CCR Data Management and Sharing Plan Submission Portal For Clinical Protocols

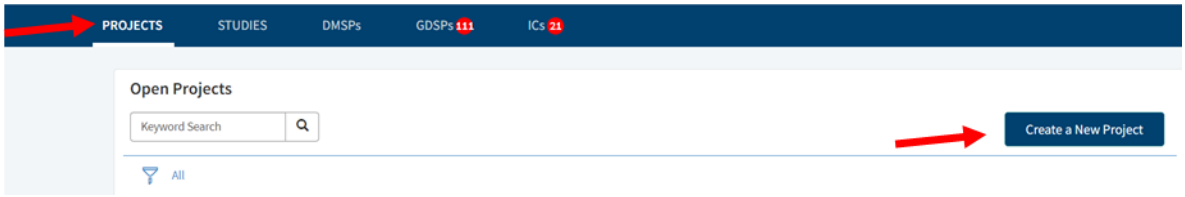
User Manual

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.

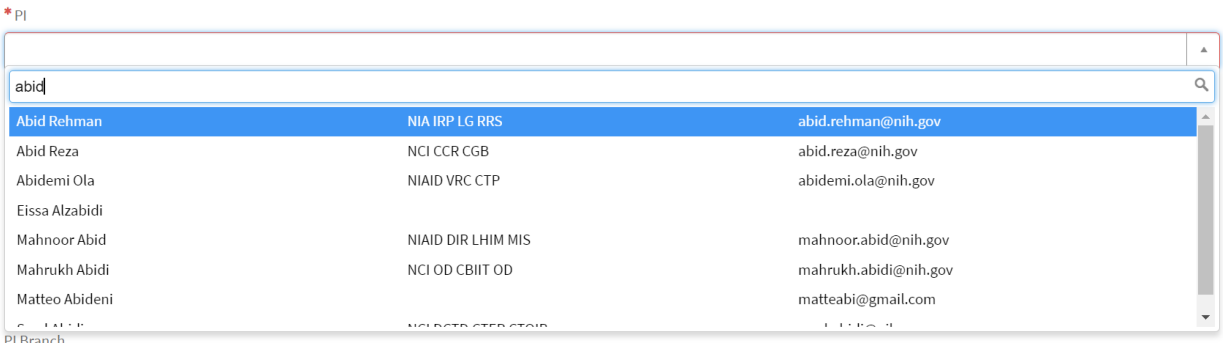


STEP 2: Complete the Project Information

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

  - Principal Investigator name

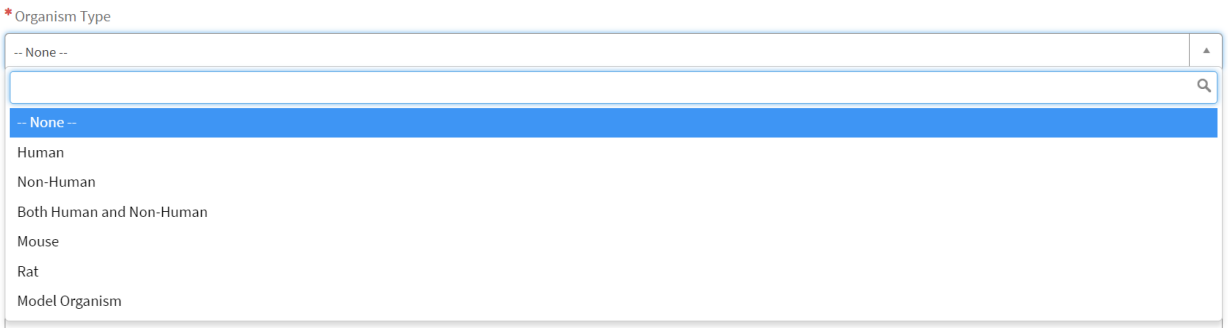
    - For clinical trials, the principal investigator is the protocol's Principal Investigator or Lead Associate Investigator.
    - Write the PI's name, and it will search the database for the appropriate match. In case of multiple matches, check the affiliations and emails from the search to find the correct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



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

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

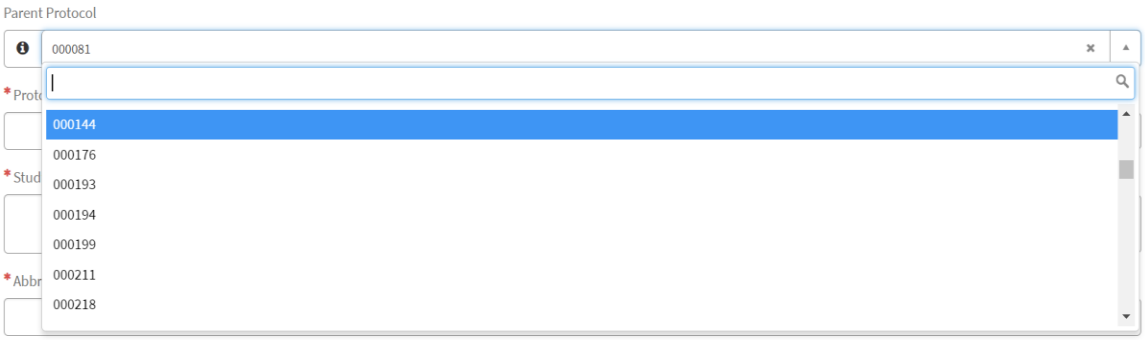
- Organism



  - 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 mise and human samples.
    - For Mouse only, select **Mouse.**
    - For Rat only, select **Rat**
    - For other model organisms not listed, Use **Model Organism**

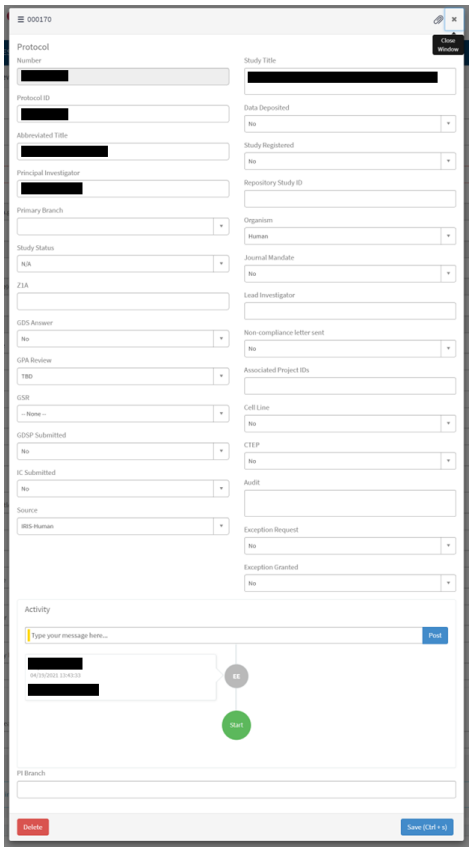
- Study ID/Protocol ID

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

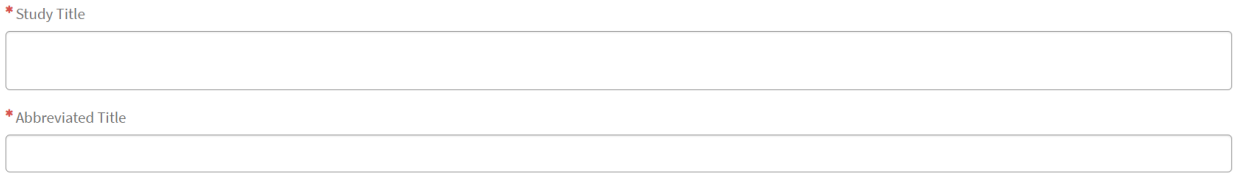


- Parent Protocols/Projects may be Tissue Procurement studies, OHRSP exemptions, or other umbrella projects in which multiple protocols/projects with different investigators are conducted under the umbrella protocol/project.
- For more information about the selected protocol, click the "ⓘ" button

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



        - Clinical Protocol ID from PROTECT.
    - Study Title and 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

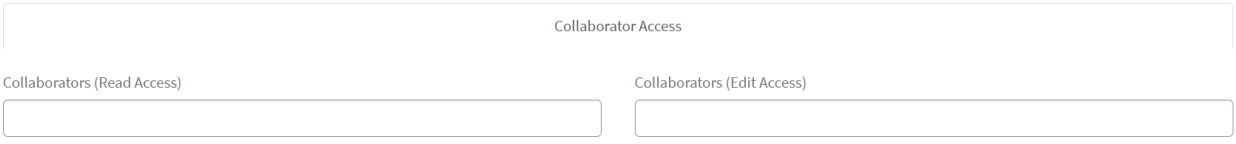
        - This is a **mandatory field**. ZIA number is the mechanism used to upload your plan to the Office of Intramural Research (OIR) into NIDB.
        - Every protocol and/or laboratory project must fall under a ZIA number, which is aligned under PIs with independent resources.

      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

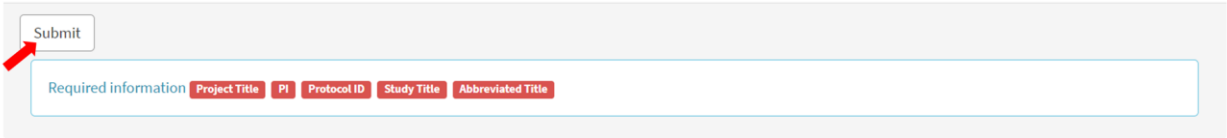
You have the option of giving other NIH staff permission to access the project and associated forms.



- 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



STEP 5: Select Form(s) to Complete

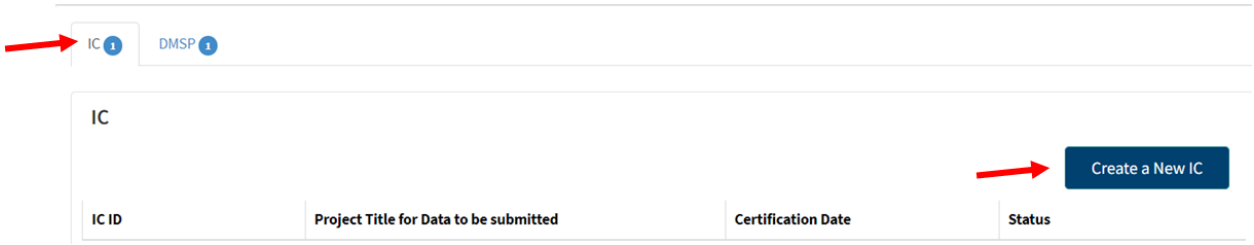
- **Human Studies** require an Institutional Certification Memo (IC) **AND** a Data Management and Sharing Plan (DMSP). Please follow the below instructions to generate these documents.

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.

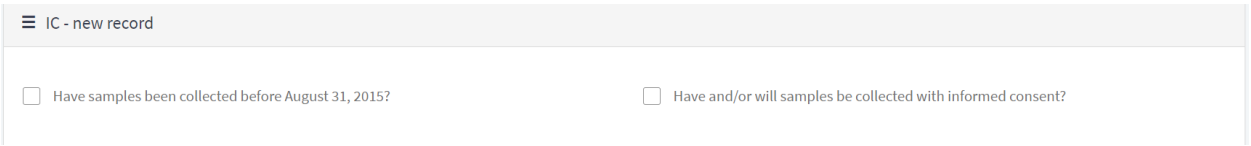
STEP 1: Select IC to Complete

- 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.



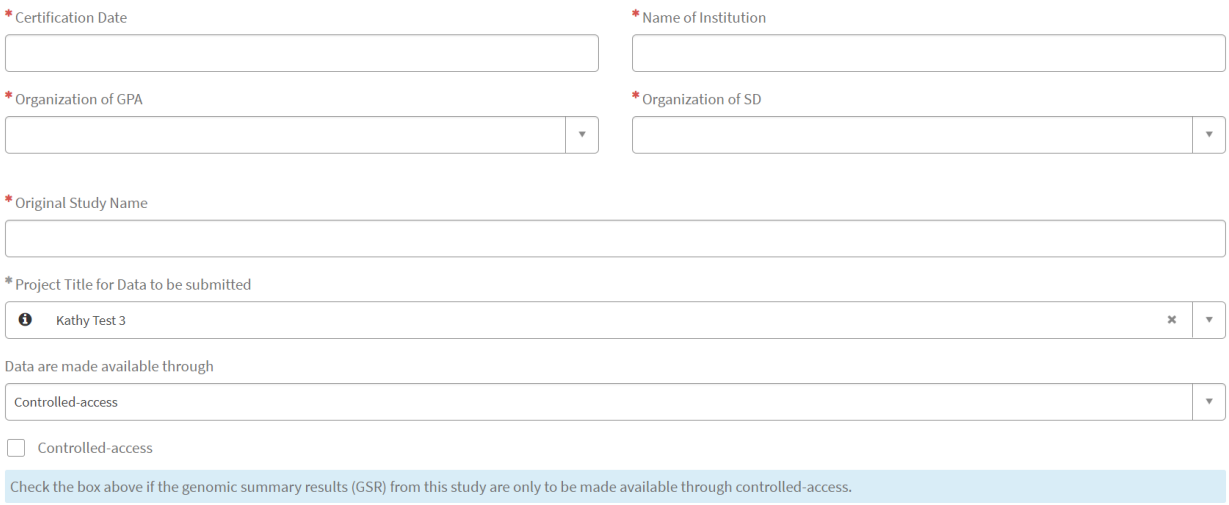
STEP 2: Select the IC timeframe

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



    - 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)

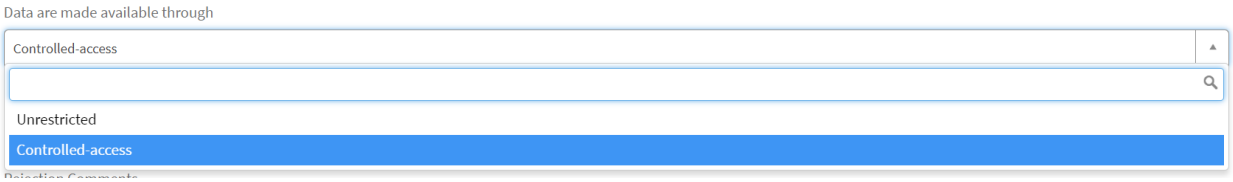
Selecting any one of the checkboxes will generate new fields for more information.



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

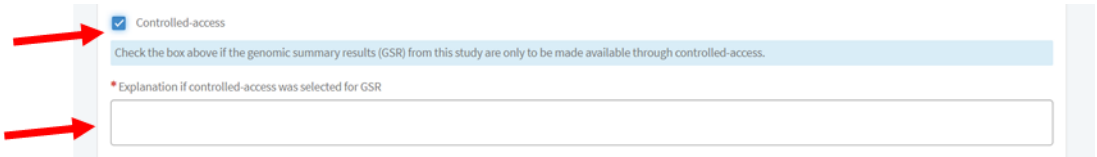
NOTE: Other NIH Institutes may use this portal, so not all information provided is prepopulated for NCI.

- 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.



<u>Note: Human studies are controlled access</u>

- 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).



**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.*

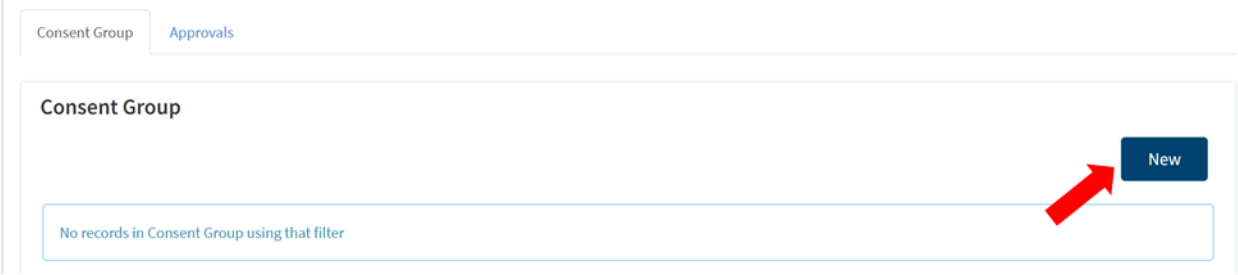
*#The Trans-NCI Genomic Data Sharing Working Group has adopted the following definition of rare disease – a disease that affects **less than 200,000 persons** in the United States, that has been set forth by the U.S. Food and Drug Administration (FDA).*

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

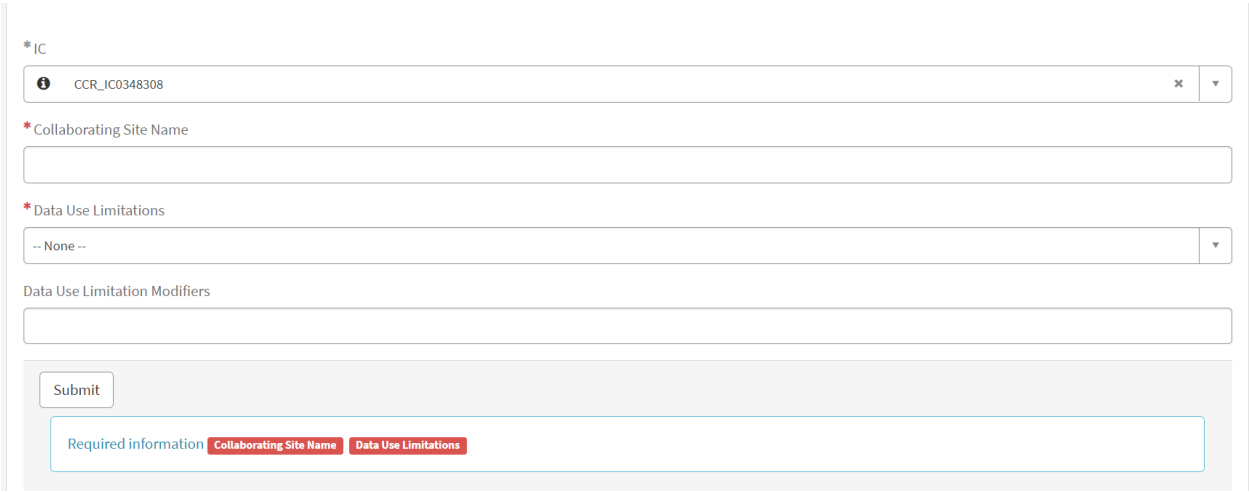
- You must add Consent Groups. Select **New** on the right.



Note:

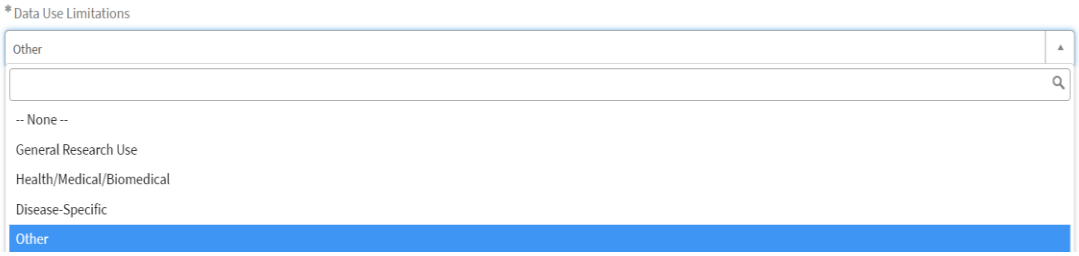
- ❖ NCI/CCR must have a separate entry
- ❖ Every collaborating research site must also have a separate entry for multi-site studies.

- This will lead to a new page. Populate these fields with the necessary information.



- 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.

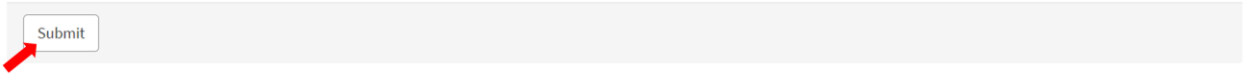
- In case you selected “Other” for the Data Use limitation field,



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

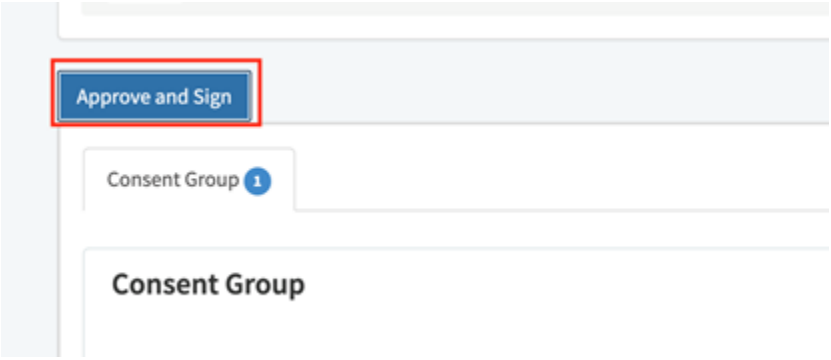
- To complete this process for collaborating sites, each participating site should provide a copy of its own Institutional Certification.

- 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

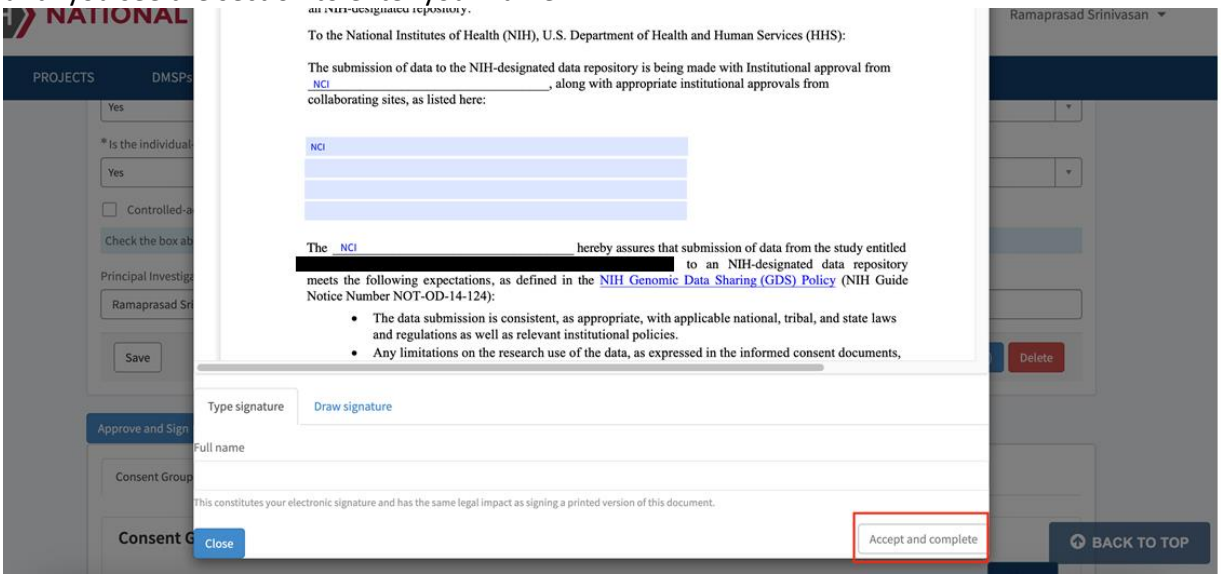


NOTE: The next 4 steps need to be **completed by the PI**

- 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

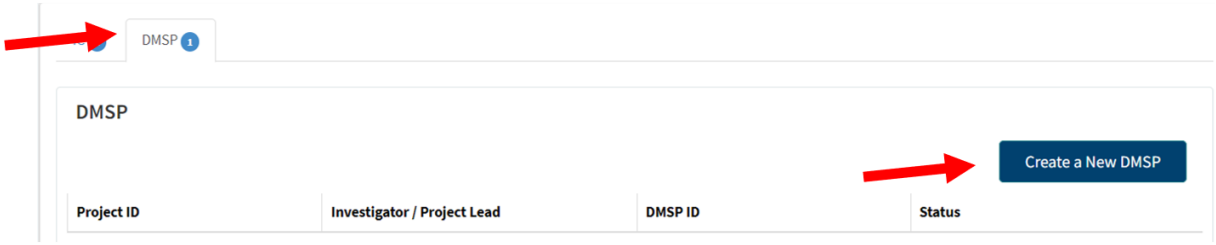
- GPA review and approval
  - Submitted IC Memos are first routed to the GPA for review.
    - Memos that require revision will be returned to the investigator with instructions from the GPA of any needed modifications.
      - Once the revisions have been made, resubmit the IC Memo for GPA review and 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

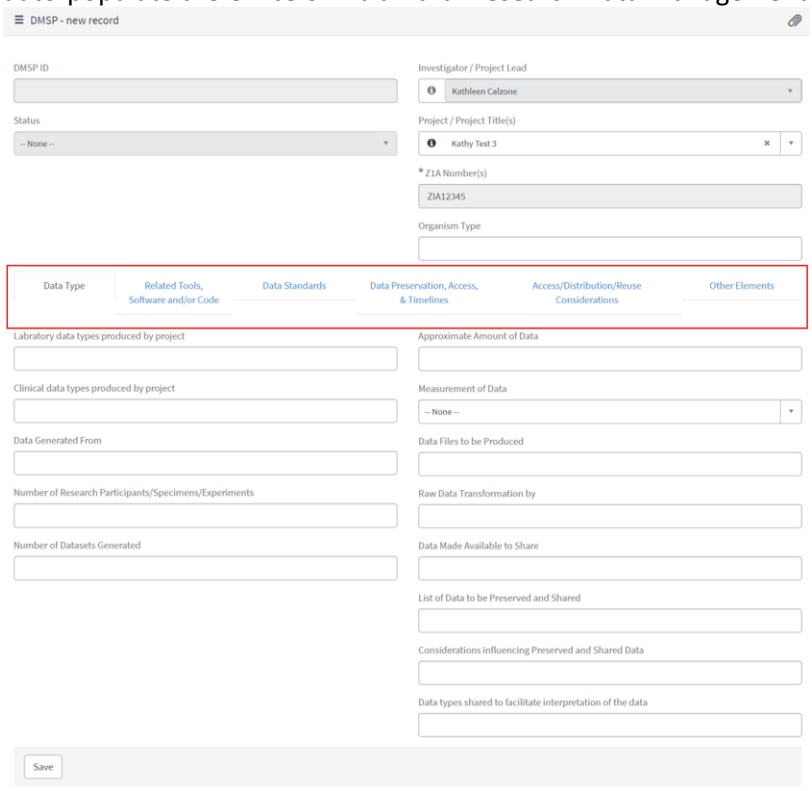
- A Data Management and Sharing Plan is established by clicking the DMSP tab at the bottom of the Project page.
- There are a minimum of 6 elements to complete your DMSP.
- The top content (PI, Project Title, ZIA, Organism) will be prepopulated from your Project form.

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.

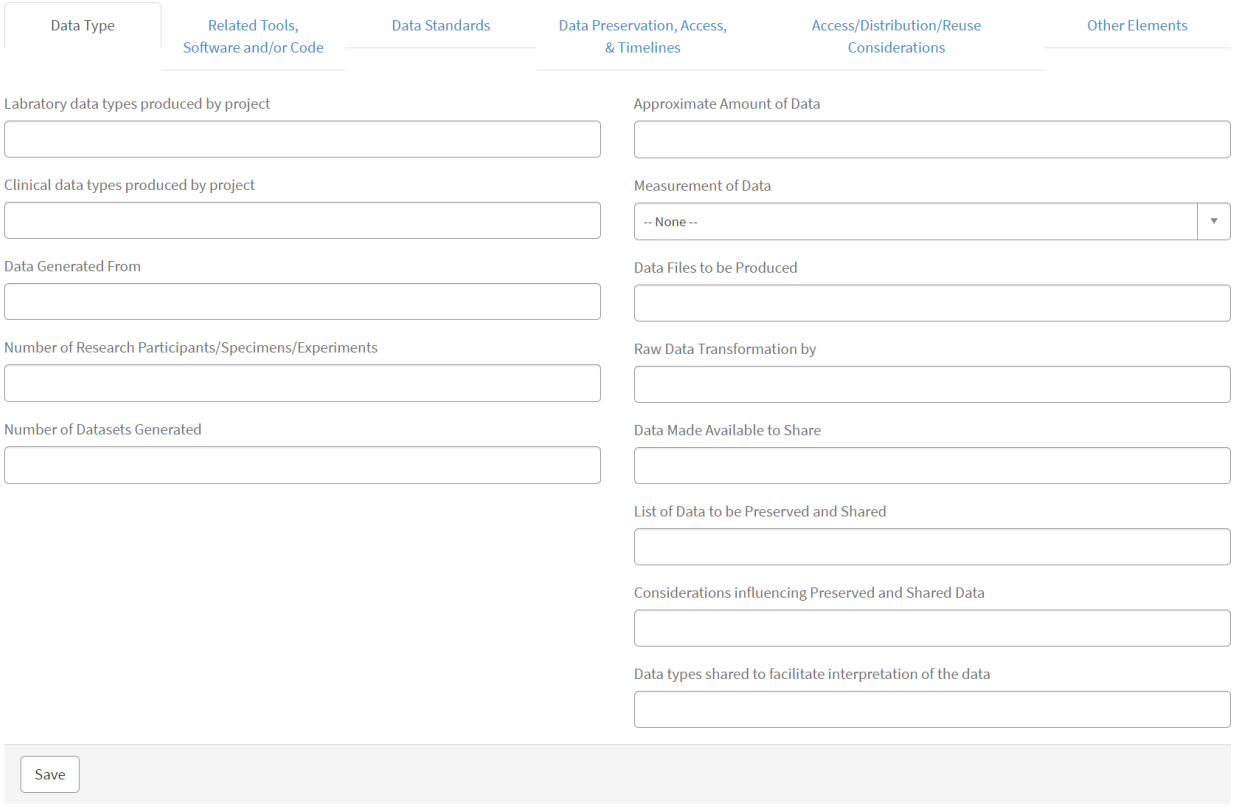


- **You must complete each tab of the DMSP**. Please be as complete as possible as these fields auto-populate the Office of Intramural Research Data Management and Sharing Plan template.



STEP 2: Complete the Data Type fields

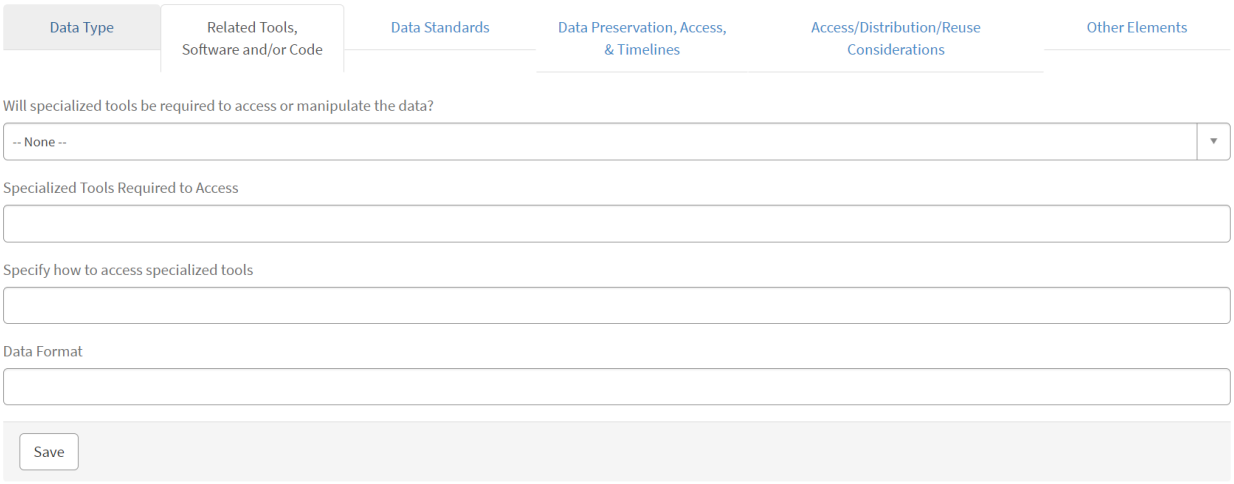
- The following fields consist of pick lists that enable you to select one or more options as well as select others to enter content not reflected on the pick list: Laboratory Data, Clinical Data, Data Generated from, Measurement of Data fields, Data Files to be Produced, Raw Data Transformation by, 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.



- Select Save before moving to the next tab.

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

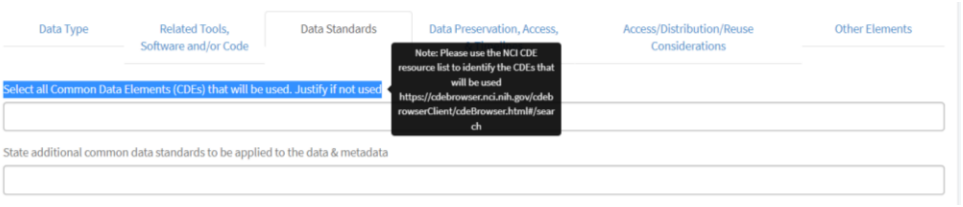
- The first field - “Will Specialized Tools be Required to Access or Manipulate the Data?” is auto-populated with None. Nothing else needs to be entered if that applies to your project/study. Select Save and move to the next tab.
- If specialized tools are required, please complete the remaining fields.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



- Select Save before moving to the next tab.

STEP 4: Complete the Data Standards fields

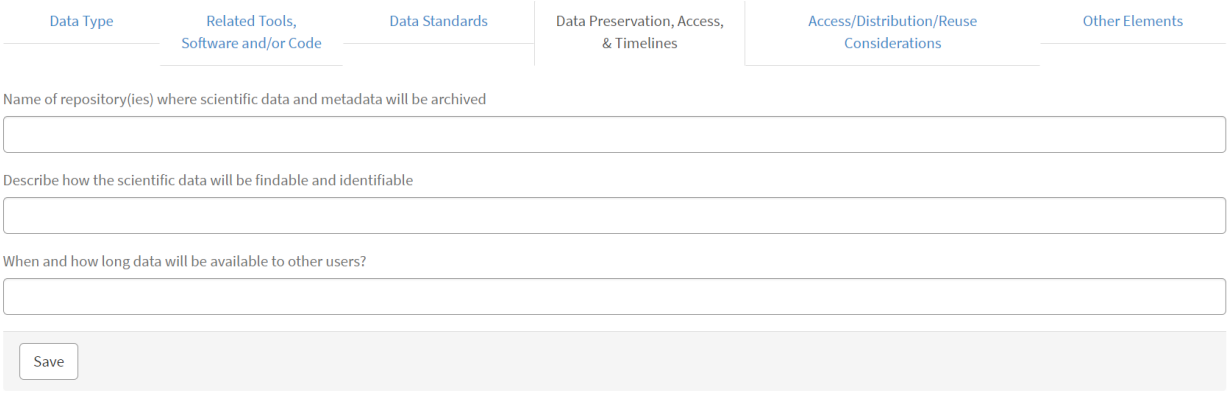
- The field "Select all Common Data Elements (CDEs) that will be used. Justify if not used" consists of a pick list where you can select all that apply and add others not in the list.
    - Hover over the title to reveal the NCI CDE Resource list link to assist you in completing this field.
    - If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



- Select Save before moving to the next tab.

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

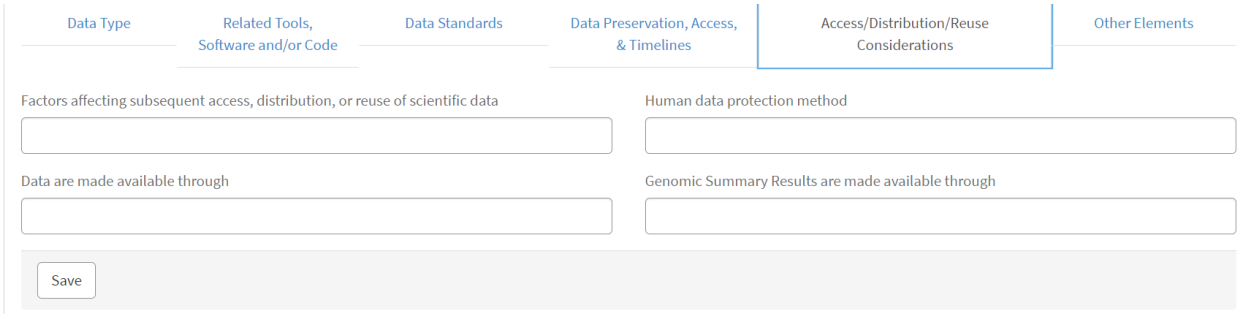
- All fields in this section consist of pick lists where you can select all that apply and add others not in the list.



- Select Save before moving to the next tab.

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

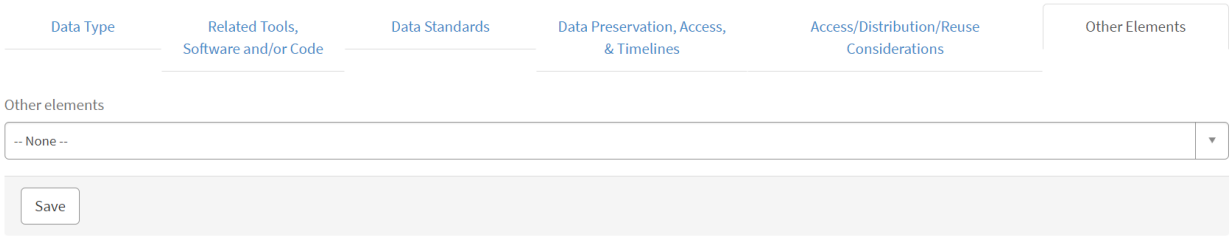
- All fields in this section consist of pick lists where you can select all that apply and add others not in the list.



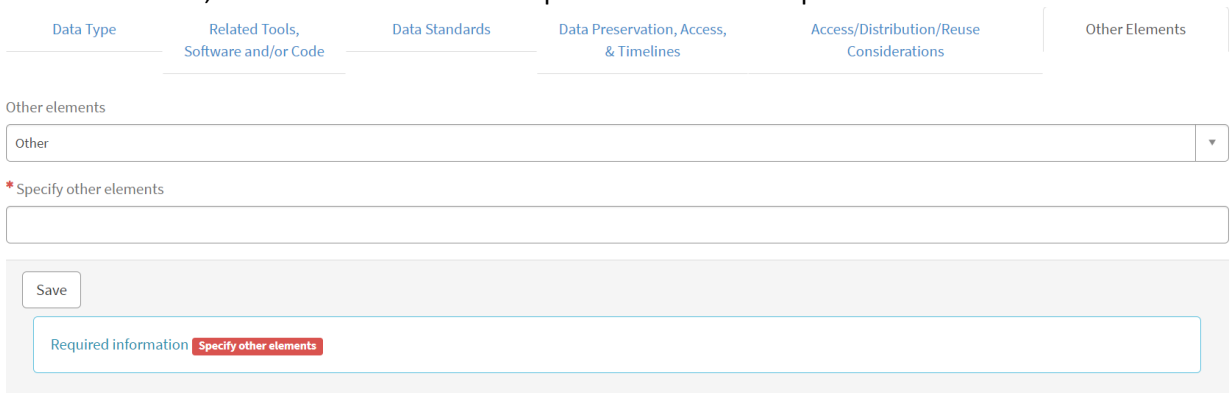
- Select Save before moving to the next tab.

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.



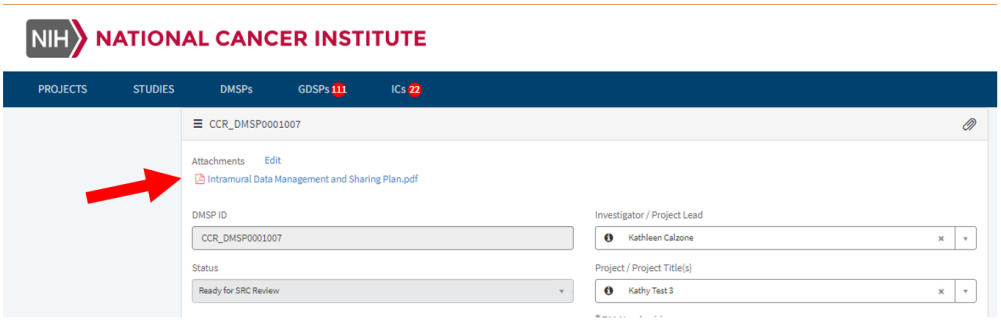
- If Other Elements, then select Other from the pick list and add the specifics.



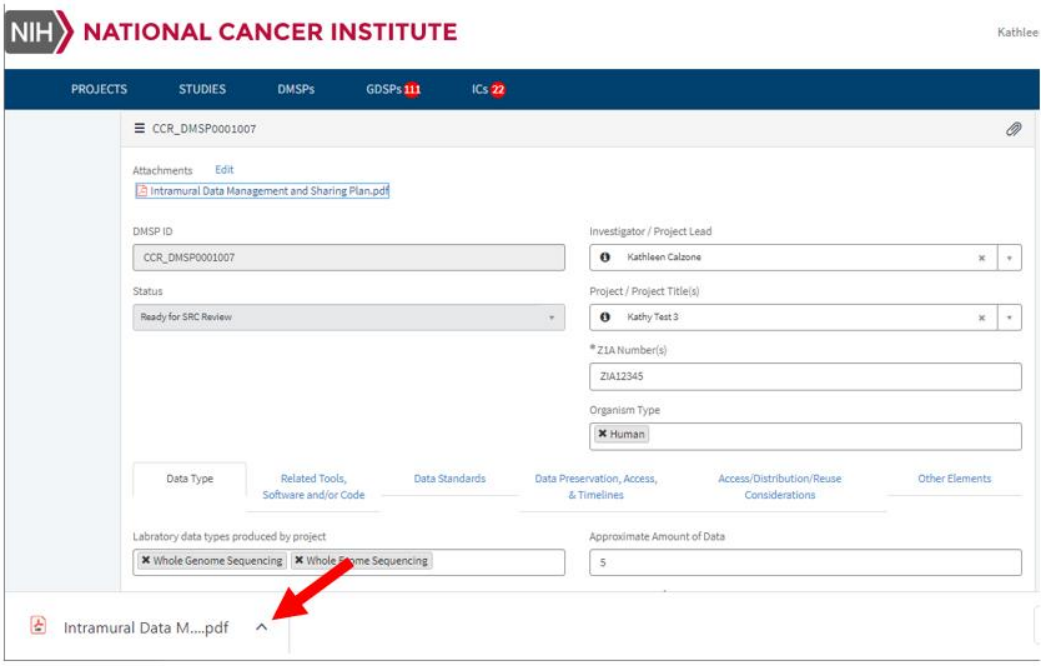
- Select Save before moving to the next tab.

Submit for Scientific Review Committee

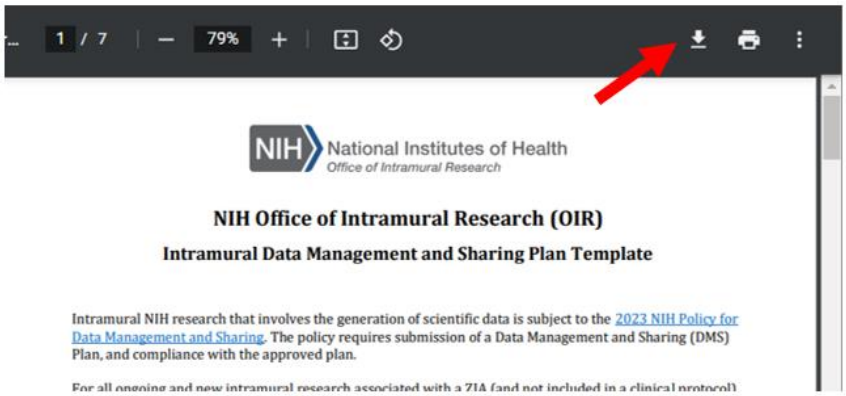
- Select ready for SRC Review.
    - The pdf of your Data Management and Sharing Plan will appear on the top left of your screen.



- 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.