Therapeutic Agent:

Therapy Type:

Therapeutic Target:

Model Name:

Model Type:

Study URL:

Study Picture File: No file selected.
Only JPEG or PNG File format, with preferred image size 200 x 160.

Clinical Trial ID Table

Clinical Trial ID:

Search:

| CLINICAL TRIAL ID | ACTIONS |
|----------------------------|---------|
| No data available in table | |

Showing 0 to 0 of 0 entries First Previous Next Last

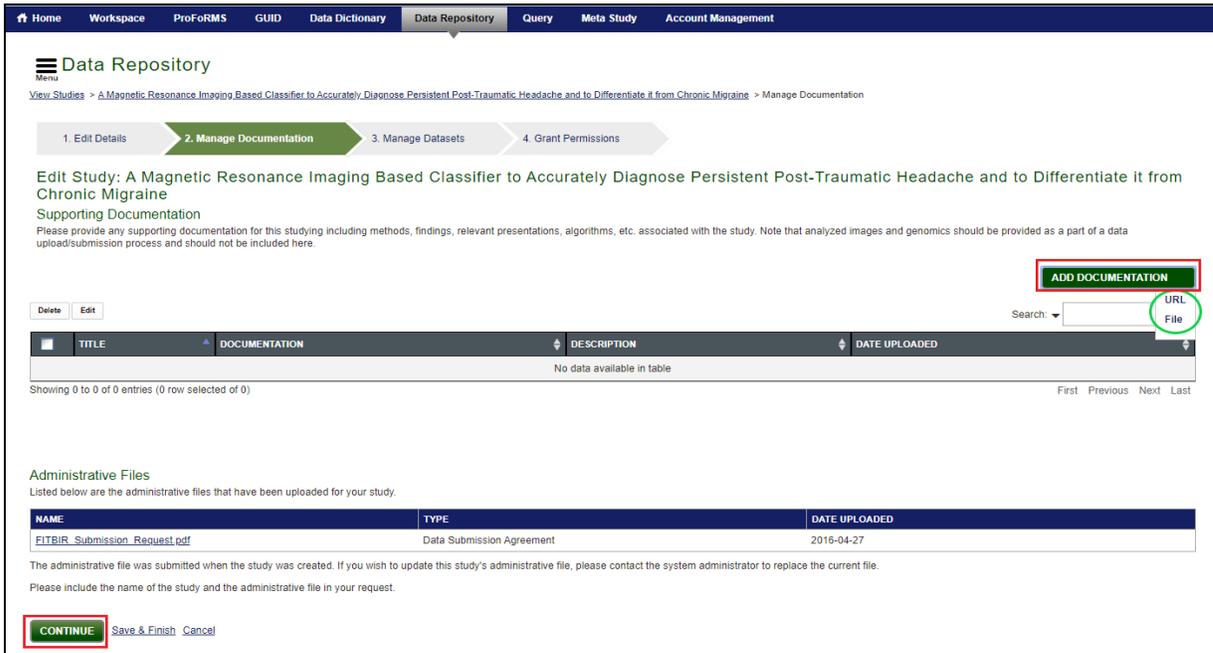
+ Study Research Management

+ Study Information

+ Study Form Structure

+ Study Keywords

8. Manage Documentation: Click the **Add Documentation** button to select the desired file or URL to upload. Click the **Continue** button.



Home Workspace ProFoRMS GUID Data Dictionary **Data Repository** Query Meta Study Account Management

Data Repository

View Studies > A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine > Manage Documentation

1. Edit Details 2. **Manage Documentation** 3. Manage Datasets 4. Grant Permissions

Edit Study: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Supporting Documentation

Please provide any supporting documentation for this studying including methods, findings, relevant presentations, algorithms, etc. associated with the study. Note that analyzed images and genomics should be provided as a part of a data upload/submission process and should not be included here.

Delete Edit Search: URL
File

| TITLE | DOCUMENTATION | DESCRIPTION | DATE UPLOADED |
|----------------------------|---------------|-------------|---------------|
| No data available in table | | | |

Showing 0 to 0 of 0 entries (0 row selected of 0) First Previous Next Last

Administrative Files

Listed below are the administrative files that have been uploaded for your study.

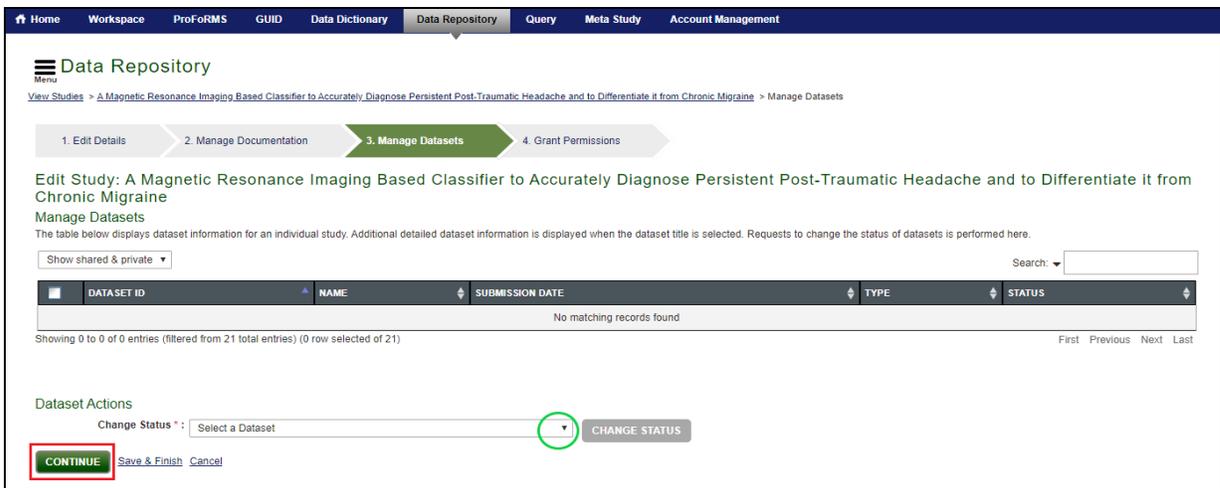
| NAME | TYPE | DATE UPLOADED |
|---|---------------------------|---------------|
| FITBIR_Submission_Request.pdf | Data Submission Agreement | 2016-04-27 |

The administrative file was submitted when the study was created. If you wish to update this study's administrative file, please contact the system administrator to replace the current file.

Please include the name of the study and the administrative file in your request.

CONTINUE Save & Finish Cancel

9. Manage Datasets: In the table below, the dataset information for an individual study is displayed when the dataset title is selected. You may request change to the status of datasets from here by selecting the drop-down menu beside “**Change Status**” to select a Dataset. Click the **Continue** button.



Home Workspace ProFoRMS GUID Data Dictionary **Data Repository** Query Meta Study Account Management

Data Repository

View Studies > A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine > Manage Datasets

1. Edit Details 2. Manage Documentation 3. **Manage Datasets** 4. Grant Permissions

Edit Study: A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine

Manage Datasets

The table below displays dataset information for an individual study. Additional detailed dataset information is displayed when the dataset title is selected. Requests to change the status of datasets is performed here.

Show shared & private Search:

| DATASET ID | NAME | SUBMISSION DATE | TYPE | STATUS |
|---------------------------|------|-----------------|------|--------|
| No matching records found | | | | |

Showing 0 to 0 of 0 entries (filtered from 21 total entries) (0 row selected of 21) First Previous Next Last

Dataset Actions

Change Status * : ▼ CHANGE STATUS

CONTINUE Save & Finish Cancel

10. In the **Grant Permissions** section, individual access to the study profile and datasets can be granted to users during submission. The different permissions are **Read, Write, and Admin**. Other users will have Read access once the datasets have been shared.

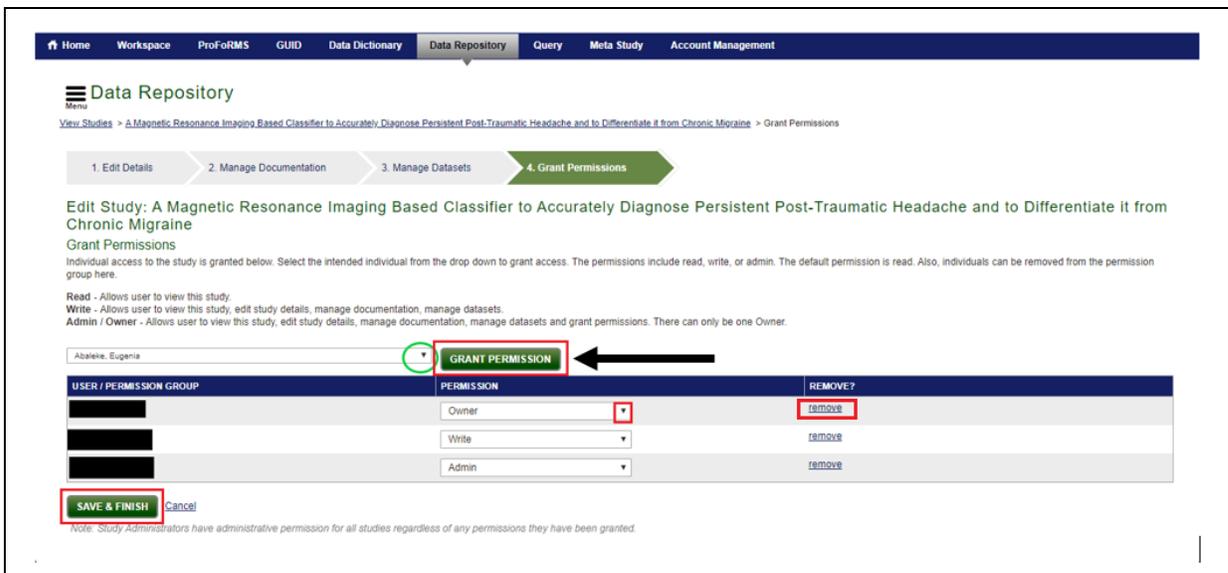
To grant access to study team members to the study profile and datasets, select a username from the Drop Down list. Click on the **Grant Permission** button. Select the permission access for the user. Note: Study Administrators have administrative permissions for **ALL** studies regardless of any permissions they have been granted. To remove users from the study profile, click **Remove**. Click **Save & Finish** to complete the process.

Below are the descriptions for the different permissions:

Read - Allows user to view this study.

Write - Allows user to view this study, edit study details, manage documentation, and manage datasets.

Admin / Owner - Allows user to view this study, edit study details, manage documentation, manage datasets and grant permissions. There can only be one Owner.

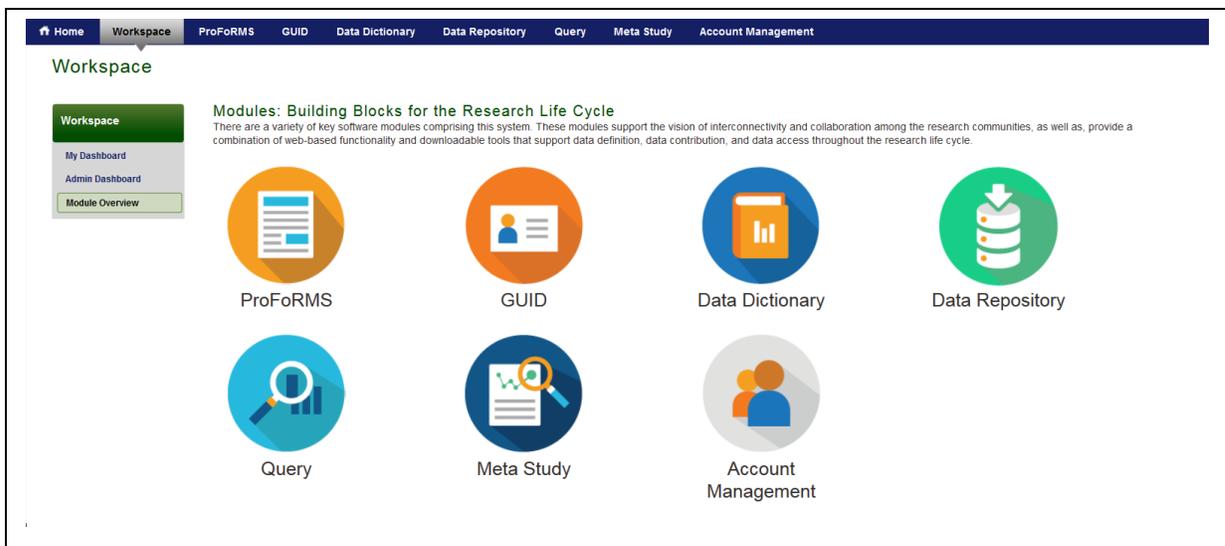


5.2.3 Create Study

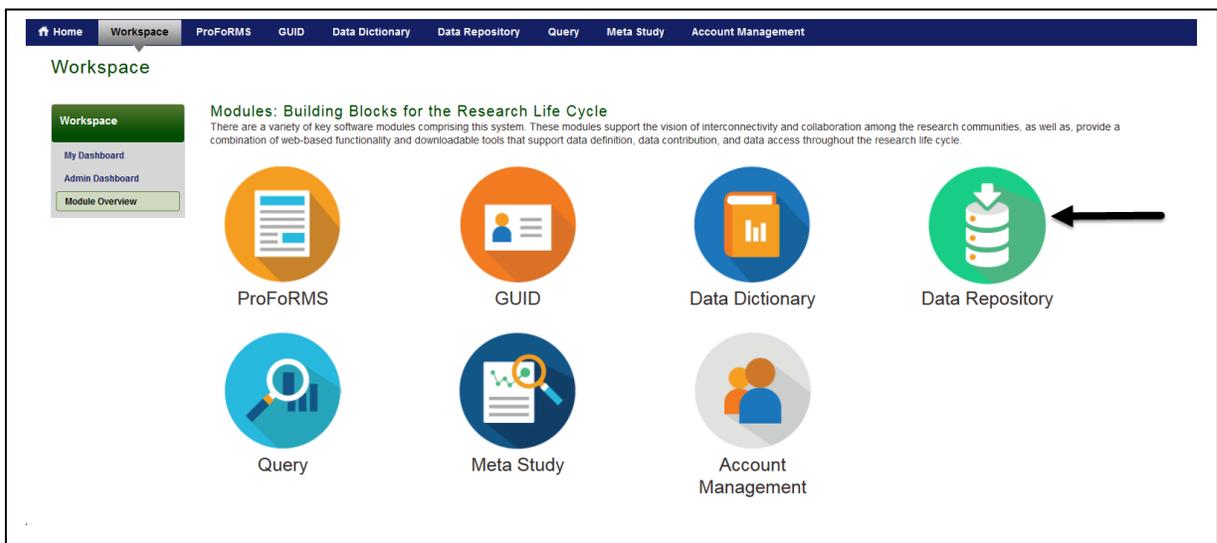
The **Create Study** functionality allows users with permission to create a study by providing the relevant information requested and submitting the request which will be reviewed by a BRICS Systems Administrator. Once approved by the Systems Administrator, users may begin to submit data to the system.

To Create a Study in Data Repository: Perform the following actions:

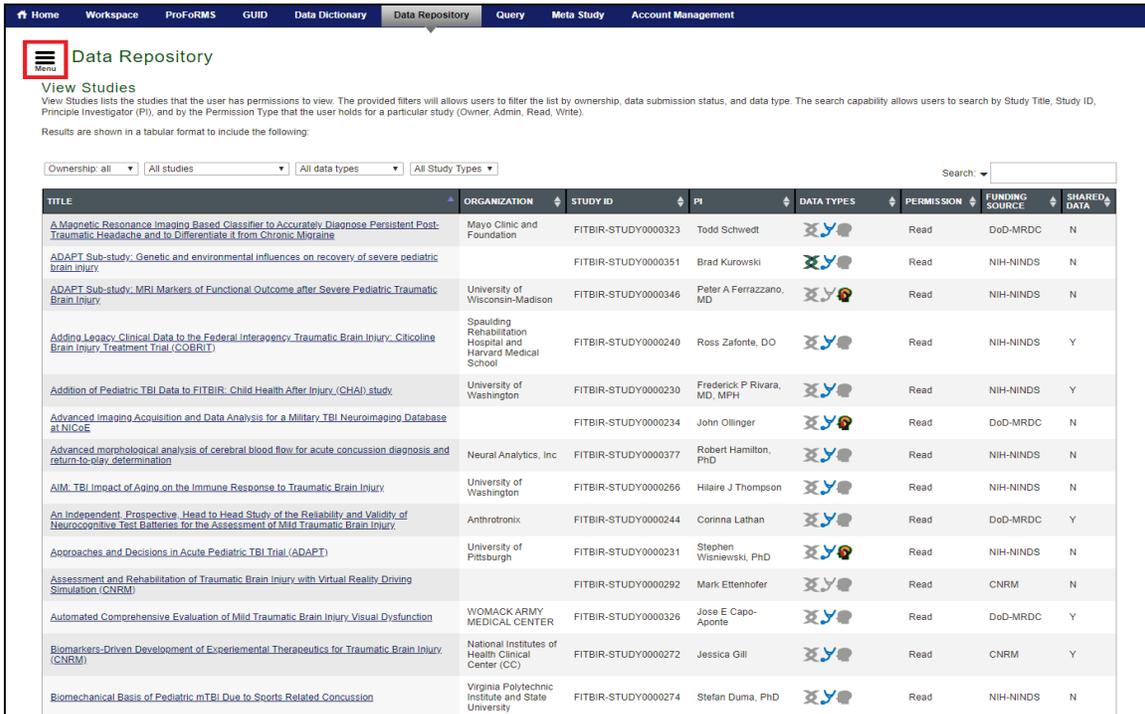
1. Login to the system.
2. Navigate to the Workspace landing page.



3. Click the **Data Repository** module icon.



- Click the  on the left-side tool bar. The Data Repository Tool menu opens and expands.



The screenshot shows the 'Data Repository' section of the application. A red box highlights the 'Menu' icon in the top left corner. Below the navigation bar, there are filters for 'Ownership: all', 'All studies', 'All data types', and 'All Study Types'. A search bar is also present. The main content is a table with the following columns: TITLE, ORGANIZATION, STUDY ID, PI, DATA TYPES, PERMISSION, FUNDING SOURCE, and SHARED DATA.

| TITLE | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE | SHARED DATA |
|--|--|---------------------|-----------------------------|------------|------------|----------------|-------------|
| A Magnetic Resonance Imaging Based Classifier to Accurately Diagnose Persistent Post-Traumatic Headache and to Differentiate it from Chronic Migraine | Mayo Clinic and Foundation | FITBIR-STUDY0000323 | Todd Schwedt | | Read | DoD-MRDC | N |
| ADAPT Sub-study: Genetic and environmental influences on recovery of severe pediatric brain injury | | FITBIR-STUDY0000351 | Brad Kurowski | | Read | NIH-NINDS | N |
| ADAPT Sub-study: MRI Markers of Functional Outcome after Severe Pediatric Traumatic Brain Injury | University of Wisconsin-Madison | FITBIR-STUDY0000346 | Peter A Ferrazzano, MD | | Read | NIH-NINDS | N |
| Adding Legacy Clinical Data to the Federal Interagency Traumatic Brain Injury, Cilicoline Brain Injury Treatment Trial (COBRIT) | Spaulding Rehabilitation Hospital and Harvard Medical School | FITBIR-STUDY0000240 | Ross Zafonte, DO | | Read | NIH-NINDS | Y |
| Addition of Pediatric TBI Data to FITBIR - Child Health After Injury (CHAI) study | University of Washington | FITBIR-STUDY0000230 | Frederick P Rivara, MD, MPH | | Read | NIH-NINDS | Y |
| Advanced Imaging Acquisition and Data Analysis for a Military TBI Neuroimaging Database at NIDCD | | FITBIR-STUDY0000234 | John Ollinger | | Read | DoD-MRDC | N |
| Advanced morphological analysis of cerebral blood flow for acute concussion diagnosis and return-to-play determination | Neural Analytics, Inc | FITBIR-STUDY0000377 | Robert Hamilton, PhD | | Read | NIH-NINDS | N |
| AIM: TBI Impact of Aging on the Immune Response to Traumatic Brain Injury | University of Washington | FITBIR-STUDY0000266 | Hilare J Thompson | | Read | NIH-NINDS | N |
| An Independent, Prospective, Head-to-Head Study of the Reliability and Validity of Neurocognitive Test Batteries for the Assessment of Mild Traumatic Brain Injury | Anthronix | FITBIR-STUDY0000244 | Corinna Lathan | | Read | DoD-MRDC | Y |
| Approaches and Decisions in Acute Pediatric TBI Trial (ADAPT) | University of Pittsburgh | FITBIR-STUDY0000231 | Stephen Wisniewski, PhD | | Read | NIH-NINDS | N |
| Assessment and Rehabilitation of Traumatic Brain Injury with Virtual Reality Driving Simulation (CNRM) | | FITBIR-STUDY0000292 | Mark Ettenhofer | | Read | CNRM | N |
| Automated Comprehensive Evaluation of Mild Traumatic Brain Injury Visual Dysfunction | WOMACK ARMY MEDICAL CENTER | FITBIR-STUDY0000326 | Jose E Capo-Aponte | | Read | DoD-MRDC | Y |
| Biomarkers-Driven Development of Experimental Therapeutics for Traumatic Brain Injury (CNRM) | National Institutes of Health Clinical Center (CC) | FITBIR-STUDY0000272 | Jessica Gill | | Read | CNRM | Y |
| Biomechanical Basis of Pediatric mTBI Due to Sports Related Concussion | Virginia Polytechnic Institute and State University | FITBIR-STUDY0000274 | Stefan Duma, PhD | | Read | NIH-NINDS | N |

- Select **Create** under Form Structures from the left-hand drop-down menu. The Create Study general details page appears.



The screenshot shows a sidebar menu titled 'Manage Studies'. It contains several options: 'View Studies', 'Create Study' (highlighted with a red box), 'Submission Tools', 'MIPAV Imaging Tool', and 'Download Tool'.

Study Overview: Complete all required fields marked with an *asterisk:

- ❖ Title*
- ❖ Abstract*
- ❖ Aims
- ❖ Recruitment Status
- ❖ Study Type*
- ❖ Therapeutic Agent
- ❖ Therapy Type
- ❖ Therapeutic Target
- ❖ Model Name
- ❖ Model Type
- ❖ Study URL
- ❖ Study Picture File
- ❖ Clinical Trial ID

Study Research Management: Complete all required fields marked with an *asterisk:

- ❖ Role*
- ❖ First Name*
- ❖ Middle Initial
- ❖ Last Name*
- ❖ Suffix
- ❖ E-Mail
- ❖ Organization Name*
- ❖ ORCID
- ❖ Picture File

Study Information: Complete all required fields marked with an *asterisk:

- ❖ Site Name*
- ❖ Address
- ❖ Country
- ❖ City
- ❖ Phone Number
- ❖ Start Date*
- ❖ End Date*
- ❖ Estimated Number of Subjects
- ❖ Primary Funding Source*

- ❖ Grant/Project ID

Study Form Structure:

- ❖ Form Structures

Study Keywords:

- ❖ Associated Keywords

7. Fill out the general details below to create a study. On the following pages, you may attach data elements and apply permissions. Fields marked with a * are required.

Home Workspace ProFoRMS GUID Data Dictionary **Data Repository** Query Meta Study Account Management

Data Repository

Create Study

Please enter your study information below. Once you've completed the mandatory fields, click the submit button. Your study request will be reviewed by a system administrator. Once the system administrator approves your request, you can start submitting data to the study.

Fields marked with a * are required. You will not be able to submit your study for approval until all required fields are answered.

- Study Overview

Title *

Abstract *

Aims:

Recruitment Status:

Study Type *

Therapeutic Agent:

Therapy Type:

Therapeutic Target:

Model Name:

Model Type:

Study URL:

Study Picture File: No file selected.
Only JPEG or PNG File format, with preferred image size 200 x 160.

Clinical Trial ID Table

Clinical Trial ID:

[ADD TO TABLE](#)

Search:

| CLINICAL TRIAL ID | ACTIONS |
|----------------------------|---------|
| No data available in table | |

Showing 0 to 0 of 0 entries First Previous Next Last

- Study Research Management

[ADD TO TABLE](#)

Research Management Table

Search:

| ROLE | FULL NAME | E-MAIL | ORGANIZATION | ORCID |
|--------------------------|--------------|----------|------------------------|-------|
| <input type="checkbox"/> | Data Manager | Jane Doe | Jane.Doe@dbc4brics.org | NIH |

Showing 1 to 1 of 1 entries (0 row selected of 1) First Previous **1** Next Last

- Study Information

Site Name * Primary Site

Address Line 1:

Address Line 2:

Country:

City:

Phone Number:

Site Table

[ADD TO TABLE](#)

Search:

| SITE NAME | ADDRESS | CITY | STATE | COUNTRY | PHONE NUMBER | ACTIONS |
|----------------------------|---------|------|-------|---------|--------------|---------|
| No data available in table | | | | | | |

Showing 0 to 0 of 0 entries First Previous Next Last

8. Click the **Submit Request** button. **Note:** Your study cannot be approved if the required data submission documentation(s) are not uploaded. Remember to submit your Approved Submission document.

Start Date * :

End Date * :

Estimated Number of Subjects :

Primary Funding Source * :

Grant ID Table

GrantProject ID :

Search:

| GRANT ID | ACTIONS |
|----------------------------|---------|
| No data available in table | |

Showing 0 to 0 of 0 entries First Previous Next Last

+ Study Form Structure

+ Study Keywords

Approved Data Submission Document
Your study cannot be approved until you upload the required documentation. Please upload your Approved Submission document.

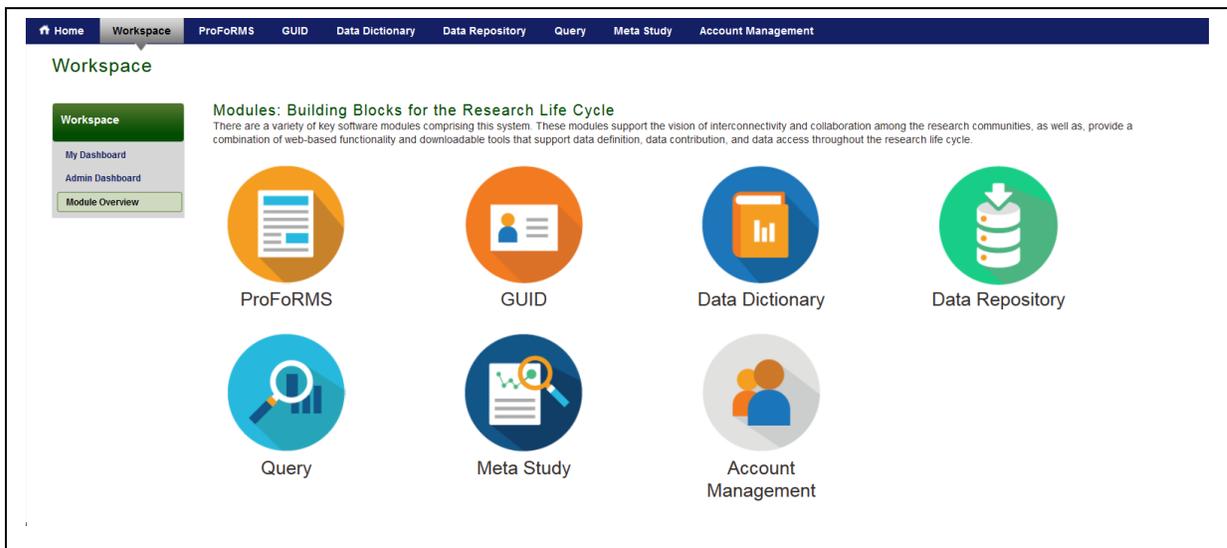
Data Submission Document * : No file chosen

5.2.4 Search Studies

The search capability allows users to search by **Study Title**, **Study ID**, **Principle Investigator (PI)**, and by the **Permission Type** that the user holds for a particular study (Owner, Admin, Read, or Write).

To Search Studies in Data Repository: **Perform the following actions:**

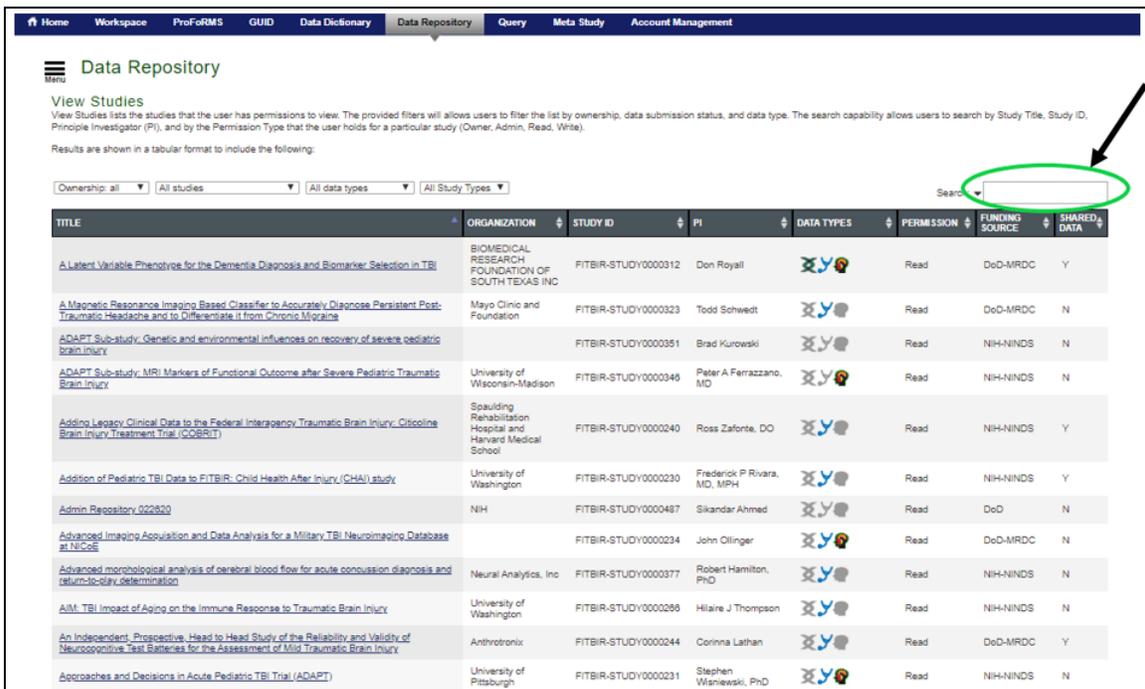
1. Login to the system.
2. Navigate to the Workspace landing page.



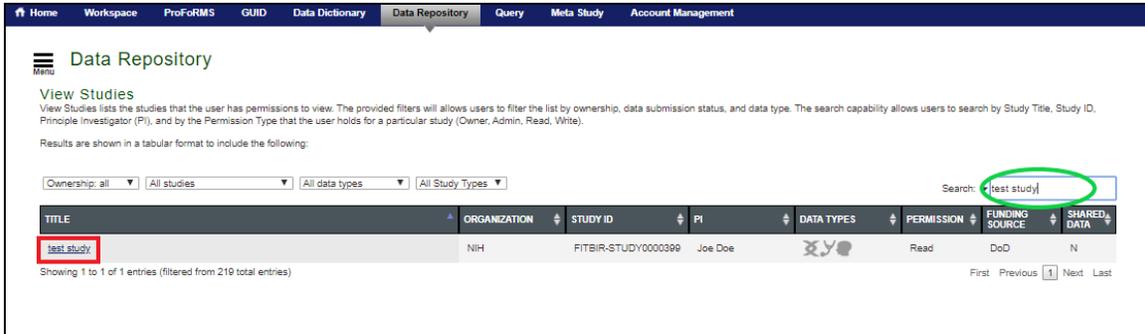
3. Click the **Data Repository** module icon.



4. By default, the system brings you to the View Studies from the Workspace landing page. In the search text-box, enter the **Study Title, Study ID, Principle Investigator (PI), and/or** by the **Permission Type** that the user holds for a particular study (Owner, Admin, Read, or Write).



5. In this example, “test study” was used for the search. The study appears in the View Studies list page as shown below:



Data Repository

View Studies

View Studies lists the studies that the user has permissions to view. The provided filters will allow users to filter the list by ownership, data submission status, and data type. The search capability allows users to search by Study Title, Study ID, Principle Investigator (PI), and by the Permission Type that the user holds for a particular study (Owner, Admin, Read, Write).

Results are shown in a tabular format to include the following:

Ownership: all | All studies | All data types | All Study Types

Search: test study

| TITLE | ORGANIZATION | STUDY ID | PI | DATA TYPES | PERMISSION | FUNDING SOURCE | SHARED DATA |
|------------|--------------|---------------------|---------|---|------------|----------------|-------------|
| test study | NIH | FITBIR-STUDY0000399 | Joe Doe |  | Read | DoD | N |

Showing 1 to 1 of 1 entries (filtered from 219 total entries)

First Previous 1 Next Last



THIS PAGE HAS BEEN LEFT INTENTIONALLY BLANK
