

Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR) Policy Document

Contents

Background	2
Applicability	4
Data Management	5
Publication	11
Expectations Defined in the Policy for Investigators	11
Definitions.....	12

Background

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 further 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.

A central function of FITBIR is to store and link together phenotypic, diagnostic and treatment variables, and outcomes data derived from individuals who participate in TBI research studies. FITBIR provides the infrastructure to store, search across, and analyze these varied types of data. In addition, FITBIR provides longitudinal storage of a research participant's information generated by one or more research studies. That is, FITBIR will enable researchers to assign a unique alphanumeric code, called a Global Unique Identifier (GUID—described in more detail below), to each study participant, which will link a single participant's data even if collected at different locations or through different studies. FITBIR gives researchers access to larger data sets than they can collect on their own, and makes it easier and faster for researchers to gather, evaluate, and share TBI research information from a variety of sources.

FITBIR is designed to shorten the period of time involved in aggregating and analyzing reliable and high quality data necessary to advance TBI research and address unmet clinical needs. FITBIR will provide a powerful forum for sharing data across TBI studies and populations. Though many TBI researchers would like to share data, the resources required and the lack of shared data definitions and standardized data collection approaches have prevented these initiatives. The [TBI Common Data Elements](#) and FITBIR are providing the tools to enable reliable data sharing.

Protecting Research Participants

The potential for public benefit to be achieved through sharing TBI research data is significant. However, genotype and phenotype information generated about individuals, such as data related to the presence or risk of developing illnesses and information regarding paternity or ancestry, may be sensitive. Therefore, protecting the privacy of the research participants and the confidentiality of their data is critically important. Risks to individuals, groups, or communities should be balanced carefully with potential benefits of the knowledge to be gained through FITBIR. The sensitive nature of information about participants and the broad data distribution goals of FITBIR highlight the importance of the informed consent process to this research.

For prospective studies, in which data submission into the FITBIR informatics system is conceived within the study design at the time research participants provide their consent, DOD and the NIH expect specific discussion within the informed consent process and documentation that participants' genotype and/or phenotype data will be shared for research purposes through the FITBIR Informatics System. Subject consent forms should include language similar to the following:

“All links with your identity will be removed from the data before they are shared.
Only de-identified data, which does not include anything that might directly identify

you, will be shared with FITBIR users and the general scientific community for research purposes.”

For retrospective studies, the agencies anticipate considerable variation in the extent to which data sharing and future research have been addressed within the informed consent documents. The submitting institution will determine whether a study is appropriate for submission to FITBIR (including an Institutional Review Board (IRB) and/or Privacy Board review of specific study elements, such as participant consent). The agencies anticipate that a number of studies proposing to include pre-existing data or samples may require additional consent of the research participants. The agencies may give programmatic consideration to requests for funds or other resources needed to conduct additional participant consent when appropriate.

The DOD and the NIH recognize that scientific, ethical, and societal issues relevant to this policy are evolving, and the agencies have established a Policy Committee to oversee FITBIR policy implementation and data use practices. The agencies will revisit and revise the policy and related practices as appropriate.

Non-Research Use of Data

As agencies of the Federal Government, the DOD and the NIH are required to release Government records in response to a request under the Freedom of Information Act (FOIA), unless they are exempt from release under one of the FOIA exemptions. Although the FITBIR-held data will be coded, and neither DOD nor the NIH will hold direct identifiers to individuals within the FITBIR Informatics System, the agencies recognize the personal and potentially sensitive nature of the genotype-phenotype data.

The DOD and NIH believe that release of un-redacted FITBIR datasets in response to a FOIA request would constitute an unreasonable invasion of personal privacy under FOIA Exemption 6, 5 U.S.C. § 552 (b)(6). Therefore, among the safeguards that the agencies foresee using to preserve the privacy of research participants and confidentiality of genetic data is the redaction of individual-level genotype, phenotype, and other clinical data from disclosures made in response to FOIA requests and the denial of requests for un-redacted datasets.

In addition, the DOD and the NIH acknowledge that legitimate requests for access to data made by law enforcement offices to FITBIR may be fulfilled. Neither DOD nor the NIH will possess direct identifiers within the FITBIR Informatics System, nor will the agencies have access to the link between the data code and the identifiable information that may reside with the primary investigators and institutions for particular studies. The release of identifiable information may be protected from compelled disclosure by the primary investigator’s institution if a Certificate of Confidentiality is or was obtained for the original study. The NIH and the DOD explicitly encourage investigators to consider the potential appropriateness of obtaining a Certificate of Confidentiality as an added measure of protection against future compelled disclosure of identities for studies planning to collect genome-wide association data. (Further information about Certificates of Confidentiality is available at: <http://grants.nih.gov/grants/policy/coc/>). These confidentiality provisions may not apply to military subjects’ chains of command.

Stigmatization

Tools for analysis of genomic data increasingly are able to make inferences about some individual traits (e.g., height, weight, skin and hair and eye color) and to identify predilections for characteristics (e.g., risk of developing some diseases) and behaviors with social stigma. In recognition of these risks, the FITBIR policy includes steps to protect the interests and privacy concerns of individuals, families, and identifiable groups who participate in TBI genetic and other research. The DOD and the NIH are asking investigators submitting datasets to FITBIR to certify that an appropriate IRB has considered such risks and that the data have been de-identified in accordance with the 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.

Oversight and Governance of FITBIR

The DOD and the NIH have developed a governance structure for FITBIR to provide oversight. The Chair of the Joint Program Committee 6, Combat Casualty Care Research Program, U.S. Army Medical and Materiel Command and the Deputy Director of the NIH National Institute of Neurological Diseases and Stroke (NINDS) co-chair and oversee the FITBIR policy and its implementation. In carrying out this responsibility, the co-chairs and the Scientific Director (or designee) from the NIH Center for Information Technology (CIT) participate on a Governing Committee, which is responsible for the on-going management and stewardship of FITBIR policy and procedures. Reporting to the Governing Committee are several groups and teams charged with the implementation, communication, and development of specific procedures related to the conduct, submission, and data release practices for FITBIR. One of these groups, the FITBIR Policy Committee, is responsible for overseeing FITBIR policy and data access to promote consistent and robust participant protections in FITBIR.

The policy addresses (1) data sharing procedures, (2) data access principles, and (3) issues regarding the protection of research participants during the submission of, storage of, and access to data within the FITBIR Informatics System. The goal of the policy is to advance science for the benefit of the public through the creation of a centralized Federal data repository for TBI research information. The principles contained in this policy were developed by the FITBIR Policy Committee and are consistent with existing NIH and DOD polices on data sharing.

Applicability

This DOD/NIH policy applies to:

- Competing grant applications that include FITBIR and are submitted to the DOD or the NIH on or after July 15, 2012;
- Proposals for contracts that include FITBIR and are submitted to the DOD or the NIH on or after July 15, 2012; and DOD and NIH intramural research projects that include FITBIR and are approved on or after July 15, 2012.
- Research studies funded by other agencies and groups who would like to deposit data into the FITBIR Informatics System.

The sharing of TBI-related research information through FITBIR is a priority to the DOD and the NIH. As such, the agencies will strongly encourage investigators to address the submission of research information to FITBIR as part of their TBI-related funding applications.

Data Management

Informatics System

To facilitate broad and consistent access to federally supported datasets on TBI research, the DOD and the NIH have developed a central FITBIR Informatics System at the NIH Center for Information Technology (CIT). The repository will provide a single point of access to basic information about federally supported datasets for TBI studies. Research studies funded by other agencies and groups may also deposit data into the FITBIR Informatics System following review and acceptance by the Data Access and Quality Subcommittee. NIH- and DOD-supported human TBI research studies—including both intramural and extramural studies—will be expected to deposit data into the FITBIR Informatics System. In the future, FITBIR may accept data from animal and computational modeling TBI research studies, as the necessary definitions and common data elements continue to evolve. Investigators applying for funding from participating agencies will be asked to submit a data sharing plan consistent with FITBIR policy as part of their application.

To ensure the security of the data held in the informatics system, the CIT will employ multiple tiers of data security based on the content and level of risk associated with the data. FITBIR will establish and maintain operating policies and procedures to address issues including, but not limited to, the privacy and confidentiality of research participants, the interests of individuals and groups, data access procedures, and data security mechanisms. These will be reviewed periodically by the FITBIR oversight bodies as appropriate.

Data Submission

Researchers conducting NIH- and DOD-supported TBI human-subjects research are required to use the [TBI Common Data Elements](#) (CDEs), an effort to create standardized definitions and guidelines about the kinds of data that should be collected, and how to collect these data in clinical studies of TBI. FITBIR will work with researchers to map their study variables to specific CDEs. In addition, FITBIR will consult with researchers to ensure the formats of the CDEs collected are compatible with the FITBIR system. In addition to CDE variables, FITBIR will accept raw data from imaging, biomarker, or physiologic studies. All data and information will be submitted to a high security network within the CIT through a secure transmission process. Submissions should also include:

- the study protocol,
- manual of operations,
- variables measured,
- case report forms, and
- other supporting documentation.

Data submitted to the FITBIR Informatics System will be 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). Creating the GUID involves several steps.

- The researcher uses his/her computer to enter pre-defined personal identifiers about research participants (e.g., birth name, Social Security number) into a specific computer program provided by FITBIR. The program processes these personal identifiers at the researcher's site into several intermediary codes known as "hash codes."
- The hash codes are then sent from the researcher's institution to the FITBIR GUID server at FITBIR where they are assigned a GUID. The FITBIR GUID server also stores the hash code-to-GUID relationship to ensure that the same research participant consistently is assigned the same GUID irrespective of whether he/she participates in different research studies or at different research sites.
- The FITBIR GUID server returns the GUID to the researcher, who assigns it to the research participant's health information.
- Once the GUID is assigned to the research information, the combined set may be uploaded into FITBIR.
- FITBIR cannot accept data without the GUID.

The process of assigning a GUID keeps direct identifiers from ever being transmitted or stored in the FITBIR system. Researchers should direct questions to their institutions or contact legal counsel about how the Privacy Rule may apply to a specific research project or organization.

In cases where a study is supported by funding mechanisms other than those provided by the DOD and NIH, it may not be possible for all data to be deposited for eventual sharing with external investigators. In such cases, the FITBIR Data Policy Committee will determine appropriate procedures in collaboration with the external funding source on a case-by-case basis, deferring to pre-existing policies, regulations, and constraints.

Submissions of data to FITBIR should be accompanied by a written certification (detailed below) stating that the identities of research participants will not be disclosed to the FITBIR Informatics System. Therefore, the FITBIR Informatics System will be unable to provide individual research results derived from analyses of submitted data to research participants. General information regarding known publications analyzing datasets in FITBIR will be made available to the public through the informatics system. In addition, all submissions to the FITBIR Informatics System should be accompanied by a certification signed by the PI 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 datasets is consistent with the standards outlined above;
 - It has considered the risks to individuals, their families, and groups or populations associated with data submitted to the FITBIR Informatics System; and
 - The genotype and/or phenotype data to be submitted were collected in a manner consistent with DOD and NIH regulations and policies.

While the DOD and the NIH encourage data sharing through this policy, circumstances beyond the control of investigators may preclude submission of TBI research data to the FITBIR Informatics System. 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.

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.

Data Submission Schedule

Outlined below is the two-tiered approach for data submission to, and sharing through, FITBIR. The first tier is for baseline data, and the second for ‘experimental’ data to test hypotheses and/or answer research questions (**see DEFINITIONS**). The objective of this two-tiered approach is to make data available to the research community as soon as possible without compromising the ability of the research team to interpret and present their main findings. Prior to award, the Principal Investigator and the DOD or NIH Program Official will determine what constitutes baseline and experimental data.

Baseline data are those data used to characterize a subject enrolled in the research study (see *Definitions* at the end of this document), including data from standard diagnostic assessments, standard clinical measures, family/subject medical history, demographic data, raw unprocessed images, genetic data, and genetic test results (that are being collected in the course of the supported research). **Not included** as baseline data are analyzed data resulting from clinical observations, outcome variables, laboratory measures, etc. These are considered experimental data. Baseline data shall be submitted to FITBIR on a quarterly basis.

The submission schedule for **baseline data** is as follows:

Data collection period	Quarterly upload due:
January 1 – March 31	June 30
April 1 – June 30	September 30
July 1 – September 30	December 31
October 1 – December 31	March 31

Experimental data (see Definitions) **shall be submitted within six (6) months after the last study participant visit in which the primary outcome is measured.** Included as experimental data are:

- Experimental results.
- Data from custom or proprietary clinical assessments/measures that support the primary aims of the proposed research or are otherwise not included in the quarterly submissions.
- Final data and/or images derived from processed images (see Definitions).
- Sufficient supporting documentation to enable efficient and appropriate use of the data by the broader research community (see Definitions).
- All other de-identified research data acquired through the supported research but not explicitly listed here.

Provisions for Data Submission

- All human subject data provided must include a FITBIR Global Unique Identifier (GUID). Data submitted to FITBIR must not include personally identifiable information (PII).
- All data collected on all human subjects enrolled in the DOD- or NIH-supported research are expected to be provided. These include data from control subjects. All reasonable efforts should be made to map the variables to the [TBI Common Data Elements](#). FITBIR staff will be available to consult in this process.
- Individual subject-level data rather than summary/aggregate data are expected.

Data Sharing Schedules

Baseline research data are generally made available for access to other approved researchers within six (6) months after submission, allowing FITBIR sufficient time to complete appropriate quality assurance/quality control (QA/QC) procedures.

Experimental research data are generally made available in a staged manner following data submission. Access is limited to the Study Team for the first 6 months following data submission. Access is expanded to include researchers who have submitted data to FITBIR (Data Submitters) during the next 6 months after submission, and is generally open to all qualified researchers 12 months after submission. Collaborative research between the Study Team and other researchers is encouraged.

Schedule for Access to Experimental Data following Submission to FITBIR

Study Team	→		
FITBIR Data Submitters	→		
Other Qualified Researchers	→		
	0 – 6 months	7 -12 months	> 12 months

In exceptional instances, deviations from the above in terms of timelines or types of data to be shared may be negotiated with the Program Official for the award before the award is made. If circumstances arise during the course of the research that might cause deviations from these terms, such deviations must receive approval from the FITBIR Data Access and Quality Committee. The investigator may request an extension to this timeframe with an approved justification. Extensions will not be granted for the singular purpose of delaying QA/QC activities. To request this extension, an investigator is required to develop a brief, written request to include:

1. The title of the FITBIR Study for which he/she is requesting the extension;
2. The scientific rationale for the extension;
3. A description of the data requiring the extension;
4. A schedule for the release of the data requiring the extension; and,
5. A description of data that will be released in the original timeframe.

For an extension supporting a longitudinal outcome, investigators should identify which time points may be provided (e.g., baseline) and which time points should be considered as primary outcome data.

FITBIR Data Access

As data become available through FITBIR, the DOD and the NIH will provide basic descriptive and aggregate summary information, basic TBI injury descriptions, and descriptions of available data for general public use. Such summary information may include automated calculations and general statistics on completed assessment instruments, for example.

Access to data for research purposes will be provided through the FITBIR Data Access and Quality Committee (DAQ). Membership of the DAQ will include Federal staff with relevant expertise in areas such as the relevant particular scientific disciplines, research participant protection, and privacy. The agencies anticipate that the FITBIR DAQ may be established based on programmatic areas of interest and the relevant needs for technical and ethics expertise. The FITBIR DAQ will operate according to common principles and follow similar procedures to ensure the consistency and transparency of the FITBIR data access process. The DAQ will review the applications of each investigator requesting data and make a determination based on their affiliation with a research institution, and on the basis of the reason for the request. It is anticipated that most requests will be legitimate and can be approved

rapidly, and that only a few will require clarification. IRB compliance is the responsibility of the applicant, and requestors will be required to provide IRB numbers and expiration dates.

Investigators and institutions seeking data from the FITBIR Informatics System will be expected to meet data security measures (such as physical security, information technology security, and user training) and will be asked to submit a [data access request](#) that is signed by the investigator. Data access requests should include a brief description of the proposed research use of the requested FITBIR data. Investigators will agree, among other things, to:

- Use the data only for the approved research;
- Protect data confidentiality;
- Follow appropriate data security protections;
- Follow all applicable laws, regulations and local institutional policies and procedures for handling FITBIR data;
- Not attempt to identify individual participants from whom data within a dataset were obtained;
- Not sell any of the data elements from datasets obtained from the FITBIR Informatics System;
- Not share with individuals other than those listed in the request any of the data elements from datasets obtained from the FITBIR Informatics System;
- Agree to the list of approved research uses within the FITBIR Informatics System along with his/her name and organizational affiliation;
- Agree to report, in real time, violations of the FITBIR policy to the DAQ;
- Acknowledge the FITBIR policy with regard to publication; and
- Provide annual progress reports on research using FITBIR data.

The DAQ will review requests to determine whether the proposed use of the dataset is scientifically and ethically appropriate. In the event that requests raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAQ will consult with other experts as appropriate. It is anticipated that denials for data access will be unusual, but in circumstances where this does occur, a request to appeal the decision is allowed and will be reviewed by the FITBIR Policy Committee.

Data Quality

The quality of data within FITBIR is crucial for ensuring its usefulness and reliability for research. Therefore, the DOD and the NIH are implementing a two-tiered data control procedure for information and images submitted to the FITBIR Informatics System. Such efforts help to ensure that the information submitted has undergone reviews for accuracy, completeness, and availability. The first level of quality control is performed by the researcher who is expected to certify the accuracy of the information prior to submission.

The second level of quality control occurs when data and/or images are submitted to the FITBIR Informatics System for broad research access. The DOD and the NIH normally provide a period of up to six months to allow the Submitter and the agencies to undertake activities to review the completeness of the submission. Such efforts include 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, access to data and brain images for research is temporarily suspended to help ensure that FITBIR makes

available only carefully reviewed information. Should the agencies determine that additional time is necessary to ensure the quality of the submitted information (e.g., time necessary to remedy concerns), the agencies may opt to extend the quality control period as necessary in the interest of science. After quality control measures are satisfied, the submitted information will be certified as accurate by the submitting researcher.

Publication

The DOD and the NIH expect all investigators who access FITBIR data to acknowledge the Contributing Investigator(s) who conducted the original study, the funding organization(s) that supported the work, and the FITBIR Informatics System in all resulting presentations, disclosures, or publications of the analyses. Data Recipients should submit manuscripts to the DAQ for administrative review at least four weeks prior to submission for publication. This review is not for scientific review, but to ensure that the terms of the user agreement have been met, the description of FITBIR procedures are accurately identified, and that FITBIR and the original researchers are appropriately acknowledged. These administrative reviews will take no longer than two weeks.

Expectations Defined in the Policy for Investigators

The detailed expectations are enumerated in the individual sections of this policy, and summarized as follows:

Investigators submitting FITBIR data are expected to:

- Provide descriptive information about their studies;
- Submit coded genotypic and phenotypic data to the FITBIR Informatics System; and
- Submit a [data submission form](#), providing assurance that all data are submitted to the DOD and the NIH in accord with applicable laws and regulations, and that the identities of research participants will not be disclosed to the FITBIR Informatics System.

Investigators requesting and receiving FITBIR data are expected to:

- Submit a description of the proposed research project;
- Submit a [data access request](#)
- Protect data confidentiality;
- Ensure that data security measures are in place;
- Notify the Data Access and Quality Committee of policy violations; and
- Submit annual progress reports detailing significant research findings.

Inquiries

Additional information and detailed implementation guidance related to the FITBIR Informatics System can be found at <http://fitbir.nih.gov>. Specific questions about this policy should be directed to the FITBIR Operations Team (FITBIR-ops@mail.nih.gov).

Definitions

Data: For human subjects, data include all research and clinical assessments and information obtained via interviews, direct observations, laboratory tasks and procedures, records reviews, genetic and genomic data, neuroimaging data, neuropsychological assessments, data from physical examinations, etc. The following are not included as data: laboratory notebooks, preliminary analyses, drafts of scientific papers, plans for future research, peer review reports, communications with colleagues, or physical objects, such as gels or laboratory specimens.

Baseline data: Baseline data include family/medical history, demographic data, data from standard diagnostic instruments, or custom measures supporting a categorization of a subject's phenotype. Additionally, raw unprocessed images and genomic submissions are also categorized as baseline data. For longitudinal neuroimaging studies, where images at different time points are considered outcome measures, only baseline raw images are defined as baseline data.

Experimental Data: Data specific to the primary aims of the research being conducted (e.g. outcome measures, other dependent variables, observations, laboratory results, analyzed images, volumetric data, etc.).

Supporting documentation: Clear documentation expected in order to enable an investigator unfamiliar with the dataset to understand and use the data. For example, supporting documentation may include non-copyrighted data collection forms, study procedures and protocols, data dictionary rationale, exclusion criteria, website references, a listing of major study publications, and the definition of a genomic analysis protocols.