Assessment Information

CoreTrustSeal Requirements 2017–2019

Repository:	The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System
Website:	https://fitbir.nih.gov/
Certification Date:	05 August 2020
This repository is owned by:	**Center for Information Technology (CIT)**

The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System

Notes Before Completing the Application

We have read and understood the notes concerning our application submission.

True

Reviewer Entry

Reviewer 1

Comments:

Reviewer 2

Comments:

CORE TRUSTWORTHY DATA REPOSITORIES REQUIREMENTS

Background & General Guidance

Glossary of Terms

BACKGROUND INFORMATION

Context

R0. Please provide context for your repository.

Repository Type. Select all relevant types from:

Domain or subject-based repository, National repository system; including governmental, Research project repository

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

Brief Description of Repository

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.

The Biomedical Research Informatics Computing System (BRICS) (http://brics.cit.nih.gov/), works to achieve these goals by enabling biomedical researchers to efficiently collect, validate, harmonize, and analyze research datasets. BRICS operates on a set of basic principles to support both centralized and cloud-based systems, with a push for data reusability and scalability. In addition, the BRICS project is committed in supporting the Findable, Accessible, Interoperable, Reusable (FAIR) principles to advance research for the scientific community. More information can be found at https://brics.cit.nih.gov/sites/default/files/styles/pdf/brics_and_fair.pdf .

These principles are the foundation of NIH’s ‘Big Data’ efforts, and ultimately facilitate knowledge sharing in this highly specialized community using the Federal Interagency Traumatic Brain Injury Research (FITBIR). BRICS assists with data standardization, definition, contribution, and access throughout the research life cycle. The platform helps ensure there are fewer isolated, disparate datasets and allows researchers to aggregate and analyze genetic, phenotypic, clinical, and medical imaging data.

Eleven major disease research programs (groups) are already benefitting from using BRICS to support more than 200 research studies by more than 400 principal investigators (PIs). To date, this has created a master cohort of over three million records representing approximately 99,000 diverse subjects across the 11 disease instances. Early applications include projects supporting Parkinson's disease (PD) and traumatic brain injuries (TBI) communities.

Because of its easily maintainable and scalable design, BRICS helps minimize cost while enabling rapid program deployment by other organizations. Today, BRICS is used as the foundation for a range of biomedical informatics platforms and data repositories including the:

- Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system
- Common Data Repository for Nursing Science (cdRNS)
- Rare Diseases Registry Program (RaDaR) (formerly Global Rare Diseases Patient Registry (GRDR))
- Center for Neuroscience and Regenerative Medicine's (CNRM) Informatics Core
- Clinical Informatics System for Trials and Research (CiSTAR)
- Parkinson's Disease Biomarkers Program Data Management Resource (PDBP DMR)
- National Eye Institute (Patient-Reported Outcomes with LASIK (PROWL), National Ophthalmic Disease Genotyping and Phenotyping Network (eyeGENE), Age-related macular degeneration (AMD) Systems Biology)
- National Trauma Research Repository (NTRR)
- National Institute of Aging (NIA)
- National Institute of Neurological Disorders and Stroke (NINDS)

The FITBIR informatics system, a BRICS instance, that is seeking Core Trust certification, 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 was developed as part of a White House initiative and has been incorporated into the National Research Action Plan (NRAP) in an effort to advance research in support of improved diagnosis and treatment for service members and civilians who have sustained a traumatic brain injury (TBI). This extensible, scalable informatics platform for TBI includes relevant imaging, clinical assessments, genomics, and other data types that will enable the Department of Defense (DoD), the National Institutes of Health (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.

The BRICS system is Federal Information Security Management Act (FISMA) moderate compliant and implements the appropriate National Institute of Standards and Technology (NIST) security controls (NIST 800-53) and is certified for Title 21 CFR Part 11 of the Code of Federal Regulations (CFR). FITBIR as the derived system inherits all the BRICS security and certification controls.

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 the 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 Committee. These committees also provide guidance for the development work provided by Publicis Sapient. A detailed description for the relationships between the relevant organizations with regard 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 .

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

Brief Description of the Repository’s Designated Community.

Federal Interagency Traumatic Brain Injury Research (FITBIR; https://fitbir.nih.gov/) - is an informatics system derived from the BRICS platform and developed for NINDS and DoD, 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 traumatic brain injury (TBI). As of December 2019, there are 115 studies in FITBIR, spanning more than a hundred Principal Investigators (PIs), dozens of universities and research systems, with data submitted for 80,000+ subjects, including 110,000+ clinical image datasets. 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 Committee (DAC), 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 3.7 million records housed in FITBIR, equating to 80,000 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 on 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 14 million records downloaded by users interested in the data stored within FITBIR in 2019 alone.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

Level of Curation Performed. Select all relevant types from:

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

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

Comments

Ph.D level of curation for Metadata and data is provided by the FITBIR and BRICS lead curator and the supporting operations team.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

Outsource Partners. If applicable, please list them.

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 the 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 16 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 Data Access committees. More details are provided in the next few paragraphs. General Dynamics Information Technology (GDIT) provides additional support for curation of metadata for the CDEs and forms. 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
- Publicis Sapient: Outsource Partner, Contractual Relationship
- GDIT: 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 hypothesis,

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.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

Other Relevant Information.

FITBIR is a national data storage system instituted as part of a White House Initiative, the National Research Action Plan (NRAP). The National Research Action Plan (NRAP) is a 10-year blueprint for interagency research to enhance the diagnosis, prevention, and treatment of traumatic brain injury (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 effect 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 currently supported at NIH facilities with all servers housed within the CIT data center. Data is backed-up at an offsite facility.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

ORGANIZATIONAL INFRASTRUCTURE

I. Mission/Scope

R1. The repository has an explicit mission to provide access to and preserve data in its domain.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System is a central repository and resource for sharing data that was developed by the Department of Defense (DOD) and the National Institutes of Health (NIH) to promote collaboration, accelerate research, and advance knowledge on the characterization, prevention, diagnosis and treatment of traumatic brain injury (TBI). FITBIR provides a common platform and standardized format for data collection, retrieval and archiving, while allowing for flexibility in data entry and analysis. 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 R10.

We have internal policies to address data management but there is no explicit statement in the policies that call it out as data management. Data management is implicitly addressed via the data submission, sharing and access policies.

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

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 maybe reactivated upon submission of an updated Informatics System Access Request and DUC.”

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

II. Licenses

R2. The repository maintains all applicable licenses covering data access and use and monitors compliance.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in 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 Data Access Committee, 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/default/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 the use of the Global Unique Identifier (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 on confluence internally for the FITBIR team and are not shared on the public site.

Study close out analysis process includes verifying 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. During this timeframe, data accessors are notified and access to data and brain images for research is temporarily suspended to help ensure that FITBIR makes available only carefully reviewed information.

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 have been distributed for approved research use will not be retrieved. FITBIR has a data access report which contains the following information which datasets where 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 (DAQC) 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 R1 for the language on termination of access.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

III. Continuity of access

R3. The repository has a continuity plan to ensure ongoing access to and preservation of its holdings.

Compliance Level:

3 – The repository is in the implementation phase

Reviewer Entry

Reviewer 1

Comments:
3 – The repository is in the implementation phase

Reviewer 2

Comments:
3 – The repository is in the implementation phase

Response:

FITBIR has been funded by 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 the 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 R10, Preservation Plan.

Since the FITBIR informatics system has been funded by a government MOU, the repository assumes responsibility for long-term preservation as long as the funding continues. The stakeholders at DoD/NINDS internally reviews 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 will be 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 is publicly available at https://brics.cit.nih.gov/sites/default/files/BRICS_Docs_pdf_0.zip.

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 new MOU that extends funding through FY2025 has options in place to address non-continuity of funding and data preservation. This is described in detail in section R10, Preservation 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 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).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 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 new storage location.

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

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

IV. Confidentiality/Ethics

R4. The repository ensures, to the extent possible, that data are created, curated, accessed, and used in compliance with disciplinary and ethical norms.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

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/default/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 Global Unique Identifier (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 Data Access and Quality Committee (DAQC) 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.

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.

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 have been distributed for approved research use will not be retrieved

The Standard Operating Procedures (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 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.

Study close out analysis process includes verifying 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. During this timeframe, data accessors are notified and access to data and brain images for research is temporarily suspended to help ensure that FITBIR makes available only carefully reviewed information.

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 have been distributed for approved research use will not be retrieved.

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 Data Access and Quality Committee (DAQC) 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 R1 for the language on termination of access.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

V. Organizational infrastructure

R5. The repository has adequate funding and sufficient numbers of qualified staff managed through a clear system of governance to effectively carry out the mission.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

The FITBIR informatics system is currently funded by a MOU mechanism with the DoD and NIH. 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 16 full time employees (FTEs) for FITBIR are split across the following specializations

1. Software Development (Total (8) FTE)

a. Developers: (5) FTE- responsible for building the platform software deliverables

b. Quality Assurance: (1.5) FTE-ensures solution meets business requirements and is free from errors and defects

c. Requirements Analyst: (0.5 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: (1) FTE- designs, builds, deploys and maintains the IT infrastructure.

2. Operations Support (Total (8) FTE)

a. End user support: (5.75 FTE)- Provides business, technical, and scientific expertise

b. Data-level curation: (2.25 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.

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 the Figure 1 provided in ANNEX A.

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). 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 Data Access Committee (DAC), 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 DAC reviews and provides feedback about whether to
1) 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 .

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

VI. Expert guidance

R6. The repository adopts mechanism(s) to secure ongoing expert guidance and feedback (either inhouse or external, including scientific guidance, if relevant).

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

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 and 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.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

DIGITAL OBJECT MANAGEMENT

VII. Data integrity and authenticity

R7. The repository guarantees the integrity and authenticity of the data.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

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 Data Access & Quality Committee (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 is 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 CRC checksum, and submitted into a specific study in the system (see R7). There are advantages to using CDEs: 1. Data validation. 2. Harmonization of data across studies. 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 a Digital Object Identifier (DOI). FITBIR mints its DOIs through 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 is not versioned because each dataset that is updated is archived by date and stored. 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. A Meta Study can contain aggregated data by querying across studies (data in the FITBIR system is harmonized by the use of CDEs). The data and other research artifacts can be loaded into a Meta Study. A DOI is minted that can be referenced in a publication. All study metadata is publicly shared https://fitbir.nih.gov/content/submitted-data .Once the metastudy is shared the data and metadata are locked and cannot be changed.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

VIII. Appraisal

R8. The repository accepts data and metadata based on defined criteria to ensure relevance and understandability for data users.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

Traumatic brain injury (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 common data elements (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 term. 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 is submitted in an easily readable comma separated value (CSV) file format and in the file all data is consistent with CDEs. All data points to be submitted must have a CDE defined in the FITBIR Data Dictionary tool. The CSV data file is validated using the FITBIR automated validation tool against a set of rules based off the metadata definitions that check for integrity and authenticity of data. and once it passes validation a submission package is generated, including a CRC checksum, and submitted into a specific study in the system (see R7). There are advantages to using CDEs: 1. Data validation. 2. Harmonization of data across studies.

All data is validated against Common Data Elements (CDEs) before submission into the FITBIR system. Each data point is validated with the identified CDE to ensure the data is 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 National Institute of Neurological Disorders and Stroke (NINDS) CDE Project. The consistent use of the CDEs support 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 is 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 the following links for more information.

CDE specifications guide link:

https://fitbir.nih.gov/sites/default/files/inline-files/Data%20Element%20Import%20Guide.pdf

https://fitbir.nih.gov/content/data-dictionary#helpful-documents

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

IX. Documented storage procedures

R9. The repository applies documented processes and procedures in managing archival storage of the data.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

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 serve as a central hub, providing functionality for defining and managing study information and storing the research data associated with each study. The database host 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 data depositors, their collaborators and approved users vetted by a Data Access Committee (DAC). Since private and shared data is 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). The system is FISMA moderate compliant and is reviewed annually by the NIH Security team.

In addition to the onsite data storage at CIT, there is an offsite backup storage location in Sterling, VA. All relevant and important data is backed up daily to this offsite location and is monitored by an NIH contracted security company. 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 only available to the FITBIR system owner and system administrators. The team also performs bi-weekly 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).

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

X. Preservation plan

R10. The repository assumes responsibility for long-term preservation and manages this function in a planned and documented way.

Compliance Level:

3 – The repository is in the implementation phase

Reviewer Entry

Reviewer 1

Comments:
3 – The repository is in the implementation phase

Reviewer 2

Comments:
3 – The repository is in the implementation phase

Response:

As referred in Section R3, since FITBIR is funded through a government MOU that extends to FY2025, long term preservation is dependent on the continuation of funding and a contingent preservation plan is in place. However, also given that FITBIR is a government funded entity, the government funders (NIH and DoD) owns custody and stewardship of the data now and in the future. Therefore all long term preservation plans and decisions are dependent on the government owners. As mentioned in R14 there are no immediate plans to change the file formats in the near future from the required csv format which is a widely used format that facilitates mapping and interoperability. We routinely review updates to industry standards and adapt the system accordingly only if directed by the government owners.

There are specific SOPs and data use agreements in place as detailed in Sections R4-R8 for data submitters and accessors that lay out clearly all responsibilities, actions and transfer of custody between the depositors and the repository. The government funders and the FITBIR repository has the rights to copy, transform and store the data as well as provide access to it. As specified in various sections there are measures in place to ensure security and address any breaches in these agreements.

Publicis Sapient has been rated Capability Maturity Model Integration for Development (CMMI-DEV) Level 3 for Software Development and Maintenance projects, which is an active designation confirmed by the CMMI Institute through December 2021. This appraisal confirmed Sapient Government Services' usage of tailorable organizational standards, processes, templates, and assets to deliver solutions for Public Sector clients. Publicis Sapient's CMMI approach utilizes established mechanisms for fulfilling both project and organizational performance objectives, as well as driving organizational process improvement. The CMMI certification can be found at https://sas.cmmiinstitute.com/pars/pars.aspx, under a search for Sapient Government Services or directly at https://sas.cmmiinstitute.com/pars/pars_detail.aspx?a=1811 .

As part of the NIH Strategic Plan for Data Science, the NIH is committed to providing permanent and accessible solutions to house datasets resulting from NIH investigator publications. Regardless of the eventual permanent solution, any and all data uploaded to FITBIR, along with all metadata annotations, will be transferred to and maintained in NIH's permanent solution for long term data preservation.

We are developing a preservation plan in discussions with the government funders, taking into account that the MOU has been extended to FY2025. This document will be available publicly once it has been reviewed and approved by the appropriate FITBIR committees.

Reviewer Entry

Reviewer 1

Comments:
Considering that a preservation plan is under development and based on the evidence presented this Requirement is accepted at Compliance Level 3. A preservation plan should be provided for the next CoreTrustSeal certification.

Reviewer 2

Comments:

There is no documented preservation approach that is publicly available and therefore the Compliance Level is 3.

XI. Data quality

R11. The repository has appropriate expertise to address technical data and metadata quality and ensures that sufficient information is available for end users to make quality-related evaluations.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

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. 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.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

XII. Workflows

R12. Archiving takes place according to defined workflows from ingest to dissemination.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

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 standard operating procedures (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 is eventually shared to users approved by the DAC after further quality assurance/quality control (QA/QC) (see R11). 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 is 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 FISMA moderate and implements the appropriate NIST 800-53 security controls, see R16 for more details.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

XIII. Data discovery and identification

R13. The repository enables users to discover the data and refer to them in a persistent way through proper citation.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

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 R7 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 a Digital Object Identifier (DOI). FITBIR mints its DOIs through Office of Science and Technical Information's (OSTI) DataCite minting service.

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 Common Data Elements (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 on 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.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

XIV. Data reuse

R14. The repository enables reuse of the data over time, ensuring that appropriate metadata are available to support the understanding and use of the data.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

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.

All data submitted to FITBIR conform to CDEs developed by the TBI research community. The TBI community and FITBIR operations team continue to curate and develop new CDEs to support future data submissions. 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.

There are no immediate plans to change the file formats in the near future from the required csv format. We routinely review updates to the industry standards and adapt the system accordingly. Data is submitted in CSV format consistent with the CDEs and submitters are expected to meet the data definitions for the system. The data is mapped to the CDE definitions that is then aggregated and available for querying based on the research question. The analysis and therefore the understandability of data is available in cited publications here https://fitbir.nih.gov/content/publications .

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

TECHNOLOGY

XV. Technical infrastructure

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

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

Response:

The FITBIR system resides in a secure data center within CIT on the NIH Campus. The backup infrastructure is supported by an alternate backup site in Sterling, Virginia. 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). In accordance to FISMA Moderate systems, the FITBIR systems adhere to the NIST 800-53 (https://nvd.nist.gov/800-53/Rev4) security standards and guidelines. All documentation is held in either NIH Security Authorization Tool (NSAT) system 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 7 virtual servers. 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 planning 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.

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

XVI. Security

R16. The technical infrastructure of the repository provides for protection of the facility and its data, products, services, and users.

Compliance Level:

4 – The guideline has been fully implemented in the repository

Reviewer Entry

Reviewer 1

Comments:
4 – The guideline has been fully implemented in the repository

Reviewer 2

Comments:
4 – The guideline has been fully implemented in the repository

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 supported by an alternate secured backup site in Sterling, Virginia. 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). In accordance to FISMA Moderate systems, the FITBIR systems adhere to the NIST 800-53 (https://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-53r4.pdf) security standards and guidelines. All documentation is held in either NSAT system at NIH or Confluence, the content management system. Both NSAT and Confluence are internal only.

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. System administrators will grant proper roles and operating boundaries for each of their users. The next design consideration is to establish control points. Firewalls will be 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 systems operations is 24x7 with redundancies and are backed up on a nightly basis, as well as archived to a secure offsite facility in Sterling, VA. 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 Assessment and Authorization (A&A) system is an NIH mandated review of the system required every 3 years. 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 carry out as 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 4 (https://nvd.nist.gov/800-53/Rev4/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/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 .

Reviewer Entry

Reviewer 1

Comments:
Accept

Reviewer 2

Comments:
Accept

APPLICANT FEEDBACK

Comments/feedback

These requirements are not seen as final, and we value your input to improve the core certification procedure. To this end, please leave any comments you wish to make on both the quality of the Catalogue and its relevance to your organization, as well as any other related thoughts.

Response:

Reviewer Entry

Reviewer 1

Comments:

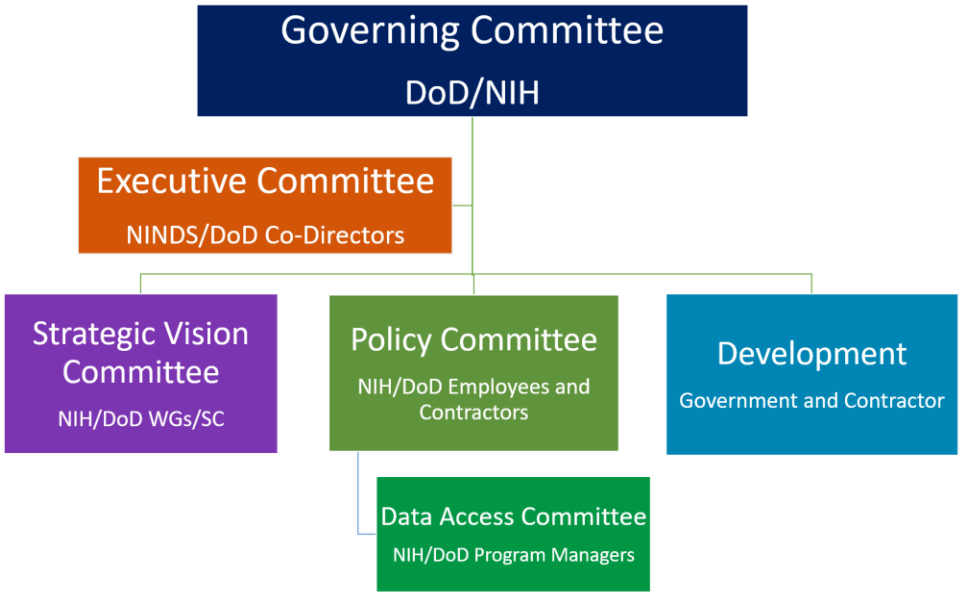
Reviewer 2

Comments:

The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System: Core Trust Seal Application

Section R0: Brief Description of Repository

The organizational relationships for FITBIR are summarized in the **Figure 1** below:



SectionR0: Outsource Partners. If applicable, please list them.

A list of partners and relationships is provided in the table below. None of the partners listed below have undertaken a trustworthy repository assessment specifically for FITBIR.

Partners	Insource or Outsource	Nature of Relationship
NIH-CIT	Insource	Organizational
NIH-NINDS	Insource	Organizational
DoD	Insource	Organizational
Publicis Sapient	Outsource	Contractual
GDIT	Outsource	Contractual

Table converted to list:

- NIH-CIT: Insource Partner, Organizational Relationship
- NIH-NINDS: Insource Partner, Organizational Relationship
- DoD: Insource Partner, Organizational Relationship
- Publicis Sapient: Outsource Partner, Contractual Relationship
- GDIT: Outsource Partner, Contractual Relationship