Federal Interagency Traumatic Brain Injury Research Informatics System (FITBIR)

Data Access Request

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FITBIR Informatics System Data Access Request

The Data Access & Quality Committee (DAQ) approves access to data and/or images from the Federal Interagency Traumatic Brain Injury (FITBIR) Informatics System for research purposes only. The DAQ will review the Informatics System Access Request (ISAR) and the Data Use Certification (DUC) of each applicant requesting data and provide access based on the expectations outlined in the FITBIR policy (see http://fitbir.nih.gov). These expectations include the protection of data privacy, confidentiality, and security. In the event that requests raise concerns related to privacy and confidentiality, risks to populations or groups, or other concerns, the DAQ will consult with other experts as appropriate.

Recipients seeking access to data or images from FITBIR are expected to submit their ISAR, including a Standard Form (SF) 424 as per the instructions below, and a DUC, signed by the Principal Investigator. Completing this ISAR is a necessary step to access data or images from FITBIR.

Steps to Request Query Access to the FITBIR Informatics System

1. Read the FITBIR Informatics System Data Use Certification (DUC) below.
2. Complete the specified portions of the SF 424: on pages 1-2, complete items 2, 5, 8 (new Data Access Request or renewal), 11, 13, 15, 18, and 19. On page 3, complete item 1, regarding human subjects, and provide your Institution's Federal-wide Assurance number. Also on page 3, provide a Research Use Statement—a brief description of your Research Project in the text box provided: the objectives, design, and analysis plan. Provide a statement as to whether you have/will apply for, obtain, or do not have a Certificate of Confidentiality for the Research Project. On pages 4+, list all the collaborating investigators at your organization. Your collaborators at different organizations must complete separate requests for the data. Coordinated requests by collaborating organizations should all use the same title in their request and each should reference the others in the Research Use Statement.
3. Provide a scanned copy of the signed DUC Recipient Information and Certifications page and a scanned SF 424 including signatures when requesting an account to FITBIR (with Query privilege) at http://fitbir.nih.gov.
4. Access Request Review: The DAQ will review requests to access the FITBIR Informatics System. Such reviews are generally completed within 10 business days.
5. The DAQ will notify FITBIR staff if the access request has been approved, and an account will then be provided. Users will receive an automated notification of their account update with any modified user name, passwords, or instructions for accessing the FITBIR Informatics System.
6. Optional: FITBIR System Training (if request approved): Contact FITBIR through FITBIR-ops@mail.nih.gov to discuss specific training needs the user may have and schedule the training.

Data Use Certification (DUC) for the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System

Introduction

The Department of Defense (DOD) and the National Institutes of Health (NIH) have developed an informatics system to store the collection of data from participants in traumatic brain injury (TBI) research studies, regardless of the source of funding. The extensive information collected by these studies, and subsequently stored in the Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics System, provides a rare and valuable scientific resource. Promoting optimal use on a national scale of this resource will require a large and concerted effort, which may exceed the research capacity of currently investigators. DOD and the NIH have responsibility to the public in general, and to the scientific community in particular, to encourage the use of these resources to achieve rapid scientific progress. In order to take full advantage of such resources and maximize their research value, it is important that data

be made available, on appropriate terms and conditions, to the largest possible number of qualified investigators in a timely manner.

Data collected by the Submitters have been stripped of all individual identifiers, but the unique and intrinsically personal nature of DNA, derivative data of which are included in FITBIR, combined with the recent increase in the accessibility of conducting genotype and other sequence analyses (in terms of technological capacity and cost), has altered the framework through which "identify-ability" can be defined. To protect and assure the confidentiality and privacy of all participants, the Recipient who is granted access to these data is expected to adhere to the specifications of this DUC. Failure to do so could result in denial of further access to data and subject the Recipient of any other applicable penalties and actions.

Submitters have made a substantial long-term contribution to FITBIR by submitting data to the Informatics System. DOD and the NIH seek to encourage appropriate data use and collaborative relationships by outside investigators with the Submitters and to ensure that the contribution of the Submitters is appropriately acknowledged.

Definitions

For purposes of this agreement:

"Data" refers to the information that has been collected and recorded from participants in TBI studies, regardless of the source of funding. Data from study participants were collected through the periodic examinations and follow-up contacts conducted pursuant to the Submitters' Cooperative Agreement grants, other grants, contracts, and other TBI studies conducted independent of DOD or NIH.

A "Submitter" is defined as a researcher who has submitted data to the FITBIR Informatics System, according to the policies laid out in the FITBIR Informatics System Submission Agreement. The Submitter may have had a past or current/active grant, contract, or consulting agreement with DOD or NIH, one of its contractors, or any other funding source.

The "Recipient" Principal Investigator is an individual who seeks access to data from FITBIR. The Recipient and his/her Organization may be a researcher at a non-profit or for-profit organization or corporation with an approved assurance from the Department of Health and Human Services Office for Human Research Protections (OHRP). The Recipient requests access to study data at his/her sole risk and at no expense to the study, DOD, and NIH.

Terms and Conditions

I request approval to access data and/or images from the Federal Interagency Traumatic Brain Injury Research Informatics systems (FITBIR) Informatics System for research purposes. I agree to the following terms:

1. Research Project. These data will be used by Recipient Principal Investigator solely in connection with the "Research Project", specifically indicated and described in the Research Use Statement on the attached SF 424 (page 3 of the form). If the Project does involve Submitter(s), their names and the work they will perform are also included in the Recipient Information and Certifications section.

This DUC covers only the Research Project contemplated in the SF 424 Research Use Statement section. Recipient agrees that data will not be used in any research that is not disclosed and approved as

part of the Research Project. Recipient will submit a completed DUC (this document) for each research project for which data are requested. This applies to all versions of FITBIR Informatics System data.

2. Non-transferability of Agreement. This DUC is not transferable. Recipient agrees that any substantive change Recipient makes to the Research Project requires execution and approval of a new DUC, in which the new Research Project is designated. If the Recipient appoints another Principal Investigator to complete the Research Project, 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 must be executed and approved.

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. GUID and Access to Submitted Data. The Global Unique Identifier (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 institutional IRB approval of their Research Project.

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

6. Notification of FITBIR of Publication. Prompt publication or other public disclosure of the results of the Research Project 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 Project will appear. Notification of such publications can occur by sending to FITBIR an updated biographical sketch http://grants.nih.gov/grants/funding/2590/biosketchsample.pdf 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 Controlled Access data 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, except for collaborators with approved DUCs. 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 and collaborators with an approved DUC, who will also agree to the terms within this DUC.

9. Acknowledgments. Recipient agrees to acknowledge the contribution of the FITBIR bioinformatics platform, the relevant FITBIR dataset identifier(s) (a serial number), and the Submitter(s) in any and all 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 DOD- and NIH-supported Federal Interagency Traumatic Brain Injury Research (FITBIR) Informatics Systems. FITBIR is a collaborative biomedical informatics system created by the Department of Defense and the National Institutes of Health to provide a national resource to support and accelerate research in TBI.

Dataset identifier(s): [provide]. This manuscript reflects the views of the authors and may not reflect the opinions or views of the DOD, NIH, or of the Submitters submitting original data to FITBIR Informatics System.

If the Research Project involves collaboration with Submitters or FITBIR staff (as indicated in the SF 424), 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 Department of Defense, the Department of Health & Human Services, or the National Institutes of Health of the Research Project, the entity, or personnel conducting the Research Project 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. Furthermore, Recipient agrees to comply with all applicable DOD and NIH rules for the protection of human subjects, and other federal and state laws for the use of these data. Recipient agrees to report promptly to FITBIR any proposed change in the research project 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 DOD and the NIH to summarize on the FITBIR Web site the Recipient's research use of 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 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 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. 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 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 authorized representatives of all parties.

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 DAQ. Additionally, DOD and NIH may terminate this agreement with 5 days written notice if the DOD and NIH determine, in their sole discretion, that the Recipient has committed a material breach of this DUC. DOD and NIH may, in their sole discretion, provide Recipient with 30 days notice to remedy a breach before termination. Upon termination of the DUC, use of the data must be discontinued. 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 DOD and 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, Recipients agree to immediately report breaches of data confidentiality to the FITBIR DAQ.

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 anyone 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 which 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 six months.
  - Protect your FITBIR password from access by other individuals—for example, store it electronically in a secure location.
- Notify FITBIR staff, as permitted by law, 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 or to others as required by law.
- When you download 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.
- If you leave your office, close out of data files or lock your computer. Consider the installation of a timed screen saver with password protection.
- Avoid storing data on a laptop or other portable medium. If 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 it properly, as permitted by law.

Recipient Information and Certifications

Date: _____

Type of Application: ___ New ___ Renewal

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 Project (title):

_____

_____

By signing and dating this DUC as part of requesting access to data in FITBIR, I certify that I will abide by 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 any research staff who will participate in the use of FITBIR.

Signature: _____ Date: _____

IRB Approval #: _____Expiration Date: _____

Inquiries and Requests to Submit Data to FITBIR should be sent to:
Office of FITBIR Operations
National Institutes of Health, Center for Information Technology (CIT)
12 South Dr. RM 2041
Bethesda, MD 20892
301-594-3532 Email: FITBIR-ops@mail.nih.gov

Project Director/Principal Investigator Contact Information (if different from above)

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: _____

Other Project Information:

1. Are Human Subjects involved? __ Yes __ No

If YES to Human Subjects

Is the Project Exempt from Federal regulations? __ Yes __ No

If yes, check appropriate exemption number. __1 __2 __3 __4 __5 __6

If no, is the IRB review pending? __ Yes __ No

IRB Approval Date: _____

2. Project Summary/Abstract:

Insert here.

Senior/Key Person Profile (Collaborating Investigator)

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: _____

Project Role: _____ Other Project Role Category: _____

Senior/Key Person Profile (Collaborating Investigator)

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: _____

Project Role: _____ Other Project Role Category: _____

Senior/Key Person Profile (Collaborating Investigator)

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: _____

Project Role: _____ Other Project Role Category: _____

Use additional sheets for additional profiles as needed.