

FITBIR Annual Report

August 1, 2013

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I. Introduction

The Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system was developed 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 relevant imaging, assessment, genomics, and other data types 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.

This report covers July 01, 2012 through June 30, 2013 (FY2013)

II. Review of Accomplishments in FY 2013

Technology Development

FITBIR is based on the Biomedical Research Informatics Computing System (BRICS) which builds upon the systems and tools developed for National Database for Autism Research (NDAR). BRICS is a collaborative, web-based system to aid and support the collection and collaboration of research studies and patient trials. The BRICS system consists of a collection of modular components which include: Global Unique Identifier (GUID), User Management, Data Dictionary Tool (DDT), Data Repository, Query, and Protocol and Form Research Management System (ProFoRMS). All of the modular components have now been delivered during FY2013. Upgraded versions of the User Management and DDT components have also been redeployed.

The system uses high-powered virtual host machines to create a virtualized environment on which the applications are deployed. This architecture provides high scalability in both processing power and storage capacity as well as providing durability and redundancy in case of a contingency event. FITBIR has a production environment and separate development environments with each containing a physical manager server and three physical host servers. Each environment has access to a combined capacity of 48 TB. An offsite storage location has been set up in Sterling, VA for disaster recovery storage. The offsite environment contains a physical server for backup. The Security Plan and Certification and Accreditation (C&A) has been completed and FITBIR has received security authorization as of 01/23/2013. FITBIR C&A expires in 3 years on 1/23/2016. FITBIR is therefore Federal Information Security Management Act of 2002 ("FISMA") compliant.

The FITBIR website (<https://fitbir.nih.gov/tbi-portal/>) has been deployed since April 2012 and is updated approximately quarterly. Detailed information about defining, contributing, and accessing data has

been made available on the website for the public to start to understand the capabilities of the system. In addition, the website provides information about policies and procedures, news articles, FAQs, participating organizations, and tools, as well as, other pertinent information related to FITBIR.

As previously mentioned, the two new modules developed for FITBIR in FY2013 include Data Access (Query) and Protocol and Form Research Management System (ProFoRMS) tools.

The Query Access component was created to provide a powerful suite of tools for accessing and retrieving data. The FITBIR Query Tool integrates with the Data Dictionary module to provide a user-friendly interface that allows users to select the type of data they want to retrieve and to filter that data for specific subject criteria. The system allows for the seamless retrieval of both data stored in the central repository and in the future data from other data repositories that have agreed to allow federated access. Once the particular data of interest has been identified, the FITBIR system allows the user to export that data and to download any associated files, such as Genomics and Imaging files. The integrated download tool provides fast download capability to the user's system.

Protocol and Form Research Management System (ProFoRMS) is a web based application that supports study design, form generation, clinical data collection and reporting. It automates the processing and monitoring of data collected for research studies. ProFoRMS will permit, design of data collection questionnaires, data capture, data import/export, data analysis, and reporting. Through its user-friendly interface, ProFoRMS will help facilitate the creation of forms, questions, intervals, and provides a data entry component allowing for first- and second-key validation workflow. With the ProFoRMS system, users will be able to design studies, design data collection forms, manage patients, capture the import/export of data, analyze clinical study data, and create reports.

In summary, the FITBIR informatics system platform allows users across different TBI research groups and institutions to submit data to a common repository where it can be combined with data from other groups and accessed by qualified researchers. FITBIR accepts Genomics, Imaging and Clinical Assessments data. Tight integration with the FITBIR Data Dictionary allows users to define their data and automatically configure a repository for that data in the system. This automation reduces the administrative work and allows users to customize the system to their data while still ensuring the quality and reliability of the data. The data submission tool developed for FITBIR manages the connection to the central repository and provides for fast transmission of data submissions. Once loaded into the system, the data can be reviewed by the user for quality assurance. An integrated workflow engine and permissions module allows the user to manage their data within the system, share it with collaborating researchers and prepare it for publication to the larger user community.

Policy Committee

The Policy Committee is composed of federal employees, predominantly program directors and policy staff from Federal granting agencies, who were appointed by the Executive Committee. (See membership list later in the report-Appendix A.) Their responsibilities include creating policies and guidelines that support the strategic vision and align with scientific and technological capabilities and operational procedures for data sharing & access, collaborations, adjudications, and publications. Over

FY 2013, the Policy Committee has ensured that policies related to FITBIR consider and reflect the needs of all stakeholders to the greatest extent possible. Specialized working groups, most notably the Data Access and Quality Committee, were formed to assist with implementation of the policies. The FITBIR Data Access Committee members have expertise in science, policy or bioinformatics resources. Collectively, the FITBIR Data Access and Quality Committee will have overall responsibility for ensuring compliance with the FITBIR Policy.

The governance committee, which was stood up in FY 2012 to ensure high-level oversight and stewardship of the FITBIR policy and procedures, was expanded in FY2013 to include a representative from the Office of the Secretary of Defense Health Affairs. This committee is designated as the lead authorities for conducting the business of the FITBIR Informatics System in a joint Memorandum of Agreement (MOA) between (1) US Army Medical Research and Materiel Command (USAMRMC), (2) Division of Computational Bioscience (DCB) of the Center for Information Technology (CIT) at the NIH, and (3) National Institute of Neurological Disorders and Stroke (NINDS) at the NIH. The FITBIR Governance document can be found in Appendix A.

Data Safeguarding and Privacy

Revisions to the FITBIR Data Sharing Policy were published in NIH Notice NS-13-008 (<http://grants.nih.gov/grants/guide/notice-files/NOT-NS-13-018.html>) approved on April 1, 2013. The overall document was shortened and reorganized to make it clearer and more concise. Also, the Data Submission and Data Sharing Schedules were modified for greater clarity and feasibility. FITBIR Policy and Agreements are posted to the FITBIR public website for public review. Further revisions to accelerate access to data are pending. In addition, the Data Access and Data Submission Agreements have been modified to make them easier to use and not require the SF-424 form and approvals from the NIH Paperwork Reduction Office are anticipated in July 2013.

A Certificate of Confidentiality was applied for and granted for FITBIR (Certificate of Confidentiality CC-NS-12-16 issued on June 15, 2012). Certificates of Confidentiality are issued by the NIH to protect identifiable research information from forced disclosure. By protecting FITBIR from being compelled to disclose information that would identify research subjects, the Certificate of Confidentiality helps achieve the research objectives and promotes participation in studies by helping assure confidentiality and privacy to participants.

NIH uses web measurement and customization technologies to help NIH Web sites function better for visitors and to better understand how the public uses the online resources. All uses of web-based technologies must comply with existing policies with respect to privacy and data safeguarding standards. Information Technology (IT) systems owned and operated by NIH are assessed using Privacy Impact Assessments (PIAs) posted for public view on the Department of Health and Human Services (DHHS) Web site (<http://www.hhs.gov/pia/nih.html>). NIH conducts and publishes a PIA for each use of a third-party website and application (TPWA) as they may have a different functionality or practice. A Privacy Impact Assessment for FITBIR was filed in FY2013. The PIA is currently is under review and a decision from the Privacy Office is expected in late July or August 2013.

Strategic Vision Committee

The Strategic Vision Committee (SVC) consists of a mix of federal liaisons and distinguished scientific experts from academia and other centers of excellence (members are listed later in this report-Appendix A). The committee has the responsibility for advising the Executive Committee for (1) strategies for maximizing the impact of the FITBIR informatics system to address critical questions in TBI diagnosis and treatment, (2) the identification and prioritization of research questions and hypotheses to be supported by the FITBIR informatics system, (3) the identification and leveraging of other related resources, tools, and projects, and (4) reviewing the draft FITBIR Annual Report and submitting strategic vision recommendations to the Executive Committee. The committee met on Nov. 19, 2012 and their recommendations and progress toward meeting them are summarized in the table below.

Strategic Vision Committee Recommendations and Progress

Recommendation	Progress
Require use of CORE CDEs on DOD- and NIH-funded grants. Recommend using as many BASIC CDEs as practical and relevant. Use SUPPLEMENTAL CDEs as needed.	Implemented.
Create CDEs for TBI and CTE Neuropathology research.	Tabled until the application in response to the RFA on the CTE Neuropathology is awarded. This task will be assigned to the investigators.
Explore possibility of developing something like WhoDrug, but a cost-free tool.	No progress.
Explore possibility of adding existing CDEs for Adverse Events (MedDRA) to FITBIR.	No progress. Plan is to follow up with the investigators who will conduct the large pediatric CER study (ADAPT) and the InTBIR study to find out if this is of interest and relevant to their research.
Encourage submission of “normative” data that is relevant to FITBIR.	No progress. Many of the studies have control groups that will build normative data. We will explore the possibility of uploading the normal pediatric MRI data that was a project supported by NIMH.
Add a site on the website about relevant resources, e.g. free analytical tools, to build on the concept of creating a “Knowledge Network”.	Analytical tools for FITBIR are under development by One Mind for Research. USC has also applied for a grant to develop tools as an extension of BIRN(pending review) and discussions with DARPA have been initiated.

Proactively disseminate information to grantees about the potential cost savings of using FITBIR and PROFORMS.	FITBIR will have a booth at the National Neurotrauma Society symposium in August. Additional steps are needed.
Prioritize the collection of these two archival data sets: NICHD TBI Network data (COBRIT Clinical Trial) and the PROTECT clinical trial data.	An administrative supplement has been given to the PROTECT study and steps to enable the cross mapping and uploading of the data have been initiated. An RFA for adding legacy data to FITBIR is published and the COBRIT investigators will be contacted to ensure they are aware of the RFA.
Investigate what is needed to federate with NIDRR TBI Models System database.	FITBIR team met with the NIDRR TBI Models System steering committee in June and a follow up call is scheduled for August.
Use a common informatics system for InTBIR Initiative because it will save money and also reduce policy issues associated with federating databases.	One Mind for Research plans to build an informatics system for the EU-funded InTBIR project. The goal is to coordinate activities to minimize redundancy and increase the value of FITBIR. Further discussions will occur at the InTBIR meeting in October, 2013.
Add a checklist of Quality Control steps to the FITBIR Data Submission Procedure.	In progress.
Develop “matchmaking” strategies to promote collaboration.	Tabled until data is available in FITBIR.
Explore potential for educational opportunities for trainees interested in using FITBIR.	Tabled until FITBIR is fully operational and has data that can be shared.

Table 1. Summary of SVC recommendations

Communications and Outreach

During FY2013, outreach efforts were made to the TBI community to seek input on the development of the FITBIR informatics system. One such method was through the development of notices about FITBIR for the NIH Guide. In addition, to regular updates to the public website there were numerous outreach efforts in FY2013 including conference presentations, individual/group demonstrations, and webinars. Press releases also provided communication outreach about FITBIR. Complete listings of these activities are listed in Appendix B.

III. Recap of FY 2013 and Plans for FY 2014

Upload legacy data to FITBIR

In FY 2013, legacy baseline data from Dr. Geoffrey T. Manley's 'Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI)' study was transformed for incorporation into FITBIR. Individual data elements were cross mapped to see if the TRACK-TBI data definitions were in synch with the TBI CDE V2.0 data elements. Unique data elements were created as needed when there was a mismatch in the definitions or when there was no definition at all. As a result of changes in the data definitions, some raw baseline data had to be converted prior to submission. Also, coded values were converted to text to allow for easier querying in the FITBIR database. Form structures were built and validated for (11) baseline data sets. Pseudo GUIDs were generated in FITBIR for 650 subjects in the TRACK-TBI study. The TRACK-TBI baseline data are now uploaded in the FITBIR Demo environment. Dr. Manley and his colleagues were provided a webinar to view the data that has been uploaded and to become familiar with the FITBIR tools. The Query tool functionality was presented during this webinar. Dr. Manley and his team now want to review the transformed data sets for data integrity. Also, his team will review and provide updates(s) to the FITBIR Operations team since raw data may have changed/been updated since the Operations team originally received the data.

In FY 2014, the outcome data from the TRACK-TBI study will be uploaded to FITBIR to include imaging data. Imaging data was collected on 287 subjects with approximately 4100 CT volumes and 3200 MR volumes (Structural, DTI, resting state fMRI). All of the TRACK TBI data will become publically available in FITBIR in FY 2014.

The investigative team for a large TBI clinical trial (Progesterone for the Treatment of Traumatic Brain Injury (ProTECT)) has been contacted and plans are underway to begin cross mapping the data in order to facilitate transferring it to FITBIR following completion of the study. This is an estimated 1200 person study that would be a valuable data set to have included in FITBIR.

Talks are also underway with NiCoE to upload legacy data sets rich with imaging data. NiCoE has recently provided the Operations team with a copy of the Data Dictionary in use for NiCoE imaging studies. Next steps include working together to cross map and then define what unique data elements need to be developed to support the upload of their data.

To assist researchers with uploading legacy data, the NIH has also committed to funding up to three small awards to add legacy clinical research data to FITBIR. An RFA has been published. Additional details are found here: <http://www.ninds.nih.gov/research/tbi/index.htm>

Outreach activities

In FY 2013, outreach activities continued to include demonstrations, webinars, and presentations. The primary focus of the Operations team is to serve the end users. The initial onboarding is accomplished via a one hour webinar. FITBIR contributors/submitters are provided with an overview of the system capabilities, steps on how to create an account, and details about protocol and informed consent

related items. Detailed explanation about the Global Unique Identifier (GUID) is also provided since often FITBIR contributors/submitters are not collecting all the necessary Personally identifiable information (PII) to generate a GUID. The next big step for the Operations team is to provide extensive, in depth training on the Data Dictionary. This training includes how to cross map data to CDEs, as well as, how to create unique data elements and form structures. This is a very iterative process with great interaction between the FITBIR contributors/submitters and the Operations team. It is strongly encouraged for FITBIR contributors/submitters to use the Protocol and Form Research Management System (ProFoRMS) tool. Training is provided for those choosing to use this tool for their electronic data capture needs. A weekly standing call will commence for FITBIR users in FY 2014 to regularly provide introductory webinars (1st and 3rd Thursdays) and deep dive webinars (2nd and 4th Thursdays).

FITBIR has been collaborating with One Mind for Research (now known as One Mind) throughout FY 2013 and attended/presented at the 2nd Annual One Mind Summit in June 2013. Also, talks are underway with Reza Ghanadan, a program director at DARPA, to see if FITBIR and DARPA can collaborate together in the future.

In FY 2014, presentations are already scheduled at the upcoming annual National Neurotrauma Society meeting (August 5-7, 2013), and the International Initiative for Traumatic Brain Injury Research (InTBIR) meeting (October 17 – 18, 2013).

Coordination with grants management, program directors/science officers, and awardees of new studies

When announcements require that investigators be prepared to submit TBI data from human subjects to FITBIR utilizing the NINDS Common Data Elements and unique data elements found in the FITBIR Data Dictionary, it is essential to have coordination between the awardee, grants management and the FITBIR Operations team. In FY 2013, plans were created to help ensure compliance with the requirements set forth in announcements was met.

NINDS Workflow for FITBIR for Newly Funded NINDS Grantees

1. NINDS Repair and Plasticity Cluster Program Analyst (RP Analyst) (currently, Debbi Bergstrom) is responsible for identifying grants “To Be Paid” that include TBI clinical studies for each Council round.
2. A list of identified grants is sent to TBI Program Director (PD) Mona Hicks for review.
3. When list is approved by Mona, RP Analyst emails relevant NINDS PDs to confirm that these grants are appropriate for FITBIR.
4. PDs send confirmation email (or verbal AOK) to the RP Analyst alerting that the Principal Investigator (PI)’s study is applicable for submission to FITBIR. At this point, Mona or the PDs may email the PIs alerting them of FITBIR applicability and temporary restriction of funds.
5. RP Analyst creates a New Grantee spreadsheet identifying the grant number, title, PI, PI’s institution-address -telephone number-email address and Grants Management Officers (GMO) assigned to the grant.

6. Upon confirmation, RP Analyst sends the New Grantee spreadsheet to Grants Management Team Leader (currently, Maxine Davis) and FITBIR-Ops Team (currently, Alison Garcia and Bianca Siravo).
7. Grants Management Team Leader informs the relevant GMOs of the PIs who are expected to participate in this data sharing platform and of the special Terms and Conditions to be posted on the Notice of Grant Award (NGA).
8. GMO adds "Terms and Conditions" to the NGA informing the PI that funds will be restricted until he/she has obtained an FITBIR Account and participated in an introductory webinar.
9. RP Analyst checks the NGA (once posted in QVR) for FITBIR language.
10. PI requests an FITBIR Account.
 - a. PI fills out one page of information on FITBIR website
<https://fitbir.nih.gov/portal/publicAccounts/createAction!create.action>.
 - b. Select FITBIR Account Privilege of User (Default Access) (no need to upload any documentation at this time)
11. FITBIR-Ops Team contacts the PI to set up an introductory call and webinar, including information on how to obtain accounts for submitting and accessing data.
 - a. Obtaining an FITBIR account for data submission (for the PI)
 - I. Create an account in FITBIR (see #9 above - Request 'Study' Privilege).
 - II. Submit Request to FITBIR.
 - III. Once granted an account, log in and create a Study in FITBIR.
 - IV. Upload Data Submission Request document when creating the Study.
 - V. FITBIR-Ops team sends out Data Submission document for review to Data Access and Quality Committee (DAQC; currently, members are Lisa Fucci-Baker of USAMRMC, Alison Garcia of CIT, and Debbi Bergstrom of NINDS).
 - VI. Following approval from DAQC, Study is approved by FITBIR-Ops team. Now data can be submitted to that study.
 - b. Obtaining an FITBIR account for data access (for the PI)
 - I. Create an account in FITBIR (see #9 above - Request 'Query' Privilege).
 - II. Upload Data Access Request form.
 - III. FITBIR-Ops team sends out Data Access Request document to DAQC for review
 - IV. Following approval from the FITBIR DAQC, the user has data access.
12. FITBIR-Ops Team contacts the PI, GMO Team Leader and GMO, Mona Hicks, the RP Program Analyst and the grant's PD to inform them that the Data Submission Form has been approved by the DAQC and that a Study has been created in FITBIR by the PI.
13. GMO releases the restricted funds and notifies the PI of the lifted restrictions.

Throughout FY 2013, as a result of several Council rounds at NINDS, the following grantees were selected to submit their data to FITBIR:

Proposal Title	PI Name	Organization	Anticipated 1st Data Upload to FITBIR
Frontal Lobe Imaging as a Biomarker of CTE	Stamm, Julie	Boston University School of Medicine	April 2014
Managing severe TBI without ICP monitoring-guidelines development and testing	Chesnut, Randall	University of Washington	April 2014
The Impact of Concussive and Sub-Concussive blows on brain network activity	Broglio, Steven	University of Michigan at Ann Arbor	January 2014
Multiplexed Multiband MR at 7T: Studies of mild TBI	Hetherington, Hoby	Yale/ University of Pittsburgh	Not required to submit data- at own discretion
Multimodality image-based assessment system for traumatic brain injury	Aylward, Stephen	KITWARE, INC	Not required to submit data- at own discretion
In Vivo Measurement of Brain Biomechanics	Bayly, Philip	Washington University	January 2014
Multiple Medical Therapies for Pediatric TBI: Comparative Effectiveness Approach	Bell, Michael J. & Wisniewski, Stephen	University of Pittsburgh at Pittsburgh	April 2014
Brain Injury Due to soccer heading and opportunities for its mitigation	Lipton, Michael Lawrence	Albert Einstein College of Medicine Yeshiva University	April 2014

The Cerebellum's Contribution to Working Memory Following Traumatic Brain Injury	Medaglia, John	Pennsylvania State University--State Park	January 2014
Phase 2 Pediatric Autologous BMMNC for Severe TBI	Cox, Charles	University of Texas Health Science Center, Houston	April 2014
Default Mode Interference and Working Memory in Mild Traumatic Brain Injury	Sours, Chandler	University of Maryland, Baltimore	Unknown- not fully on boarded (account has been created)
Neurosensory Assessment of Concussion	Tommerdahl, Mark A	University of North Carolina, Chapel Hill	Unknown- not on boarded yet

Table 2. NINDS grantees

A SharePoint site for tracking the status of FITBIR research studies at has recently been created and can be found here: <https://extshare.ninds.nih.gov/sites/fitbirwg/>. Account creation, onboarding progress, background study information, anticipated data collection start dates are some of the items captured in the tracking document.

The FITBIR Operations team has been closely working with Holly Campbell Rosen, a science officer at CDMRP, to coordinate education and dissemination of information amongst the science officers overseeing DOD FITBIR grantees. Meetings and webinars have been held with the science officers throughout FY 2013. The following grantees were designated in FY 2013 to submit data to FITBIR.

Proposal Title	PI Name	Organization	Anticipated 1st Data Upload to FITBIR
Low-level Laser Therapy for Traumatic Brain Injury	Vakoc, Benjamin	Massachusetts General Hospital	Unknown- not on boarded yet
A Novel Tool for Field Assessment of Mild Traumatic Brain Injury	Espinoza, Tamara	Emory University	January 2014

Miniature Field Deployable System for Rapid TBI Assessment	Koppes, William	BrainScope Company, Inc.	April 2014
Battlefield Seizure Detector for TBI Assessment (SeizTBI)	Bibian, Stephane	NeuroWave Systems, Inc.	Unknown- not onboarded yet
Transitioning the Defense Automated Neurobehavioral Assessment (DANA) to Operational Use	Lathan, Corinna	AnthroTronix, Inc	Unknown- not on boarded yet
NKI Concussion Score	Kiderman, Alexander	Neuro Kinetics, Inc.	April 2014
Transforming Research and Clinical Knowledge in Traumatic Brain Injury (TRACK-TBI)	Manley, Geoffrey	California, University of, San Francisco	November 2013

Table 3. DOD grantees**Create policies and data dictionary for preclinical studies**

In FY 2013, a working group was established to start building a data dictionary for preclinical TBI research for future incorporation into FITBIR. This goal is to promote bi-directional translational research and facilitate meta-analysis of preclinical research. There are currently five preclinical CDE modules under development, including one of Core CDEs and 4 others that are specific to preclinical models: 1) Controlled cortical impact; 2) Fluid percussion; 3) Weight drop; and 4) Blast injury. The items and definitions for the preclinical data dictionary are anticipated to be completed by Fall 2013; however, conversion into codes and formatting for the CDEs will require additional staff beyond the allocated resources. A presentation on the preclinical CDEs will be given at the National Neurotrauma Society symposium (August 4 – 7).

Preclinical TBI Research Common Data Elements Workgroup

Douglas Smith, Chair	University of Pennsylvania
C. Edward Dixon	University of Pittsburgh
Christine Duhaime	Harvard University
David Hovda	UCLA
Michelle LaPlaca	Georgia Institute of Technology
Linda Noble	UCSF
Frank Tortella	Walter Reed Army Institute of Research
Stephen Ahlers, Ad Hoc	Walter Reed Army Institute of Research
Douglas Gibson, Federal Liaison	DOD/MRMC
Ramona Hicks, Federal Liaison	NIH/NINDS

Table 4. Preclinical Workgroup

Data Element work with NINDS CDE project

Throughout 2013, the FITBIR Operations team has worked very closely with the NINDS Common Data Element (CDE) project.

Additional FITBIR capabilities in FY 2014

In FY 2014, the modular components of BRICS will be enhanced to more fully meet the long-term requirements of the FITBIR informatics system. ProFoRMS major enhancements will include better international support (additional languages), better form design capabilities, and 21 CFR part 11 compliance. Data Dictionary enhancements include greater search capabilities and improved connectivity support for external research entities. Publicly available summary data generated from legacy data input into the system will also be available. Query access component enhancements will allow investigators to be able to create meta-studies from data across many studies through the use of the GUID. A meta-study may reference data from several research groups, and it will allow investigators to save their queries for later review and analysis. Additionally, meta-studies will be able to be shared, allowing a direct mapping of experimental data with a publication. This functionality will allow investigators to assign a research subject, and their associated data, to a cohort.

IV. Budget

Throughout FY2013 cost-effective software technologies, favoring free and open- source software solutions were utilized whenever possible.

Module 1, the design and implementation of the FITBIR informatics system, from the Memorandum of Agreement states the following:

- Module 1: Design and implementation of the Federal Interagency Traumatic Brain Injury Research (FITBIR) Database. The project is modeled after the National Database for

Autism Research (NDAR) project. NDAR, developed and deployed by Biomedical Imaging Research and Services Section of NIH/CIT, is a secure collaborative biomedical informatics system sponsored by the following NIH institutes, NIMH, NICHD, NIEHS, NINDS, and NIDCD. Reusing technology developed for NDAR will provide significant cost savings (approximately 35- 50%) and deployment time. Primary functionality and tools of NDAR which can be reused for this project include anonymous subject ID generation, web-based data entry, data validation, data sharing, image analysis, bioinformatics tools, data analysis, and operations. NIH/CIT is uniquely capable of building a central, federated database that can serve as a data repository and also can link existing databases.

Approved Module 1 expenses included equipment, software, contract staff, co-location space, and project related travel. As a result of tight financial controls and strong management oversight, for part FY11 (33%), FYs 12-13 (total of 2.3 years) the project spent a total of \$6.2M which is 62% of the total budget (\$10.1M) allocated for four years.

Future funding for FITBIR

The current FITBIR MOA expires on 31 March 2015. To secure funding starting in 2015, it was imperative to get FITBIR as a line item in a Program Objective Memorandum (POM). The final product of the programming process within the Department of Defense, the POM, displays the resource allocation decisions of the Military Departments in response to and in accordance with Defense Guidance. CAPT Biggerstaff presented the FITBIR budget to his superiors at OASD(HA) in June 2013 and was able to secure future funding for FITBIR. Only the proposed Operations & Maintenance (O&M) lines were funded. The sustainment will be funded at \$2.8M/yr. starting in FY15 for 5 years. The Research and Development (R&D) items proposed were passed for funding at this time.

V. Summary

Over the past year, FITBIR, a secure bioinformatics platform has grown facilitating standardization of data fields, data sharing and scientific collaboration for TBI research. FITBIR has been designed as a research portal that links data, supporting documentation, publications, and grants related to TBI. In FY2014, FITBIR will continue to accept TBI data and will provide the ability for query and retrieval of data from the FITBIR Database for research purposes. The standard software development lifecycle process (requirements, design, development, testing) will continue in FY 2014 with three main development themes. These themes will include Operational and Maintenance Support (O&M), additional FITBIR enhancements, and possible federation to other sites (including both biospecimen repositories and data repositories).

Appendix A

FITBIR Governance Document

Governance Document

Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System

Summary and Purpose of the Agreement

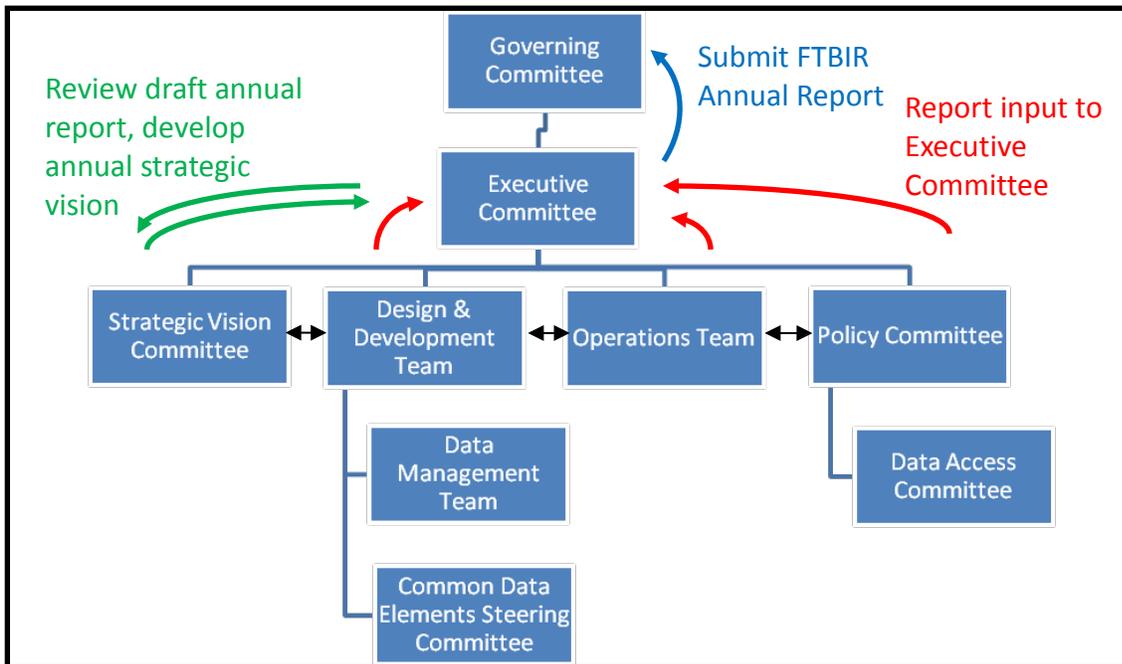
The Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System is a collaborative effort by participating National Institutes of Health (NIH) Institutes and Centers (ICs) and US Army Medical Research and Materiel Command (USAMRMC) to develop a data repository and bioinformatics platform for traumatic brain injury (TBI) research. The funding for the FITBIR Informatics System has been provided by USAMRMC with the NIH providing contributions in staff and technical resources. Conceived in 2011, FITBIR began to accept data in 2012. Data will be made available to the TBI research community in accordance with FITBIR’s Data Sharing Policy. This document formalizes the organizational framework whereby participating research agencies agree to work together.

Authority

The signatories of this document have been designated as the lead authorities for conducting the business of the FITBIR Informatics System in a joint Memorandum of Understanding among the USAMRMC, the Division of Computational Bioscience of the Center for Information Technology (CIT) and the National Institute of Neurological Disorders and Stroke (NINDS) at the NIH regarding development and maintenance of the FITBIR Informatics System (April 20, 2011).

Organizational Structure

Clear lines of authority are required to ensure that decision making is both efficient and representative of FITBIR’s stakeholders.



For each group or committee listed above, the membership, responsibility, operating protocols, and decision making authority are described.

Governing Committee

Membership:	The FITBIR Governing Committee is comprised of the representatives from the NIH and the USAMRMC as voting members. Additional members may be added in the future.
Responsibilities:	The Governing Committee makes all decisions related to overall strategic vision, operating procedures, and will regularly assess FITBIR activities.
Operating Protocols:	Voting members are entitled to one vote on the Governing Committee. Each voting member may designate a delegate to act in his/her stead. The Governing Committee meets as many times as deemed necessary, but at least two times per year.
Decision-making:	Decisions are based on a two-thirds majority vote of voting members.
Current Members:	Dr. Dallas Hack (Co-Chair), USAMRMC Dr. Walter Koroshetz (Co-Chair), NIH/NINDS Dr. Sean Biggerstaff, OASD/HA Dr. Benes Trus, NIH/CIT

Executive Committee

Membership:	The Executive Committee consists of three Co-Directors appointed by the Governing Committee.
Responsibilities:	The Executive Committee manages and coordinates work on the overall strategic vision, design, policies and operations of FITBIR. NIH/CIT is responsible for the day-to-day program management. Co-Directors oversee and manage the following subprojects: <ul style="list-style-type: none"> • Design & Development Team - NIH/CIT • Operations Team – NIH/CIT • Policy Committee – NIH/NINDS & USAMRMC • Strategic Vision Committee – NIH/NINDS & USAMRMC

The Co-Directors also serve as federal liaisons on many of the subcommittees. The Executive Committee prepares a FITBIR Annual Report to the Governing Committee.

Operating Protocols: The Executive Committee meets bi-weekly to discuss and monitor the development and implementation of FITBIR. The Executive Committee reports to the Governing Committee biannually, with additional meetings as needed, and follows its guidance.

Decision-making: Decision making is reached by consensus.

Current Members: Dr. Douglas Gibson, USAMRMC
 Dr. Ramona Hicks, NIH/NINDS
 Dr. Matthew McAuliffe, NIH/CIT

Strategic Vision Committee

Membership: The Strategic Vision Committee is led by NIH/NINDS and USAMRMC. 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. Members serve for a two year term.

Responsibilities: The Strategic Vision Committee has responsibility for advising the Executive Committee for the following:

- Strategies for maximizing the impact of the FITBIR Informatics System to address critical questions in TBI diagnosis and treatment.
- Identification and prioritization of research questions and hypotheses to be supported by the FITBIR Informatics System.
- Identification and leveraging of other related resources, tools, and projects.
- Recommendations to the Executive Committee following review of the draft FITBIR Annual Report for vision setting.

Operating Protocols: The Strategic Vision Committee will meet shortly after the signing of the Governance MOU, in order to provide initial input to the Governing Committee and Executive Committee. After that, the Strategic Vision Committee will meet yearly, unless indicated otherwise. Policy Committee members are invited to the FITBIR Governing Committee meetings.

Decision-making: Recommendations are based on a majority vote and forwarded to the Governing Committee and Executive Committee for approval.

Current Members: Dr. Douglas Gibson, USAMRMC (Co-Coordinator)
 Dr. Ramona Hicks, NIH/NINDS (Co-Coordinator)

Committee Members:

- Dr. Thomas DeGraba, NICoE
- Dr. Ramon Diaz-Arrastia, USUHS
- Dr. Robert Harbaugh, Penn State
- Dr. Geoffrey Manley, UCSF
- Dr. Rema Raman, UCSD

Federal Liaisons:

- Dr. Matthew McAuliffe, NIH/CIT
- Dr. Greg Farber, NIH/NIMH
- Dr. Michael Schoenbaum, NIH/NIMH
- Dr. Vinay Pai, NIH/NIBIB

Design and Development Team

- Membership:** The Design and Development Team is led by the NIH Center for Information Technology (CIT) and supported by contractors. Members are nominated by the CIT and confirmed by the FITBIR Executive Committee.
- Responsibilities:** The Design and Development Team is responsible for the systems development implementation and technical support of FITBIR.
- Operating Protocols:** The Design and Development Team develops and supports FITBIR, taking direction from the Executive Committee, with additional input from other teams and committees.
- Decision-making:** The Design and Development Team makes detailed decisions required for the development of FITBIR.
- Current Organization:** Dr. Matthew McAuliffe, NIH/CIT (Chair)
- Members: Contractors will be hired by NIH/CIT

Data Management Team

- Membership:** The Data Management Team is appointed by the Executive Committee and comprised of data base managers from academia, industry, government, and private and non-profit foundations that have expert experience managing databases for TBI research.
- Responsibilities:** The Data Management Team will ensure that FITBIR meets the needs of its stakeholder community for uploading and accessing data. In addition, the team will provide input on general design considerations, data collection forms, and operating procedures for FITBIR.

Operating Protocols: The Data Management Team will meet shortly after the signing of the Governance MOU, in order to provide initial input into the Design and Development Team. After that, the Data Management Team will meet yearly, with additional meetings as needed. The Data Management Team will prepare an annual report of its activities for submission to the Executive Committee for the FITBR Annual Report.

Decision-making: Recommendations are reported to the Operations Team.

Current Members: Dr. Matthew McAuliffe, NIH/CIT (Chair)

Members will be appointed by the Executive Committee.

Common Data Elements Steering Committee

Membership: The TBI Common Data Elements (CDEs) Steering Committee is comprised of scientific experts from academia, industry, government, and private and non-profit foundations. The Steering Committee is coordinated and led by NINDS and supported by contractors. Members are appointed by a Federal Oversight Committee for TBI CDEs, which is coordinated by NINDS.

Responsibilities: The TBI CDE Steering Committee provides oversight and guidance for managing and updating the data elements for FITBIR. This includes designating data elements as “core”, “basic” or “supplemental” and providing definitions and protocols for data collection.

Operating Protocols: The TBI CDE Steering Committee will meet at least once a year in person, and if necessary, more often via conference calls. The Steering Committee may establish working groups and subcommittees to review the CDEs that are in the FITBIR Informatics System.

Decision-making: The Steering Committee reviews input from investigators, user groups, and feedback collected from the website every 6 months. There will need to be a quorum at each meeting for voting purposes for maintaining and/or updating the TBI-specific data elements. The Steering Committee reports to the Design and Development Team.

Current Members: Ms. Joanne Odenkirchen, NIH/NINDS (Coordinator)

Dr. Cynthia Harrison-Felix, Craig Hospital
Dr. Joseph Giacino, Spaulding Rehabilitation Center
Dr. Jamie Hutchison, The Hospital for Sick Children Toronto
Dr. Andrew Maas, University Hospital Antwerp
Dr. Geoffrey Manley, UCSF
Dr. Gerard Riedy, Walter Reed Army Medical Center
Dr. Alex Valadka, Seton Brain & Spine Institute

Dr. Elisabeth Wilde, Baylor College of Medicine

Operations Team

- Membership:** The Operations Team is led by NIH/CIT and supported by employees and contractors. Members are nominated by the CIT and confirmed by the FITBIR Executive Committee.
- Responsibilities:** The Operations Team is responsible for the secure and correct functioning of the FITBIR Informatics System, a protected resource for TBI research data. Operational procedures will be established to ensure that the data contained in FITBIR are efficiently made available to qualified researchers according to the protections defined in FITBIR and other Federal policies. The operations team will assist the investigators and user groups with implementing standard operating procedures for:
- Account Requests
 - Data Submission Requests
 - Web-based Data Entry Tools and Forms
 - Data Access Requests
 - Quality Assurance and Quality Control
 - Establishment of a Federated Data Source
 - Common Data Elements and Definitions
 - GUID Generation Permission Request
 - Request for Time Extension for Sharing
 - Deviations to Data Sharing Terms
 - Administrative Access to FITBIR.
- Operating Protocols:** The Operations Team takes direction from the Executive Committee, along with input from other teams and committees. The Operations Team prepares an annual report of its activities for submission to the Executive Committee for the FITBIR Annual Report.
- Decision-making:** The Operations Team makes detailed decisions required for the operation of FITBIR that are approved by the Executive Committee.
- Current Members:** Dr. Matthew McAuliffe, NIH/CIT (Chair)
- Members: Contractors will be hired by NIH/CIT.

Policy Committee

- Membership:** The Policy Committee is composed of Federal employees or contractors appointed by the Executive Committee. Predominantly, this includes program directors and policy staff from Federal granting agencies.

Responsibilities: 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 for:

- Data Sharing
- Data Access
- Collaborations
- Adjudications
- Publications

The Policy Committee will ensure that policies related to FITBIR consider and reflect the needs of all stakeholders to the greatest extent possible. Specialized working groups, most notably the Data Access and Quality Committee (DAQC), will be formed to assist with implementation of the policies. The Policy Committee also contributes to overall strategic vision and scope.

Operating Protocols: The Policy Committee will meet as necessary, but at least every 6 months. Policy Committee members are invited to the FITBIR Governing Committee meetings.

Decision-making: Policy recommendations will be based on a majority vote and forwarded to the Governing Committee for approval.

Current Members: Dr. Deborah Hirtz, NIH/NINDS (Chair)

Dr. Debra Bergstrom, NIH/NINDS

Ms. Savita Nagim, USAMRMC

Ms. Alison Garcia, NIH/CIT

Dr. Douglas Gibson, USAMRMC

Dr. Ramona Hicks, NIH/NINDS

Dr. Stuart Hoffman, VA

Dr. A. Cate Miller, NIDRR

Dr. Sarah Goldman, DCoE

Dr. Karen Schwab, DVBIC

Dr. Anne Sperling, NIH/NIMH

Data Access and Quality Committee (DAQC)

- Membership:** The FITBIR Data Access and Quality Committee (DAQC), a sub-committee of the Policy Committee, will consist of a minimum of 3 Federal government employees or contractors with expertise in science, policy or bioinformatics, and will be appointed by the Policy Committee.
- Responsibilities:** The DAQC reviews and provides feedback about whether to 1) accept FITBIR data submissions; and 2) grant access to FITBIR data. Such reviews include, for example, examining submission and access documentation for consistency with expectations outlined in the FITBIR Data Access Policy. The DAQC prepares an annual report of its activities for submission to the Executive Committee for the FITBIR Annual Report.
- Operating Protocols:** The DAQC will review data access requests and data submissions at least twice monthly either online or in person.
- Decision-making:** Decisions are based on a majority vote. Decisions that are appealed will be forwarded to the Policy Committee for its review and final decision-making.
- Current Members:** Dr. Debra Bergstrom, NIH/NINDS (Chair)
Ms. Lisa Fucci-Baker, USAMRMC
Ms. Alison Garcia, NIH/CIT

Approvals

This Memorandum of Understanding and Agreement will be reviewed on an annual basis and amended as necessary.

COL Dallas C. Hack, MD	Date
US Army Medical Research and Materiel Command	

CAPT Sean Biggerstaff, PhD	Date
Office of the Assistant Secretary of Defense	
For Health Affairs	

Walter Koroshetz, MD	Date
National Institutes of Health	
Deputy Director, NINDS	

Benes L. Trus, PhD	Date
National Institutes of Health	
Acting Scientific Director, CIT	

Appendix B

FITBIR Communications and Outreach

I. Presentations

Conference Presentations (Speaker/Poster/Exhibitor)

- 07/22- Annual National Neurotrauma Society meeting: Phoenix, AZ
07/25/12
- 08/12- Military Health System Research Symposium (MHSRS): Ft. Lauderdale, FL
08/15/12
- 10/9- American Congress of Rehabilitation Medicine: Vancouver, Canada
10/13/12
- 04/29- National Capital Area TBI Research Symposium: Bethesda, MD
04/30/13
- 5/17- 2nd Annual One Mind Summit: Baltimore, MD
5/18/13

II. Individual demonstrations

- 8/21/2012 CDMRP Demo
- 9/11/2012 FITBIR System Walkthrough to Board of Governors (Dr. Koroshetz & Dr. Trus)
- 09/19/2012 Dr. Latour and Dr. Gullapalli: NINDS/CNRM and UMD- School of Medicine
- 09/26/2012 Patrick Donohue: Sara Jane Brain Foundation
- 10/10/2012 Dr. Kouyate: Director of Software Development at MedRed
- 10/30/2012 CDMRP Demo
- 12/05/2012 Dr. Gunjan Parikh: UMD- School of Medicine/NIH)
- 01/24/2013 Dr. Margo Lauterbach: Concussion Clinic at Sheppard Pratt
- 04/16/2013 Allen Chuang: NINDS
- 05/07/2013 Michael Bell, MD, Steve Wisniewski, PhD: University of Pittsburgh
- 06/20/2013 Reza Ghanadan: DARPA

III. Congressional Briefings

None

IV. Webinars

9/26/2012 Sean Hill and Stephen Larson: INCF, One Mind
10/24/2012 Dr. Hetherington: Yale University*
10/26/2012 Dr. Broglio: Univ. of Michigan*
11/6/2012 Julie Stamm: Boston University*
11/20/2012 Dr. Temkin : Univ.of Washington*
12/26/2012 Dan Sweeney, Howison Schroeder, and Yakov Eydelman: NKI, Inc.*
2/12/2013 Dr. Bayly: Washington Univ. (St. Louis)*
2/18/2013 Dr. Puccio: University of Pittsburgh*
2/21/2013 Dr. Tom DeGraba: NiCOE*
2/22/2013 Dr. Rene Hernandez: MRMC
2/25/2013 Dr. Hilaire Thompson: University of Washington*
2/28/2013 Tom Gibney: KDG, Inc
2/28/2013 Dr. Adil Alaoui: Georgetown University
3/4/2013 Sierra Fourwinds: Silverwind Research*
3/5/2013 Gerard Reidy: NiCOE
3/13/2013 Gustavo Petroni, Silvia Lujan, Daniel Giordano: University of Washington,
Fundación Alas, and Centro de Informática e Investigación Clínica*
3/29/2013 Dr. Phil Bayly: Washington University*
4/3/2013 Dr. Richard Watts: University of Vermont
4/10/2013 Barry Kosofsky: Cornell (Enygmagym)*
4/17/2013 Dr. Dzung Pham: NINDS*
4/25/2013 Dr. Raj Gupta: MRMC
4/30/2013 Dr. Lipton: Yeshiva
5/3/2013 John Medaglia: Penn State*
5/9/2013 Jeanette Soderberg: INCF
5/13/2013 NINDS Program Directors & CDMRP Science Officers*
5/15/2013 Pre-Clinical TBI Working group
5/16/2013 Dr. Cox UT Houston*
Note (*) Multiple webinars attended

Notices

Release Date: March 21, 2013

NIH Notice NS-13-008

<http://grants.nih.gov/grants/guide/notice-files/NOT-NS-13-018.html>)

Journals

<http://www.ncbi.nlm.nih.gov/pubmed/23725058>

J Neurotrauma. 2013 Jun 2.

Progress in Developing Common Data Elements for Traumatic Brain Injury Research: Version 2 - The End of the Beginning.

Hicks R, Giacino J, Harrison-Felix CL, Manley GT M D Ph D, Valadka A, Wilde EA.

SourceNational Institute of Neurological Disorders and Stroke, National Institutes of Health, 6001 Executive Blvd., Bethesda, MD, Bethesda, Maryland, United States, 20892 ; hicksra@mail.nih.gov.