

Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR)

Data Access Request

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Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System Data Access Request

Steps to Request Access to the FITBIR Informatics System

1. Email FITBIR-ops@mail.nih.gov to schedule an introductory call.
2. Review the [FITBIR Policy](#) document.
3. Review and sign the FITBIR Informatics System Data Use Certification (DUC) below.
4. Go to the [FITBIR website](#) and click on “Log Into FITBIR”.
5. After the page redirects, select “Request a New Account”. Fill in the required fields and select Continue.
6. On the next page select “Query Tool” under Account Privileges.
7. Under Upload Additional Files, for File Type select Data Access Request. Locate DUC and click “Upload”
8. Then select “Submit Request”
9. The FITBIR Data Access and Quality Committee (DAQC) will review requests to access the FITBIR Informatics System. Such reviews are generally completed within 10 business days.
10. The DAQC will notify you and FITBIR staff when the access request has been approved, and an account will then be provided. In unusual circumstances when a request is denied, appeals may be sent to FITBIR-ops@mail.nih.gov for consideration by the FITBIR Policy Committee.
11. Once notified by email that your account is approved, login to [FITBIR](#).

FITBIR Data Use Certification (DUC) Terms and Conditions

I request approval to access data and/or images from the FITBIR Informatics System for research purposes. I agree to the following terms:

1. Research. These data will be used by Recipient Principal Investigator solely in connection with the research “Study” specifically indicated and described on the Recipient Information and DUC form below. If the “Study” includes individuals who are also submitting data to FITBIR (Submitters), their names and the work they will perform are also included on the form.
2. Non-Transferability of Agreement. This approval is not transferable and covers only the research “Study” described on the Recipient Information and DUC form below. Recipient agrees that data will not be used in any research that is not disclosed and approved as part of the research “Study”. Recipient will submit a completed DUC (this document) for each research “Study” for which data are requested. Recipient agrees that any substantive change Recipient makes to the research “Study” requires execution of a new DUC, in which the new research “Study” is designated. If the Recipient appoints another Principal Investigator to complete the research “Study”, a new DUC in which the new Recipient is designated is necessary. If the Recipient changes institutions and wishes to retain access to FITBIR Informatics data, a new DUC in which the new institution acknowledges and agrees to the provisions of the DUC is necessary.
3. Non-Identification of Subjects. Recipient agrees that data will not be used, either alone or in conjunction with any other information, in any effort whatsoever to establish the individual identities of any of the subjects from whom data were obtained. Recipient agrees to notify FITBIR as soon as possible if, upon use of FITBIR data, the Recipient discovers identifying information in those data.
4. Global Unique Identifier (GUID) and Access to Submitted Data. The GUID is a computer-generated alphanumeric code that is unique to each research participant. The GUID allows FITBIR to link together

all submitted information on a single participant, giving researchers access to information even if the data were collected at different locations or through different studies. If Recipients request access to data on individuals for whom they themselves have previously submitted data to FITBIR, they may gain access to more data about an individual participant than they themselves collected. Consequently, these research activities may be considered “human subjects research” and may require that they obtain IRB approval of their research “Study”.

5. Data Disclaimers. Recipient agrees that the DOD and NIH do not and cannot warrant the results that may be obtained by using any data included therein. The DOD and NIH disclaim all warranties as to the accuracy of the data in the FITBIR Informatics System or the performance or fitness of the data for any particular purpose.

6. Notification to FITBIR of Publication. Prompt publication or other public disclosure of the results of the research “Study” is required. Recipient agrees to notify FITBIR via email FITBIR-ops@mail.nih.gov as to when and where a publication (or other public disclosure) of a report from the research “Study” will appear. Notification of such publications can occur by sending an email to FITBIR with an updated biographical sketch or CV of the publishing author.

7. Data Access for Research. Data from completed studies are eligible for restricted “Controlled Access” by qualified researchers pursuant to the terms set forth in this agreement. Recipients of data from FITBIR acknowledge that other researchers have access to the data and that downloading, utilization, and duplication of research are distinct possibilities.

8. No Distribution of Data. Recipient agrees to retain control over data, and further agrees not to transfer data, with or without charge, to any other entity or any individual. Recipient agrees not to sell the data in any form to any entity or individual or to distribute the data to anyone other than his/her research staff who will also agree to the terms within this DUC. This applies to all versions of FITBIR data.

9. Acknowledgments. Recipient agrees to acknowledge the contribution of the FITBIR Informatics System, the relevant FITBIR dataset identifier(s) (a serial number), and the Submitter(s) in oral and written presentations, disclosures, and publications resulting from any and all analyses of data using the FITBIR tools, whether or not Recipient is collaborating with Submitter(s). The manuscript should include the following acknowledgement or other similar language:

Data and/or research tools used in the preparation of this manuscript were obtained and analyzed from the controlled access datasets distributed from the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System. FITBIR is a collaborative biomedical informatics system created by the Department of Defense (DOD) and the National Institutes of Health (NIH) to support and accelerate research on TBI. Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the DOD, the NIH, or of the Submitters submitting original data to the FITBIR Informatics System.

If the research “Study” involves collaboration with Submitters or FITBIR staff, then Recipient will acknowledge Submitters as co-authors, if appropriate, on any publication. In addition, Recipients agree to include a reference to FITBIR Informatics System datasets analyzed and to cite FITBIR and the Federal funding sources in abstracts as space allows.

11. Non-Endorsement; Liability. Recipient agrees not to claim, infer, or imply endorsement by the United States Government, the DOD, the Department of Health & Human Services, or the NIH of the “Study”, the entity, or personnel conducting the Research “Study” or any resulting commercial product(s). The United States Government assumes no liability except to the extent provided under the Federal Tort Claims Act (28 U.S.C. § 2671-2680).

12. Recipient's Compliance with Institutional Requirements. Recipient acknowledges that access, if provided, is for research that is approved by the Institution, which must be operating under an Office of Human Research Protections (OHRP)-approved Assurance and/or equivalent international regulatory

agencies. Furthermore, Recipient agrees to comply with all applicable DOD and NIH rules for the protection of human subjects, and other relevant federal, state, and/or international laws for the use of these data. Recipient agrees to report promptly to FITBIR any proposed change in the research "Study" and any unanticipated problems involving risks to subjects or others. This DUC is made in addition to, and does not supersede, any of Recipient's institutional policies or any local, State, and/or Federal laws and regulations that provide additional protections for human subjects.

13. Recipient's Permission to Post Information Publicly. Recipient agrees to permit the DOD and the NIH to summarize on the FITBIR website the Recipient's research use of the FITBIR Informatics System along with the Recipient's name and organizational/institutional affiliation.

14. Privacy Act Notification. In order to access the FITBIR Informatics System, the Recipient agrees to provide the information requested below.

The Recipient agrees that information collected from the Recipient, as part of the Data Access Request, may be made public in part or in whole for tracking and reporting purposes. This Privacy Act Notification is provided pursuant to Public Law 93-579, Privacy Act of 1974, 5 U.S.C. Section 552a. Authority for the collection of the information requested below from the recipient comes from the authorities regarding the establishment of the NIH, 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 Sections 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 primary uses of this information are to document, track, and monitor and evaluate the use of the FITBIR Informatics datasets, as well as to notify interested recipients of updates, corrections or other changes to the database.

The Federal Privacy Act protects the confidentiality of the Recipient's DOD and NIH records. The DOD and 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.

15. Security. Recipient acknowledges the expectations set forth by the attached "FITBIR Information Security Best Practices" for the use and security of data.

16. Annual Update. Recipient will provide to FITBIR-ops@mail.nih.gov and upload to their FITBIR account an annual summary of research accomplishments from using FITBIR Informatics System and an updated biographical sketch <http://grants.nih.gov/grants/funding/2590/biosketchsample.pdf> or CV. Future access to FITBIR will be contingent upon receiving the annual update.

17. Amendments. Amendments to this DUC must be made in writing and signed by the Recipient and the FITBIR DAQC.

18. Termination. Either party may terminate this DUC without cause provided 30 days written notice to the other party. Recipients agree to immediately report violations of FITBIR Policy to the FITBIR DAQC. Additionally, the DOD and NIH may terminate this agreement with 5 days written notice if the DOD and the NIH determine, in their sole discretion, that the Recipient has committed a material breach of this DUC. The DOD and the NIH may, in their sole discretion, provide Recipient with 30 days notice to remedy a breach before termination. Closed accounts may be reactivated upon submission of an updated Informatics System Access Request and DUC.

19. One-Year Term and Access Period. Recipients who are granted permission to access data from FITBIR Informatics System receive an account that is valid for a period of one year. This DUC will

automatically terminate at the end of one year. An account may be renewed upon recertification of a new DUC, and is contingent upon receiving the annual update. Accounts that remain inactive for 12 consecutive months may be closed at the discretion of the DOD and the NIH.

20. Accurate Representations. Recipient expressly certifies that the contents of any statements made or reflected in this document are truthful and accurate.

FITBIR Information Security Best Practices

The purpose of these Security Best Practices, which are subject to applicable law, is to provide minimum security standards and best practices for individuals who use FITBIR to submit, access, and analyze data. Keeping FITBIR information secure through these best practices is important. Subject to applicable law, Recipient agrees to immediately report breaches of data confidentiality to the FITBIR DAQC.

Best Practices

- Do not attempt to override technical or management controls to access data for which you have not been expressly authorized.
- Do not use your trusted position and access rights to exploit system controls or access data for any reason other than in the performance of the proposed research.
- Ensure that everyone directed to use the system has access to, and is aware of, FITBIR Information Security Best Practices and all existing policies and procedures relevant to the use of FITBIR, including but not limited to, the FITBIR Policy at <http://FITBIR.nih.gov>.
- Follow the FITBIR password policy that includes:
 - Choose passwords of at least seven characters including at least three of the following types of characters: capital letters, lower case letters, numeric characters and other special characters.
 - Change your passwords every 60 days.
 - Protect your FITBIR password from access by other individuals—for example, store it electronically in a secure location.
- Notify FITBIR staff at FITBIR-ops@mail.nih.gov of security incidents, or any incidents of suspected fraud, waste or misuse of FITBIR or when access to FITBIR is no longer required.

Security Standards

- Protect the data, providing access solely to authorized researchers permitted access to such data by your institution.
- Neither store nor transmit links between personally identifiable information and GUIDs.
- When downloading FITBIR data, download the data to a secured computer or server with strong password protection.
- For the computers hosting FITBIR data, ensure that they have the latest security patches and are running virus protection software.
- Make sure the data are not exposed to the Internet or posted to a website that may be discovered by Internet search engines, such as Google or MSN.
- When leaving the office, close out of data files or lock the computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing data on a laptop or other portable medium. When storing data on such a device, encrypt the data. Most operating systems have the ability to natively run an encrypted file system or encrypt portions of the file system (Windows = EFS or Pointsec and Mac OSX = File Vault).
- When finished using the data, destroy the data or otherwise dispose of them properly.

Public reporting burden for this collection of information is estimated to vary from 15 min to 1.5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to: NIH, Project Clearance Branch, 6705 Rockledge Drive, MSC 7974, Bethesda, MD 20892-7974, ATTN: PRA (0925-xxxx). Do not return the completed form to this address.*

Recipient Information and Data Use Certifications

First Name: _____ Last Name: _____

Degree: _____ Academic Position (or Title): _____

Institution: _____ Department: _____

Street Address: _____

City: _____ State/Province: _____

Zip/Postal Code: _____ Country: _____

Telephone: _____ FAX: _____

E-mail Address: _____

Research "Study" (title and brief description): _____

I certify that I will abide by the terms and conditions of the DUC, and the DOD and NIH principles, policies and procedures for the use of the FITBIR Informatics System. I further acknowledge that I have shared this document and the DOD and NIH policies and procedures with all research staff who will participate in the use of FITBIR.

Signature: _____ Date: _____

IRB Approval #: _____ Expiration Date: _____

Inquiries and Requests Access Data in FITBIR should be sent to:

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

Email: FITBIR-ops@mail.nih.gov