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I. Introduction

This tutorial walks you through the basics of completing a Submission Request using the <u>CRDC Submission</u> <u>Portal</u>. If you have questions that are not answered here, please contact the CRDC Help Desk (NCICRDC@mail.nih.gov).

II. Prerequisites

The main prerequisite for completing a Submission Request is creating a <u>Login.gov</u> account. Although not required, it is strongly recommended that the <u>Login.gov</u> identity be associated with your company or institution. Users can also choose a personal email as their identifier. **Note:** NIH staff can use their PIV cards as their identity.

Visit Login.gov to create an account.

Notes:

- <u>Login.gov</u> requires two-factor authentication. This needs to be set up when you create the Login.gov account using the same email address.
- If you do not actively use the CRDC Submission Portal within 180 days, your access to the portal will be deactivated. To reactivate your access please contact the CRDC Help Desk (NCICRDC@mail.nih.gov).

III. Starting the Data Submission Request Application

Visit the <u>CRDC Submission Portal</u> and once there, click **Log In** in the middle of the screen or in the upperright corner. You will be redirected to the NIH single sign-on page where you can log in using either the <u>Login.gov</u> (non-NIH staff) identity or a PIV card (NIH staff).

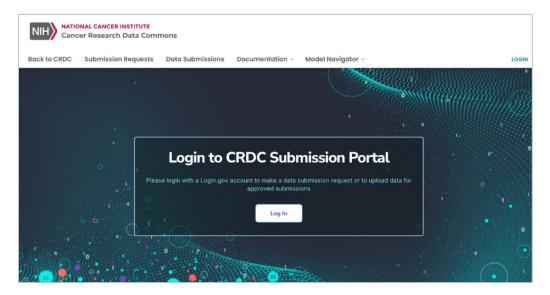


Figure 1. CRDC Submission Portal Landing Page

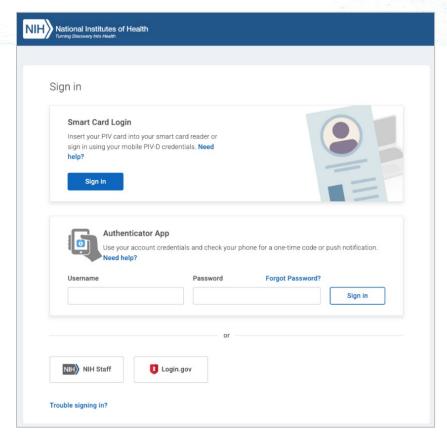


Figure 2. NIH Login Page

If you are using the <u>Login.gov</u> identity, you are prompted to provide consent for sharing the login information with NIH by clicking the **Grant** button.

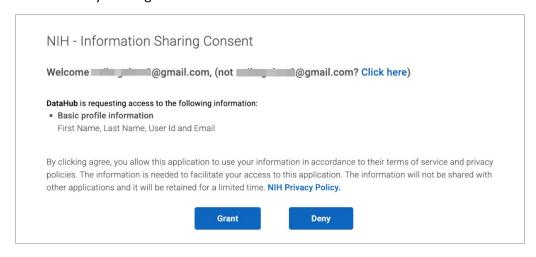


Figure 3. NIH — Information Sharing Consent: Click Grant

The CRDC Submission Request portal appears, where you can do the following:

- To start a new request, click the Start a Submission Request button immediately above the table
 on the right side. See Figure 4. A new pop-up window (Figure 5) appears, prompting the user to
 provide consent before proceeding with the submission request process.
- If you are a returning data submitter, the Submission Request List table appears, which lists all
 current submission requests. To continue, click the Resume button associated with the submission
 request. See Figure 4.

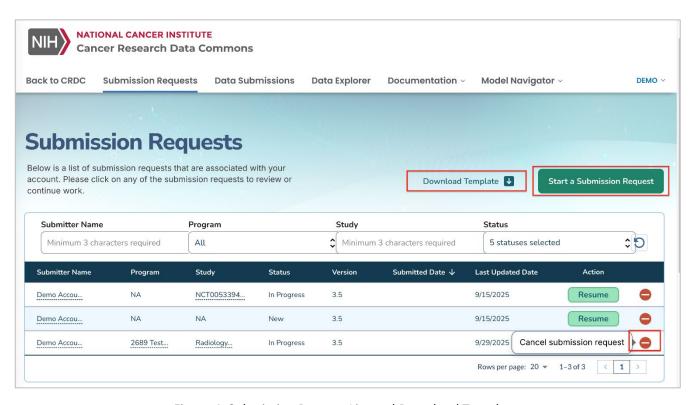


Figure 4. Submission Request List and Download Template

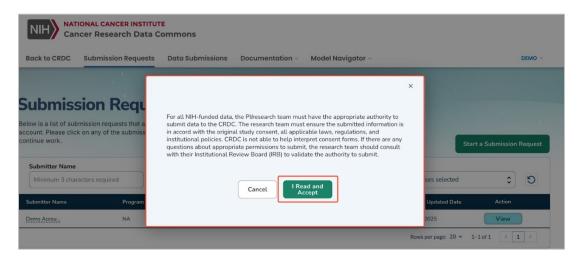


Figure 5. User Consent Required Before Submission Request

- Download and Import option: Alternately, instead of filling out the Submission Request Form online, users may choose to download the Submission Request Form template in Excel format (see Figure 4).
 This option allows users to:
 - o Fill out the required details of the form (explained in section V) offline.
 - o **Import** the completed Excel file back into portal, where all details will automatically populate the online Submission Request Form. See Figure 11 on page 7.
 - Export: Users can download the online form as an Excel file using the Export button. Import
 and Export Form options can be found on all the pages of Submission Request Form. See
 Figure 11 on page 7.
 - In case you want to **Cancel** the Submission Request, click the cancel icon. A window opens to **confirm** the cancellation. See Figures 4 and 6.

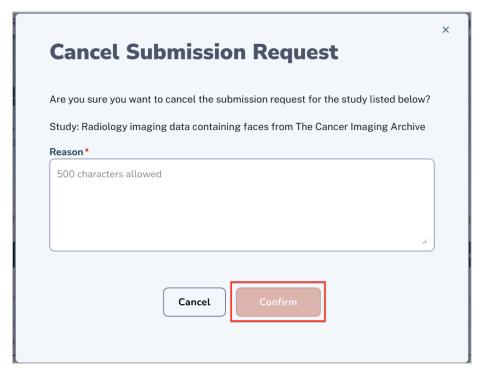


Figure 6. Confirm Cancelling Submission Request

- Submission Requests may be automatically **Deleted** if there is no activity for 120 days. Prior to
 deletion, the system will send several email notifications to the Points of Contact(s) listed in the
 Submission Request Form.
- The Cancelled and Deleted Submission Requests can be **Restored** to In Progress status by clicking on the Restore icon and confirming the action in the pop-up window. See Figures 7 and 8.

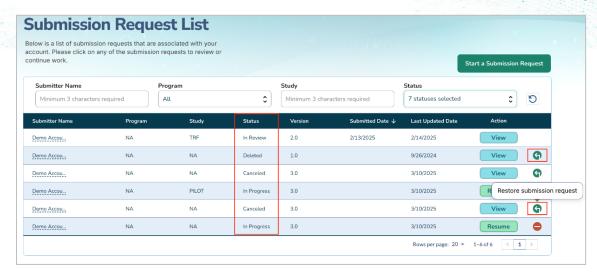


Figure 7. Restore Cancelled and Deleted Requests

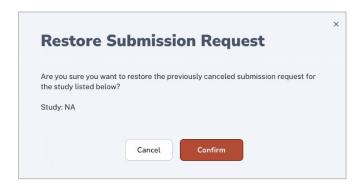


Figure 8. Confirm to Restore Submission Request

• The filters at the top of the Submission Request List table help refine your search when the list of submission requests is lengthy. By default, five statuses are selected: New, In Progress, Submitted, In Review, and Inquired (see Figure 9). These statuses are described in detail in the "Status Bar" section on page 7.

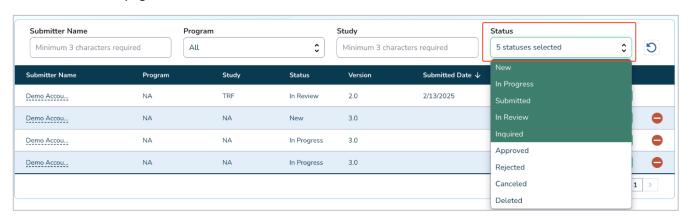


Figure 9. Filters to Refine the Submission Request Search

IV. Data Submission Request Form Walkthrough

This walkthrough includes images from the Submission Request Form highlighting critical requested information. Note the following as you progress through filling out this form:

- Pages and page sections can be filled in any order.
- Progress is automatically saved so you can return as needed. However, if any field is incorrectly filled, you are asked whether you want to cancel, save, or discard the changes. See Figure 10.



Figure 10. Unsaved Changes Message Pop-Up Window

- For subsequent submission requests, the **Principal Investigator and Contact** section is pre-filled, although it can be edited.
- The form cannot be submitted without completing all the required fields.

1. Features of the Submission Request Form

Status Bar

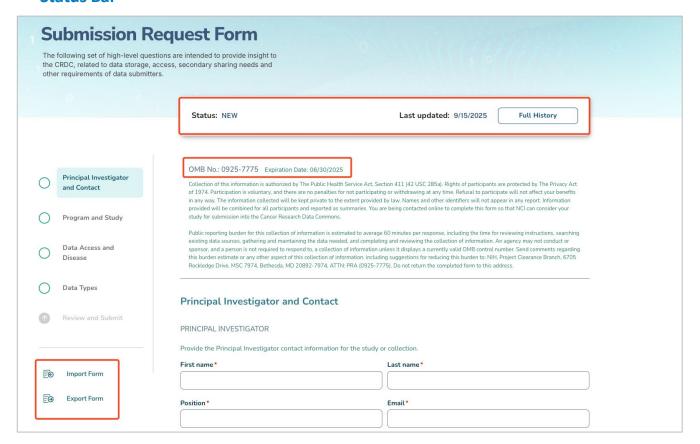


Figure 11. First Page of the Submission Request Form with Highlighted Areas to Illustrate its Features

The **Status Bar** appears on all the form pages. Status values include:

- **New** Application is started but no information has been entered.
- In Progress The form is partially filled out and it is not completed or submitted.
- **Submitted** The form has been completed and submitted.
- In Review The form has been submitted, and the Submission Review Committee (SRC) is reviewing it.
- **Inquired**—The Submission Review Committee has requested for additional information before finalizing their decision.
- Approved/Rejected The Submission Review Committee has noted their decision.
- **Conditionally Approved**—The form was approved with a pending condition that must be resolved before the submitter is able to start data submission. The conditions can be:
 - If the study contains controlled access data, it must first be registered at the database of Genotypes and Phenotypes (dbGaP).

- If a data model update is required for the study, the update must be completed before the data submission can begin.
- For the controlled access study, the name of the Genomic Program Administrator (GPA) was not provided for.

The condition will be removed only after the study/program is registered on dbGaP. The submitter provides the dbGaP ID, and the GPA's name is provided to the CRDC Help Desk (MCICRDC@mail.nih.gov). Once the required data model is completed, the CRDC Team will notify the PI once updates are in place. See Figure 12.

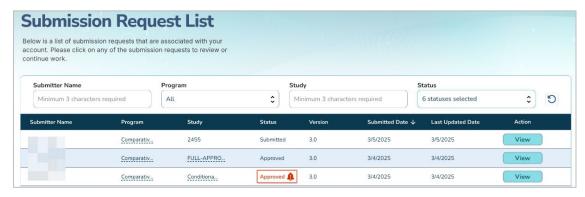


Figure 12. Conditional Approval

- **Cancelled** The form has been cancelled by the submitter.
- Deleted The form has been automatically deleted due 120 days of inactivity.

The Last updated field shows the last date that information was added or changed in the form.

The **Full History** button pops up a window showing the history of all status changes since the form was started.

Import and **Export Form options**: These features allow users to either **import** a completed Submission Request Form into the portal or **export** the online form in Excel format.

Navigation Buttons

At the bottom of each page, three navigation buttons help you move between the form's pages and save progress. You can also cancel your submission request.



Figure 13. The Save, Cancel Request or Back/Next Buttons Are at the Bottom of Each Page

Add and Remove Buttons

In various places on the application form, **Add** buttons (a green circle with a white plus sign and a label) allow you to add multiple instances of that section. For example, the **Add Contact** button allows you to enter contact information for multiple people. Clicking the **Remove** button allows you to delete that section.

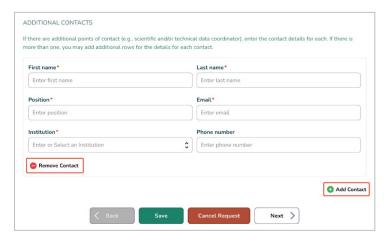


Figure 14. Remove or Add Contact Buttons are Available for Fields that Allow Additional Entries

2. Submission Request Form: Principal Investigator and Contact

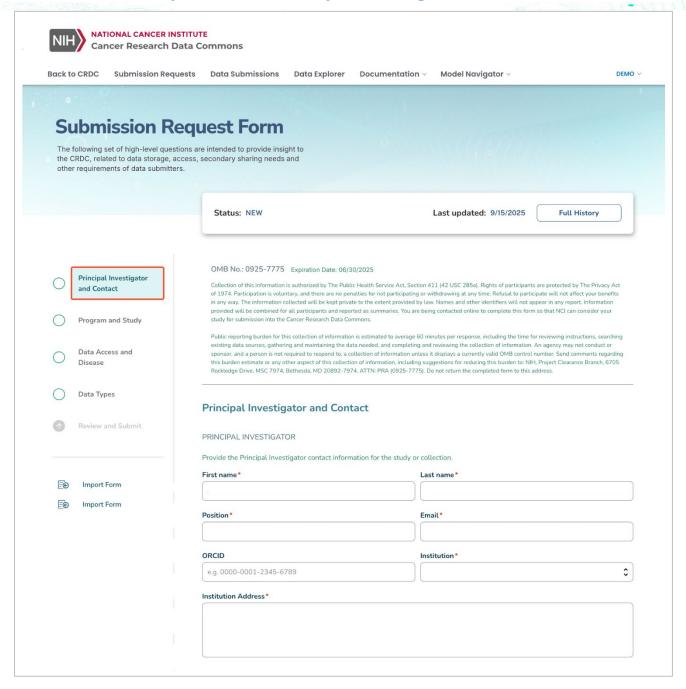


Figure 15. Page One of the Submission Request Form

This part of the form collects information about the Principal Investigator (PI) for the project, primary contact, and contact information for any additional staff who may be helping with the request and submission. The **Add Contact** button in the **Additional Contacts** section can be used to add as many additional contacts as needed.

This page has several required fields for each of the contacts:

• First Name: The first (given) name of the contact

- Last Name: The last (family) name of the contact
- Position: The position or title the person holds at their company or institutions
- Email: A valid email address, which will be used for communications. Please be accurate.
- ORCID: The Open Researcher and Contributor ID (ORCID) of the PI
- **Institution:** This field is the company or institution with which the person is associated. The dropdown list narrows the options as you start typing. If you don't find your institution, type in your institution name.
- Institution Address (PI Only): The official address of the company or institution the PI works for Note that a contact can be removed with the **Remove Contact** option at the bottom of each frame.

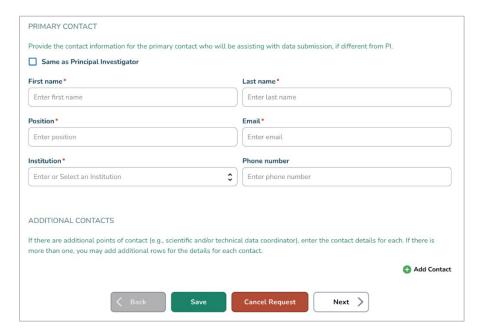


Figure 16. Page One of the Submission Request Form Also Collects Information on the Primary Contact

Provide the details of the person who will assist with the data submission process, if different from the PI. The Primary Contact will receive automatic email notifications related to the Submission Request and Data Submission Process. If there are multiple points of contact, please use the **Add Contact** button to add additional contacts. In case the PI is the primary contact, make sure to check the box for **Same as Principal Investigator.**

3. Submission Request Form: Program and Study

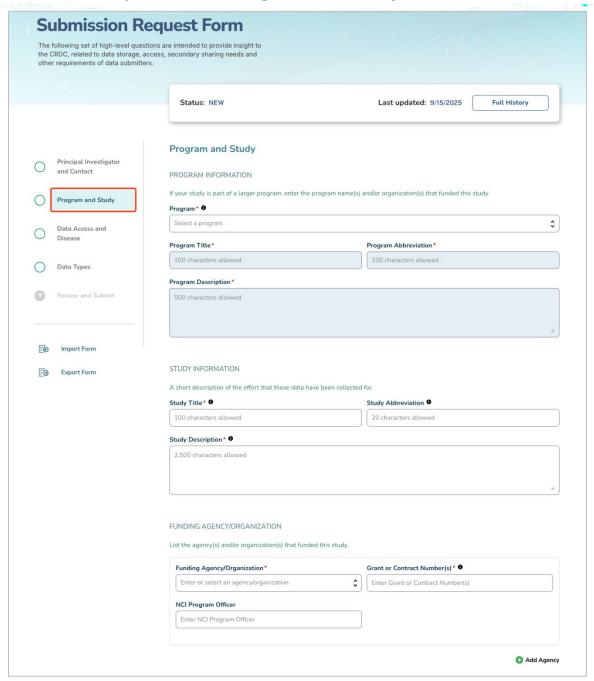


Figure 17. Page Two of the Submission Request Form

The **Program and Study** section provides information about the overall program that funded the activities and details the study that falls under this program. The following fields are included:

Program Information: This is the name of the broad administrative group that oversees the
data collection. Examples include Clinical Proteomic Tumor Analysis Consortium (CPTAC) or
Human Tumor Atlas Network (HTAN) Programs, which tend to be large, NCI-funded efforts
with several projects or studies in them.

- **Study Information:** Much like a paper title, this is intended to provide a short, single way to refer to this collection of data. Longer descriptions should be put in the **Study Description** field. If you have used a Study Title when registering in dbGap, please use that same Study Title here. (See dbGaP registration information below.)
- Funding Agency/Organization: Please note which agencies or programs funded the work and any of the assigned grant or contract numbers. Note that additional funding agencies can be provided by using the Add Agency button. If your funding agency is not listed in the dropdown list, please send an inquiry email to the CRDC Help Desk (NCICRDC@mail.nih.gov).

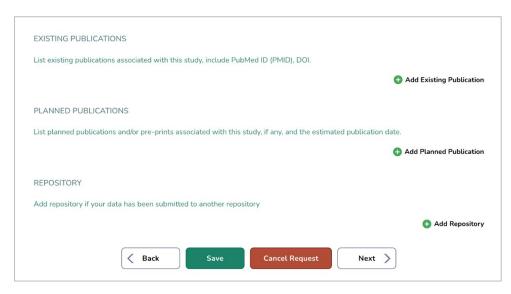


Figure 18. Information About Publications and Repositories Outside of CRDC

- Existing Publications and Planned Publications: Neither of these are required for a Submission Request, but if you do provide publication information, some fields are required.
 - Please note that while we ask for the publication date of any planned publications you may share, CRDC cannot guarantee to make the data available by that date, although we will make every effort to meet your deadline.
- Repository: If you plan to submit (or have already submitted) data from the same study to another
 repository outside of CRDC, please enter the name of that data repository here. As with
 Publications, this is an optional section; however, if data are deposited outside of the CRDC,
 providing this detail is useful to the Submission Review Committee.
 - Note that data repositories or data commons that are part of the CRDC include the Genomic Data Commons (GDC), Proteomic Data Commons (PDC), Imaging Data Commons (IDC), Integrated Canine Data Commons (ICDC), Clinical and Translational Data Commons (CTDC) and Cancer Data Service (CDS). Read more information about CRDC's Data Commons.

4. Submission Request Form: Data Access and Disease

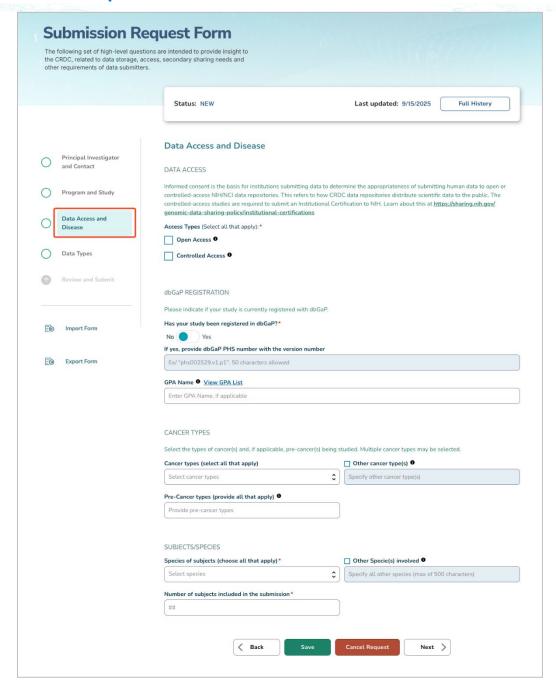


Figure 19. Page Three of the Submission Request Form

This page collects information on cancer type(s) you want to submit and whether any of the data will require users to get permission to access it or if it is openly available to the research public. Please note that if access is controlled, CRDC requires users to apply for access at dbGaP.

- Data Access: Indicates that the data are one of the following:
 - Open Access (anyone can access your data without restriction)

- Controlled Access (users are asked to seek permission through dbGap before they are allowed to access your data). One or both options must be selected.
 - Note that if your controlled access data are accepted, you are required to register the study at dbGaP prior to starting data submission to the <u>CRDC Submission Portal</u>.
- **dbGaP Registration:** If you have already registered with dbGaP, provide the PHS number for your project in the Submission Request Form. You are prompted to select **Yes** with the slider and provide the PHS number in the text box.
- **GPA Name:** Provide the name of the Genomic Program Administrator for the study registered in dbGaP. You may either select the GPA name from the drop-down menu or type the name directly.
- Cancer Types: You can select multiple items from the dropdown list. Select all types that apply. If the cancer types are not on the list, provide those in the Other cancer type(s) text box.
- **Subjects/Species:** Multiple options are provided in the dropdown list. If you cannot find the species in the dropdown menu, select the **Other Specie(s) involved** field and type in the name of the specie(s). This section also asks for the total number of subjects in the submission.

5. Submission Request Form: Data Types

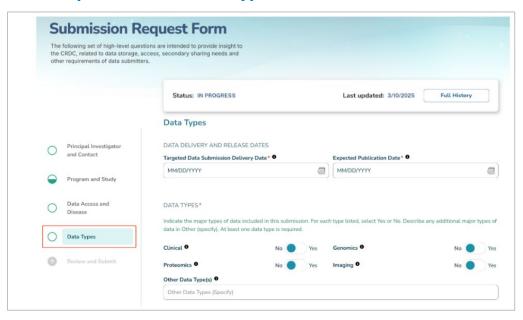


Figure 20. Page Four of the Submission Request Form

This section covers the types of data included in the study. Most fields can be answered by using the Yes/No sliders next to each option.

- Data Delivery and Release Date: The targeted data submission delivery date to CRDC and the
 expected publication date of the respective study.
 - Note that both dates are considered estimates. CRDC does not expect that submitters will hold to this start date and does not guarantee to release data by the expected study publication date, although we will make every effort to meet your deadlines.

- Data Types: Select Yes for the data types relevant to your submission. Some of the fields (such as
 Imaging and Clinical) open additional data type-specific questions if you select Yes. If you plan to
 submit data types not listed in this field, use the Other Data Type(s) field to provide that
 information.
 - Clinical: If this is selected, another field opens with options detailing the types of information
 collected about the participants/subjects of the study such as demographics, treatment dates,
 and outcomes. Any additional information not listed can be provided in the Other Clinical Data
 Types text box.
 - **Imaging:** If this is selected, a prompt opens to indicate if the data planned for submission will be de-identified.

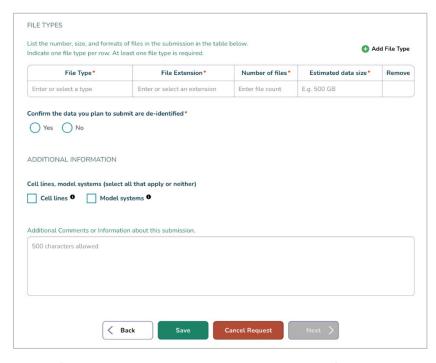


Figure 21. Page Four of the Submission Request Form Also Collects Information About File Types

- **File Types:** This section covers the kinds of data files that will be uploaded on the portal as well as the number of files and data size. These numbers are estimates only and the CRDC team will not hold an approved submission to the information provided here but requests that you make the most accurate estimate that you can. Use one row per file type and add additional rows using the **Add File Type** button.
- Confirm the data you plan to submit are de-identified: Select Yes or No.
 - Note that this de-identification attestation pertains to all data that will be submitted.
 - This means that all identifiers used in the study cannot be traced back to an individual and that the submission will be free of all Personally Identifiable Information (PII) or Protected Health Information (PHI).
 - Even for studies that will be placed under controlled access, there must not be any information that would allow the identification of a participant.
- **Cell lines, model systems:** Indicate whether the data are from cell lines or model systems.

 Additional Information: Any additional information needed for the Submission Review Committee to consider.

6. Submission Request Form: Review and Submit

This section is locked until all required fields have been completed in the previous sections. **When all required fields have been completed**, the **Review and Submit** section will be available and allow you to review all information entered on a single page.

Once you are satisfied that the information is complete, click the **Submit** button at the bottom of the page. **This locks the form from further editing** and notifies the Submission Review Committee that your request is ready for review.

V. Features of the Offline Submission Request Form (Excel Template)

- Instructions Tab: The first sheet in the offline form (shown in Figure 22) provides an overview of the template and step-by-step guidance on how to complete it. We recommend that users review these instructions before entering any information. There are some fields that include controlled vocabulary dropdowns, and certain selections may activate or deactivate additional fields in the workbook.
- Each subsequent sheet in the offline form corresponds to a specific page of the online Submission Request Form: PI and Contact, Program and Study, Data Access and Disease and Data Types (as described in "Data Submission Request Form Walkthrough" on page 6).
- Once all details are provided. Save the form.
- **Import** the form using the Import Form button. See that button in Figure 11 on page 7. All details from the imported form will automatically populate the online form.
- Review and submit the form on the portal.

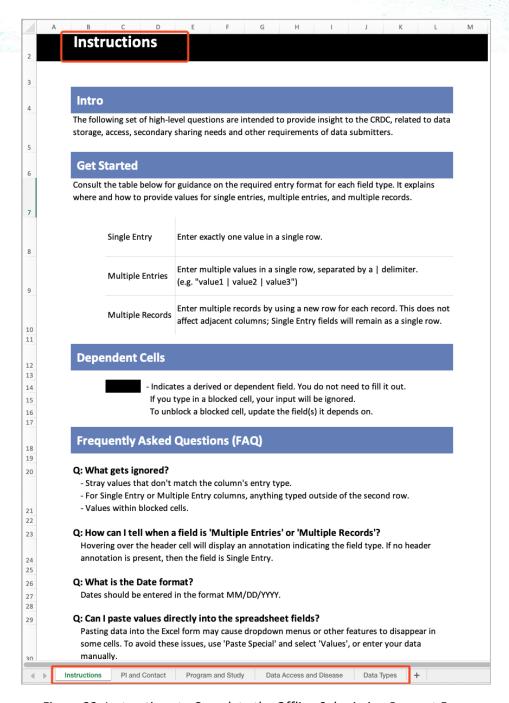


Figure 22. Instructions to Complete the Offline Submission Request Form

VI. Check the Data Submission Portal for Updates

The CRDC Submission Review Committee meets on a regular basis to review Submission Request applications. It takes four to six weeks from the time an application is made until the requester hears back from the committee.

The Submission Request application review can result in three different outcomes:

- Your request is approved. This starts the process of submitting the data files to the CRDC Submission Portal. The Principal Investigator or project contact is assigned a concierge who will help walk you through that process.
- Your request is rejected. This means that the committee has decided that your submission is not a
 good fit for CRDC, and you should find an alternative way to distribute your data.
- There are additional questions. In this instance, you will be contacted via CRDC Help Desk email (NCICRDC@mail.nih.gov) for additional information that the committee needs to come to a decision.