

CCR Data Management and Sharing Plan Submission Portal For Clinical Protocols

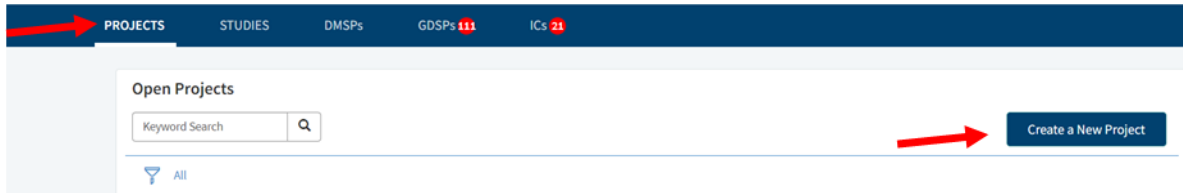
User Manual

Version I : 8/28/2023

Creating a Project

STEP 1: Open the Create a New Project tab

- Select Projects on the upper left of the menu bar
- Select Create a New Project by clicking the tab on the right. See the figure below.



STEP 2: Complete the Project Information

- Several Project fields auto-populate your subsequent forms, so please be complete.
- Required Project Information includes:
 - Project Title and Abbreviated Project Title

* Project Title

- Principal Investigator name

* PI

- For clinical trials, the principal investigator is the protocol's Principal Investigator or Lead Associate Investigator.
- Write the PI's name, and it will search the database for the appropriate match. In case of multiple matches, check the affiliations and emails from the search to find the correct match.

* PI

Search Results for 'abid'		
Abid Rehman	NIA IRP LG RRS	abid.rehman@nih.gov
Abid Reza	NCI CCR CGB	abid.reza@nih.gov
Abidemi Ola	NIAID VRC CTP	abidemi.ola@nih.gov
Eissa Alzabidi		
Mahnoor Abid	NIAID DIR LHIM MIS	mahnoor.abid@nih.gov
Mahrukh Abidi	NCI OD CBIIT OD	mahrukh.abidi@nih.gov
Matteo Abidani		matteabi@gmail.com

- Email, phone number, title, and branch will be auto-populated from NIH Enterprise Directory (NED).

PI Email

abid.reza@nih.gov

PI Title

N/A

PI Phone

+1 240 858 7909

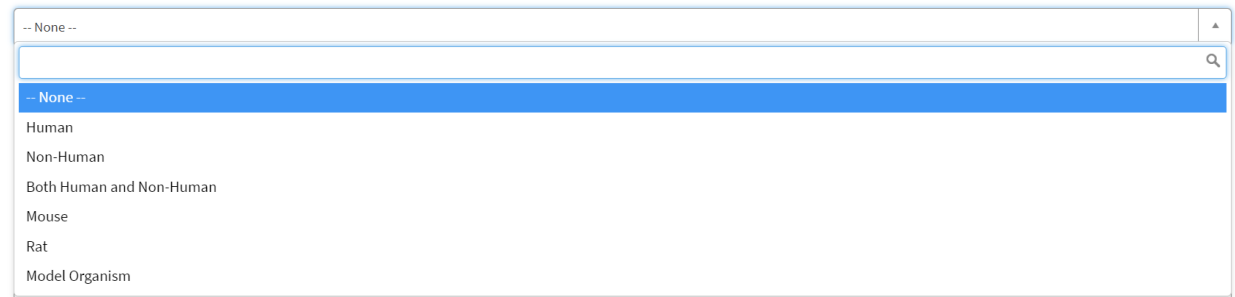
PI Branch

NCI CCR CGB

- If there is an error, please get in touch with your Administrative Officer to get NED content updated.

- Organism

* Organism Type



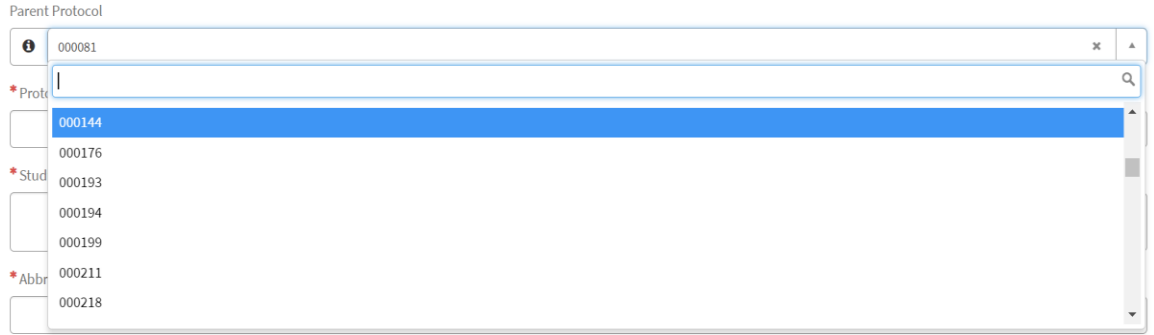
- Specify the organism(s) type, including all that apply.
 - For humans only, select **Human**
 - For non-humans other than mice, rats and model organisms use **Non-Human**
 - For both human and non-human study, use **Both Human and Non-Human**. For example, if your study includes mice and human samples.
 - For Mouse only, select **Mouse**.
 - For Rat only, select **Rat**
 - For other model organisms not listed, Use **Model Organism**

- Study ID/Protocol ID

Parent Protocol

* Protocol ID

- Select the Parent Protocol/Project from the dropdown list. Text input will narrow down the list.



- Parent Protocols/Projects may be Tissue Procurement studies, OHRSP exemptions, or other umbrella projects in which multiple protocols/projects with different investigators are conducted under the umbrella protocol/project.
- For more information about the selected protocol, click the “i” button



it will pop a new window with more information for further verification.

- Clinical Protocol ID from PROTECT.
- Study Title and Abbreviated Title

* Study Title

* Abbreviated Title

- These may differ if your study is part of a larger project or the same as the Project title and can be copied and pasted.
 - Please provide the same abbreviated Study title used in your protocol.
- ZIA number

Z1A

- This is a **mandatory field**. ZIA number is the mechanism used to upload your plan to the Office of Intramural Research (OIR) into NIDB.
- Every protocol and/or laboratory project must fall under a ZIA number, which is aligned under PIs with independent resources.

Note: many submissions get rejected because the submitter forgot to include the ZIA number. Please provide this to save your valuable time.

- **Other information**
 - Journal mandate
 - Complete this item ONLY if you need to complete these forms because a journal has required you to share data and specify the journal.
 - Lead investigator
 - Complete this item ONLY if there is a lead Associate Investigator, and specify that individual.
 - Associated Study IDs
 - Complete this item ONLY if there is another study ID, such as a cooperative group study ID or industry study ID.

STEP 3: Establish Collaborator Access

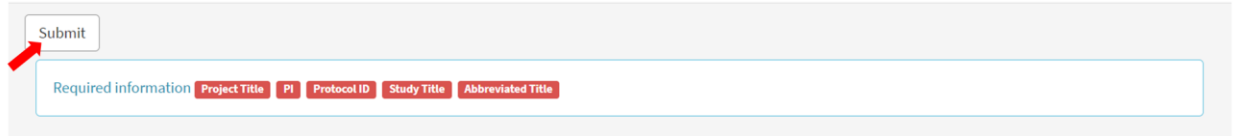
You have the option of giving other NIH staff permission to access the project and associated forms.

Collaborator Access	
Collaborators (Read Access)	Collaborators (Edit Access)
<input type="text"/>	<input type="text"/>

- Go to Collaborator Access
 - There are two access types: Read Only or Write.
 - Enter the NIH Username/ Full name (which will link to full name and email) that corresponds to the access you wish to give that individual. **In case of multiple matches, check the affiliations and emails from the search to find the correct match.**

- Consider including your Protocol Coordinator from the Protocol Support Office

STEP 4: Select Save



A screenshot of a web form interface. At the top left, there is a button labeled "Submit" with a red arrow pointing to it. Below the button is a horizontal list of fields: "Required information", "Project Title", "PI", "Protocol ID", "Study Title", and "Abbreviated Title". Each field name is enclosed in a small red box.

STEP 5: Select Form(s) to Complete

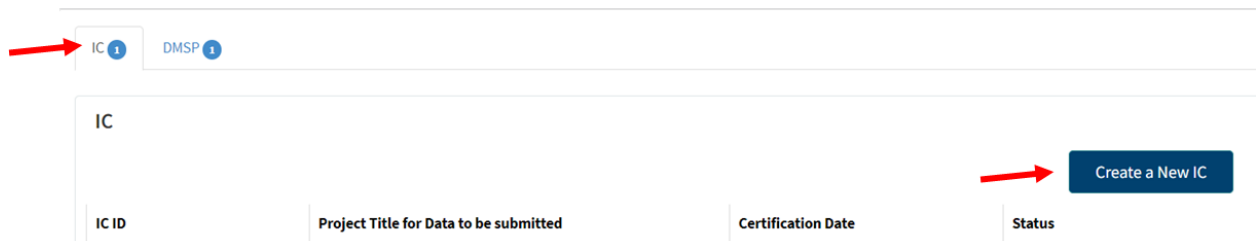
- **Human Studies** require an Institutional Certification Memo (IC) **AND** a Data Management and Sharing Plan (DMSP). Please follow the below instructions to generate these documents.

Creating Institutional Certification Memo(s)

- An Institutional Certification Memo is established by clicking the IC tab at the bottom of the Project page.
 - **Note:** more than one Institutional Certification Memo is required if the research began prior to August 31, 2015 (with or without consent) and continued past the policy implementation date when consent is mandatory. One memo is required for each instance:
 - 1) prior to August 31, 2015, with consent
 - 2) prior to August 31, 2015, without consent
 - 3) after August 31, 2015, with consent
 - **Only ONE Institutional Certification Memo can be generated at a time.** If your project requires more than one memo, you must repeat the procedures described below for EACH instance requiring an Institutional Certification Memo.

STEP 1: Select IC to Complete

- Select the IC tab, then click Create a New IC in the blue box on the right at the bottom of the screen to start generating an Institutional Certification Memo. See the figure below.



STEP 2: Select the IC timeframe

- You must select at least one of the options below to generate the fields for a new IC memo.

The screenshot shows a form titled 'IC - new record'. It contains two checkboxes with the following text: 'Have samples been collected before August 31, 2015?' and 'Have and/or will samples be collected with informed consent?'. Both checkboxes are currently unchecked.

- Indicate if the samples have been collected before August 31, 2015 (Yes/No)
- Indicate if the samples were collected with or without consent (Yes/No)

Selecting any one of the checkboxes will generate new fields for more information.

* Certification Date

* Name of Institution

* Organization of GPA

* Organization of SD

* Original Study Name

* Project Title for Data to be submitted

Data are made available through

Controlled-access

Check the box above if the genomic summary results (GSR) from this study are only to be made available through controlled-access.

STEP 3: Complete all information NOT prepopulated from the Project Information

NOTE: Other NIH Institutes may use this portal, so not all information provided is prepopulated for NCI.

- Certification Date -- Use “mm/dd/yyyy” format – use the date you going to submit the IC form.
- Name of Institution – use “NCI”
- Organization of GPA – use “NCI”
- Organization of SD (Scientific Directors) – use “NCI”
- Original Study Name
- Project Title will be auto-populated from the Project Information entered.
- Select data access, unrestricted or controlled access.

Data are made available through

Controlled-access

Unrestricted

Controlled-access

Note: Human studies are controlled access

- Determine whether Genomic Summary Results (GSR) must be retained under controlled access. If yes, check the controlled-access box **AND** provide a justification in the box provided (see the figure and definitions of sensitive study populations*, # below).

Controlled-access

Check the box above if the genomic summary results (GSR) from this study are only to be made available through controlled-access.

* Explanation if controlled-access was selected for GSR

**Sensitive study populations are considered those that may have heightened privacy risks or have other restrictions on the use of the data, e.g., populations from isolated geographic regions, affected with rare or potentially stigmatizing traits and/or diseases, or populations with data restrictions.*

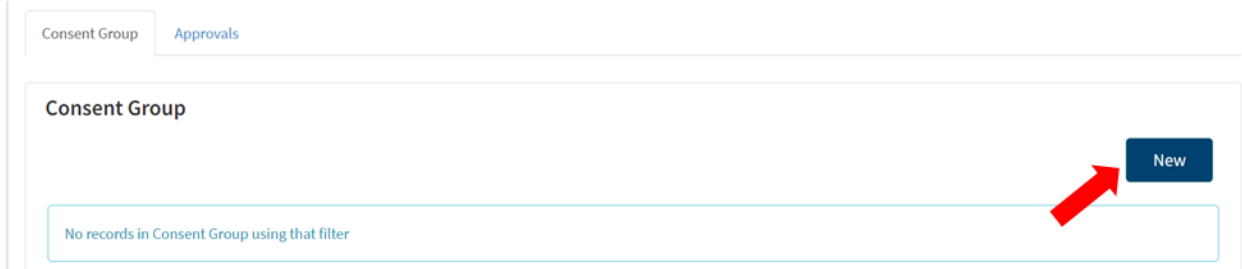
#The Trans-NCI Genomic Data Sharing Working Group has adopted the following definition of rare disease – a disease that affects **less than 200,000 persons** in the United States, that has been [set forth](#) by the U.S. Food and Drug Administration (FDA).

STEP 4: Select Save

- This will establish your IC memo in the system and allow you to add Consent groups.

STEP 5: Establish the Consent Groups

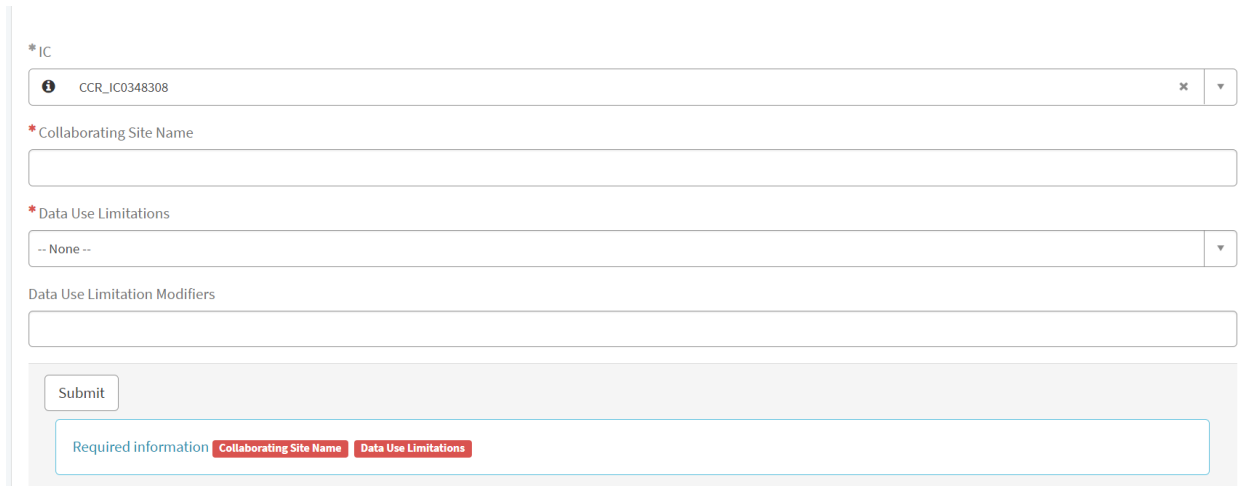
- You must add Consent Groups. Select **New** on the right.



The screenshot shows a web interface with two tabs: 'Consent Group' (selected) and 'Approvals'. Below the tabs is a header 'Consent Group' and a large empty text area with the message 'No records in Consent Group using that filter'. On the right side of this area is a blue button labeled 'New', which is pointed to by a red arrow.

Note:

- ❖ NCI/CCR must have a separate entry
 - ❖ Every collaborating research site must also have a separate entry for multi-site studies.
- This will lead to a new page. Populate these fields with the necessary information.



The screenshot shows a form for adding a new Consent Group. It includes the following fields:

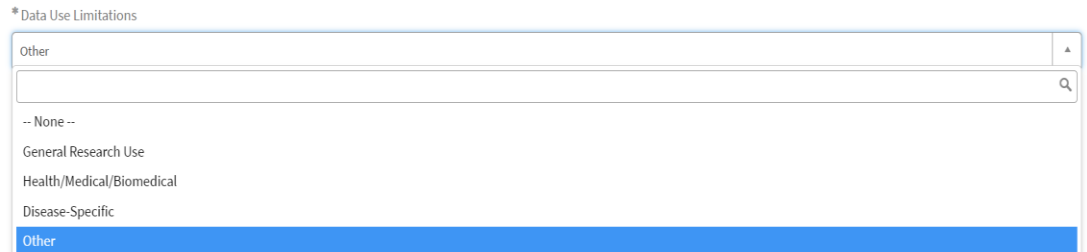
- *IC: A dropdown menu with the value 'CCR_IC0348308' and a search icon on the left and a close icon on the right.
- *Collaborating Site Name: An empty text input field.
- *Data Use Limitations: A dropdown menu with the value '-- None --'.
- Data Use Limitation Modifiers: An empty text input field.

At the bottom, there is a 'Submit' button and a red error message box that says 'Required information Collaborating Site Name Data Use Limitations'.

- Select Data Use Limitations
 - Data Use Limitations are based on the terms of the informed consent of the study participants from whom the genomic data have been generated.
 - Most studies are General Research Use **UNLESS** specified in the consent.

- In case you selected “Other” for the Data Use limitation field,

*Data Use Limitations



Other

-- None --

General Research Use

Health/Medical/Biomedical

Disease-Specific

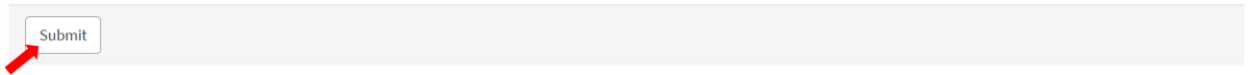
Other

you must provide a specific reason in the Specify Other field.

*Specify Other

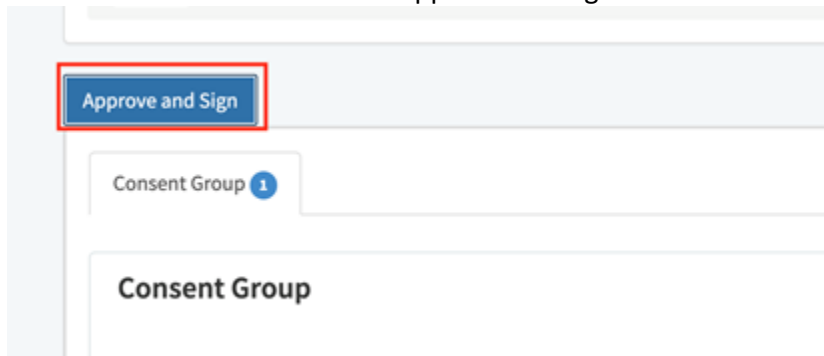


- To complete this process for collaborating sites, each participating site should provide a copy of its own Institutional Certification.
- Data Use Limitation Modifiers
 - Modifiers are based on consent.
 - Most studies have no modifiers.
 - Select Submit – this will create the Institutional Certification in the system for review and approval/signatures.
- Click Submit for PI signature



NOTE: The next 4 steps need to be **completed by the PI**

- Scroll down and click the blue “Approve and Sign” button



- Once the pop-up appears scroll down on your browser using the bar all the way to the right until you see the section to enter your name.

- Enter your name.
- Click the “Accept and Complete” button.

STEP 5: Review and Approval

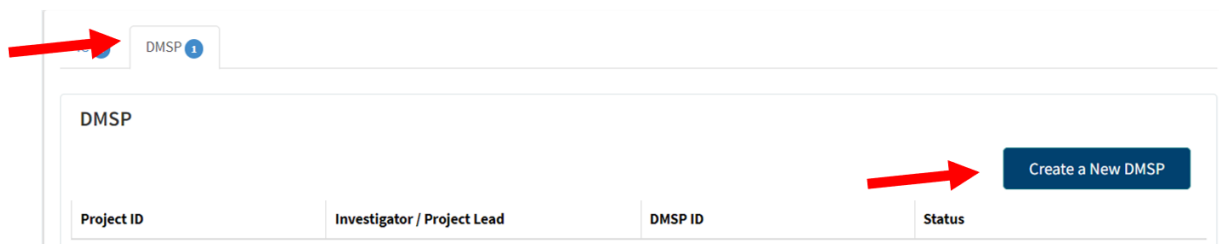
- GPA review and approval
 - Submitted IC Memos are first routed to the GPA for review.
 - Memos that require revision will be returned to the investigator with instructions from the GPA of any needed modifications.
 - Once the revisions have been made, resubmit the IC Memo for GPA review and approval.
 - The submitter will be notified of GPA approval via an email from the submission system.
 - The GPA will submit the GPA-approved IC memo to the CCR Scientific Director for review and approval.
- Scientific Director review and approval
 - Approval by the Scientific Director completes the IC Memo approval process. The submitter will be notified, via email, of approval by Scientific Director.

Creating a Data Management and Sharing Plan

- A Data Management and Sharing Plan is established by clicking the DMSP tab at the bottom of the Project page.
- There are a minimum of 6 elements to complete your DMSP.
- The top content (PI, Project Title, ZIA, Organism) will be prepopulated from your Project form.

STEP 1: Select DMSP to Complete

- Select the DMSP tab, then click Create a New DMSP in the blue box on the right at the bottom of the screen to start generating the plan. See the figure below.



- **You must complete each tab of the DMSP.** Please be as complete as possible as these fields auto-populate the Office of Intramural Research Data Management and Sharing Plan template.

DMSP - new record

DMSP ID:

Investigator / Project Lead: Kathleen Calzone

Status: -- None --

Project / Project Title(s): Kathy Test 3

* ZIA Number(s): ZIA12345

Organism Type:

Data Type | Related Tools, Software and/or Code | Data Standards | Data Preservation, Access, & Timelines | Access/Distribution/Reuse Considerations | Other Elements

Laboratory data types produced by project:

Clinical data types produced by project:

Data Generated From:

Number of Research Participants/Specimens/Experiments:

Number of Datasets Generated:

Approximate Amount of Data:

Measurement of Data: -- None --

Data Files to be Produced:

Raw Data Transformation by:

Data Made Available to Share:

List of Data to be Preserved and Shared:

Considerations influencing Preserved and Shared Data:

Data types shared to facilitate interpretation of the data:

Save

STEP 2: Complete the Data Type fields

- The following fields consist of pick lists that enable you to select one or more options as well as select others to enter content not reflected on the pick list: Laboratory Data, Clinical Data, Data Generated from, Measurement of Data fields, Data Files to be Produced, Raw Data Transformation by, Data Made Available to Share, List of Data to be Preserved and Shared, Considerations Influencing Preserved and Shared Data, and The Following Data Will be Preserved and Shared.

Data Type	Related Tools, Software and/or Code	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements
Laboratory data types produced by project			Approximate Amount of Data		
<input type="text"/>			<input type="text"/>		
Clinical data types produced by project			Measurement of Data		
<input type="text"/>			-- None --		
Data Generated From			Data Files to be Produced		
<input type="text"/>			<input type="text"/>		
Number of Research Participants/Specimens/Experiments			Raw Data Transformation by		
<input type="text"/>			<input type="text"/>		
Number of Datasets Generated			Data Made Available to Share		
<input type="text"/>			<input type="text"/>		
			List of Data to be Preserved and Shared		
			<input type="text"/>		
			Considerations influencing Preserved and Shared Data		
			<input type="text"/>		
			Data types shared to facilitate interpretation of the data		
			<input type="text"/>		
<input type="button" value="Save"/>					

- Select Save before moving to the next tab.

STEP 3: Complete the Related Tools, Software, and/or Code fields

- The first field - "Will Specialized Tools be Required to Access or Manipulate the Data?" is auto-populated with None. Nothing else needs to be entered if that applies to your project/study. Select Save and move to the next tab.
- If specialized tools are required, please complete the remaining fields. All fields in this tab consist of pick lists.

[Data Type](#) | [Related Tools, Software and/or Code](#) | [Data Standards](#) | [Data Preservation, Access, & Timelines](#) | [Access/Distribution/Reuse Considerations](#) | [Other Elements](#)

Will specialized tools be required to access or manipulate the data?

-- None --

Specialized Tools Required to Access

Specify how to access specialized tools

Data Format

Save

- Select Save before moving to the next tab.

STEP 4: Complete the Data Standards fields

- The field “Select all Common Data Elements (CDEs) that will be used. Justify if not used” consists of a pick list where you can select all that apply and add others not in the list.
 - Hover over the title to reveal the NCI CDE Resource list link to assist you in completing this field.
 - If CDEs do not apply to your Project/Study, select Not Used (N/A) and justify in the text box below.

[Data Type](#) | [Related Tools, Software and/or Code](#) | [Data Standards](#) | [Data Preservation, Access, & Timelines](#) | [Access/Distribution/Reuse Considerations](#) | [Other Elements](#)

Select all Common Data Elements (CDEs) that will be used. Justify if not used

Note: Please use the NCI CDE resource list to identify the CDEs that will be used
<https://cdebrowser.nci.nih.gov/cdebrowserClient/cdebrowser.html#/search>

State additional common data standards to be applied to the data & metadata

- Select Save before moving to the next tab.

STEP 5: Complete the Data Preservation, Access, & Timelines fields

- All fields in this section consist of pick lists where you can select all that apply and add others not in the list.

[Data Type](#) | [Related Tools, Software and/or Code](#) | [Data Standards](#) | [Data Preservation, Access, & Timelines](#) | [Access/Distribution/Reuse Considerations](#) | [Other Elements](#)

Name of repository(ies) where scientific data and metadata will be archived

Describe how the scientific data will be findable and identifiable

When and how long data will be available to other users?

Save

- Select Save before moving to the next tab.

STEP 6: Complete the Access, Distribution, Reuse Considerations fields

- All fields in this section consist of pick lists where you can select all that apply and add others not in the list.

The screenshot shows the 'Access/Distribution/Reuse Considerations' tab selected. The navigation tabs are: Data Type, Related Tools, Software and/or Code, Data Standards, Data Preservation, Access, & Timelines, Access/Distribution/Reuse Considerations, and Other Elements. The form contains four pick list fields: 'Factors affecting subsequent access, distribution, or reuse of scientific data', 'Human data protection method', 'Data are made available through', and 'Genomic Summary Results are made available through'. A 'Save' button is located at the bottom left of the form area.

- Select Save before moving to the next tab.

STEP 7: Complete the Other Elements fields

- The single field on this tab, "Other Elements" is auto-populated with None. Nothing else needs to be entered if that applies to your project/study. Select Save and move to the next tab.

The screenshot shows the 'Other Elements' tab selected. The navigation tabs are: Data Type, Related Tools, Software and/or Code, Data Standards, Data Preservation, Access, & Timelines, Access/Distribution/Reuse Considerations, and Other Elements. The form contains one pick list field labeled 'Other elements' with the value '-- None --' selected. A 'Save' button is located at the bottom left of the form area.

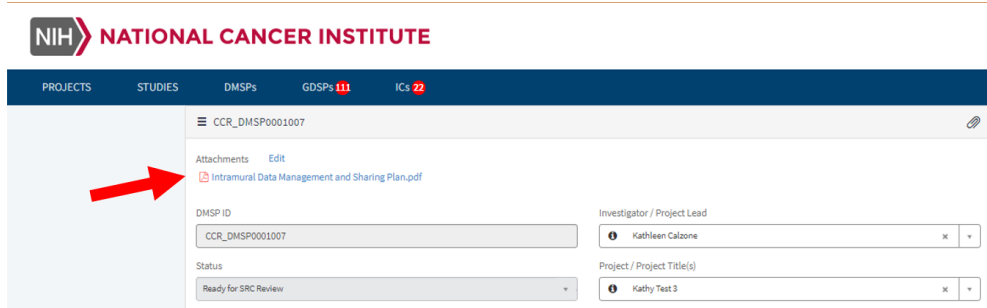
- If Other Elements, then select Other from the pick list and add the specifics.

The screenshot shows the 'Other Elements' tab selected. The navigation tabs are: Data Type, Related Tools, Software and/or Code, Data Standards, Data Preservation, Access, & Timelines, Access/Distribution/Reuse Considerations, and Other Elements. The form contains one pick list field labeled 'Other elements' with the value 'Other' selected. Below this field is a text input field with the label '* Specify other elements'. A 'Save' button is located at the bottom left of the form area. A red error message 'Required information Specify other elements' is displayed below the 'Specify other elements' field.

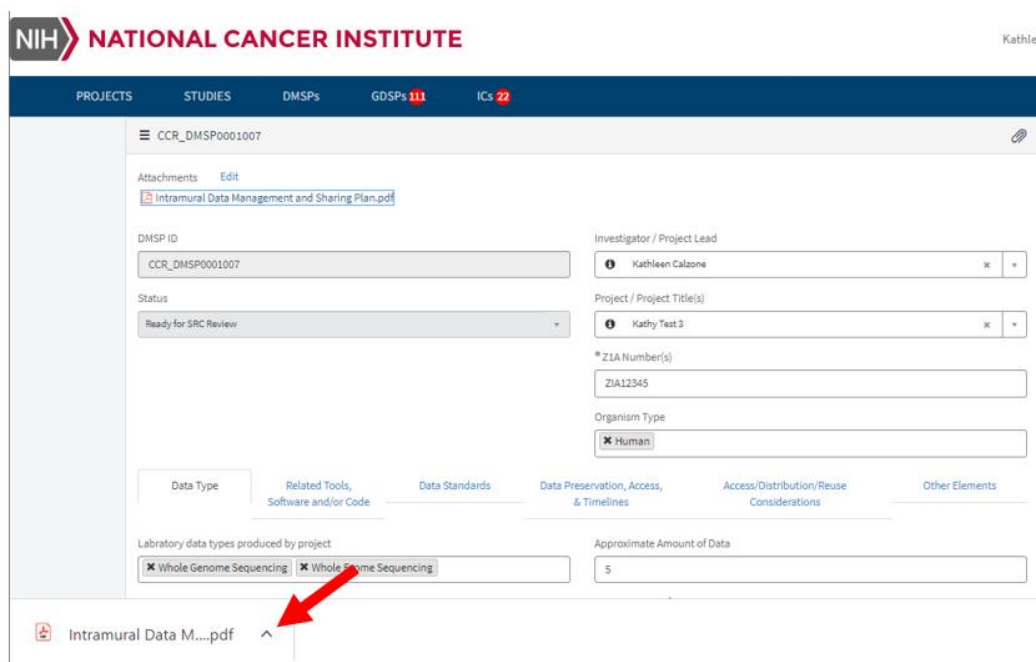
- Select Save before moving to the next tab.

Submit for Scientific Review Committee

- Select ready for SRC Review.
 - The pdf of your Data Management and Sharing Plan will appear on the top left of your screen.



- Clicking on the pdf will download the pdf of the plan.



- Save the plan on your computer by opening the document, selecting the download tab, then selecting the location on your computer to store the document.



- Then click the "submit for GPA approval" button that appears.

Post Scientific Review Committee

- Plans that require revision
 - Login to the [portal](#) and select DMSPs from the top menu bar



- Find the DMSP that requires revision, open the file, and make the specified changes.
 - **Once all changes have been made, select Save, followed by Submit**, which will route the document for GPA review. The GPA will be responsible for routing the document for the Scientific Director's approval.
- Plans that require NO revision
 - Select Ready for Submit, which will route the document for GPA review. The GPA will be responsible for routing the document for the Scientific Director's approval.