Supporting Statement A for

National Institute of Neurological Disorders and Stroke Federal Interagency Traumatic Brain Injury Research

(FITBIR) Data Access Request

(NINDS/NIH)

OMB# 0925-0677 Exp date: 08/31/16

Date: 09/08/2016

Name: Sophia Jeon

Address: 31 Center Drive, Building 31, Room 8A03, Bethesda MD 20892

Telephone: 301-435-7571

Fax: 301-480-9172

Email: sophia.jeon@nih.gov

Check off which applies:

- New Revision
- **X Reinstatement with Change**
- Reinstatement without Change
- Extension
- Emergency
- Existing

Table of contents

**List of Attachments**

***Attachment A - Data Access Request Form***

***Attachment B - PIA***

***Attachment C - FITBIR Data Access Quality Committee***

***Attachment D – Privacy Memo***

**A. Justification**

## A.1 Circumstances Making the Collection of Information Necessary

The National Institutes of Health (NIH) created the Federal Interagency Traumatic Brain Injury Research Informatics System, an informatics system and central data repository, housed at the NIH Center for Information Technology, to support and accelerate research on traumatic brain injuries (TBI). FITBIR collects a wide range of data types, including phenotypic and clinical data as well as medical images, derived from individuals who participate in TBI research, regardless of the source of funding. FITBIR provides the infrastructure to store, search across, retrieve, analyze, and share these varied types of data.

The potential for public benefit to be achieved through sharing TBI research data is significant. However, genotype and phenotype information generated about individuals, such as data related to the circumstances of injury and outcomes may be sensitive. Therefore, protecting the privacy of the research participants and the confidentiality of their data is critically important. Risks to individuals, groups, or communities should be balanced carefully with potential benefits of the knowledge to be gained through FITBIR.

The information requested from the investigator seeking access to FITBIR data, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. The Data Access Request provides a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested from the recipient investigators comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156, (http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD." The NIH System of Record Notice was previously published in the Federal register on September 26, 2002, Volume 67, No 187, page 60742.

## A.2 Purpose and Use of the Information Collection

The primary uses of this information are to document, track, monitor, and evaluate the use of the FITBIR datasets, as well as to notify interested recipients of updates, corrections, or other changes to the database. As data submission and access procedures are maturing, NIH has developed a Data Access Request Form more tailored to the unique needs of FITBIR. The type of information requested in the FITBIR Data Access Request Form satisfies the terms and conditions of the FITBIR Data Sharing Policy. The form contains a section wherein investigators can provide a description of the research project they are proposing to perform with FITBIR data. The form also reminds investigators to provide an annual summary of research accomplishments from using FITBIR in an updated biographical sketch or CV. As investigators typically update their sketches and CVs on a regular basis, this is unlikely to be an undue burden when requested. This valuable information will help NIH understand and evaluate the use of FITBIR in the TBI research community.

Under the currently approved OMB# 0925-0677, the agency has collected information from a total of 90 respondents who spent a total of approximately 45 burden hours since the beginning of 2014. NINDS plans to continue to document, track, monitor and evaluate the use of the FITBIR datasets by collecting

information from investigators in the future but the current OMB approval of the NINDS FITBIR Data Access Request (OMB #0925-0677) expired on 08/31/2016 and 60-day comment period extended beyond this expiration date. Therefore, this is a request to reinstate it for another 3 years, with change to the original request. Additional questions are added to the currently approved form to collect more detailed information about the investigator's project (e.g., project's summary/abstract) as well as supplementary information that identifies the investigator's collaborators on the project, if applicable. We do not think this will significantly increase their burden hours because investigators can simply copy and paste their existing abstracts they have written for grants, scientific meetings or conferences.

### A.3 Use of Information Technology and Burden Reduction

To gain access to FITBIR data, an investigator must obtain FITBIR data access privileges. To obtain these privileges, an investigator must complete, sign, scan, and upload the Data Access Request form (**Attachment A**) to the FITBIR web portal. Thus, the process for obtaining access to data within FITBIR is designed to be both electronic (information may be typed into the form and the form is uploaded via a web portal) and mechanical (signatures are requested on the form, which is then scanned and uploaded):

The FITBIR Data Access Request form requests the following pieces of information:

- The title and a brief summary/abstract of the Research Project for which FITBIR data are sought. A single paragraph is sufficient.
- Contact information for the investigator seeking access (the FITBIR Data Recipient).
- Signature from the Recipient Investigator certifying that they will abide by the DUC and the NIH principles, policies and procedures for the use of FITBIR. Investigators also acknowledge that they have shared the Data Access Agreement document and the NIH policies and procedures with any research staff who will participate in the use of FITBIR.

Once completed, the request package is then sent for adjudication to the Data Access and Quality Committee (DAQ) established to oversee access to the FITBIR shared data. When the investigator's request is approved, the investigator is notified by e-mail and explained the conditions under which the approval is granted.

A privacy impact assessment (PIA) for the FITBIR Informatics System that was completed in 2013 is attached as a supporting document (**Attachment B**). The PIA is currently undergoing an update and is being reviewed in 2016.

### A.4 Efforts to Identify Duplication and Use of Similar Information

To protect and assure the confidentiality and privacy of all research participants whose data have been submitted to FITBIR, investigators who seek access to these data are expected to adhere to the specifications of the principles outlined the FITBIR Data Sharing Policy (see https://fitbir.nih.gov/sites/default/files/assets/FITBIR_Data_Sharing_Policy.pdf, section entitled, "Data Access"). Furthermore, each research project is unique, and collecting information about these projects, through the FITBIR Data Access Request Form, will enable NIH to document, track, monitor, and evaluate the use of the FITBIR datasets, as well as to notify interested recipients of updates, corrections, or other changes to the database.

Due to the sensitive nature of the data contained in FITBIR, and in accordance with existing NIH policies, such as that for FITBIR and genome-wide association studies (GWAS, see https://gds.nih.gov/), FITBIR data access approvals are granted for one year and may be renewed thereupon.

### A.5 Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this study.

### A.6 Consequences of Collecting the Information Less Frequently

The information requested in the FITBIR Data Access Request does not ask investigators to generate any new information, because the type of information being requested is fundamental to conducting any research study. The data are collected on a needed basis. We anticipate no more than once a year per researcher/investigator request.

Additionally, the FITBIR Data Access Request states that data recipients may be asked to provide an annual summary of research accomplishments from using FITBIR in an updated biographical sketch or CV (as noted above, FITBIR data access approvals are granted for one year and may be renewed thereupon). As investigators typically update their sketches and CVs on a regular basis, this is unlikely to be an undue burden when requested.

As stated before, protecting the privacy of the research participants and the confidentiality of their data is critically important. Essential aspects of that protection are careful screening who may obtain access to the database, and ongoing monitoring of the use of those data.

### A.7 Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

Not Applicable.

### A.8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

In accordance with 5 CFR 1320.8(d), on July 8, 2016, a 60-day notice for public comment was published in the *Federal Register* (81 FR 44644). No public comments were received. The Data Access Request has been reviewed and approved by the FITBIR Data Access and Quality Committee (DAQ). The DAQ represents a subset of members of the FITBIR Data Policy Committee and includes NIH and DOD scientific and programmatic staff. The Committee members' contact information is provided as a supporting document (**Attachment C**)

### A.9 Explanation of Any Payment of Gift to Respondents

No payment or gift will be provided to respondents.

### A.10 Assurance of Confidentiality Provided to Respondents

The Federal Privacy Act protects the confidentiality of the Recipient's NIH records. The NIH and any sites that are provided access to the datasets will have access to the data collected from the Recipient for the purposes described above. In addition, the Act allows the release of some information in the Recipient's records without his/her permission; for example, if it is required by members of Congress or other authorized individuals. The information requested is voluntary, but necessary for obtaining access to data.

The information requested from the investigator seeking access to FITBIR data, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. The Data Access Request provides a Privacy Act Notification pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested from the recipient investigators comes from the authorities regarding the establishment of the National Institutes of Health, its general authority to conduct and fund research and to provide training assistance, and its general authority to maintain records in connection with these and its other functions (42 U.S.C. 203, 241, 289l-1 and 44 U.S.C. 3101), and Section 301 and 493 of the Public Health Service Act. These records will be maintained in accordance with the Privacy Act System of Record Notice 09-25-0156, September 26, 2002, 67 FR 60742-60794 (http://oma.od.nih.gov/ms/privacy/pa-files/0156.htm) covering "Records of Participants in Programs and Respondents in Surveys Used to Evaluate Programs of the Public Health Service, HHS/PHS/NIH/OD."

Although the FITBIR data will be coded and the NIH will not hold direct identifiers to individuals within the NIH FITBIR data repository, the agency recognizes the personal and potentially sensitive nature of the genotype-phenotype data. Investigators and institutions seeking access to data or images from FITBIR are expected to meet data security measures and to submit a Data Access Request, including a Data Use Certification, signed by the investigator (see **Attachment A**). The FITBIR Data Access and Quality Control Committee reviews and approves all access requests (see https://fitbir.nih.gov/content/access-data).

### A.11 Justification for Sensitive Questions

The Federal Interagency Traumatic Injury Research Informatics System does not ask any questions of a sensitive nature, such as sexual behavior and attitudes, religious beliefs, and other matters that are commonly considered private; and therefore, does no need to provide a justification for this type of information.

Upon submission of data, FITBIR staff performs a quality control review to ensure that no personally identifiable information (PII) is contained in the dataset or supporting documentation. Only data that have undergone a quality control review are approved for sharing with the research community.

### A.12.1 Estimated Annualized Burden Hours

There are two scenarios for completing the form. Sometimes the Principal Investigator completes the whole document, and other times he/she has a Research Assistant complete it (after which the Investigator reviews and signs it). Burden for this collection of information is estimated to vary from 30-95 minutes per response. OMB approval reinstatement is requested for 3 years. There are no costs to respondents other than their time. The total estimated annualized burden hours are 63.

Table A12-1. Annual Burden Hours to Respondents

| Estimated Annual Burden Hours for Respondents | | | | | |
|---|---|---|---|---|---|
| Form | Type of Respondent | No. of Respondents | Annual Frequency per Response | Hours per Response (minutes/hour) | Total Hours |
| FITBIR Informatics System Data Access Request | Individuals (Principal Investigators) | 40 | 1 | 95/60 | 63 |
| **Total** | | **40** | **40** | | **63** |

### A.12.2 Annualized Cost to Respondents

Table A12-2. Annual Cost to Respondents

| Estimated Annual Cost Burden for Respondents | | | |
|---|---|---|---|
| Form | Estimate total Annual Burden hours | Wage Rate* | Total Costs |
| FITBIR Informatics System Data Access Request | 63 | $36.13 | $2276 |

*Hourly wage rates for 19-1029 Biologic Scientist is $36.13 (based on http://www.bls.gov/oes/current/oes191029.htm).

### A.13 Estimate of Other Total Annual Cost Burden to Respondents or Record Keepers

No additional costs are anticipated other than the respondents' burden given in A12.

### A.14 Annualized Cost to the Federal Government

The anticipated cost to the Federal Government is approximately $8,407.00 annually.

| Cost Descriptions | Grade/Step | Salary | % of Effort | Fringe (if applicable) | Total Cost to Gov't |
|---|---|---|---|---|---|
| **Federal Oversight** | | | | | |
| FITBIR Operations Staff | GS-15/Step 5 | $145,162 | 2.4% | | $3,484 |
| Data Access Committee 1 | GS-13/Step 1 | $92,145 | 2.4% | | $2,211 |
| Data Access Committee 2 | GS-12/Step 3 | $82,656 | 2.4% | | $1,984 |
| **Contractor Cost** | | | | | |
| FITBIR Operations staff | | $36,400 | 2.0% | | $728 |
| Travel | | | | | |
| Other Cost | | | | | |
| | | | | | |
| **Total** | | | | | $8,407 |

### A.15 Explanation for Program Changes or Adjustments

NINDS plans to continue to document, track, monitor and evaluate the use of the FITBIR datasets by collecting information from investigators in the future but the current OMB approval of the NINDS FITBIR Data Access Request (OMB #0925-0677) expired on 08/31/2016 and 60-day comment period extended beyond expiration. Therefore, this is a request to reinstate it for another 3 years, with change to the original request. Additional questions are added to the currently approved form to collect more detailed information about the investigator's project (e.g., project's summary/abstract) as well as supplementary information that identifies the investigator's collaborators on the project, if applicable. We do not think this will significantly increase their burden hours because investigators can simply copy and paste their existing abstracts they have written for grants, scientific meetings or conferences.

### A.16 Plans for Tabulation and Publication and Project Time Schedule

There is no specific plan to publish the data collected from this form. These data are for internal monitoring purposes.

### A.17 Reason(s) Display of OMB Expiration Date is Inappropriate

We are requesting no exemption.

### A.18 Exceptions to Certification for Paperwork Reduction Act Submissions

Not applicable.