Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR) and National Trauma Research Repository (NTRR)

Data Sharing Policy

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Overview

From here on, the Federal Interagency Traumatic Brain Injury Research (FITBIR) and the National Trauma Research Repository (NTRR) will collectively be referred to as "the Informatics System." The 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) and polytrauma. The Informatics System provides a common platform and standardized format for data collection, retrieval, and archiving while allowing for flexibility in data entry and analysis. It currently includes two data store modules-the Data Repository Module and the Meta Study Module (See Section on Data Repository vs. Meta Study Module for further details). Information and detailed implementation guidance related to the Informatics System can be found at FITBIR: https://fitbir.nih.gov/ or NTRR: https://ntrr.nih.gov/.

Summary of Expectations

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

Investigators submitting Informatics System data are expected to:

- Submit a Data Submission Request, 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 Informatics System; and
- Upload ALL data to the Informatics System on an annual basis.

Investigators requesting and receiving Informatics System 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 acknowledgments of the Informatics System in all publications and presentations.

Applicability

Agencies' Data Sharing Policies apply as follows:

- DoD-funded research projects 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.

- **(Note: For FITBIR Only):** Per NOT-NS-23-046, investigators involved in clinical (i.e., human subjects research) TBI studies that meet at least 1 of the following criteria (taken from NOT-NS-17-029) **must submit their data to the FITBIR Data Repository**

    - TBI-related clinical trials (i.e., studies funded under any of the NINDS Clinical trial FOAs),

    - All unsolicited clinical (i.e., human subjects research) TBI research grants with a budget greater than or equal to $500,000/year in direct costs

    - NINDS ancillary studies, regardless of budget, to either TBI-related clinical trials or clinical TBI research grants (i.e., human subjects research) with budgets greater than or equal to $500,000/year in direct costs.

    - Clinical (i.e., human subjects research) TBI research awards made under funding opportunity announcements (FOAs) with specific requirements for FITBIR data submission.

    - NIH, VA, and DoD program staff may request that clinical research projects submit data to the FITBIR Data Repository even though these projects are not covered under the new FITBIR data submission policy

(Note: For DoD-funded FITBIR studies only): Any DoD-funded prospective clinical study including 50 or more subjects must submit their data to the FITBIR Data Repository.

Consistent with the overall NIH Data Management and Sharing Policy, NINDS-funded TBI research data involving human subjects research that does NOT meet any of the above criteria will be required to house data in the Meta Study Module within FITBIR. Note, if a study that does not meet the above criteria prefers to submit its data to the Data Repository, they are allowed to do so, given prior programmatic approval. (See Section on Data Repository vs. Meta Study Module for further details)

- TBI genomic studies that generate large-scale genomic data, regardless of the size of the budget, or NIH grant funding mechanism, should follow the guidance of the NIH Genomic Data Sharing Policy.

- Research studies supported by other agencies and groups that would like to share data in the Informatics System may request permission to do so by contacting an appropriate program representative who will forward the request to a member of the Data Integration Committee, which includes Program staff from the NIH and DoD. This committee will determine whether data submission is feasible on a case-by-case basis.

Oversight and Governance

The DoD and the NIH have developed a governance structure for the Informatics System 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 Director of the NIH National Institute of Neurological Diseases and Stroke (NINDS) co-chair and oversee the 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 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. One of these groups, the Policy Committee, is responsible for overseeing the Data Sharing Policy and Data Access to promote consistent and robust participant protections.

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 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 and trauma research information. The principles contained in this policy were developed by the Policy Committee and are consistent with existing NIH and DoD policies 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 and trauma research data is significant. However, the broad data distribution goals of the Informatics System highlight the importance of protecting the privacy of the research participants and the confidentiality of their data. The 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 Informatic System users and the general scientific community for research purposes."

For retrospective studies conducted before the development of the Informatics System, 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 the Informatics System (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 system employs multiple tiers of data security based on the content and level of risk associated with the data. The Informatics System 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 Informatics System 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 Informatics System-held data will be coded, and neither the DoD nor the NIH will hold direct identifiers to individuals within the 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 Informatics System 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 the Informatics System may be fulfilled. Neither the DoD nor the NIH will possess direct identifiers within the 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. These confidentiality provisions may not apply to military subjects' chains of command.

Data Submission

NIH- and DoD-supported human TBI and trauma research studies—including both intramural and extramural studies—will be required to deposit data into the Informatics System. Research studies funded by other agencies and groups may also deposit data into the Informatics System, pending review by the 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 the Informatics System policy as part of their application and are expected to use the TBI Common Data Elements (CDEs) or Trauma CDEs.

Submission to the Data Repository of FITBIR requires submitting data using standardized common data elements (CDEs). The Operations team will work with researchers to map their study variables to specific CDEs within the larger FITBIR Data Element Dictionary. In addition, Operations will consult with researchers to ensure the formats of the CDEs collected are compatible with the Informatics System. In addition to CDE variables, the Informatics System 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 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 Operations 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 the Informatics System 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 the Informatics System—or each subject's record—has a different GUID). The Operations staff will assist investigators in how to create the GUID, which is an essential requirement for uploading data to the Data Repository.

Investigators submitting datasets to the Informatics System 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 Data Access and Quality Committee (DAQC) will consult with other experts as appropriate.

Submissions of data to the Informatics System shall be accompanied by a certification signed by the Principal 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 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 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 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 the submission of TBI or polytrauma research data to the Informatics System. Applications submitted to these agencies for support of TBI and polytrauma 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 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 Quality

The DoD and the NIH implemented a two-tiered data control procedure for information and images submitted to the Data Repository 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 Informatics System for broad research access. The Informatics System 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 the Informatics System is complete (i.e., not missing records intended for submission), contains no identifying information, displays correctly, and that the Informatics System 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 the Informatics System 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.

Data Repository vs. Meta Study Module

The Data Repository Module is a highly structured and harmonized data store mainly designed to accommodate primary data. This structure facilitates dataset aggregation among studies, efficient querying, and reusability. In contrast, the Meta Study Module is a more flexible data store primarily designed to accommodate aggregated secondary analysis data, though in select cases, it can also serve as a primary data store. (See the Applicability section above for details regarding specific requirements for submitting data to each module.) Specifically, while submission to the Data Repository requires submitting data using standardized common data elements (CDEs) available in the Data Element Dictionary; the Meta Study Module's data-submission format is more flexible and does not include this requirement. However, data submitted to the Meta Study module is still assigned a Digital Object Identifier (DOI), allowing researchers to cite FITBIR data in publications to support making data more findable. Notably, FITBIR does not accept Personally Identifiable Information (PII) or Protected Health Information (PHI), regardless of whether data is submitted to the Data Repository or Meta Study.

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

- **Meta Analyses**
  - Facilitates aggregation of data derived from other studies within the BRICS Data Repository Module for meta-analyses
  - Facilitates aggregation of data derived from other studies within the BRICS Data Repository Module plus accommodates upload(s) of data external to BRICS to be included in meta-analyses

- **Data Store**
  - Facilitates storage of data in a structured, yet comparatively flexible, format that supports the minimum requirements of the NIH Data Management and Sharing Policy

Data Submission Schedule

Data include all research and clinical assessments, 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.

Note: The following information is specific to FITBIR. The FITBIR data submission policy (NOT-NS- 17-029) requires annual submission of all clinical research outcome and non-outcome data. For NIH grants, reporting

of FITBR data submission progress should be included as part of the studies' annual Research Performance Progress Report. Funds may be restricted if studies fail to comply with the annual data submission policy. Furthermore, the previous accelerated sharing of Core and Basic CDEs in FITBIR, as outlined in NOT-NS-14-022, is no longer applicable.

Data Sharing

Scientific data generated using federal funds and sharing such data are subject to the terms and conditions of the relevant funding mechanism, as applicable, or the existing repository data-sharing requirements.

FITBIR and NTRR policy require that twelve months after the award period ends, data and supporting materials will be available to all qualified and approved researchers (Recipients). Notably, upon initial creation, both Data Repositories and Meta Studies are private and only accessible to the owners of the data and the FITBIR operations team. Hence, early submission of data is always encouraged. In the case of early submission, investigators still have 12 months from the end of the performance period before these data are required to be available to the general research community (via a controlled and tracked approval process, i.e., Data Access Committee Approval). Investigators are responsible for the accuracy of the data they submit to the Informatics System.

NIH, VA, and DoD understand that some scientific data generated with NIH, VA, or DoD funds may be proprietary. These cases must be formally disclosed upon making a Data Submission or Data Access Request.

Even if it is not required by their respective funding agency, data Recipients are encouraged to share any published secondary analysis of primary repository data within a Meta Study Module.

Data Access

The Informatics System will provide descriptive summary information of submitted data for general public use. Researchers may submit (and request access to) studies in the Federal Interagency of Traumatic Brain Injury (FITBIR) informatics system for noncommercial research. The research project should convey an intention to enhance knowledge and technology for the characterization, prevention, diagnosis, management, and treatment of traumatic brain injury.

The investigator or their organization may own or have in-licensed intellectual property that is directly relevant to the research project. Such existing intellectual property must be disclosed as part of the FITBIR Data Use Certification (DUC).

Access to data for research purposes will be provided through the 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 DAQC will operate according to common principles and follow similar procedures to ensure the consistency and transparency of the Informatics System 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 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 Policy Committee.

Investigators and institutions seeking data from the 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 Informatics System 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 must be submitted;
- Protect data confidentiality;
- Follow appropriate data security protections;
- Follow all applicable laws, regulations and local institutional policies and procedures for handling Informatics System 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 Informatics System;
- Not share with individuals other than those listed in the request any of the data elements from datasets obtained from the Informatics System;
- Agree to the list of approved research uses within the 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 Data Sharing Policy to the DAQC;
    - Adhere to the Data Sharing Policy below with regard to publication; and
    - Provide annual progress reports on research using Informatics System data.

Publication

The DoD and the NIH strongly encourage collaboration, but at a minimum, all investigators who access Informatics System data are expected to acknowledge the funding organization(s) that supported their work, the Contributing Investigator(s) who conducted the original study, and the 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 Informatics System procedures are accurately identified, and the Informatics System 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 Informatics System Operations
National Institutes of Health, Center for Information Technology (CIT)
Building 12A
12 South Dr. RM 2041
Bethesda, MD 20892
FITBIR email: FITBIR-ops@mail.nih.gov
NTRR email: NTRR-ops@mail.nih.gov