

SOP-11 FITBIR Form Structure (FS) Creation & Publication

Form structures are the containers for data elements and common data elements. Form structures are associated in studies for submitting research data or later used to create electronic Case Report Forms (eCRFs).

Form structures adhere to a strict publication process prior to researchers submitting data to that particular form structure. Form structures are initially created in a draft state - they can be modified and data elements may be removed or attached to the form structure. However, research and submission data cannot be submitted to draft form structures.

Once a study is ready to submit data to a form structure, the researcher must request publication for the form structure. After a form structure has been approved by a FITBIR administrator, the form structure becomes published and research data may now be uploaded.

Prerequisites:

- Valid FITBIR account with Dictionary privilege
- FITBIR Data Dictionary has been searched to see if a form structure already exists in the system and **NONE** were found.

Procedure:

This procedure provides process steps for creating a form structure request initiation, authorization, and validation.

Form Structure Request Initiation

1. Point your browser to the FITBIR website at <http://fitbir.nih.gov>.
2. CLICK THE LOG INTO FITBIR tab.
3. There are two ways to find the Data Dictionary tool:
 - a) Through Workspace -> Data Dictionary Tool
 - OR-
 - b) Through the Data Dictionary tab in the top blue navigation.
4. Launch Data Dictionary Tool
5. Click Create Form Structure
6. Step 1. Edit Details: Fill in all required fields marked with an asterisk *
7. Click Continue when complete.
8. Step 2. Attach Elements. Add Element Group and/or add repeatable Groups by clicking the respective buttons.

- a. Note: Elements added to forms can be qualified via the selection from the drop down menus in the column titled “Required?”
 - b. Note: Conditionally Required (CR) means that if a previous question is answered in a particular way, then the question marked CR must be answered. (Example: If Gender is Female, then the question “Have you ever been pregnant” could be asked and answered).
 - c. Note: Conditionally Prohibited (CP) means that if a previous question is answered in a particular way, then the question marked CP must NOT be answered. (Example: If Gender is Male, then the question “Have you ever been pregnant” need not be asked or answered).
9. Click Continue when complete
 10. Step 3. Grant Permissions: There are no required fields. Fill in as needed. Read Permission—read/write/admin/owner—other team members have access to form—this is important functionality. Can go back later to add or remove people.
 11. Click Save & Finish when complete.
 12. A confirmation message will appear alerting you that the data element is in a draft state.

Form Structure Publication Request Initiation

1. In the Data Dictionary tool, select Browse Form Structures.
2. Search for desired form structure and click on it once found.
3. Under Publication State, click the Request Publication link. The status is changed to Awaiting Publication.

Form Structure Request Review and Authorization

1. FITBIR Staff review the information provided in form structure publication request.
2. FITBIR Staff verify that the form structure does not already exist in FITBIR.
3. FITBIR Staff reviews the information and authorizes or denies the publication request.
4. The FITBIR Admin sends you an automated email message notifying you of the decision.

Form Structure Publication Validation

1. Watch your email inbox for a message from FITBIR-help@nih.gov with the subject “Request to publish form structure has been approved by an admin.”
2. If Form Structure is approved for publication, the next time you log into FITBIR, it should be available for use in Form Structures.