



## SOP-02 FITBIR Data Submission Privilege Request

FITBIR is a restricted access portal to research data relevant to traumatic brain injury (TBI) research. A FITBIR account is required to submit or access TBI-related data. Investigators and data managers at research sites are invited to request an account. To provide maximum protection for the confidentiality of research participants whose data is stored in FITBIR, professional credentials are verified by the FITBIR Data Access & Quality Committee (DAQ) during the account request process.

To submit data to FITBIR, an investigator is required to complete a [FITBIR Data Submission Request](#). With an approved submission request, an investigator can submit descriptive data, experimental data, and a variety of supporting documentation associated with a research study to a FITBIR Study — a virtual container for storing research data. To create a FITBIR Study, an investigator must have a current Data Submission Agreement uploaded to FITBIR.

The person responsible for collecting the data is typically the Principal Investigator. Alternatively, it could be a Co-Investigator who is responsible for data coordination for the study. **The person who signs the form will create the FITBIR Study.**

### Prerequisites:

1. Valid FITBIR account with STUDY privilege (see SOP 03 FITBIR Request Additional Account Privileges, if needed)
2. Signed, PDF of the Data Submission Request

### Procedure:

This procedure provides process steps for study submission initiation, authorization, and validation. The entire procedure typically requires 1-3 business days (assuming Prerequisites are already met)

### Study Submission Privilege Request Initiation

1. Point browser to the FITBIR website at <http://fitbir.nih.gov>.
2. Click LOG INTO FITBIR
3. After entering username and password, you will be directed to your Workspace.
4. Click on the Data Repository icon in the Workspace or the Data Repository tab in the top navigation.
5. Click the Create Study option under Manage Studies
6. Fill in all required text marked with a \*
7. Upload the approved and signed Data Submission Agreement
8. Click [Submit Request] when complete.

9. If all required fields were successfully entered, a confirmation page will be displayed.
10. FITBIR Admin is notified that there is a request awaiting review.

### **Study Submission Privilege Request Review and Authorization**

1. FITBIR Staff review the information provided in Study Submission request.
2. FITBIR Staff may contact applicant for more information about the Study Submission into FITBIR informatics system.
3. FITBIR Staff summarize this information and provides it to the FITBIR Data Access and Quality Committee (DAQ).
4. The FITBIR DAQ reviews the information and authorizes the Study Submission in FITBIR.
5. With authorization from the FITBIR DAQ, FITBIR Admin grants Study submission to the user.
6. The FITBIR Admin sends an automated email message notifying you of the status of your FITBIR study request.

### **Study Validation**

1. Watch your email inbox for a message from "FITBIR-ops@mail.nih.gov" with subject "Status of your FITBIR study request."
2. If approved, you may now submit data to the study.
3. Return to the FITBIR website to login.