FITBIR Form Structure Creation Guide

This guide is aimed to walk users through the form structure creation process in the FITBIR system. Form structures are the containers for data elements. They are "vehicles" by which data is submitted to FITBIR.

Form structures adhere to a strict publication process prior to researchers submitting data to that particular form structure. Form structures are initially created in draft state – they can be modified and data elements may be removed or added to the form structure. Research data can be validated using a draft form structure in the Validation Tool, but it cannot be uploaded to the database until it is validated.

Once the study team has validated research data using the Validation Tool, and is ready to upload data to the database, the researcher may request publication of the form structure. Once the form structure has been approved by a FITBIR administrator, it will be in a "Published" state, and can then be used to upload research data via the Upload Tool.

For more information please visit the FITBIR wiki covering form structures [http://ibis-wiki.cit.nih.gov/foswiki/Main/DataElements/FormStructures]

1. **Steps for Creating a Form Structure using the FITBIR Form Structure Template. The Template contains the data elements for the Main and Form Administration Groups**
   a. **Log into the FITBIR Portal**
   b. **Navigate to the Data Dictionary**
   c. **In the Search box, enter the short name of the form structure: 'FormTemplate_FITBIR'**
   d. **Select 'Create Draft Copy'**
   e. Because this form structure is a copy of a shared draft, certain fields will be pre-populated. Update the following fields to reflect your form structure. All fields that are marked with an asterisk are required.
      i. Title
      ii. Short Name
      iii. Description
      iv. Disease
      v. Organization is optional
      vi. Form Type
      vii. Does this represent a copyrighted form?
      viii. Documentation is optional, but FITBIR Ops encourage uploading a copy of your case report form.
      ix. Click continue when complete
   f. **Select 'Add Group' button to add form specific data elements to the form**
      i. Enter in a group name which corresponds with the form structure
      ii. Select the number of times you wish the question to be repeated
         1. FITBIR Ops recommends selecting "Up to" if you are unsure

       iii. Enter the Threshold (the number which will correspond with your choice for "number of times repeated" above)

          1. FITBIR Ops recommends selecting "0" if you are unsure

       iv. Click on the "Save Group" button

    g. Add the data elements into the new element group(s):

       i. Underneath the new group, click on "Add Data Elements," which will direct you to the Data Dictionary. Search for the data elements you would like to add to your form structure. Select the data elements by checking the checkbox next to the data element.

       ii. Once you are done searching and checking off data elements, click the "Add Selected Elements" button. The data elements will be added to your group in the **order which they were selected.**

          1. FITBIR Ops recommends adding the data elements to your form structure in the order that they appear on the form

       iii. To adjust the order of data elements within an element group once they have been added to a form structure, simply click on the data element, drag, and drop the data elements to the desired position.

       iv. There are three statuses for the optionality of a data element:

          1. Required: Validation tool will produce an error and not allow the data set to pass if a cell is left blank for the data element.

             a. GUID should ALWAYS be required.

          2. Recommended: Validation tool will produce a warning, but still allow the data set to pass if a cell is left blank for that data element.

             a. The default is recommended.

          3. Optional: Validation tool will NOT produce an error or warning and will allow the data set to pass if a cell is left blank for that data element.

       v. Remove a data element from the form structure:

          1. Under the "Removal All?" column, click on "remove" text

       vi. Move data elements between element groups:

          1. Using the drop down menu in the Group column, for each data element, select which new element group you would like to move the data element.

             a. FITBIR Ops recommends doing this in the order that the data elements appear on the form

2. **Steps for Creating a Form Structure without the FITBIR Form Structure template. The Main and Form Administration Groups should be added to the form structure.**

    a. Log into the FITBIR Portal

    b. Navigate to Data Dictionary

    c. Select Create Form Structure from the left-hand Menu drop down

    d. Complete all required fields marked with an asterisk

       i. Title

       ii. Short Name

   iii. Description

   iv. Disease

   v. Form Type

   vi. Does this represent a copyrighted form?

   vii. Documentation is optional, but FITBIR Ops encourage uploading a copy of your case report form.

   viii. Click continue when complete

 e. Main Group

   i. The Main Group is a standardized group of data elements that must be included in all FITBIR form structures, including standardized, addendum, and "homespun" form structures in order to provide consistency and context for all data submitted to the FITBIR database. The Main Group data elements will be added by selecting "Add Data Elements." You do not need to add a new group to add the Main Group. The Main Group must contain the following data elements with the corresponding optionality:

GUID	REQUIRED
SubjectIDNum	OPTIONAL
AgeYrs	RECOMMENDED
VisitDate	RECOMMENDED
SiteName	RECOMMENDED
DaysSinceBaseline	OPTIONAL
CaseContrlInd	OPTIONAL
GeneralNotesTxt	OPTIONAL

 f. Create new element groups to organize the form structure's data elements

   i. Go to the bottom of the page and click the "Add Group" button

   ii. Enter in a group name which corresponds with the form structure

   iii. Select the number of times you wish the question to be repeated

     1. FITBIR Ops recommends selecting "Up to" if you are unsure

   iv. Enter the Threshold (the number which will correspond with your choice for "number of times repeated" above)

     1. FITBIR Ops recommends selecting "0" if you are unsure

   v. Click on the "Save Group" button

 g. Add the data elements into the new element group(s):

   i. Underneath the new group, click on "Add Data Elements," which will direct you to the Data Dictionary. Search for the data elements you would like to add to

your form structure. Select the data elements by checking the checkbox next to the data element.

    ii.   Once you are done searching and checking off data elements, click the "Add Selected Elements" button. The data elements will be added to your group in the **order which they were selected.**

        1.   FITBIR Ops recommends adding the data elements to your form structure in the order that they appear on the form

    iii.   To adjust the order of data elements within an element group once they have been added to a form structure, simply click on the data element, drag, and drop the data elements to the desired position.

    iv.   There are three statuses for the optionality of a data element:

        1.   Required: Validation tool will produce an error and not allow the data set to pass if a cell is left blank for the data element.

            a.   GUID should ALWAYS be required.

        2.   Recommended: Validation tool will produce a warning, but still allow the data set to pass if a cell is left blank for that data element.

            a.   The default is recommended.

        3.   Optional: Validation tool will NOT produce an error or warning and will allow the data set to pass if a cell is left blank for that data element.

    v.   Remove a data element from the form structure:

        1.   Under the "Removal All?" column, click on "remove" text

    vi.   Move data elements between element groups:

        1.   Using the drop down menu in the Group column, for each data element, select which new element group you would like to move the data element.

            a.   FITBIR Ops recommends doing this in the order that the data elements appear on the form

h.   Form Administration Group

    i.   After the Main Group, the user should create the Form Administration Group. This group contains four data elements to identify the background of how the forms were administered. This group will be a part of all forms in the FITBIR system. These data elements define what time point the CRF was taken, and who filled out the form.

ContextType	Recommended
ContextTypeOTH	Recommended
DataSource	Recommended
DataSourceOTH	Recommended

i.   Change the requirements for the data elements to whatever is appropriate for your study using the drop down menu. FITBIR Ops recommends changing data elements from "Optional" to "Recommended"

    i.   Adjusting the order of element groups:

1. Click on the title bar of the group and drag and drop the group to the desired position
2. Note: The Main Group cannot be moved
    ii. Editing data element group settings:
        1. Click on the "Edit Group" button
        2. Make the desired changes
    iii. To remove a data element group:
        1. Click on the "Remove Group" text
    iv. Once you are finished creating your groups and adding your data elements, click on "Continue."
j. Grant Permissions:
    i. Find the user name in the drop down menu and select it. Then click on the "Grant Permission" button.
    ii. Once added, chose the desired level of permission to that form structure: Owner, Admin, Write, Read
        1. Admin/Owner: Allows user to view draft form structure, edit form structure details, attach data elements and grant permissions
            a. Note: There can only be ONE Owner per form structure (by default it is the creator of the form structure, but can be changed)
        2. Write: Allows user to view draft form structure, edit form structure details, and attach data elements
        3. Read: Allows user to view draft form structure
    iii. Click on the "Continue" button found at the bottom of the page
    iv. Removing permissions:
        1. Search for form structure
        2. Select "edit" form the Menu on the right
        3. Click on the "3. Permissions" chevron
        4. Click the "remove" button
            a. The user will no longer have Admin/Write/Read privileges to your form structure
k. Final Review
    i. Review all of the data elements and make sure they are in the correct order and have the correct requirements (optionality, group, threshold, etc.)
    ii. If there are no issues, click on the "Finish" button found at the bottom of the screen
    iii. The form structure will be saved in DRAFT status

3. **Maintaining Existing Form Structures**
a. Viewing your form structure:
    i. Click "Search Form Structure" form the left-hand Menu icon
b. Editing your form structure:

        i.   Click on the Menu icon and select "Search Form Structure"

        ii. Type your form structure's name and open the form structure

        iii. Click on the "Edit" text on the right hand side

   c. Deleting your form structure:

        i.   Click on the Menu icon and select "Search Form Structure"

        ii. Type your form structure's name and open the form structure

        iii. Click on the "Delete" button

   d. To view a detailed data element report of all data elements used in your form structure:

        i.   Click on "Data Element Report" from the right-hand Menu

        ii. To export the data element report as a CSV file click "Click Here" above "Variable Name"

   e. Request publication of form structure:

        i.   Select "Request Publication" under the section labeled "Publication State"

4. **Searching for Form Structures**
   a. Instead of starting from scratch you may find shared draft or published form structures available in the Data Dictionary that may serve as a starting point for you by selecting "Browse Form Structures" from the left-hand Menu icon in the data dictionary.

5. **Shared Draft Form Structures**
   a. Shared draft form structures are "starting points" for building form structures. They are basically "buckets" for the common data elements associated with a particular standardized form provided by the NINDS CDE project.
   b. Building a form structure from Shared Draft:
      i.   Enter the Data Dictionary on the FITBIR portal
      ii. Search form structures for the shared draft form structure you would like to use
      iii. Select "Create Draft Copy" located on the menu on the right
      iv. Enter the form short name following these naming conventions:
         1. **Short name:** Form Name/Acronym you are building the shared draft form structure for_FITBIR, ex. AUDIT_FITBIR (please note that the 27 character short name has a functional limit of 20 since "_FITBIR" must be included)
      v. Create new groups for the form structure's existing data elements:
         1. Go to the bottom of the page and click the "Add Group" button
         2. Enter in a group name which corresponds with the shared draft form structure
         3. Select the number of times you wish the question to be repeated
            a. FITBIR Ops recommends selecting "up to" if you are unsure
         4. Enter the threshold (the number which will correspond with your choice for "number of times repeated" above)

a. FITBIR Ops recommends selecting "0" if you are unsure
       5. Click on the "Save Group" button
   vi. Change the requirements for the data elements from "Optional" to "Recommended" using the drop down menu
   vii. Add the data elements into the new group:
       1. Use the drop down menu for each data element in the group column and select the name of the group you previously created (This will move the data element into the newly created group; you will see that the data elements leave the Main Group and will appear in the new group)
          a. FITBIR Ops recommends doing this in the order that the data elements appear on the form
       2. You also have the option to manually drag and reorder the data elements
   viii. Add Main Group questions
       1. Click on the "Add Data Elements" button
       2. Type in the Main Group data element you with to add to the form into the search bar, click on the box corresponding to the data element, and click "Add Selected Elements" (Repeat for the remaining Main Group data elements)
       3. Use the drop down menu to change the requirement of the question to match the requirements in the table shown above in the Main Group table
       4. Click on the "Continue" button found at the bottom of the page once you are done
   ix. Grant Permissions
       1. Find user name in drop down menu and select it
       2. Once added choose the desired level of permission to that form structure: Owner, Admin, Write, Read
       3. Click on the "Continue" button found at the bottom of the page
   x. Final Review
       1. Review all of the data elements and make sure that they are in the correct order, and have the correct requirements
       2. If there are no issues, click on the "Finish" button found at the bottom of the screen
c. Published Form Structures
   i. If you find a published form structure that is applicable to your study, you may use it as is OR create a draft copy to adjust it to your needs.
   ii. BE SURE the Published Form Structure contains the appropriate Main Group
       1. **If not, contact FITBIR Operations Team**
   iii. If it is a STANDARDIZED form, then please follow the rules below for creating an **addendum form structure (Section IV).**

6. **Creating Addendum Form Structures**
   a. Addendum form structures must be created if there are study-specific

data elements you would like to add to a standardized instrument in the FIRTBIR data dictionary to hold these extra data elements.

      i. Note: If the data elements you are adding affects the summary scores of the standardized form structure you will have to make a new form structure

b. To create an addendum, follow these naming conventions:

      i. Title: Form Name and acronym followed by Appendix and FITBIR study number

      ii. Example: Patient Health Questionnaire 9 (PHQ9) Appendix for FITBIR _Study0000217

      iii. Short name: Form Name/Acronym you are building the appendix for_Appdx_Number portion of FITBIR Study ID

      iv. Example: PHQ9_Appdx_0000217

c. In addition to adding the study-specific data elements, you MUST include the data elements in the MAIN GROUP and the FORM ADMINISTRATION GROUP listed above.