Assessment Information

CoreTrustSeal Requirements 2020–2024

Repository:	The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System
Website:	https://fitbir.nih.gov/
Requirements version:	CoreTrustSeal Requirements 2023-2025
This repository is owned by:	**Center for Information Technology (CIT)**
Created at:	March 28, 2024, 5:11 p.m.

CORE TRUSTWORTHY DATA REPOSITORIES REQUIREMENTS

Background Information

Re3data Identifier

Please fill you Re3data identifier from the website: https://www.re3data.org/

Response:

The persistent identifiers for FITBIR listed in re3data.org (https://www.re3data.org/repository/r3d100012837) are the following:

- RRID:SCR_006856
- RRID:nlx_151755
- FAIRsharing_doi:10.25504/fairsharing.rz7h29

Repository type

Please select your repository type.

Response:

- Specialist repository

Overview

Provide a short overview of key characteristics of the repository, reflecting the repository type selected. This should include information about the scope and size of data collections, data types and formats. Further contextual information may also be added.

Research supported by the Center for Information Technology (CIT), National Institute of Neurological Disorders and Stroke (NINDS) at the National Institutes of Health (NIH), Department of Health and Human Services (DHHS) and the Department of Defense (DoD), strives to understand, and treat traumatic brain injury (TBI).

Sharing of data is a cornerstone for modern biomedical research. The goal of such data sharing is to accelerate research by allowing aggregation, re-analysis, and rigorous comparison with other data, tools, and methods. Community-wide sharing requires reasonable data sharing policies that do not undermine the integrity of the individual research studies, acknowledge the contributions of the data collectors, and promote collaboration, but also allow for new and/or dissenting assessments. To accomplish these goals, informatics systems also benefit from common data element (CDE) definitions, standards, and user-friendly interfaces for uploading, accessing, and analyzing data. Funding institutions have a vested interest in providing access to data generated by their grantees because it will increase the return on investment by accelerating the testing of new hypotheses, allowing multi-study data aggregation to increase the statistical power for analysis, and providing existing comparator data and identifying patterns not easily extracted from a single study.

CIT at NIH leads the continuous development of the Biomedical Research Informatics Computing System (BRICS) (https://www.cit.nih.gov/about-cit/scientific-application-services; http://brics.cit.nih.gov) platform, which is a comprehensive data informatics system designed to enable biomedical researchers to efficiently collect, validate, harmonize, and analyze research datasets. The BRICS project is committed to supporting the Findable, Accessible, Interoperable, Reusable (FAIR) principles to advance research for the scientific community.

The Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system, a BRICS instance, that is seeking Core Trust recertification, uses these principles to aggregate and harmonize data for the TBI research community. A more detailed description for FITBIR is provided in subsequent sections.

The FITBIR informatics system (https://fitbir.nih.gov/) was developed as part of a White House initiative and has been incorporated into the National Research Action Plan (NRAP) to advance research in support of improved diagnosis and treatment for service members and civilians who have sustained a TBI. The National Research Action Plan (NRAP) is a 10-year blueprint for interagency research to enhance the diagnosis, prevention, and treatment of TBI, posttraumatic stress disorder (PTSD), and to improve suicide prevention. It was released on August 10, 2013, by President Barack Obama. The aims include improving prevention, diagnosis, and treatment of TBI and other mental health conditions such as Post Traumatic Stress Disorder (PTSD) that affect veterans and their families. The findings resulting from NRAP will be rapidly translated into new effective prevention strategies and clinical innovations, as well as identify biomarkers to detect these disorders early and accurately. FITBIR was named the data repository for the TBI research data collected under this directive. FITBIR is an extensible, scalable informatics platform for TBI that includes relevant imaging, clinical assessments, genomics, and other data types that will enable the DoD, the NIH, and other federal agencies and stakeholders to (1) utilize a common platform for standardization of definitions and data elements, tools, and outcome measurements, (2) apply bioinformatics solutions to data collection, storage, access, and analysis, (3) leverage current and future investments in TBI research by integrating datasets from numerous small and large studies, and (4) share de-identified data and collaborate on scientific research projects, including comparative effectiveness research studies on optimal treatments and diagnostic tools. Sharing data, methodologies, and associated tools, rather than summaries or interpretations of this information, can accelerate research progress by allowing re-analysis of data, as well as re-aggregation, integration, and rigorous comparison with other data, tools, and methods. This community-wide sharing requires common data definitions and standards, as well as comprehensive and coherent informatics approaches. Clear lines of authority are required to ensure that decision making is both efficient and representative of FITBIR's stakeholders. The organizational relationships for FITBIR are summarized in Figure 1 provided in ANNEX A.

Figure 1:
Governance for FITBIR is shared across the various committees identified in Figure 1 that includes the Governance Committee, Executive Committee, Strategic Vision Committee, Policy Committee and Data Access and Quality Committee. These committees also provide guidance for the development work provided by Publicis Sapient. A detailed description of the relationships between the relevant organizations with regards to FITBIR is provided in Section R5.

Information for Figure 1, organizational relationships, is publicly available on the FITBIR website, in the section "What is FITBIR", under the frequently asked questions (FAQs) at https://fitbir.nih.gov/content/frequently-asked-questions.

Designated Community

A clear definition of the Designated Community demonstrates that the applicant understands the scope, knowledge base, and methodologies—including preferred software/formats—of the group(s) of users at whom the curation and preservation measures are primarily targeted. The definition should be specific so that reviewers can assess whether that community is being served in the responses to other requirements.

Response:

FITBIR was developed to create a secure, centralized research repository to advance comparative effectiveness research in support of improved diagnosis and treatment for those who have sustained a TBI. As of January 2024, there are 184 primary research studies in FITBIR, spanning more than a hundred Principal Investigators (PIs), dozens of universities and research systems, with data submitted for 101,000+ subjects, including 295,000+ clinical image datasets. Additionally, Program Announcement from the DoD/ Defense Health Program (DHP)/ Congressionally Directed Medical Research Program (CDMRP)/ Joint Program Committee-6/Combat Casualty Care Research Program (CCCRP) entitled 'Federal Interagency Traumatic Brain Injury Research Analysis Award Announcement -Opportunity Number: W81XWH-19-PHTBIRP-FITBIRA' was released in 2019. Funding for the FITBIR Analysis award supports studies utilizing existing FITBIR data.

The TBI research community includes scientific, consumer advocacy communities, and the public at large interested in brain injuries. These include all organizations and TBI investigators, including international organizations, Government Agencies within the United States, Extramural Organizations that include academic institutions, biotechnology companies, foundations, other Federal Government organizations outside the US, and research institutes as well as intramural organizations within the DoD and NIH. TBI researchers are provided access, through a Data Access and Quality Committee (DAQ), to the data (clinical assessment, imaging, genomics) and can use the system query tool to harmonize and aggregate data across studies. Additionally, the FITBIR public site provides summary data (https://fitbir.nih.gov/content/submitted-data) and its visualization (https://fitbir.nih.gov/visualization) for a quick snapshot of the data available in the informatics system.

With close to 5.99 million records housed in FITBIR, equating to 101,149 subjects, our presence within the traumatic brain injury community has grown and our interactions at conferences have sparked many interested researchers to learn more. We support users by training them in how to use the FITBIR system and help them set their studies up to make the process as easy as possible. We have had over 241.7million records downloaded by users interested in the data stored within FITBIR in 2023 alone.

Levels of Curation

Please fill you level(s) of curation.

Response:

- D. Data-level curation – as in C above, but with additional editing of deposited data

Levels of Curation - explanation

Please add the description for your Level(s) of Curation.

Response:

- Ph.D. level of curation for Metadata and data is provided by the FITBIR and BRICS lead curator and the supporting operations team.
- The FITBIR Data Dictionary and Data Repository modules enable validation of study data and metadata. Any modifications to data structures in the Data Dictionary of datasets in the Data Repository are recorded and viewable to users through a version history log and accompanying metadata.
- Each primary research study in the FITBIR Data Repository undergoes a quality control check (referred to as a "study closeout analysis") before the data is shared with FITBIR Data Access users. FITBIR Operations runs a series of python scripts that analyze the data for consistency and potential issues including: (1) missing subject demographic information (2) duplicate records (3) partial data (4) incorrect instrument scoring or data entry and (5) subject identification inconsistencies across records. A separate quality check is performed for imaging data (if applicable) that analyzes images for: (1) duplicates (2) unnecessary images (3) subject identification inconsistencies across records and (4) potential personal identifiable information (PII). These findings are compiled in a report sent to the study team and -- with further discussion and clarification -- any remaining issues are resolved. This may take the form of resubmissions that are given a new dataset ID and whose relationship to other datasets can be specified with a link. Once the data has passed these quality checks and the finalized datasets have been verified by the study team, the data is shared within FITBIR.
- If a study team notifies FITBIR operations that their shared datasets need to be revised, these datasets are archived, corrected datasets are resubmitted (and given a new dataset ID), and users who had previously accessed the now archived datasets are notified of the change. Flags,

descriptions, and dataset links can be utilized to further annotate datasets and specify contextual information e.g., reason for archiving.

Cooperation and outsourcing to third parties, partners and host organisations

Please describe any cooperation and outsourcing to third parties, partners and host organisations.

Response:

Publicis Sapient is the primary contractor and considered an outsource partner based on the support they provide for BRICS/FITBIR initiative. The governance and requirements of the system are provided by the system owners (DoD, NINDS, CIT). The system owners are also Data Stewards with Publicis Sapient providing development and subject matter expertise to address evolving science. Publicis Sapient has extensive experience as a contractor organization working on Federal government IT initiatives. The staff of 34 full-time and 7 part-time employees includes programmers, bioinformaticians, database administrators, and project managers. Publicis Sapient provides support for the development and management of the system as well as subject matter expertise for the data and metadata in the repository. Subject matter experts are also part of the Policy and DAQ committees. More details are provided in the next few paragraphs. A list of partners and relationships is provided in the table (in ANNEX A) and as a list below. None of the partners listed below have undertaken a trustworthy repository assessment specifically for FITBIR.

• NIH-CIT: Insource Partner, Organizational Relationship
• NIH-NINDS: Insource Partner, Organizational Relationship
• DoD: Insource Partner, Organizational Relationship
• Veterans Affairs (VA): Insource Partner, Organizational Relationship
• Publicis Sapient: Outsource Partner, Contractual Relationship

Publicis Sapient is responsible for [1] computational and project management [2] analytical support and [3] resource administration [4] bioinformatics Software Integration and Support

Publicis Sapient works with the customer to define, prioritize, and document requirements. The team of Business Analysts, Software Engineers, and Subject Matter Experts further decomposes the information into detailed functional, technical, security, and performance requirements. This includes engaging the project development and test teams to ensure that requirements are valid, testable, and realistic.To determine the best modeling technique based on how well the structures are defined, volume and frequency of updates, Publicis Sapient takes a measured approach to how the data will be accessed and stored. The team uses an iterative development of platform independent conceptual models to identify data relationships. These conceptual models drive the design of the data store, taking into account requirements around data analytics pipelines, storage needs, data access, and data reporting or visualization requirements. Publicis Sapient's domain experts at CIT have expertise in modeling complex data sets such as high throughput gene expression, RNA-Seq, SNPs and sequence variation, and integrating them into a single model on analytics platforms using statistical computing languages like R and Python.

While designing system architecture, Publicis Sapient architects consider the business vision and requirements, user base and their locations, security, scalability and performance, latest technology trends, flexibility and extensibility, data volume and storage, organization culture and talent, and total cost of ownership. For bioinformatics systems, an additional design emphasis is placed on modeling and managing data so that researchers can establish relationships, test their hypotheses, and turn data into knowledge that may lead to discoveries.

Please see Figure 1 in section R0 (brief description of the repository) as well as the table included in this section, for details on the organizational relationships.

Applicants renewing their CoreTrustSeal certification: summary of significant changes since last application.

Please fill this field when you are renewing your CoreTrustSeal Certification.
This field can be marked with not applicable (N.A.) if you are acquiring a CoreTrustSeal certificate for the first time.

Response:

Since the last application (certification date: August 5th, 2020), there have been numerous enhancements to system security, functionality, data curation, and user experience. A high-level summary of key changes is included below:

• New JavaScript-based Submission and Download tools
o Previously, users would submit and download data via a downloadable Java Webstart application; however, numerous study sites (e.g., the VA) ran into difficulty downloading these executables due to their site's IT security measures in place. FITBIR has now implemented browser-based Submission and Download tools that run from within the FITBIR portal site in any internet browser. This enhancement has mitigated previous security concerns and simultaneously improved the user experience.

• Security fixes
o With regular CIT penetration testing, BRICS can identify and address potential security vulnerabilities. Since the last application, has addressed vulnerabilities related to cross site scripting (XSS), cross site request forgery (CSRF), insecure direct object reference, and old webservice endpoints that were insecure. More information on security fixes with each software release can be found on the BRICS Release Notes page (https://brics.cit.nih.gov/release-notes)

• API integration
o FITBIR now provides users with API access to the following modules: Query Tool, Data Repository, and Data Dictionary. Users can now utilize FITBIR functionality with their preferred scripting language and build more complex data workflows and pipelines.

• Improved user experience
o With input from user experience (UX) engineers at Publicis Sapient, FITBIR has made significant aesthetic changes to the user interface on the FITBIR portal site. Some of the main changes include improved menu organization and interaction, and improved navigation and display of the Data Repository and Data Dictionary modules.

• Improved Query functionality
o Major improvements to the Query Tool Module include: faster data load times, the ability to search across all studies and forms by individual Global Unique Identifiers (GUIDs), the ability to define and save queries, the ability to hide data columns, the ability to toggle how data values are formatted, the addition of subject count to studies and form structures, and the addition of permissible value count metrics that allows users to easily see the distribution of data values for particular data types in a dataset.

• Improved summary data visualizations and metrics
o FITBIR has made numerous graphical and organizational improvements to the Summary Data Visualization (https://fitbir.nih.gov/visualization) and Summary Data (https://fitbir.nih.gov/content/submitted-data) pages, allowing users to more easily understand what data exists in FITBIR. Users can easily view and download important study details such as participant age ranges, participant gender, and total number of images for a given imaging modality. For very common measures in the TBI community such as the Glasgow Coma Scale (GCS) (https://fitbir.nih.gov/gcs-visualization) and the Glasgow Outcome Scale-Extended (GOSE) (https://fitbir.nih.gov/gos-e-visualization), FITBIR has provided useful summary data visualizations that help users get a sense of how these measures change over time for participants in FITBIR studies.

• Enhanced data interoperability
o In 2022, FITBIR received an NOT-OD-22-069 Award “Support for existing data repositories to align with FAIR and TRUST principles and evaluate usage, utility, and impact”. As part of our proposal to align with FAIR principles, we have begun the process of assigning Unified Medical Language System (UMLS) concept unique identifiers (CUI) to FITBIR data elements and permissible values. This allows users to more easily map FITBIR data to datasets comprised of other source vocabularies. In addition, it makes FITBIR data more machine readable.

• Improved account management and security
o FITBIR has improved account management and security by automating the process of locking and deactivating accounts based on inactivity. An account will be locked after 365 days of inactivity and deactivated after a further 180 days of inactivity. Furthermore, FITBIR has enhanced its Account module with improved dashboard and table views for easier account management by the FITBIR Operations team.

• Enhanced Data Repository features
o Studies in the FITBIR Data Repository can now be grouped together into study groups that specify various relationships between studies e.g., primary study vs. secondary study, follow-up study, or other. Datasets within a study can now be linked as well, allowing users to follow the versioning of submissions.

• Biosample ordering integration
o FITBIR has integrated NINDS-funded TBI study biosample ordering capabilities by interfacing with the BioSEND API (https://biosend.org/). Users approved for biosample ordering can now query and order from the BioSEND biosample catalog from within the FITBIR Query Tool module and filter their selections with form joins based on existing participant data in the FITBIR database.

Organisational Infrastructure

R1 Mission & Scope (R01)

R01. The repository has an explicit mission to provide access to and preserve digital objects.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

FITBIR Informatics System is a central repository that was developed by the NIH, in collaboration with the DOD, to promote collaboration, accelerate research, and advance knowledge on the characterization, prevention, diagnosis, and treatment of TBI. FITBIR’s mission (https://fitbir.nih.gov/content/about) is to provide researchers access to a common platform for digital object collection, retrieval, sharing, and preservation. Importantly, FITBIR is designed to support NIH FAIR data sharing goals including:

• Create an integrated environment that broadens the usefulness of scientific data and advances hypothesis-driven and hypothesis-generating research.
• Accelerate scientific discovery while extending the value of scientific data in all areas of TBI research.
• Promote rapid availability of important findings, making discoveries available to the research community for further analysis and interpretation.
• Provide policies for data management. The general policy information is available at https://fitbir.nih.gov/content/policies-and-procedures.
• Data Preservation: Long term preservation of data has been addressed in detail in section R9.

Data management is addressed via the data submission, sharing and access policies.

Data Access Policy: https://fitbir.nih.gov/sites/fitbir/files/inline-files/FITBIR_Data_Access_Request_DUC.pdf
Data Submission Policy: https://fitbir.nih.gov/sites/fitbir/files/inline-files/FITBIR_Submission_Request.pdf
Data Sharing policy: https://fitbir.nih.gov/sites/fitbir/files/inline-files/FITBIR_Data_Sharing_Policy_final.pdf

Link:

About | FITBIR (nih.gov)

R2 Rights Management (R02)

R02. The repository maintains all applicable rights and monitors compliance.

Compliance level:

Implemented: the requirement has been fully implemented by the repository –

Response:

- FITBIR is governed by policies and not licenses per se. These policies are in place to address and protect data, its management, and usage. None of the landing pages will provide information on licenses or policies except for the ones documented in the next point. All signed policies by the investigators are private and are only available behind an authenticated system. These are not and will not be made publicly available as the information is considered PII.
- The FITBIR policies are documented at https://fitbir.nih.gov/content/policies-and-procedures
- FITBIR only accepts de-identified human subject data to comply with applicable laws and regulations. Users, granted access by the DAQ, are permitted to use the data in any lawful way but not reshare the data. Any updates regarding the FITBIR policy are relayed to users via email they used when registering to access the repository.
- User accounts are audited and require yearly renewal with updated user documentation.
- The policy content is always available at the FITBIR Website.
- A Certificate of Confidentiality (CoC) has been issued by NIH for FITBIR protecting the privacy of research subjects by prohibiting disclosure of identifiable, sensitive research information to anyone not connected to the research except when the subject consents or in a few other specific situations. The CoC is available on the FITBIR public site at https://fitbir.nih.gov/sites/fitbir/files/inline-files/Confidentiality%20Certificate_FITBIR_0.pdf. Please see attached CoC for your convenience.

The FITBIR operations team has internal processes in place to train the members through the process of data management from ingestion to dissemination. This includes training for FITBIR policies (data sharing, data submission, data access), de-identification of data supported by use of a GUID – a Privacy Preserving Record Linkage (PPRL) system, guidelines/rules for data validation during the submission process, study closeout analysis and mitigation strategies in the event of disclosure risks to the data submitted. These processes are documented on Confluence internally for the FITBIR team and are not shared on the public site.

All submitted data are initially kept in a private status and is only viewable by user accounts with explicit permissions granted by the study administrator. Once a study team has completed their data submissions, a study closeout analysis is performed by a member of the FITBIR Operations team to verify that the information received by FITBIR is complete (i.e., not missing records intended for submission), contains no identifying information, displays correctly, and that the FITBIR Toolset functions as expected with the information. Only after this process is complete and the study team verifies the accuracy and completeness of their data, can the study data be set to a shared status and thus viewable to FITBIR Data Access users.

Submitting investigators and their institutions may use the GUID as a means to request removal of data on individual participants from the FITBIR Informatics System in the event that a research participant withdraws his/her consent. However, data that has been distributed for approved research use will not be retrieved. FITBIR has a data access report which contains the following information which datasets were downloaded, when, by whom, and from where.

Investigators submitting datasets to FITBIR are expected to certify that an appropriate Institutional Review Board (IRB) has considered such risks and that the data have been de-identified in accordance with DOD and NIH regulations before the data are submitted. In addition, in the event that requests raise questions or concerns related to privacy and confidentiality, risks to populations or groups, or other relevant topics, the FITBIR Data Access and Quality Committee (DAQ) will consult with other experts as appropriate.

FITBIR Policies for users can be found at: https://fitbir.nih.gov/content/policies-and-procedures. Failure by the investigators to follow these policies perils their grants and institutional access. See section R4 for the language on termination of access.

Links:

- Certificate of Confidentiality
- policies-and-procedures

R3 Continuity of Service (R03)

R03. The Repository has a plan to ensure ongoing access to and preservation of its data and metadata.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

FITBIR has been funded by a Memorandum of Understanding (MOU) mechanism by the DoD and NIH since 2012 and a new MOU has been signed by all parties and extends through FY2025. The MOU is an efficient mechanism available to government agencies to foster collaboration between the agencies

without the restrictions of strict contract terms or the time it takes to award a contract. These are still binding terms that need to be met by all the agencies involved with the flexibility to add requirements as needed. The MOU is a proprietary document that contains confidential information.

Contracts and MOUs are not/nor will be publicly available on the website to protect confidentiality and proprietary information. The funding commitment will ensure the continued availability and accessibility of the TBI data. Nonetheless, the nature of budgetary decisions and obligations by the Federal Government cannot be ascertained beyond the specified MOU period; therefore, ensuring data availability beyond that commitment is not guaranteed but is likely as specified in section R09, Preservation Plan.

The FITBIR informatics system (developed by CIT and its contractor) has been funded by the government as defined by the NINDS/DoD MOU, therefore, the funding agencies assume responsibility for long-term preservation. The stakeholders at DoD/NINDS internally review current contract performance before the end of the existing contract cycle to decide whether another contract period will be supported. In the event another contract period is supported, the current contract includes a clause to handle continuity of access to repository data whether the current contractor is selected for the next contract period or not. In such a hypothetical situation, the data will be preserved and transferred to the next contractor. More specifically, the contractor shall coordinate with the incumbent contractor and the Government to implement an orderly, secure, and efficient transition of contract activities and contract-generated data, systems, analytical tools and other documents and materials, and to ensure a seamless continuation of contract services and operation of FITBIR during the transition period. The technical details of the FITBIR system and architecture with other relevant documentation are publicly available on the BRICS Home page at https://brics.cit.nih.gov/.

If funding is discontinued, the Governance committee will determine preservation options for the submitted data. During that time data will be archived and stored on a secure server. The current MOU has options in place to address non-continuity of funding and data preservation. This is described in detail in section R09, Preservation Plan, along with a detailed contingency plan.

In the meantime, FITBIR has a contingency plan in place for long term preservation and management of data in the event of non-funding. All access to data is managed and owned by the funding agencies. Please see details below.

FITBIR Contingency Data Plan

Scenario 1: NINDS chooses not to support or use the FITBIR system.

CIT would continue to support the DoD and their grantees. All DoD grantees would continue to submit data using the standard workflows and Standard Operating Procedures (SOPs). CIT would continue to support the FITBIR system and infrastructure.
There are two options for consideration for NINDS data housed in FITBIR:
1. All NINDS funded studies and associated data files would be made private in FITBIR, no new NINDS data could be submitted to FITBIR, all NINDS supported user accounts would be deactivated. All NINDS study data would continue to be housed within the existing FITBIR database, or
2. All NINDS funded studies and associated data files would be removed from the FITBIR database and placed in a storage location defined by NINDS and at NINDS's cost. All NINDS supported user accounts would be deactivated. Upon written notification, CIT will perform the agreed upon aforementioned option.

Scenario 2: DoD chooses not to fund or use the FITBIR system. Upon written notification, CIT will

1. Immediately stop supporting DoD data submission to FITBIR and disable all DoD user accounts.
2. Immediately stop development of FITBIR software for the DoD
3. Support the DoD effort to contract with an appropriate storage location (e.g. cloud) and use funds from the MOU to support the movement of the data files to the DoD specified storage location, assuming enough funds are available on contract. If no funds are available, contingency funds must be made available to start the work. Data transfer will be completed within 90 days after notification.

This process assumes notification 90 days in advance of the contractor's period of performance (POP) ending date. If the DoD notifies the NIH less than 90 days before the POP, the DoD and NIH will negotiate the process of the DoD providing funding for a contractor to move the data to a new storage location.

This process also assumes data files are transferred and not transformed to be stored in another database. Transforming data to be loaded into another database is a major data curation project with significant costs.

Scenario 3: Both DoD and NINDS choose not to fund or use the FITBIR system. Upon written notifications, CIT will:

1. Immediately stop supporting DoD and NINDS data submissions to FITBIR and disable all user accounts.
2. Immediately stop development of FITBIR software
3. Support the DoD and NINDS efforts to contract with an appropriate repository and use any remanding funds from the MOU to support the movement of the data files to the specified storage location(s), assuming enough funds are available on contract. If no funds are available, contingency funds must be made available to support the work. Data transfer will be completed within 90 days after notification.

This process assumes notification 90 days in advance of the contractor's POP ending date. If the shutdown is requested less than 90 days before the POP, the DoD and NIH will negotiate the process of moving the data to a new storage location.

This process also assumes data files are transferred and not transformed to be stored in another database. Transforming the data to be loaded into another database is a major data curation project with significant costs.

Link:

- BRICS Home Page

R4 Legal & Ethical (R04)

R04. The repository ensures to the extent possible that data and metadata are created, curated, preserved, accessed and used in compliance

with legal and ethical norms.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

The FITBIR informatics system complies with disciplinary and ethical norms by ensuring de-identification of the data to protect privacy as stipulated by laws such as The Health Insurance Portability and Accountability Act (HIPAA). Funded research that generates the data must also meet such obligations including IRB review and compliance with human subjects' regulations and laws such as informed consent. The FITBIR Data Sharing policies also specifies the legal ways in which the data may be used (https://fitbir.nih.gov/sites/fitbir/files/inline-files/FITBIR_Data_Sharing_Policy_final.pdf) which are consistent with disciplinary and ethical norms.

Data submitted to the FITBIR Informatics System is de-identified such that the identities of data subjects cannot be readily ascertained or otherwise associated with the data by the FITBIR staff or secondary data users. In addition, de-identified data will be coded using a unique code known as a GUID. Use of the GUID minimizes risks to study participants because it keeps one individual's information separate from that of another person without using names, addresses, or other identifying information. The unique code also allows FITBIR to link together all submitted information on a single participant, giving researchers access to information that may have been collected elsewhere. The GUID is a computer-generated alphanumeric code [example: 1A462BS] that is unique to each research participant (i.e., each person's information in FITBIR—or each subject's record—has a different GUID). FITBIR will assist investigators in how to create the GUID, which is an essential requirement for uploading data to FITBIR.

Investigators submitting datasets to FITBIR are expected to certify that an appropriate IRB has considered such risks and that the data have been de-identified in accordance with DOD and NIH regulations before the data are submitted. In addition, in the event that requests raise questions or concerns related to privacy and confidentiality, risks to populations or groups, or other relevant topics, the FITBIR DAQ will consult with other experts as appropriate.

Submissions of data to FITBIR shall be accompanied by a certification signed by the Principal Investigator, and stored in the FITBIR system, to assure that:

- The data submission is consistent with all applicable laws and regulations, as well as institutional policies.
- The appropriate research uses of the data and the uses that are explicitly excluded by the informed consent documents are delineated.
- The identities of research participants will not be disclosed to the FITBIR Informatics System; and
- An IRB of the submitting institution and/or Privacy Board, as applicable, reviewed and verified that:
- The submission of data to the FITBIR Informatics System and subsequent sharing for research purposes are consistent with the informed consent of study participants from whom the data were obtained.
- The investigator's plan for de-identifying data sets is consistent with the standards outlined above.
- The risks to individuals, their families, and groups or populations associated with data submitted to the FITBIR Informatics System have been considered; and
- The genotype and/or phenotype data to be submitted were collected in a manner consistent with DOD and NIH regulations and policies.
- In the event an IRB determines GUID generation is not all permissible, an alternate ID can be issued to submit data to FITBIR. This alternate ID is called a Pseudo GUID. A Pseudo GUID is a unique ID that should only be used if a researcher is unable to generate a valid GUID due to insufficient PII for a participant or if an IRB denies GUID generation. A Pseudo-GUID is a unique ID that is not based on PII. Funding agencies must approve all Pseudo GUID requests.

Applications submitted to these agencies for support of TBI research in which the above expectations for data submission cannot be met will be considered for funding on a case-by-case basis by the relevant agency. Investigators are encouraged to submit a short list of planned papers on primary and secondary study objectives to their science officers when negotiating data sharing requirements.
The SOPs for submitters for these are policies are available publicly on the FITBIR site at:
https://fitbir.nih.gov/content/standard-operating-procedures

FITBIR staff are required to take mandatory training developed and administered by NIH annually in the area of Information Security and Information Management with additional modules specifically if you work with biomedical data. As described in section R4, The FITBIR operations team has a set of internal SOPs to address data access requests, de-identification of data and management of data within the secure system. These are available on an internal content management system that is not available publicly. The FITBIR operations team uses these SOPs to train the team members through the process of data management from ingestion to dissemination. This includes trainings for FITBIR policies (data sharing, data submission, data access), de-identification of data through the use of a GUID, guidelines/rules for data validation during the submission process, study closeout analysis and mitigation strategies in the event of disclosure risks to the data submitted. These processes are documented and internal to the FITBIR team and are not shared on the public site.

Investigators submitting datasets to FITBIR are expected to certify to the operations team that an appropriate IRB has considered such risks and that the data have been de-identified in accordance with DOD and NIH regulations before the data are submitted. In addition, in the event that requests raise questions or concerns related to privacy and confidentiality, risks to populations or groups, or other relevant topics, the FITBIR DAQ will consult with other experts as appropriate.

Only after the study closeout process is completed by FITBIR Operations and the study team (see R02) can the study data be set to a shared status and thus viewable to FITBIR Data Access users.

Data downloaded from FITBIR is mandated to be destroyed once finished using the data or when access to FITBIR is revoked. In the event that there are violations to the policies, there are options in place to address these breaches. See language below from the Data Access Policy.

"17. Termination. Either party may terminate this DUC without cause provided 30 days written notice to the other party. Recipients agree to immediately report violations of FITBIR Policy to the FITBIR DAQ. Additionally, DOD and NIH may terminate this agreement with 5 days written notice if the DOD and

NIH determine, in their sole discretion, that the Recipient has committed a material breach of this DUC. DOD and NIH may, in their sole discretion, provide Recipient with 30 days' notice to remedy a breach before termination. Upon termination of the DUC, use of the data must be discontinued. Closed accounts may be reactivated upon submission of an updated Informatics System Access Request and DUC."

Links:

- policies-and-procedures
- standard-operating-procedures
- FITBIR_Data_Sharing_Policy

R5 Governance & Resources (R05)

R05. The repository has adequate funding and sufficient numbers of staff managed through a clear system of governance to effectively carry out the mission.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

Utilizing funding available through the FITBIR MOU, CIT and NIH have contracted with Publicis Sapient to provide complementary scientific and technical expertise. The DoD and NIH oversee a portfolio of research on fundamental understanding of TBI as part of NINDS and DoD. NINDS is one of the 27 Institutes and Centers of the NIH (the largest funder of biomedical research in the world) and is widely recognized as a leader in the area of TBI research. Publicis Sapient has extensive experience as a contractor organization working on Federal government IT initiatives.

The Publicis Sapient staff of 34 full-time employees (FTEs) and NIH staff of 3 part time employees (PTE) for FITBIR are split across the following specializations.

1) Software Development (Total (18) FTE and (3) PTE)
a) Developers: (13) FTE and (3) PTE- responsible for building the platform software deliverables
b) Quality Assurance: (3.5) FTE-ensures solution meets business requirements and is free from errors and defects.
c) Requirements Analyst: (2) FTE- responsible for ensuring that the requirements of the business clients are captured and documented correctly before a solution is developed and implemented.
d) Infrastructure Engineer: (3) FTE- designs, builds, deploys and maintains the IT infrastructure.

2) Operations Support (Total (7) FTE)
a) End user support: (7) FTE- Provides business, technical, and scientific expertise.
b) Data-level curation: (2.0) FTE- Exploring, cleaning, annotating, publishing and presenting structured data sources. PhD expertise provided.

Also, the FITBIR's scientific direction includes the input of Dr. Matthew McAuliffe, who is an expert in the area of biomedical informatics and provides scientific input on how to reuse the data. He leads or is a member of many NIH initiatives including, Trans-NIH BioMedical Informatics Coordinating Committee (BMIC) CDE task force, NIH Scientific Data Councils working groups, and others. The members of FITBIR scientific teams attend scientific meetings and symposia to maintain up to date understanding and training in biomedical informatics and TBI. In addition, FITBIR staff are required to take mandatory training developed and administered by NIH annually in the area of Information Security and Information Management with additional modules specifically if you work with biomedical data. Additionally, professional development coursework is available for technical and non-technical staff via online (such as Lynda.com, O'Reilly) and in person training certification courses.

FITBIR's overarching governance is comprised of a structure that ensures FITBIR's goals are conceived and executed via a framework that defines boundaries to ensure delivery of the strategic vision to the FITBIR stakeholder community. Each committee ensures the right stakeholders are engaged with the Publicis Sapient partners to shape the FITBIR project roadmap.

The FITBIR Governing Committee is comprised of the representatives from the NIH (NINDS) and the DoD as voting members. Additional members may be added in the future. The Governing Committee makes all decisions related to overall strategic vision, operating procedures, and will regularly assess FITBIR activities.

The Executive Committee consists of three Co-Directors appointed by the Governing Committee. The Executive Committee manages and coordinates work on the overall strategic vision, design, policies and operations of FITBIR. This committee also manages the contracts with the outsource partners. In addition, the committee provides guidance for system development both for hardware and software enhancements.

The Strategic Vision Committee is led by members of the NIH/NINDS and DoD Working Groups (WGs) and Steering Committees (SCs), and the VA. It is comprised of a minimum of five stakeholders appointed by the FITBIR Executive Committee, including federal government employees, distinguished scientific experts from academia, industry, and private and non-profit foundations. The Strategic Vision Committee has responsibility for advising the Executive Committee.

The Policy Committee is composed of Federal employees or contractors (from Publicis Sapient) appointed by the Executive Committee. Predominantly, this includes program directors and policy staff from Federal granting agencies. The Policy Committee is responsible for creating policies and guidelines that support the strategic vision and align with scientific and technological capabilities and operational procedures.

The FITBIR DAQ, a subcommittee of the Policy Committee, consists of a minimum of 3 Federal government employees or contractors (from Publicis Sapient) with expertise in science, policy or bioinformatics, and are appointed by the Policy Committee. The DAQ reviews and provides feedback about whether to accept FITBIR data submissions; and 2) grant access to FITBIR data.

Development work that includes operations support is done by both government employees as well as technology contractors led by the Publicis Sapient partner. More information on the organizational relationships and the role of Publicis Sapient is detailed in section R0 (Outsource Partners).

Information for Figure 1, organizational relationships, is publicly available on the FITBIR website, in the section “What is FITBIR”, under the frequently asked questions (FAQs) at https://fitbir.nih.gov/content/frequently-asked-questions.

Link:

- frequently-asked-questions
-

R6 Expertise & Guidance (R06)

R06. The repository adopts mechanisms to secure ongoing expertise, guidance and feedback-either in-house, or external.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

The informatics system has a yearly governance committee meeting which involves input from the program staff at the NIH who are experts in their fields but also recognized experts in clinical science, traumatic brain injury, and biomedical informatics. At this meeting, the FITBIR team receives feedback and suggestions on the governance, and scientific progress made in the previous year. The FITBIR team also holds a Stakeholders meeting every 2-3 years to receive feedback and suggestions on the technical and scientific progress made in the previous year. Regular project status meetings and Configuration Control Boards (CCBs) are held monthly to provide scientific guidance on system enhancements. Additionally, the FITBIR staff attend ad-hoc or regularly scheduled scientific conferences and symposia to solicit expert feedback on data deposition, curation, and reuse. The FITBIR operations team regularly meets with grantees to assist in the submission of data and act as an additional conduit to provide feedback to the technical team for the development of new functionality and tools in support of FITBIR grantees.

Links:

Digital Object Management

R7 Provenance and authenticity (R07)

R07. The repository guarantees the authenticity of the digital objects and provides provenance information.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

Grantees of the NIH or DoD, involved in TBI research, must submit the data to the FITBIR system if stipulated in their notice of award. The FITBIR DAQ approves submission of data and/or images into the FITBIR Informatics System. The DAQ will review the Informatics System Data Submission Request and will decide whether to permit the submission based on the expectations outlined in the FITBIR policy. In the event that submissions raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAQ will consult with other experts as appropriate.

The process for submitting data is documented at: https://fitbir.nih.gov/content/contribute-data.

The first step for submission is setting up a Study within the system. After approvals have been obtained, meta-data describing the study can be entered by the PI or data manager and is reviewed/updated by the FITBIR Operations team. The data tag suite (DATS) https://github.com/datatagsuite meta-data standard is used to support discoverability of datasets. The process to submit data is the same for all data types (clinical, imaging, genomics) as described below. The Comma Separated Value (CSV) data file, with data consistent with CDEs, is validated using the FITBIR automated validation tool and once it passes validation a submission package is generated, including a Cyclic Redundancy Check (CRC) checksum, and submitted into a specific study in the system (see R14). Data can now be curated, validated against CDEs, and then submitted into the PI’s specific study by the PI or users with the proper credentials to the study. Each dataset is assigned a specific unique ID. The datasets cannot be modified and cannot be deleted without the intervention of the FITBIR Operations team. If a dataset needs to be updated, the old dataset is archived, and the new dataset is submitted. By default, the system assigns the sharing preference as ‘private’ where only users to that specific study can access the data. When the data is in the private state, the PI has the option to share data with specific collaborators (preferential sharing). After a certain period, defined by the data sharing policy, the data enters a new ‘shared’ state, which is accessible to the approved users. Once the Study moves the data to the shared state the Study is minted with a Digital Object Identifier (DOI). FITBIR mints its DOIs through the Office of Science and Technical Information’s (OSTI) DataCite minting service.

Investigators can only submit data to the studies that they have approved access to and are authenticated by permission levels. Therefore no one other than authenticated users with specific permissions can submit data to the system. The system has an automated validation set of rules based on the CDE

definitions that check for integrity and validity of data.

Data are not explicitly versioned because each dataset that is updated is archived by date and stored; however, metadata tags can be used to link updated datasets with their archived versions. Once the data is published the submitter can only request that the dataset be archived. An updated dataset can then be submitted to the system. No data is overwritten at any time to maintain integrity and there is an audit trail captured by the system for data provenance. The archived version of the data is only accessible to system administrators not the general users.

Metadata changes to CDEs and forms have versioning controls and version numbers along with a logged audit trail to capture changes. There is a stringent audit trail required as per 21 CFR part 11 to verify that digital object have not been altered or corrupted, a note for version control and provenance.

Another unique use of the system is the Meta Study module that can be used for meta-analysis of the data as well as a collaboration tool between scientific groups. The BRICS Meta Study module is a flexible data store allowing for management and storage of primary and secondary data from research studies. Each Meta Study is assigned a unique persistent identifier, a DOI, to support data discovery and provides permission-based access to datasets and metadata that coexist within the module. With the NIH Data Management and Sharing Policy coming into effect January 25, 2023, utilization of the BRICS Meta Study module aligns with NIH's mandate to use a quality data repository that improves the FAIRness (Findable, Accessible, Interoperable, and Re-usable) of the data.

The two main use cases for the BRICS Meta Study module are as follows:

a. Meta Analyses
i. Facilitates aggregation of data from different studies within the BRICS Repository module for meta-analyses
ii. Accommodates upload(s) of data external to BRICS to be included in meta-analyses
b. Data Store/Repository
i. Facilitates storage of data from studies that do not have requirements to upload data to the BRICS Repository module
ii. Supports NIH Data Management and Sharing Policy Meta Study can contain aggregated data by querying across studies (data in the FITBIR system is harmonized by the use of CDEs).

All study metadata are publicly shared https://fitbir.nih.gov/content/submitted-data. Once the Meta Study is shared the data and metadata are locked and cannot be changed.

Links:

- submitted-data
- datatagsuite
- contribute-data

R8 Deposit & Appraisal (R08)

R08. The repository accepts data and metadata based on defined criteria to ensure relevance and understandability for users.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

TBI research data was initially collected in different ways and by disparate systems making sharing and reusing of data problematic. Because of the wide variability in systems and databases, many types of TBI injuries were classified as the same class of injury, impeding development of targeted therapies for the disease. To overcome these barriers, the TBI community recommended use of the CDE methodology for the development of FITBIR.

A CDE is defined as a fixed representation of a variable collected within a specified clinical domain that needs to be interpretable unambiguously in human and machine-computable terms. It consists of a precisely defined question with a specified format, with a set of permissible values as responses. Typically, CDE development for biomedical disease programs involves multiple steps - identification of a need for a CDE or group of CDEs, stakeholders and expert groups for CDEs selection, iterations and updates to initial development with ongoing input from broader community, with final endorsement of the CDEs by the stakeholder community for its usage and widespread adoption.

All clinical assessment data are submitted in a user-friendly CSV file format, ensuring readability. The data within this file adheres strictly to CDEs. Additional files such as imaging and genomic data remain unaltered and are linked to the CSV uploads through file path references.

Prior to submission, all data points undergo validation using the FITBIR automated validation tool. This tool checks the integrity and authenticity of the data against a set of predefined rules based on metadata definitions. Furthermore, extra-validation checks are conducted for 40 common clinical instruments to ensure the presence of required item level data and accurate calculation of total scores according to instrument specifications.

Upon successful validation, a submission package is generated, incorporating a CRC checksum, and submitted to the specified study within the system. Utilizing CDEs offers two significant advantages: (1) Ensuring data validation and (2) Facilitating harmonization of data across different studies.

All data are validated against CDEs before submission into the FITBIR system. Each data point is validated with the identified CDE to ensure the data are

consistent with the specific CDE's permissible value or range. The FITBIR data dictionary provides defined CDEs, as well as unique data elements (UDEs) for specific implementation of the BRICS instance. Reuse of CDEs is significantly encouraged, and in the case of FITBIR's data dictionary, it incorporates and extends the CDE definitions developed by the NINDS CDE Project. The consistent use of the CDEs supports FAIR data initiatives and intrinsically supports data harmonization.

The operations team works synergistically and continually with the team while they are submitting data so that issues are addressed in real time. Once a study has completely submitted all data and has generated a primary publication associated with the study, the operations team will review the paper and validate demographic information to ensure the data in the repository is consistent with the paper. The operations team also has a defined set of checks using automated analysis prior to study closeout. This report is shared with the PI to address data quality before any data are shared for meta-analysis in the system. In addition, all meta-data that describes a study, based the DATs specification, is reviewed for accuracy by the Operations team.

Please refer to the following links for more information.

CDE specifications guide link:

https://fitbir.nih.gov/sites/fitbir/files/inline-files/Data%20Element%20Import%20Guide.pdf
https://fitbir.nih.gov/content/data-dictionary#helpful-documents

Links:

- helpful-documents
- Data-Element-Import-Guide

R9 Preservation plan (R09)

R09. The repository assumes responsibility for long-term preservation and manages this function in a planned and documented way.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

FITBIR adheres to rigorous data preservation measures to ensure the longevity and accessibility of data and retains responsibility for the preservation planning and actions undertaken to ensure data remain usable by the Designated TBI Community for years to come.

As mentioned in section VIII (R8), FITBIR mandates collection, validation, and submission of data using CDEs. These standards are transparently documented on FITBIR's public site (https://fitbir.nih.gov/content/data-dictionary#helpful-documents). The required use of CDEs, availability of documentation combined with detailed version history, and metadata associated with study-related data make it possible for long term preservation and use of data. The FITBIR data dictionary has detailed version history including information about what/when changes were made, which data elements are retired or deprecated, and "see also" functionality to find similar concepts in the dictionary. Study metadata is entered by the user and validated by the FITBIR system owners ensuring preservation criteria for information metadata are met. DataCite DOIs are issued at the study level, not at the dataset level, and therefore do not change over time. Data is submitted in CSV format, a universal standard ensuring ease of mapping and interoperability. CSV's simplicity, platform independence, compatibility, and transparency make obsolescence unlikely and make it a viable option for long-term data preservation. Utilization of the CSV format significantly reduces the need for future format migrations or emulations.

FITBIR does not delete/remove data and metadata from collection/holdings- these items are placed in an "archived" status. Data submitters may request their data be archived and FITBIR system owners would make any necessary modifications and provide updates to the user community. However, data that has been distributed for approved research use will not be retrieved. More detailed information on digital object preservation and appraisal is outlined in section R11. Regardless of whether data is readily accessed by the research community or not, there is no minimum stated retention and/or preservation period. Digital objects in FITBIR have been deemed to retain their original level of significance and value.

FITBIR's preservation plan ensures that changes to data, metadata, technology, and user requirements are handled in a stable and timely manner. A formal preservation policy and preservation plan adopted by the FITBIR repository has been developed and is publicly available (https://fitbir.nih.gov/system/files/inline-files/FITBIR_Preservation-Plan_083123.pdf) A detailed description of how FITBIR promotes collaboration and sustains data integrity of research studies is documented at the link provided in parenthesis ("Development of an informatics system for accelerating biomedical research" https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7376384/).

Links:

- Data Preservation and Access Practices
- Data Dictionary Helpful Documents
- Development of an informatics system for accelerating biomedical research.

R10 Quality Assurance (R10)

R10. The repository addresses technical quality and standards compliance, and ensures that sufficient information is available for end users to make quality-related evaluations.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

As described in Section VIII (R8), Traumatic brain injury (TBI) research data in FITBIR is collected using common data elements. The repository has stringent validation processes based on these definitions for the data that is submitted. This process includes validating each data point against its CDE (identified in the FITBIR system's data dictionary), to ensure the data conforms to the data ranges or permissible values of the CDEs. To guarantee data integrity, Secure Hash Algorithm (SHA)-256 checksums are employed. These checksums verify that the data remains unchanged throughout the submission process. Once validated, a submission package is generated, including a CRC checksum, and submitted into a specific study in the system (see R7). Once the data pass validation, a submission package is generated that includes a CRC checksum that ensures data integrity during submission.

The repository documents how metadata and data quality are ensured via the data deposition procedure. It also has automated methods to determine whether the data quality adheres to the schema strategy (e.g., the data validator).

Once a study has completely submitted all data and has generated a primary publication associated with the study, the operations team will review the paper and validate demographic information to ensure the data in the repository is consistent with the paper. In addition, there is ongoing dialogue between the scientific community and members of FITBIR scientific teams to maintain data quality and harmonization of data to the defined ontologies. FITBIR contains metadata on any citations that generated from the data as well as links to those publications https://fitbir.nih.gov/content/publications and https://fitbir.nih.gov/publicationstats-.

If a study team notifies FITBIR operations that their shared datasets need to be revised, these datasets are archived, corrected datasets are resubmitted (and given a new dataset ID), and users who had previously accessed the now archived datasets are notified of the change. Flags, descriptions, and dataset links can be utilized to further annotate datasets and specify contextual information e.g., reason for archiving. In some cases, data access users reach out to FITBIR Operations to inform them of dataset issues or to seek clarification about study data. These scenarios require direct communication with the study team to rectify any potential issue or clarify any question. This may result in the submission or resubmission of data or uploading additional supporting documentation to the study profile. Data access users will be notified when these modifications are made to a study with shared data.

Links:

- publicationstats
- publications

R11 Workflows (R11)

R11. Digital object management takes place according to defined workflows from deposit to access.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

FITBIR has documented workflows descriptions for all stages of data from ingestion to dissemination:

a. Getting an account: https://fitbir.nih.gov/content/get-account
b. Contributing data: https://fitbir.nih.gov/content/contribute-data
c. Accessing data: https://fitbir.nih.gov/content/access-data

Data submission and use is clearly communicated: https://fitbir.nih.gov/content/policies-and-procedures and general FITBIR documentation can be found at: https://fitbir.nih.gov/content/user-guides.

The FITBIR operations team has a set of internal SOPs to address data access requests, de-identification of data and management of data within the secure system. These are available on an internal content management system that is not available publicly. Please see more details on internal processes in section R4.

TBI research data funded by the DoD or NIH is validated against CDEs, submitted to a specific study and stored in a private state for a time defined in FITBIR's policy. The data are eventually shared to users approved by the DAQ after further quality assurance/quality control (QA/QC) (see R10). Grantees are expected to upload data to FITBIR on an annual basis as defined in the Terms and Conditions of their grant. Prior year's data are archived once a new, complete dataset is uploaded. The system tracks when/by whom/why requests to archive are made and executed. The same applies for requests to delete data from the system.

Data downloads are audited and can be seen at: https://fitbir.nih.gov/visualization - select Visualization: Data Flow. In addition, PI can login to FITBIR and see specific downloads from their study. This has two benefits: 1) the PI can reach out to the researcher and discuss possible collaborations. 2) The PI can provide some level of quantification as to the use of data that they have shared – to possibly enhance grant applications.

There are multiple levels of security including physical, system and data security – also see R16. FITBIR only stores de-identified data and uses a "Global" (i.e. global to the FITBIR system) unique ID (GUID) process to support the de-identification of data, see https://fitbir.nih.gov/content/global-unique-identifier.

The system is regularly probed to ensure all system libraries are up to date. The FITBIR system was rated Federal Information Security Management Act (FISMA) moderate and implements the appropriate National Institute of Standards and Technology (NIST) 800-53 security

controls(https://nvd.nist.gov/800-53/Rev4), see R16 for more details.

Links:

- contribute-data
- policies-and-proceduresuser-guides
- global-unique-identifier
- visualization
- access-data
- get-account

R12 Discovery and Identification (R12)

R12. The repository enables users to discover the digital objects and refer to them in a persistent way through proper citation.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

FITBIR enables meta-data search (https://fitbir.nih.gov/content/submitted-data) of studies that supports the discovery of Studies and their data. Meta-data describing a study can be entered by the PI or data manager and is reviewed/updated by the FITBIR Operations team. The data tag suite (DATS) https://github.com/datatagsuite meta-data standard is used to support discoverability and reuse of datasets – see section R07 for a detailed description. Metadata for the CDEs are also available in the NIH CDE repository.

Data within a study can be in one of two states: private or shared. When the data is in the private state, the PI has the option to share data with specific collaborators (preferential sharing). After a certain period, defined by the data sharing policy, the data enters a new ‘shared’ state, which is accessible to approved users. Once the Study moves the data to the shared state the Study is minted with a DOI.

Data definitions and metadata for the CDEs and forms are also available in the NIH National Library of Medicine (NLM) CDE Repository https://cde.nlm.nih.gov/ that is a centralized resource for NIH. The NIH CDE Repository has been designed to provide access to structured human and machine-readable definitions of data elements that have been recommended or required by NIH Institutes and Centers and other organizations for use in research and for other purposes.

The DAR has recommended language for data citations. According to the Data Access Request Policy, users have to include the following information in any oral or written presentations. We have provided the portion of the policy that mentions what information should be included for data citations.

“9. Acknowledgments. Recipient agrees to acknowledge the contribution of the FITBIR bioinformatics platform, the relevant FITBIR dataset identifier(s) (a serial number), and the Submitter(s) in any and all oral and written presentations, disclosures, and publications resulting from any and all analyses of data using the FITBIR tools, whether or not Recipient is collaborating with Submitter(s). The manuscript should include the following acknowledgement or other similar language: Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the DOD- and NIH-supported Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics Systems. FITBIR is a collaborative biomedical informatics system created by the Department of Defense and the National Institutes of Health to provide a national resource to support and accelerate research in TBI. Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the DOD, NIH, or of the Submitters submitting original data to FITBIR Informatics System. If the Research Project involves collaboration with Submitters or FITBIR staff then Recipient will acknowledge Submitters as co-authors, if appropriate, on any publication. In addition, Recipients agree to include a reference to FITBIR Informatics System datasets analyzed and to cite FITBIR and the federal funding sources in abstracts as space allows.”

This information is available on page 4 of the Data Access Request Policy document that users sign.

Links:

- CDE Repository
- submitted-data
- datatagsuite

R13 Reuse (R13)

R13. The repository enables reuse of the digital objects over time, ensuring that appropriate information is available to support understanding and use.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Meta-data describing a study can be entered by the PI or data manager and is reviewed/updated by the FITBIR Operations team. The data tag suite

(DATS) https://github.com/datatagsuite meta-data standard is used to support discoverability and reuse of datasets.

Data submitted to FITBIR conforms to CDE standards developed by the TBI research community including the DoD, NINDS CDE program. The TBI CDE community and FITBIR operations team continue to regularly meet to curate and develop new CDEs to support future data submissions. The FITBIR Data Dictionary module supports versioning of form structures and data elements and provides a detailed history of changes. In addition, the development team continues to develop new tools and application programming interfaces (APIs) to support data submission.

It is also important to note that the data downloaded from FITBIR is bundled with a spreadsheet of the CDEs associated with the specific user query. This allows the user to accurately understand the data. In addition, once the study is in a shared state, users can download descriptive files uploaded to the study providing additional meta information about the study.

The FITBIR system is designed to support the submission of any imaging file type and omics file type. Tabular data are submitted in CSV format consistent with the CDEs and submitters are expected to meet the data definitions for the system. The data are mapped to the CDE definitions that are then aggregated and available for querying based on the research question. We routinely review updates to the industry standards and adapt the system accordingly. In the event that a dataset needs to be modified, a revised dataset can be submitted and linked to the preceding version. Users who have previously downloaded the original dataset are then notified of the change.

The analysis and therefore the understandability of data are available in cited publications here https://fitbir.nih.gov/content/publications.

The FITBIR operations meets with and onboards new DoD or NINDS grantees and provides them with a detailed orientation of the FITBIR system, including the submission process, data access, timelines, and policies. The full-time FITBIR Operations staff also serve as a valuable resource and source of knowledge for the user community who need assistance with understanding any aspect of the system and the data within. FITBIR Operations also provides and maintains many publicly available resources such as user guide documentation, tutorial videos, webinars, commonly used forms and CDEs, FAQs, SOPs, how-to infographics, publication metrics, reporting on news and events, etc. Furthermore, FITBIR Operations participates annually as exhibitors at notable symposiums such as the National Neurotrauma Society (NNS) and Military Health System Research Symposium (MHSRS), fostering engagement, collaboration, and data reuse within the research community.

Links:

- datatagsuite
- publications

Information Technology & Security

R14 Storage & Integrity (R14)

R14. The repository applies documented processes to ensure data and metadata storage and integrity.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

Relevant processes and procedures (https://fitbir.nih.gov/content/standard-operating-procedures; https://fitbir.nih.gov/content/policies-and-procedures) are documented online and are managed by the FITBIR team in consultation with program staff at CIT/DoD/NINDS who oversee the management of the contract funding of this resource. The Data Repository module for the various BRICS instances serves as a central hub, providing functionality for defining and managing study information and storing the research data associated with each study. The database hosts two types of data (private and shared). By default, the system assigns the sharing preference as ‘private’ where only users to that specific study can access the data. When the data is in the private state, the PI has the option to share data with specific collaborators (preferential sharing). After a certain period (defined by the data sharing policy for each BRICS instance), the data enters a new ‘shared’ state, which is accessible to the approved users. Once the data is shared, no changes to the data are permitted unless they are approved for a specific reason (e.g. subject withdrawal).

All data is hosted in a secure facility at CIT and is only available to the system administrators, data depositors, their collaborators and approved users vetted by the FITBIR DAQ. Since private and shared data are hosted on government servers, it must maintain strict security and fault tolerance capabilities as specified by FISMA law (https://en.wikipedia.org/wiki/Federal_Information_Security_Management_Act_of_2002).

In addition to the onsite data storage at CIT, there is an offsite backup storage location in Sterling, VA. All relevant and important data are backed up daily to this offsite location and is monitored by an NIH contracted security company. BRICS transitioned to a new backup system in February 2023. Data will be stored both onsite and offsite in an AWS cloud environment with additional storage layers and security. The team performs yearly Contingency Plan tests, which is a framework for procedures to ensure resumption of operations in case of an emergency. This document is maintained within the CIT NIH Security Authorization Tool (NSAT) system and is only available to the FITBIR system owner and system administrators. The team also performs monthly restore tests to confirm the integrity of the backups and monitors the backup process on a weekly basis to ensure consistency. These steps are documented internally in the FITBIR online content management system (Atlassian Confluence).

Links:

- FISMA

- policies-and-procedures
- standard-operating-procedures

R15 Technical Infrastructure (R15)

R15. The repository is managed on well-supported operating systems and other core infrastructural software and hardware appropriate to the services it provides to its Designated Community.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

The hardware, software, networking and applications are all maintained by the FITBIR system administration team, in accordance with NIH policies and procedures. The U.S. Department of Health and Human Services (HHS), of which NIH is under, requires Privacy Impact Assessments (PIAs; https://oma.od.nih.gov/DMS/Pages/Privacy-Program-Privacy-Impact-Assessments.aspx) to be conducted on all Information Technology (IT) systems and uses Third-Party Websites and Applications (TPWAs). HHS also requires quarterly reviews and annual FISMA reports. The FITBIR admin team maintains all servers and storage according to strict and well-defined laws and regulations (e.g. FISMA moderate; https://www.nist.gov/programs-projects/federal-information-security-management-act-fisma-implementation-project).. All documentation is held in either NSATsystem at NIH or Confluence. Both NSAT and Confluence are internal only.

Information is publicly available for:

1. FITBIR technical infrastructure at https://fitbir.nih.gov/sites/default/files/BRICS_Design_Document_SOP.pdf
2. Standards and Security information in the last two questions of the frequently asked questions (FAQs) at https://fitbir.nih.gov/content/frequently-asked-questions.

The FITBIR system is maintained and deployed via a configuration management policy, and this is secured within the infrastructure repository, with FITBIR admin only access. The inventory is reviewed on a monthly basis and stored within the FITBIR content management system. The infrastructure is deployed in a VMWare virtual environment, with Red Hat virtual servers. As of January 2023, 80-85% of the servers have been upgraded to Red Hat 8 with the remaining in Red Hat 7. Migration to Red Hat 9 is planned for later this year. Both VMWare and Red Hat licenses provide FITBIR with 24/7 technical support. Both levels of Infrastructure are secured, and patches deployed on a schedule, with critical vulnerabilities remediated within 15 days of notification. To support researchers distributed globally, FITBIR is deployed on a high-speed network and hardware, including solid-state storage and 10G network.

The operation of FITBIR and the various BRICS instances is 24x7 with redundancies and backups done on a nightly schedule. The FITBIR database is backed up in accordance with NINDS and CIT Security Policies and Guidelines and provides a restore capability to revert to in the event of a database corruption or system failure.

CIT policies and procedures are available on an internal content management system. We have our roadmap items in Jira and track any future plans through this mechanism. All Infrastructure planning and roadmap items are documented internally within the Jira system. The FITBIR development team under the direction of the government tracks the progress for all roadmap items and plans for enhancements and improvements to the FITBIR infrastructure. The plan is reviewed by the system owners (the government funders NIH and DoD, and Matthew McAuliffe, co-Director of FITBIR) and prioritized based on requirements.

Links:

- NIST 800-53
- BRICS_Design_Document_SOP
- frequently-asked-questions
- FISMA-implementation-project

R16 Security (R16)

R16. The repository protects the facility and its data, metadata, products, services, and users.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

Response:

The FITBIR system resides in a badged, monitored, and audited secure data center within CIT on the restricted NIH Campus. The backup infrastructure is based on a 3-tier system that includes local backup and AWS cloud storage. Backups are encrypted and protected from potential security threats such as ransomware. The hardware, software, networking, and applications are all maintained by the FITBIR system administration team, in accordance with NIH policies and procedures. The FITBIR admin team maintains all servers and storage according to strict and well-defined laws and regulations (e.g. FISMA

moderate; https://www.nist.gov/programs-projects/federal-information-security-management-act-fisma-implementation-project).See R14&R15 for further information.. The FITBIR design incorporates several security and integrity controls to ensure the system and its associated systems are continually protected. This is done through a multi-tiered approach to ensuring data integrity is achieved through only authorized user functions and assignments.

The first design consideration is user authorization and permissions. These users will be unable to perform any transactions outside of their assigned areas and permissions are based on the account roles within the BRICS system. System administrators will grant proper roles and operating boundaries for each of their users. FITBIR has implemented Multi-Factor Authentication (MFA) requiring all users to use PIV cards or Login.gov. User information is protected via account roles and permissions. All user's passwords are encrypted in the database and FITBIR logs all user activity with the system security logs being ingested to CIT Splunk monitoring system. The limited PII that describes the users (Name, affiliation, email address, etc.) is provided by the users, is not considered sensitive, and is important to making data FAIR and the system secure. Only FITBIR admins can create or modify account permissions within the system and account configuration adheres to the NIH account lifecycle and password policy. The FITBIR Users, based on their roles, are only allowed to see their studies and publicly available studies.

The next design consideration is to establish control points. Firewalls are placed to partition the functions each instance is able to perform. In addition to NIH firewalls and intrusion detection, the FITBIR servers all have firewalls implemented to only allow required ports. The purpose is to reinforce work areas, permissions, and access to prevent any duplication, unintentional changes, or malicious changes of data. The system design also incorporates the important audit trail capability which will allow administrators to track the history of all users in order to provide history, error identification, and accountability for system users. The NIH Incident Response Team (IRT) team regularly scans the FITBIR system for security and privacy vulnerabilities. Any issues are addressed within established timeframes as set by NIH security policy.

The FITBIR system's operations are 24x7 with redundancies and are backed up on a nightly basis, as well as archived to long-term archival cloud storage. The Backup policy is reviewed monthly and documented within the FITBIR content management system. Disaster Recovery (DR) policies are also documented and reviewed yearly as part of the Assessment and Authorization (A&A) system. The system is not self-assessed – the A&A system is an NIH mandated review of the system required every 3 years. An A&A review of BRICS for the new NIST 800-53 Rev 5 is currently in progress. The assessment documentation is private and internally available through NSAT or the Content Management System. The DR policy documents clearly lay out the roles in case of an emergency with the system admins reporting to system owner and decisions are made immediately. The FITBIR database is backed up in accordance with NINDS and CIT Security Policies and Guidelines and provides a failover capability to revert to in the event of a database corruption or system failure.

Security is a critical component during biomedical informatics platform development. Planning for security must be carried out as the initial part of design work because maintaining privacy of patient data is essential for meeting various compliance regulations (e.g. HIPAA privacy rule). The BRICS security design is compliant at the Federal Information Security Modernization Act (FISMA): https://www.nist.gov/programs-projects/federal-information-security-management-act-fisma-implementation-project; https://en.wikipedia.org/wiki/Federal_Information_Security_Management_Act_of_2002) Moderate level. Confidentiality of research subjects is maintained, but data and study protocols are shared to promote scientific collaboration. Appropriate controls and assurance requirements conform to the Federal Information Processing Standards (FIPS) 200 (https://csrc.nist.gov/publications/detail/fips/200/final) and NIST SP 800-53 Revision 5 (https://nvd.nist.gov/800-53/Rev5/impact/moderate), and the Department of Health and Human Services policies for information systems.

Information is publicly available for:
1. FITBIR technical infrastructure at https://fitbir.nih.gov/sites/fitbir/files/inline-files/BRICS_Design_Document_SOP.pdf
2. Standards and Security information in the last two questions of the frequently asked questions (FAQs) at https://fitbir.nih.gov/content/frequently-asked-questions.

Links:

- NIST SP 800-53 Revision 4
- Federal Information Processing Standards (FIPS) 200
- BRICS_Design_Document_SOP
- NIST 800-53
- FISMA-implementation-project
- FISMA
- frequently-asked-questions

Applicant feedback

R17 Applicant Feedback

We welcome feedback on the CoreTrustSeal Requirements and the Certification procedure.

Compliance level:

Implemented: the requirement has been fully implemented by the repository - 1

The new CoreTrustSeal sections (2023-2025) are more logically organized.

It'd be helpful if the web application text boxes allowed formatting such as bullets and text formatting.

Link