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TITLE: Integrating Traumatic Brain Injury Model Systems Data into the Federal Interagency Traumatic Brain Injury Research Informatics Systems

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14. ABSTRACT Over one year was spent obtaining the regulatory approvals required for this project to pilot test the transfer of Traumatic Brain Injury (TBI) Model System (TBIMS) data to the Federal Interagency TBI Research (FITBIR) Informatics System. Local IRB approval and HRPO approval has been obtained for the TBI Model System (TBIMS) National Data and Statistical Center (NDSC), all 16 TBIMS Centers, and a follow-up center. The first two project aims (to evaluate the compatibility of TBIMS and FITBIR data sharing policies, and to prepare a crosswalk between the TBIMS and the TBI Common Data Elements (CDEs) implemented by FITBIR) have been completed by NDSC staff and discussed with the TBIMS Project Directors. The third project aim (to program the transfer of TBIMS data to FITBIR) is progressing. Forms for submitting the majority of unique data element (UDE) variables have been designed by NDSC staff and approved by FITBIR. The process of preparing forms for the remainder of the TBIMS UDEs is underway; however we are in the process of hiring a replacement for the second person doing this work, who has also resigned. The plan is to complete all programming for transferring all de-identified TBIMS NDB data to FITBIR before getting final approval from the TBIMS Project Directors to actually transfer the TBIMS data to FITBIR (aim 4). Project aim 5 is complete with TBIMS staff consenting 1,608 TBIMS participants and collecting the necessary personal identifying information to create GUIDs; and aim 6 is over half completed with TBIMS staff collecting new Form I CDEs on 131 TBIMS participants and new Form II CDEs on 437 cases. A 6 month NCE has been requested and is pending.					
15. SUBJECT TERMS Traumatic brain injury (TBI); TBI Model System National Database					
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## **1. INTRODUCTION:**

Since 1989, the Traumatic Brain Injury (TBI) Model System (TBIMS) Program has enrolled over 15,000 adults with moderate to severe TBI in a National Database (NDB) and collected longitudinal follow-up data at 1, 2, 5, 10, 15, 20, and 25 years post injury. The Federal Interagency TBI Research (FITBIR) Informatics System has been established to accelerate TBI research by operationalizing precise definitions of common data elements (CDEs) selected for consistent use in TBI research, and to serve as a repository for housing CDEs and other variables collected across the many TBI research studies. The ultimate objective of this project is to incorporate data from the TBIMS NDB into FITBIR for easy access and linking to other TBI studies by the TBI research community.

## **2. KEYWORDS:**

Traumatic brain injury (TBI); TBI Model System National Database; FITBIR

## **3. ACCOMPLISHMENTS:**

### **What were the major goals of the project?**

The major goals of this project are to evaluate: 1) the compatibility of the data sharing policies and procedures between the TBIMS and FITBIR, 2) the exact crosswalk between the TBIMS NDB and the TBI CDEs implemented by FITBIR, 3) the degree to which TBIMS variables can be converted to FITBIR CDEs, aliases, and new data elements, and these variables formatted in existing published or new FITBIR data forms, 4) the feasibility of downloading a de-identified version of the current TBIMS NDB to FITBIR, 5) the feasibility of adding the FITBIR Global Unique Identifier (GUID) over time as new and existing patients are contacted for data collection, and 6) the feasibility of prospectively collecting more CDEs that are not currently variables in the TBIMS NDB by a sample of current TBI Model Systems.

### **What was accomplished under these goals?**

To summarize regulatory approval to date on this pilot project, local IRB and HRPO approval has been obtained for the TBI Model System (TBIMS) National Data and Statistical Center (NDSC), all 16 TBIMS Centers, and a follow-up center. The fact that this approval process took over a year to complete contributed to the delays experienced in this project.

The review of TBIMS and FITBIR data sharing policies have been completed and discussed with the TBIMS Project Directors. Crosswalks have been identified for all TBIMS common data element (CDE) variables to be entered into FITBIR. Forms for submitting the majority of the unique data element (UDE) variables have been designed and approved by FITBIR. The process of preparing forms for the remainder of the TBIMS UDEs was underway when the second staff member assigned to this task resigned. We are in the process of hiring a replacement. The plan is to complete all programming for transferring all de-identified TBIMS NDB data to FITBIR before getting final approval from the TBIMS Project Directors to actually transfer the TBIMS data to FITBIR.

The pilot test of using GUIDs is complete with a total of 1,608 GUIDs entered into the TBIMS NDB. Data Collectors (and some Data Managers and Project Directors) at local centers applied for and were granted FITBIR accounts to gain access to the GUID Tool. They were trained in creating GUIDs and entering the GUIDs in the TBIMS NDB. Centers (1) gained the consent of TBIMS participants to have their data submitted to FITBIR, (2) collected personal identifying information (PII), (3) used the PII to create GUIDs, and (4) submitted the GUIDs to the TBI National Database.

The pilot test of adding new CDEs to the TBIMS National Database (NDB) is over half complete with new CDEs collected on 131 Form I cases and 437 Form II cases. New Form I CDEs include type of

TBI, duration of loss of consciousness (LOC) and post-traumatic amnesia (PTA), years of education, and status of school attendance and current employment. New Form II CDEs include years of education, status of school attendance and current employment, and the 22 items in the Neurobehavioral Symptom Inventory (NSI).

**What opportunities for training and professional development has the project provided?**

Data collectors at each of the TBIMS have been trained in consenting patients to participate in the GUID pilot, collecting the required PII, using the FITBIR GUID Tool to create GUIDs, entering those GUIDs into the TBI National Database, and the collection of all the new CDEs.

**How were the results disseminated to communities of interest?**

Project progress, results of comparing TBIMS and FITBIR data sharing policies, the CDE crosswalks between the TBI National Database and FITBIR, the GUID pilot process, and the CDE pilot process have been discussed with the TBIMS Project Directors at their December 2014, June and December 2015, and June 2016 meetings in Arlington, Virginia.

**What do you plan to do during the next reporting period to accomplish the goals?**

We will continue tracking the local IRB renewals and submit to HRPO as received. Coding of FITBIR CDEs and new data elements will be completed with the assistance of FITBIR when a new staff member is hired and trained. While the GUID pilot test is over, many TBIMS are voluntarily continuing to consent cases and create GUIDs. Centers agreeing to participate in the collection of new CDEs will continue that effort for one more quarter, when the collection of new CDE forms is expected reach a total of 800.

**4. IMPACT:**

**What was the impact on the development of the principal discipline(s) of the project?**

The impact on staff of the TBIMS NDSC and individual Centers around the country has been substantial. The requirement to gain regulatory approval from both local IRBs and HRPO was complex, burdensome, and lengthy. No other TBIMS project has required a year to gain regulatory approval. Once all approvals have been granted, the actual consenting and collection of the GUID and CDE pilot data have been routine.

**What was the impact on other disciplines?**

Nothing to report

**What was the impact on technology transfer?**

The transfer of data from the TBIMS to FITBIR has proven far more complex than anticipated, and the loss of two staff, not easily replaced, has only compounded the difficulty.

**What was the impact on society beyond science and technology?**

Nothing to report

## **5. CHANGES/PROBLEMS:**

### **Changes in approach and reasons for change**

No significant changes in approach have occurred.

### **Actual or anticipated problems or delays and actions or plans to resolve them**

The resignation of the second programmer assigned to the task of transferring the TBIMS data into FITBIR has once again delayed the project and resulted in a second request for a no cost extension of the project. Without a qualified programmer with the skills and experience to transfer the TBIMS data into FITBIR, that central portion of the project has seen no progress in the last 2 months. We have posted and actively advertised the position, and have two candidates scheduled for interviews. If we can't hire a replacement programmer who can begin full-time work on this project before the end of the calendar year, the requested 6 month NCE will not be adequate to complete the project. The 6 month NCE was requested by our Business Office (Bob Swanson) from Mirlene Desir on September 21<sup>st</sup> and a response is still pending.

### **Changes that had a significant impact on expenditures**

Project delays and the no-cost extensions have not impacted total expenditures.

### **Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents**

Nothing to report

## **6. PRODUCTS:**

### **Publications, conference papers, and presentations**

Nothing to report

### **Website(s) or other Internet site(s)**

Nothing to report

### **Technologies or techniques**

### **Inventions, patent applications, and/or licenses**

Nothing to report

### **Other Products**

Nothing to report

## 7. PARTICIPANTS & OTHER COLLABORATING ORGANIZATIONS

### What individuals have worked on the project?

Name: Cynthia Harrison-Felix, PhD  
Project Role: Principal Investigator  
Researcher Identifier (e.g. ORCID ID): 0000-0003-0489-4681  
Nearest person month worked: Less than 1 person month to date  
Contribution to Project: Overall project management and quality assurance

Name: Gale Whiteneck, PhD  
Project Role: Co-Investigator  
Researcher Identifier (e.g. ORCID ID): 0000-0003-3609-5104  
Nearest person month worked: 1 person month to date  
Contribution to Project: Day to day operations of the project

Name: David Mellick  
Project Role: Information Technology Project Manager  
Researcher Identifier (e.g. ORCID ID): 0000-0002-2180-5575  
Nearest person month worked: 3 person months to date  
Contribution to Project: Technical management of the project

Name: Kendra Noble  
Project Role: Research Assistant  
Researcher Identifier (e.g. ORCID ID): 0000-0002-2669-4894  
Nearest person month worked: 3 person months to date  
Contribution to Project: Preparation of TBIMS/FITBIR crosswalk

Name: Jennifer Coker  
Project Role: IRB/HRPO Coordinator  
Researcher Identifier (e.g. ORCID ID): 0000-0003-0760-7449  
Nearest person month worked: Less than 1 person month  
Contribution to Project: Coordination between sites and HRPO regarding IRB and HRPO approvals.

### Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Nothing to report

### What other organizations were involved as partners?

Organization Name:	Indiana University/Rehabilitation Hospital of Indiana
Location of Organization:	Indianapolis, IN
Partner's contribution to the project:	Collaboration

Organization Name:	Moss TBI Model System
Location of Organization:	Elkins Park, PA
Partner's contribution to the project:	Collaboration

Organization Name:	Northern New Jersey TBIMS
Location of Organization:	West Orange, NY
Partner's contribution to the project:	Collaboration

Organization Name:	North Texas TBIMS
Location of Organization:	Dallas, TX
Partner's contribution to the project:	Collaboration
Organization Name:	Virginia Commonwealth TBIMS
Location of Organization:	Richmond, VA
Partner's contribution to the project:	Collaboration
Organization Name:	University of Washington TBIMS
Location of Organization:	Seattle, WA
Partner's contribution to the project:	Collaboration
Organization Name:	Carolinas Traumatic Brain Injury Rehabilitation and Research System
Location of Organization:	Charlotte, NC
Partner's contribution to the project:	Collaboration
Organization Name:	TIRR-Memorial Herman
Location of Organization:	Houston, TX
Partner's contribution to the project:	Collaboration
Organization Name:	Spaulding-Harvard Traumatic Brain Injury Model Systems
Location of Organization:	Boston, MA
Partner's contribution to the project:	Collaboration
Organization Name:	New York Traumatic Brain Injury Model System (Mt Sinai)
Location of Organization:	New York, NY
Partner's contribution to the project:	Collaboration
Organization Name:	Rusk Rehabilitation TBIMS at NYU
Location of Organization:	New York, NY
Partner's contribution to the project:	Collaboration
Organization Name:	University of Alabama at Birmingham Traumatic Brain Injury Model Systems
Location of Organization:	Birmingham, AL
Partner's contribution to the project:	Collaboration
Organization Name:	The Ohio Regional TBI Model System
Location of Organization:	Columbus, OH
Partner's contribution to the project:	Collaboration
Organization Name:	Mayo Clinic Traumatic Brain Injury Model System
Location of Organization:	Rochester, MN
Partner's contribution to the project:	Collaboration
Organization Name:	South Florida TBI Model System
Location of Organization:	Miami, FL
Partner's contribution to the project:	Collaboration



Organization Name:	University of Pittsburgh Medical Center Traumatic Brain Injury Model System
Location of Organization:	Pittsburgh, PA
Partner's contribution to the project:	Collaboration

**8. SPECIAL REPORTING REQUIREMENTS:** Not applicable

**9. APPENDICES:** Not applicable