Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR)

Data Sharing Policy

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Contents

Overview

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. Additional information and detailed implementation guidance related to the FITBIR Informatics System can be found at http://fitbir.nih.gov.

Expectations Defined in the Data Sharing Policy for Investigators

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

Investigators submitting FITBIR data are expected to:

- Submit a Data Submission Form, providing assurance that all data are submitted in accord with applicable laws and regulations, and that the identities of research participants will not be disclosed to the FITBIR Informatics System; and
- Upload ALL data to FITBIR on a quarterly basis.

Investigators requesting and receiving FITBIR data are expected to:

- 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;
- Submit annual progress reports detailing significant research findings; and
- Include acknowledgements of the FITBIR Informatics System in all publications and presentations.

Applicability

This Data Sharing Policy applies to:

- DOD and NIH extramural and intramural research projects approved on or after January, 2014 that include TBI clinical studies, defined as:
    - Patient-oriented research. Research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. Excluded from this definition are *in vitro* studies that utilize human tissues that cannot be linked to a living individual. It includes:
        - mechanisms of human disease;
        - therapeutic interventions;

        - clinical trials;
        - development of new technologies;
    - Epidemiological and behavioral studies;
    - Outcomes research and health services research.
- Research studies supported by other agencies and groups who would like to deposit data into the FITBIR Informatics System.

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 Data Sharing 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 Data Sharing 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 Data Sharing Policy and Data Access to promote consistent and robust participant protections in FITBIR.

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

Data Management

Protecting Research Participants

The potential for public benefit to be achieved through sharing TBI research data is significant. However, the broad data distribution goals of FITBIR highlight the importance of protecting the privacy of the research participants and the confidentiality of their data. FITBIR Data Sharing 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 informed consent process is a critical step and subject consent forms in prospective studies 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 do 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 conducted before the development of FITBIR, 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). Some studies may require additional consent of the research participants. 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.

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 the 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 the 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 are 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 the 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 (http://grants.nih.gov/grants/policy/coc/) as an added measure of protection against future compelled disclosure of identities for studies planning to collect genome-wide association data. These confidentiality provisions may not apply to military subjects' chains of command.

Data Submission

NIH- and DOD-supported human TBI research studies—including both intramural and extramural studies—will be required to deposit data into the FITBIR Informatics System. Research studies funded by other agencies and groups may also deposit data into the FITBIR Informatics System, pending review by the FITBIR Policy Committee in collaboration with the external funding source on a case-by-case basis, deferring to pre-existing policies, regulations, and constraints. Investigators applying for funding from participating agencies will be asked to include a data sharing plan consistent with FITBIR policy as part of their application and are expected to use the CORE TBI Common Data Elements (CDEs) at a minimum.

FITBIR Operations team 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 Informatics System. In addition to CDE variables, FITBIR will accept raw data from imaging, biomarker, or physiologic studies, additional supporting documentation as follows:

- the study protocols;
- manual of operations;
- variables measured;
- case report forms; and
- other relevant documents.

All data and information will be submitted to a high security network within the CIT through a secure transmission process, including the 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). 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 Principle Investigator 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;

- 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.

While the agencies expect 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. 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.

Data Submission Schedule

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. In addition, supporting documentation that is needed to enable an investigator unfamiliar with the dataset to understand and use the data is also required. 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. 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. All data*will be submitted to FITBIR on a quarterly basis according to the following schedule:

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

* Clinical trials are exempted from this schedule; all data from clinical trials must be submitted within a year following the end of the performance period of the award.

FITBIR Data Sharing Schedule

Six months after submission of the data, the ***Core*** (required) and ***Basic*** (recommended) TBI common data elements (***CDEs***) that are used in the study will be made available to all qualified and approved researchers (Recipients) as determined by the Data Access and Quality Committee (DAQC). Other data

fields can also be made available at the submitting principal investigator's (Submitter's) discretion. Outcomes data and other data elements needed by the principal investigator to test his/her hypotheses or research questions, referred to as ***Experimental Data***, will be made available in a staged manner. Six months after the award period ends, ***Experimental Data*** will be open to other researchers who have submitted data to FITBIR (Submitters). Twelve months after the award period ends, ***Experimental Data*** will be open to all qualified and approved researchers (Recipients)**.**

Table. Summary of the FITBIR Data Sharing Schedule

Core and Basic CDEs	Data are uploaded quarterly after subject enrollment begins and data are available six months after submission to all approved FITBIR Data Recipients. Specific CDEs can be exempted pending approval by the DAQC if they are needed to test the primary study hypothesis or research question.
Experimental Data	All approved FITBIR Data Recipients gain access either: a) Six months after the award period ends if they are a FITBIR Submitter; or b) Twelve months after the award period ends for those who are not FITBIR Submitters. Access can also be granted earlier if agreed to by the Submitters of ongoing study(s) or in rare cases when the DAQC over rules the Submitters' denial on the grounds that the request does not compromise completion of the ongoing study.

Investigators are also strongly encouraged to collaborate and share data throughout the study to accelerate research and advance knowledge on TBI. To facilitate collaboration, data access request forms may be submitted before the end of the performance period to the DAQC for initial review and then forwarded on to the relevant Submitters. The Submitters may choose to collaborate and/or to provide access to all or some of their ***Experimental Data***, in which case the data will be made available to the data Recipients. Alternatively, the Submitters may choose to deny early access, in which case the request will be reviewed by the DAQC in consultation with the Submitters. In this case, approvals for early access will only be granted by the DACQ if it is clear that the data request does not negatively impact the completion of the original study. For example, prospective data collection projects that are powered to answer specific questions would be jeopardized by premature analysis of these same questions. However, if important research can be accomplished without jeopardizing the study, the value of the FITBIR data will be greatly enhanced by data sharing that advances the science of TBI.

FITBIR Data Access

FITBIR will provide descriptive summary information of submitted data for general public use. Access to data for research purposes will be provided through the FITBIR DAQC. Membership of the DAQC will include Federal staff with expertise in areas such as the relevant particular scientific disciplines, research participant protection, and privacy. The FITBIR DAQC will operate according to common principles and follow similar procedures to ensure the consistency and transparency of the FITBIR data access process. The DAQC will review the applications of investigators 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 appropriate and can be approved rapidly, and that only a few will require clarification. In the event that requests raise concerns related to privacy and confidentiality, risks

to populations or groups, or other concerns, the DAQC will consult with other experts as appropriate. A request to appeal the decision is allowed and will be reviewed by the FITBIR Policy Committee.

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; if the Recipient wants to use the data to investigate additional research questions, a second data access request form must be submitted.
- 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;
- Provide IRB numbers and expiration dates;
- Agree to report, in real time, violations of the FITBIR Data Sharing Policy to the DAQC;
- Adhere to the FITBIR Data Sharing Policy below with regard to publication; and
- Provide annual progress reports on research using FITBIR data.

Data Quality

The DOD and the NIH are implementing a two-tiered data control procedure for information and images submitted to the FITBIR Informatics System 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. FITBIR will provide a period of three 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 strongly encourage collaboration, but at a minimum all investigators who access FITBIR data are expected to acknowledge the funding organization(s) that supported their work, the Contributing Investigator(s) who conducted the original study, and the FITBIR Informatics System in all resulting presentations, disclosures, or publications of the analyses. Data Recipients should submit manuscripts to the DAQC for administrative review at least four weeks prior to submission for publication. This review is not a scientific review, but an administrative review to ensure that the terms of the user agreement have been met, the description of FITBIR procedures are accurately identified, and FITBIR and the original researchers are appropriately acknowledged. These administrative reviews will take no longer than two weeks.

Inquiries

Specific questions about this policy should be directed to:

Office of FITBIR Operations
National Institutes of Health, Center for Information Technology (CIT)
Building 12A
12 South Dr. RM 2041
Bethesda, MD 20892
301-594-3532
Email: FITBIR-ops@mail.nih.gov