

# NCTN/NCORP Data Archive

## Usage Guide – Requesting Data

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V5.5, June 3, 2024

### I) National Clinical Trials Network (NCTN)/NCI Community Oncology Research Program (NCORP) Data Archive

The National Cancer Institute (NCI) has created a centralized, controlled-access database, called the [NCTN/NCORP Data Archive](#), for storing and sharing de-identified datasets generated from NCI-funded clinical trials. These data constitute a unique scientific resource, which the NCI is committed to making available in a timely manner, on appropriate terms and conditions, to the largest possible number of researchers who wish to analyze the data in a secondary study designed to enhance the public health benefit of the original work.

### II) Scope

With some exceptions, the NCTN/NCORP Data Archive includes clinical data from:

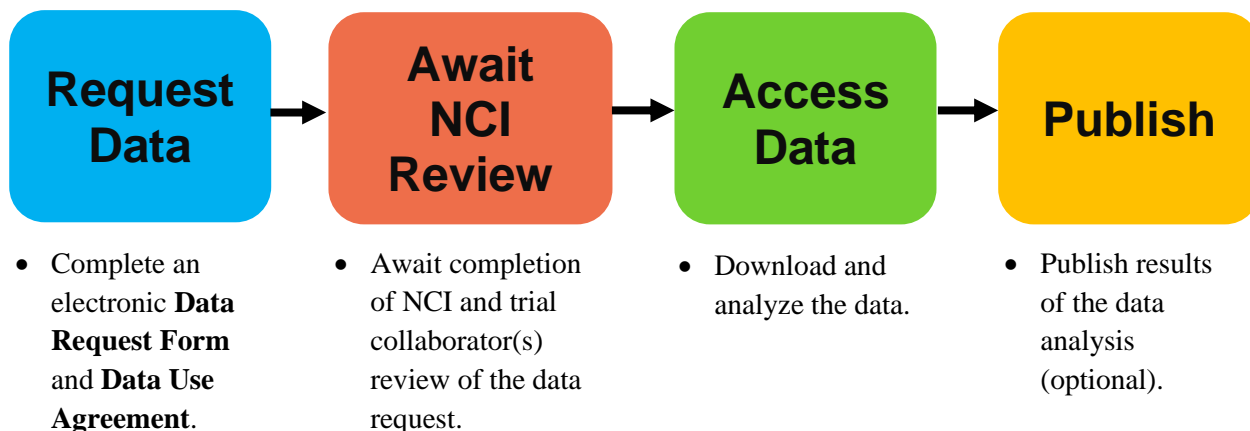
1. Primary publications of phase 2/3 and phase 3 trials published as of January 1, 2015 and,
2. Non-primary publications of phase 2/3 and phase 3 trials presenting updated survival data published as of April 1, 2018.

Note: Data are not available immediately upon publication.

NCTN/NCORP Data Archive contents include clinical datasets, data dictionaries, and metadata. For select trials, imaging data are also available via a link to [The Cancer Imaging Archive \(TCIA\)](#), NCI's official imaging repository for NCTN Trials. Datasets are patient-level and de-identified, and include data for all variables used in the analyses presented in each corresponding publication (with minor exceptions). Data can be used to approximate published study findings, but exact reproduction of previous manuscripts may not be possible in some cases (e.g., when data must be modified for de-identification purposes, when data have been further cleaned since publication, etc.).

### III) Data Request Process

#### III.I) Data Request Overview



To request data, the following are required:

1. An NCTN/NCORP Data Archive user account
2. A complete online **Data Request Form**, including:
  - A list of up to 5 trials and/or publications from which data are being requested
  - A research title and a brief research plan that includes a clearly defined medical or scientific objective
3. A Data Use Agreement (DUA) containing legally binding signatures by the requestor and (if applicable) an Authorized Representative from the requestor's Entity.

### ***Request Data***

To request data, requestors create an NCTN/NCORP Data Archive user account and complete a **Data Request Form**. After submitting the **Data Request Form**, requestors and, if applicable, their Authorized Representative must sign a Data Use Agreement sent via email.

Requestors may seek Archive data with or without employment under, or affiliation with, an Entity (i.e., organization, institution, or university).

If a requestor wishes to request data under employment/affiliation with an Entity, all resources used within a research plan must belong to the Entity and work performed must fall strictly within the scope of the requestor's employment/affiliation with the Entity.

Requests from requestors employed/affiliated with an Entity require the signature of an Authorized Representative on the Data Use Agreement. The Authorized Representative must have an individual, institutional email address and legally binding signature authority for the requestor's Entity. Requestors can generally identify an appropriate Authorized Representative by contacting their Entity's Technology Transfer, Sponsored Research, or Corporate Contracts office.

If a requestor will use their own resources and the work falls outside the scope of their employment/affiliation with any Entity, they may seek data without an Entity. Requestors without an Entity may only request data from trials not conducted under a collaborative agreement.

Note: Collaborative agreements are formal legal agreements between an entity responsible for a trial (e.g., NCI) and an industry collaborator that governs the conduct of the trial.

Requestors located outside of the United States must be associated with a legal Entity.

### ***Await NCI Review***

After a request is submitted and the Data Use Agreement is signed, the request is reviewed by NCI for adherence to legal and administrative requirements. Although a medical or scientific objective is required, there is no scientific review of data requests. If data are requested from one or more trials conducted under a collaborative agreement, the request will be sent to the applicable industry collaborator(s), which may provide comments on the request.

Requests from countries outside of the United States may require additional reviews and processing time.

### ***Access Data***

If a request is approved, only the requestor and Other Approved Users included in the Data Use Agreement may access the datasets. All persons who will access the data must be included in the request and must be affiliated with the same Entity as the requestor. If individuals from multiple Entities will be collaborating on a research project, one individual from each Entity must create an Archive account, submit a Data

Request, and sign an Entity-specific DUA. Collaborating Entities must have all persons from that Entity who will be accessing the data listed as an Other Approved User in the Entity's **Data Request Form**.

Note: Additional Other Approved Users may be added after a request is approved through an expedited review process, described in [III.IV\) Renewing or Reviewing an Approved Data Request](#).

Note: For requests without an Entity, only the requestor may view and use the data. Other Approved Users cannot be added in the **Data Request Form**.

If a request is approved, the requestor may download the clinical dataset(s) and associated documentation via secure links within the Archive website.

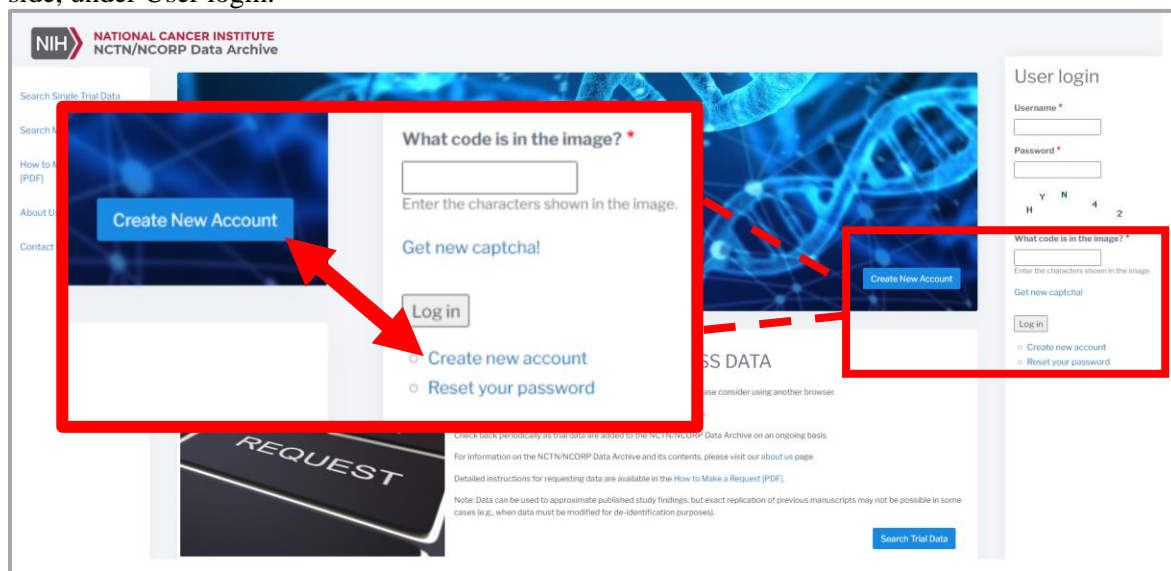
An approved data request and Data Use Agreement allows a requestor and Other Approved Users to access the requested data for 3 years. Requests can be renewed for additional 3-year periods by submitting a new Data Request with a newly signed Data Use Agreement for an expedited review process, as described in [III.IV\) Renewing or Revising an Approved Data Request](#).

### III.II) Creating a User Account

Although the Archive allows prospective requestors to search for data without registering as a user, an Archive User Account is required to request data.

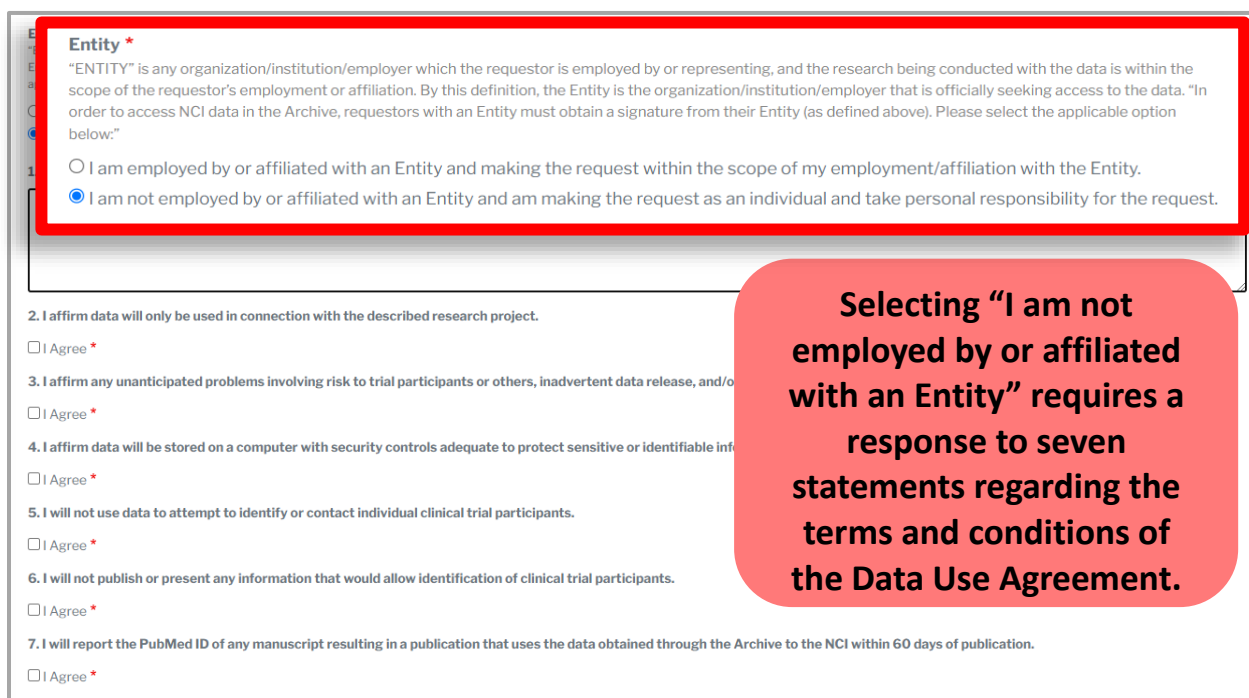
#### Instructions for creating a User Account:

1. Navigate to the NCTN/NCORP Data Archive: <https://nctn-data-archive.nci.nih.gov>.
2. Select **Create new account** either in the blue banner at the top of the page or from the right-hand side, under User login.



3. Provide first and last name, phone number (optional), and location information.
4. If employed by or affiliated with an Entity and making the request within the scope of this employment/affiliation, select the appropriate radio button within the **Entity** section and provide an "Entity Name", "Department", and "Entity Type". Skip to step 6.
5. If not employed by or affiliated with an Entity and making the request solely as an individual, select the appropriate radio button within the **Entity** section and complete items #1 – 7 that appear below the radio button.
  - a. Notes regarding requests from users with no Entity:

- i. The request review timelines are longer than those for requests from requestors with an Entity.
- ii. No resources from any Entity may be used, including email addresses.
- iii. Requestors must take personal responsibility for the legal terms and conditions contained within the Data Use Agreement.
- iv. Data collected on trials conducted under a collaborative agreement cannot be requested without an Entity.



**Entity \***

"ENTITY" is any organization/institution/employer which the requestor is employed by or representing, and the research being conducted with the data is within the scope of the requestor's employment or affiliation. By this definition, the Entity is the organization/institution/employer that is officially seeking access to the data. "In order to access NCI data in the Archive, requestors with an Entity must obtain a signature from their Entity (as defined above). Please select the applicable option below:"

☐ I am employed by or affiliated with an Entity and making the request within the scope of my employment/affiliation with the Entity.

☒ I am not employed by or affiliated with an Entity and am making the request as an individual and take personal responsibility for the request.

2. I affirm data will only be used in connection with the described research project.

☐ I Agree \*

3. I affirm any unanticipated problems involving risk to trial participants or others, inadvertent data release, and/or other issues that may arise from the use of the data will be reported to the NCI.

☐ I Agree \*

4. I affirm data will be stored on a computer with security controls adequate to protect sensitive or identifiable information.

☐ I Agree \*

5. I will not use data to attempt to identify or contact individual clinical trial participants.

☐ I Agree \*

6. I will not publish or present any information that would allow identification of clinical trial participants.

☐ I Agree \*

7. I will report the PubMed ID of any manuscript resulting in a publication that uses the data obtained through the Archive to the NCI within 60 days of publication.

☐ I Agree \*

6. Provide **Login Credentials** including an email address and Username.
  - a. **If requesting data under an Entity, an official, individual, institutional email address must be used. Signing up with a non-Entity email address (e.g., gmail, Hotmail, etc.) will require creation of a new Archive account with an Entity email address and will introduce delays in the processing of any requests for data.**
  - b. If requesting data as an individual (i.e., without an Entity), a personal email address must be used. Signing up with an Entity email address will require creation of a new Archive account with a non-Entity email address and will introduce delays in the processing of any requests for data.
7. Verify the accuracy of all information.
8. Read and accept the Terms & Conditions of Use to continue.
 

Note: The Terms & Conditions of Use must be accepted to request data.
9. Enter the captcha code, then click **Create new account** at the bottom of the page.
10. Confirmation that the account has been created in the Archive will appear as a green banner at the top of the screen.
11. An email from **NCTN/NCORP Data Archive** with "Account details" in the subject should arrive to the email address provided in the **User Registration** page within 24 hours. Click on the link in

the email to open the **Set password** webpage. Check junk/spam mail folders if the message cannot be located.

**From:** NCTN/NCORP Data Archive <NCINCTNDataArchive@mail.nih.gov>  
**Date:** Wed, 31 Jan 2024 at 16:22  
**Subject:** Account details for <your email address> at NCTN/NCORP Data Archive  
**To:** <your email address>

[your email address,](#)

Thank you for registering at NCTN/NCORP Data Archive. You may now log in by clicking this link or copying and pasting it into your browser:

[https://nctn-data-archive.nci.nih.gov/user/reset/7075/1706736144/o699a\\_75wFaZXAYKzRAqICZUNbBihj\\_O0NXjvU1CWuo](https://nctn-data-archive.nci.nih.gov/user/reset/7075/1706736144/o699a_75wFaZXAYKzRAqICZUNbBihj_O0NXjvU1CWuo)

This link can only be used once to log in and will lead you to a page where you can set your password.

After setting your password, you will be able to log in at <https://nctn-data-archive.nci.nih.gov/user> in the future using:

username: [your email address](#)

password: Your password

-- NCTN/NCORP Data Archive team

12. On the **Set password** page, specify a password and click **Log in**. A green banner will confirm that the new password has been saved.

Set password

Set New Password \*

Password \*

Password strength:

Confirm password \*

Passwords match:

Please set a new password so that you can login next time.

This is a one-time login.

Click on this button to log in to the site and change your password.

This login can be used only once.

Log in

Data can now be requested.

### ***III.III) Requesting Data***

#### ***III.III.I) Overview of Archive Data***

Data in the Archive are linked to a publication. With some minor exceptions, datasets contain all data used to generate the results in the associated publication.

Data in the Archive are categorized according to the publication in which they were presented.

Publication Types:

1. Single-trial publications: publications reporting on data from only 1 trial
2. Multi-trial publications: publications reporting on data from more than 1 trial

Data may be requested by trial (with an NCT number) or by publication (with a PMID). The only way to receive data from a multi-trial publication is to request that publication by PMID. A total of 5 selections (NCT number and/or PMID) can be made per request.

1. **If a trial (by NCT number) is selected:** all available datasets from all single-trial publications reporting on the trial will be included in the request. Datasets from multi-trial publications that include the selected trial will not be included in the request.
2. **If a single-trial publication (by PMID) is selected:** all available datasets from the trial reported on by that publication will be included in the request. This includes any primary or non-primary publications associated with only that trial. Datasets from multi-trial publications that include the aforementioned trial will not be included in the request.
3. **If a multi-trial publication (by PMID) is selected:** the dataset from that multi-trial publication will be included in the request. In addition, all available datasets from all the single-trial publications reporting results on any of the trials included in chosen multi-trial publication will be included in the request. Note that datasets from multi-trial publications typically only include data that are not in the applicable trials' single-trial publication datasets, as those are also provided should the request be approved.

Given that data are not typically duplicated in Archive submissions:

1. Some data presented in non-primary publications (e.g., updated survival publications, toxicity publications, etc.) may be contained within the datasets associated with the primary publication(s).
  - a. According to the rules stated above, all primary publication data for a trial are provided when a non-primary publication including that same trial is selected, in addition to data newly presented in the non-primary publication.
2. Some non-primary publications may present new analyses that use only data already contained within one or more previously submitted datasets.
  - a. Datasets for these non-primary analysis publications contain a reference to the applicable primary publication datasets instead of duplicating the data.
3. If a publication presents any data that have been updated from the data presented in the primary publication, these updated data will be included in the secondary analysis dataset(s).

Requests for data may be initiated either by first searching for data in the Archive (i.e., via the “Search Single-Trial Publications” link or the “Search Multi-Trial Publications” link), or, if the desired data are already known, by completing a Data Request Form via the “Request Data” link.

### ***III.III.II) Searching for Data***

Available data can be searched using the “Search Single-Trial Publications” link or the “Search Multi-Trial Publications” link found in the left-hand Main Menu. If the data of interest were presented in a publication reporting data from only 1 trial, use the “Search Single-Trial Publications” link. If the data of interest were presented in a publication reporting data from more than 1 trial, use the “Search Multi-Trial Publications” link.

**Note:** A trial could be identified via both search links if the Archive contains data from the trial presented in both a single-trial publication and a multi-trial publication. If the Archive only contains data from a trial presented in a single-trial publication OR a multi-trial publication, the trial will only appear in 1 search link.

## Instructions:

1. **Login** to the User Account created in [III.II\) Creating a User Account](#).
2. Select **Search Single-Trial Publications** or **Search Multi-trial Publications** from the left-hand Main Menu panel.

3. On the **Search** page, use the search fields and click **Apply Filters** to search the Archive database for data that meet a certain set of criteria. After selecting **Apply Filters**, scroll down to view the resulting datasets, which appear below the list of all available search filters.

Study ID	NCT Trial Number	Disease Types	Dataset ID	Has a Collaborative Agreement	PubMed ID	Images available?
EX1234	NCT12345678	Bone Neoplasm - Miscellaneous	NCT12345678-D1, NCT12345678-D2	Yes	87654321	No

4. To view additional information on a trial (including the number of available datasets), click on the hyperlinked NCT number. Select the title of an individual dataset and then select the Data Dictionary PDF to view the complete list of variables provided in the associated dataset. All datasets associated with a requested trial will be provided upon request approval, as described above.

The screenshot shows the NCTN/NCORP Data Archive interface. A red box highlights the 'NCT12345678' trial number in the 'Clinical Trial Information' section. Another red box highlights the 'Title' of the dataset 'NCT12345678-D1' in the 'Dataset Information' section. A third red box highlights the 'Data Dictionary' link 'NCT12345678-D1-Data-Dictionary.pdf' in the 'Data Dictionary' section. A red callout box on the right provides instructions: 'In the Search Trial Page, clicking on the “NCT trial number” will lead to the Clinical Trial Information page. In the Clinical Trial Information page, clicking the “Title” will lead to the Dataset Information page. In the Dataset Information page, the data dictionary can be downloaded.'

5. To access the **Data Request Form** and request data, select the dataset(s) of interest using the checkbox to the left of each trial(s) and click **Request selected data**. This will launch a **Data Request Form** with those trials or PMIDs auto-populated in the form. Instructions for completing this form can be found starting in Section [III.III.IV\) Completing a Data Request Form](#).

### III.III.III) Accessing the Data Request Form

1. **Login** to the User Account created in [III.II\) Creating a User Account](#).
2. Select **Request Data** from the left-hand Main Menu.

### III.III.IV) Completing a Data Request Form

3. Access the Archive’s **Data Request Form** as described in either of the preceding steps.
4. Complete **Step 1** of the **Data Request Form**.
  - a. Provide a **Research Plan Title** and **Research Plan Description**.
    - i. Although Archive requests do not undergo scientific review, sufficient information must be provided to enable NCI and/or the trials’ pharmaceutical collaborators to understand the intended use of the data (e.g., which data will be used and what analyses will be performed, etc.).



**Create Request**

✓ Request Trials was applied to 1 item.

Step 1 Step 2 Step 3

**Research Plan Title \***

Please provide a short descriptive title for your research plan.

Example Research Plan Title

In order to access the data, you will need to complete and submit a research plan. Requests for data from multi-trial publications may further increase the duration of data from trials conducted under collaborative agreements can take up to four additional weeks of review. Requests that data

**Research Plan Description \***

Briefly describe your initial research plan. Please provide a one-paragraph description of how the data will be used. Although research plans are not reviewed for scientific merit, sufficient information must be provided to enable NCI and/or the trials' pharmaceutical collaborators to understand the intended use of the data (e.g., which data will be used and what analyses will be performed, etc.).

Example Research Plan Description

Content limited to 1000 characters, remaining: 967

- b. Select up to a total of 5 trials (NCT numbers) and/or publications (PMIDs).
  - i. If datasets were selected from the **Search Single-Trial Publications** or the **Search Multi-Trial Publications** views, the selected trial numbers (affiliated with single-trial publications) or PMIDs (affiliated with multi-trial publications) should be auto-populated under “Requested Data (Required).” Additional trials and PMIDs may be added in the **Requested Data** section, up to a maximum of 5.
    - a. Note: Higher volumes of requested data result in greater request review timelines.

**Requested Data (Required) \***

Please indicate the trial(s) and/or publication(s) from which you are requesting data in addition to any trials and/or publications auto-populated below if you used the “Search” feature to access this form. You may select up to a total of five (5) trials and/or publications per data request. You may request data from publications of single trials (by entering a NCT Number or PMID) or data from publications containing data from multiple trials (by entering a PMID). For trials, the format for the ClinicalTrials.gov registry number is “NCT” followed by an 8-digit number. For publications, the format for the PubMed database is an 8-digit number (decimals for versioning are accepted).

If your request is approved, you will receive:

**NCT Trial Number(s) and/or PubMed ID(s)**

To request data, the NCT Number or PMID must be entered in the Requested Data section of the Data Request Form.

+

NCT12345678

+

NCT00000077

+

NCT00000088

+

NCT12341234

Up to 5 NCT numbers and/or PMIDs can be entered in one Data Request Form.

- ii. Data presented in a single-trial publication may be requested by NCT number or PMID.
- iii. Data presented in a multi-trial publication may only be requested by PMID.
- c. Indicate whether other individuals from the same Entity will use the data.

- i. If additional individuals will be using the data, provide the name and email address for each individual. Be sure to use an individual email address for each Other Approved User.

The screenshot displays three versions of the 'Other Approved Users' section of the request form, illustrating different states or components. Red boxes highlight specific elements, and dashed red lines connect them across the versions.

- Top Left Version:** Shows the 'Other Users?' section with two radio buttons: 'I will be the only person from my entity (if applicable) accessing the data.' (unselected) and 'There will be other persons accessing the data from my entity.' (selected). Below is a table for 'Other Approved Users' with columns for 'Name of Approved User' (Firstname Lastname, Department) and 'Email' (other approved user email address). A 'Remove' button is at the bottom.
- Top Right Version:** Similar to the top left, but with a red asterisk next to the title 'Other Approved Users at Entity(If Applicable)'.
- Bottom Version:** A larger, more detailed view of the 'Other Approved Users' section. It includes the same radio buttons and a table with the same columns. The 'Remove' button is also present.

Note for requestors with an Entity:

- ii. **Transferring data to anyone not listed as an “Other Approved User” is considered a breach of the Data Use Agreement and is not permitted. Unauthorized transfers of data may result in legal action.** Verify that all others at the Entity who would use the data are included as “Other Approved Users.”

Note for requestors without an Entity:

- iii. **Transferring data to anyone is considered a breach of the Data Use Agreement and is not permitted. Unauthorized transfers of data may result in legal action.**
- d. Provide the **Name, Title, Email, and Entity** for an **Authorized Representative**, if applicable. Authorized Representatives must:
  - i. Belong to the same Entity as the Requestor and all Other Approved Users.
  - ii. Have legally binding signatory authority for the Entity.
  - iii. Have an official Entity email address.
  - iv. Have an individual email address. A general inbox or distribution list cannot be accepted.
- e. Confirm the **Authorized Representative** has signature authority for the Entity and check the checkbox below their Entity name.

**Other Approved Users at Entity (If Applicable)** \*

**Other Users?** \*

☐ I will be the only person from my entity (if applicable) accessing the data.

☒ There will be other persons accessing the data from my entity.

Please tell us who will be using the data at your Entity.

Note: If users from multiple Entities are involved in your data request, a separate Data Request Form and Data Use Agreement must be submitted for each Entity.

**Other Approved Users**

Name of Approved User
<input type="text"/> Firstname Lastname <input type="text"/> Department <input type="text"/> Biology <input type="text"/> Email <input type="text"/> other approved user email address <input type="button" value="Remove"/>

**Authorized Representative (If Applicable)** \*

An **Authorized Representative** is someone who is delegated signature authority to bind your Entity to the legal terms of the DUA. The policy is such that the signatory for the DUA must be associated with the Entity of the Requestor and approved users (if applicable).

**Name of Authorized Representative** \*

Firstname Lastname

**Title** \*

Authorized Representative's Title

**Email** \*

authorized representative email address

The Authorized Representative, who is delegated signature authority to bind your entity to the legal terms of the DUA, must use their official Entity email. Providing an unofficial Entity email (e.g., gmail) will create delays in the processing and review of your request.

**Authorized Representative's Entity** \*

Example Entity Name

☒ I confirm that the individual designated as the Authorized Representative above has signatory authority for the entity. \*

- f. After completing the required fields, click **Next** to continue to **Step 2** of the **Data Request Form** or click **Save** to return to the request later.

Note: Saved (i.e., “Not Submitted”) or submitted requests (i.e., “Under Review”) can be accessed from the left-hand menu through the **View Existing Requests** link.

5. **Complete Step 2 of the Data Request Form.**

- Step 2, Summary of Requested Data**, will provide a summary of all data that will be requested based on the trials and/or publications selected in **Step 1**.
- Review the data to be requested. To make any edits, click the “**Back**” button.
- Indicate whether any imaging data are requested in the **Imaging Data** section, where a list of any requested trials with imaging data available in The Cancer Imaging Archive (TCIA) will be provided.

Note: The option to request Imaging Data will not appear if the requested trials do not have imaging data available in TCIA.

**Create Request**

Step 1 Step 2 Step 3

**Step 2: Summary of Requested Data**

This page (Step 2 of the request), will specify the publication(s) from which you are requesting data based on your selection(s) in the previous Step 1. Data in the Archive are tied to and grouped by publication.

**Clinical Data** (listed by publication in which the data were used)

Data included in your request based on the trials and/or single-trial publication(s) you selected in Step 1 (publications that only include data from one trial)

- NCT12345678, EX1234  
"Example Primary Publication Title", PMID: 87654321
- "Erratum for Example Primary Publication Title", PMID: 97538642
- NCT00000077, STID-4321  
"Example Primary Publication Title", PMID: 12345678
- NCT00000088, S1555  
"Example Primary Publication Title", PMID: 75318642
- NCT1234234, EXID4444  
"Example Primary Publication Title", PMID: 98989898

**Imaging Data**

Please review the Archive's How to Make a Request (PDF) and the Imaging Data Request Form (PDF) before proceeding. Imaging data are available for the trials listed above.

☒ Imaging Data Requested  
☐ Imaging Data Not Requested

Click "Next" to proceed with requesting the data above. To cancel, click "Back".

[Back](#) [Next](#) [Save](#)

- d. After completing the required fields, click **Next** to continue to **Step 3** of the **Data Request Form** or click **"Save"** to return to the request later.
6. **Complete Step 3 of the Data Request Form.**
  - a. **Step 3, Submitting the Request**, will provide a downloadable summary of the request and describe the **Data Use Agreement** signature process.

**Create Request**

Step 1 Step 2 Step 3

**Step 3: Submitting the Request**

Please download the Request Summary PDF below and verify that all information is correct. To change any information, return to a previous step by first clicking "Save" in the Archive website and then re-opening the Data Request Form (DRF) by clicking "Edit" and modifying it appropriately.

After verifying all information is correct, click "Submit" to proceed with the request. You and your Entity's Authorized Representative will then receive a Data Use Agreement (DUA) specific to this request. This legal document must be signed by you and then your Entity's Authorized Representative, if applicable.

As indicated in Step 1 of this Data Request Form, an Authorized Representative is someone who is delegated signature authority to bind your Entity to the legal terms of the DUA. The representative is usually located in a Technology Transfer Office, Sponsored Research Programs, Office of General Counsel, or Business Development Office. NCI policy is such that the signatory for the DUA must be associated with the Entity of the Requestor and any other approved users. The data request will not be processed until the Authorized Representative signs the DUA, if applicable.

Sample DUAs can be viewed at the links below.

**Downloads**

Request Summary:  
[Download Request Summary](#)


Sample Data Use Agreements:  
[Data Use Agreement template for Trials with No Collaborative Agreement \(PDF - 144KB\)](#)  
[Data Use Agreement template for Trials with Collaborative Agreements \(PDF - 144KB\)](#)

Click "Submit" to send the data request to NCI and to have a DUA sent to you and your Entity's Authorized Representative (if applicable).

[Back](#) [Save](#) [Submit](#)

- i. Read the information provided in **Step 3**.

## ii. Download and review the request summary.


**NATIONAL CANCER INSTITUTE**  
NCTN/NCORP Data Archive

### NCTN/NCORP Data Archive request Overview

#### Request

Generated on: February 29, 2024

**Title:** Example Research Plan Title

**Description:** Example Research Plan Description

To complete the research plan described above, data from the following trial(s) is being requested:

Study ID	NCT Trial Number(s)	PubMed ID (PMID)	Disease Type	Dataset ID	Descriptions of Dataset
EX1234	NCT12345678	87654321	Bone Neoplasm - Miscellaneous	NCT12345678-D1	There are 2 datasets associated with PMID 87654321, NCT12345678-D1 and NCT12345678-D2. This dataset, NCT12345678-D1, contains the baseline characteristics and clinical outcomes data. There is one row per patient. The contents of this submission reflect the correct data described in the June 20, 2022, erratum (PMID 97538642).
EX1234	NCT12345678	87654321	Bone Neoplasm - Miscellaneous	NCT12345678-D2	There are 2 datasets associated with PMID 87654321, NCT12345678-D1 and NCT12345678-D2. This dataset, NCT12345678-D2, contains adverse event data. There are multiple rows per patient. The contents of this submission reflect the correct data described in the June 20, 2022, erratum PMID 97538642.
EX1234	NCT12345678	97538642	Bone Neoplasm - Miscellaneous	NCT12345678-D3	An erratum (PMID 97538642) correcting some minor typos in the original primary publication of trial NCT12345678 (EX1234) was published on June 20, 2022. The data submitted to the Archive (NCT12345678-D1 and NCT12345678-D2) reflect the information corrected by this erratum.
STID4321	NCT00000077	12345678	Bone Neoplasm - Miscellaneous	NCT00000077-D1	Example dataset description
SI555	NCT00000088	75318642	Bone Neoplasm - Miscellaneous	NCT00000088-D1	Example dataset description
EXID4444	NCT12341234	88888888	Bone Neoplasm - Ewing Sarcoma	NCT12341234-D1	Example dataset description

Page 1 of 2

**Request Submitted By:** Firstname Lastname

Username: your email address  
Phone Number: 555-123-4567  
Email: your email address

Country: US  
State: Anywhere  
City: Anywhere

**Entity:**

☒ I am employed by or affiliated with the entity  
☐ I am not employed by or affiliated with the entity

Entity Name: rock  
Entity Type: Other  
Department: Other

**Other Approved Users:**

☐ I will be the only person from my organization  
☒ There will be other persons accessing the data

Approved User's Name: Firstname Lastname  
Department: Biology  
Email: other approved user email address

**Authorized Representative**

Name and Title of Authorized Representative:  
Firstname Lastname, Authorized Representative's Title  
E-mail Address: authorized representative email address  
Authorized Representative's Entity: Example Entity Name

☒ I confirm that the individual designated as the Authorized Representative above has signatory authority for the entity.

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**The Request Summary contains pertinent information about the request, including research plan title/description, requested datasets, requestor, other approved users, and authorized representative.**

iii. Return to **Step 1** to make any necessary edits to the request.

## iv. Download and review the sample Data Use Agreements (DUA).

Note: NCI cannot accept edits to the DUAs on a case-by-case basis.

v. When the **Request Summary** is complete and accurate, click “**Submit.**”

## a. Submitting a request will initiate the following process:

- i. **NCI review of the request.** Any administrative issues identified during this review that require corrections will be communicated by email to the email address provided in the User Account Profile.
- ii. **Request for a Data Use Agreement signature.** A DUA will be sent by email to the Requestor and then the Authorized Representative to sign.
- iii. **Sharing of request with pharmaceutical collaborators, if applicable.**
- vi. Confirmation that the request was submitted in the Archive will appear as a green banner at the top of the screen. A system email will also be sent to the requestor indicating that the request has been successfully submitted.

**III.III.V) Provide DUA Signature(s)**7. Monitor for email correspondence from [NCINCTNDataArchive@mail.nih.gov](mailto:NCINCTNDataArchive@mail.nih.gov).

- a. Issues identified during NCI’s review of the request are communicated by email.

- b. Once any issues are resolved, the Data Use Agreement is sent by email.
8. Sign the Data Use Agreement (DUA).
  - a. The DUA will then be automatically routed to the Authorized Representative, if applicable, to sign as well. After NCI receives the DUA with both signatures, processing of the request will continue. There are no further required actions.

If the request is approved, an NCTN/NCORP Data Archive Administrator will reach out by email with instructions for accessing the requested data. A ReadMe file containing a summary of the DUA’s key points will be provided.

If Imaging Data were requested, follow the instructions in the request approval email notification to create an account on the TCIA website. Then reply to the NCTN/NCORP Data Archive approval email with the created TCIA username.

Data from an approved request can be accessed by clicking the **View Existing Requests** link (via the left-hand menu) and clicking **Download Data**. The DUA countersigned by NCI can be downloaded by clicking **Download Countersigned DUA** in the Data Use Agreement column.

**View Existing Requests**

Request Status: - Any -

Request ID:

Title:

Title	NCT Trial Number(s)/PMID(s)	Data Use Agreement (DUA)	Date DUA Uploaded	Date Request Submitted	Request Status	Operations
Example Research Plan Title	NCT12345678	<a href="#">Download countersigned DUA</a>	03/01/24	02/24/24	Approved	<a href="#">Download Data</a>

### III.IV) *Renewing or Revising an Approved Data Request*

Once a request is approved, the title and research plan description cannot be modified; an Entity cannot be added, changed, or removed; and the requested data cannot be changed. A new request must be submitted with any changes to these fields.

However, approved requests can be modified in certain administrative ways (e.g., replacing the requestor with an Other Approved User, adding additional Other Approved Users, etc.) directly from the approved request webpage view. A request revision must have an identical research plan description to that in the initial approved request and may be eligible for an expedited review process.

Revised requests require a new Data Use Agreement (DUA), which provides access to the requested data for three (3) years from the date the new DUA becomes effective. Therefore, requests can also be renewed (i.e., data access can be requested for another 3-year period) by way of this same process.

Follow the instructions below to renew a DUA and/or to revise a request.

#### Instructions for renewing or revising an approved request:

1. Login to the Archive.
2. Navigate to “View Existing Requests” on the left-hand menu.

3. Select the approved request to be renewed or revised.
4. Select “Renew or revise the request”.
5. Complete **Step 1** of the **Data Request Form**.
  - a. The information from the previously approved request will auto-populate into the new request form. Make any necessary changes to the Other Approved Users and Authorized Representative information.
  - b. The request title, research plan description, and trials and/or publications requested cannot be changed. If any of these fields must be edited, submit a new data request following the instructions in [III.III. Requesting Data](#).
  - c. After updating any necessary fields, click **Next** to continue to **Step 2** of the **Data Request Form** or click **Save** to return to the request later.
6. Review **Step 2** of the **Data Request Form**.
  - a. **Step 2, Summary of Requested Data**, will provide a summary of all data that will be requested based on the trials and/or publications selected in **Step 1**. **Step 2** cannot be edited.
  - b. Click **Next** to continue to **Step 3** of the **Data Request Form** or click “**Save**” to return to the request later.
7. Complete **Step 3** of the **Data Request Form**.
  - a. **Step 3, Submitting the Request**, will provide a downloadable summary of the request and describe the **Data Use Agreement** signature process.
    - i. Read the information provided in **Step 3**.
    - ii. Download and review the request summary.
    - iii. Return to **Step 1** to make any necessary edits to the request.
    - iv. Download and review the sample Data Use Agreements (DUA).

Note: NCI cannot accept edits to the DUAs on a case-by-case basis.
    - v. When the **Request Summary** is complete and accurate, click “**Submit**.”
      1. Submitting a request will initiate the following process:
        - a. **NCI review of the request.** Any administrative issues identified during this review that require corrections will be communicated by email to the email address provided in the User Account Profile.
        - b. **Request for a Data Use Agreement signature.** A DUA will be sent by email to the Requestor and then the Authorized Representative to sign. Additional instructions regarding DUA signatures are provided in [III.III.V Provide DUA Signature\(s\)](#).
    - vi. Confirmation that the request was submitted in the Archive will appear as a green banner at the top of the screen. A system email will also be sent to the requestor indicating that the request has been successfully submitted.

An NCTN/NCORP Data Archive Administrator will reach out by email with information regarding the outcome of the review. If the request is approved, access to the data is granted for 3 years from the DUA’s NCI countersignature date.



## IV) Frequently Asked Questions

### **How can I know if specific data are available?**

You can search for specific data using the “Search Single-Trial Publications” or “Search Multi-Trial Publications” links found in the left-hand menu. Select a trial of interest to view the available datasets affiliated with the trial and a brief description of the datasets. Select the title of an individual dataset and then select the Data Dictionary PDF to view a list of the variables included in the associated dataset. A user account is not required to view data dictionaries. If a data request is approved, you will receive all available datasets affiliated with a requested trial (except for datasets from multi-trial publications unless they are specifically requested by PMID in Step 1 of the Data Request Form).

### **Can I request data from single-trial and multi-trial publications in the same request?**

Yes. In the Requested Data section of Step 1 in the Data Request Form you may enter NCT numbers or PMIDs to request data from single-trial publications and PMIDs to request data from multi-trial publications. All datasets which will be provided if the request is approved will be summarized in Step 2 of the Data Request Form. However, higher volumes of requested data result in greater request review timelines.

### **Does the Archive contain any patient Protected Health Information (PHI)?**

No. Data in the Archive are fully de-identified and contain no PHI.

### **How long does the review of requests take?**

Review timelines vary due to a variety of factors. Requests for data from trials not conducted under a collaborative agreement typically require 1 – 2 weeks of review time from receipt of an Authorized Representative signature, and requests for data from trials conducted under a collaborative agreement typically require 2 – 4 weeks of review time from receipt of an Authorized Representative signature, but these timelines are not a guarantee. There is no estimated review timeframe for requests from users outside of the United States.

### **How can I get an update on the status of my request?**

Login to your Archive account and click “View Existing Requests” on the left-hand menu to view all requests you have initiated. If the **Request Status** reads “Under Review”, you have successfully submitted the request and NCI is reviewing it. If the **Request Status** reads “Revisions requested” or “Pending signatures”, an action is required from you to allow NCI to continue processing the request. Check the email provided in your user account for instructions from an Archive Administrator regarding the action required. You can reach out to an Archive Administrator [NCINCTNDataArchive@mail.nih.gov](mailto:NCINCTNDataArchive@mail.nih.gov) with additional questions regarding your request.

### **Can I continue using the data if I change to a different Entity?**

You cannot continue to use the data under the same Entity that signed the original Data Use Agreement (DUA). To continue using the data, you must create a new user account with your new Entity information (including an official email address from your new Entity) and submit a new request. In most cases, requests submitted to change Entities are eligible for expedited review.

### **Can I share the data with anyone?**

Data can be shared with anyone listed as an Other Approved User on your request. Transferring data to anyone not listed as an “Other Approved User” is considered a breach of the Data Use Agreement and is not permitted. Unauthorized transfers of data may result in legal action.

### **Can I collaborate on data analyses with anyone?**



You can collaborate on data analyses with anyone permitted to use the data by the NCTN/NCORP Data Archive. To collaborate with someone from your own Entity, simply list the individuals with whom you wish to collaborate as “Other Approved Users”. To collaborate with someone from outside your own Entity, they must submit a request of their own with an Authorized Representative signature from their Entity.

**Can I provide the inbox for the Research/Contracts Office as the Authorized Representative email?**

It is an NCI legal requirement that the individual, Entity email is provided for the Authorized Representative (AR). This serves as evidence that the AR belongs to the same Entity as the requestor. We also use this email to send the Data Use Agreement (DUA) to the AR for signature and must ensure that the DUA reaches the AR designated in the request.

**Can I publish using the data?**

The results of any data analyses performed using data obtained through the NCTN/NCORP Data Archive can be published. However, publication or disclosure of any individual data (including example data) is considered an unauthorized data transfer and is not permitted. Aggregate data can be used in publications.

**Do I have to include any acknowledgments in my publications?**

The clinical trials from which data were used must be acknowledged in any manuscripts from the use of the data. Example acknowledgment language can be found in the Data Use Agreement. Additional acknowledgments are required if also publishing using imaging data obtained through the Archive’s data integration with The Cancer Imaging Archive (TCIA).

**Do I have to inform NCI when I publish?**

You must abide by all terms and conditions contained within the DUA that you and your institution signs. For requests for data from trials not conducted under a collaborative agreement, you do not need to inform NCI before publishing, but you must send the PubMed ID of any publications within 60 days of publication. For requests for data from trials conducted under a collaborative agreement, you must also send any planned publication (including presentations, abstracts, manuscripts, dissertations, etc.) to NCI and the pharmaceutical collaborator(s) for review prior to publishing. Additional details can be found within the sample Data Use Agreements on the [Archive homepage](#).

**If NCI previously reviewed my publication and I have reformatted it for another journal/conference, do I need to inform NCI?**

Any reformatted or revised versions of publications that NCI previously reviewed must be submitted for another review period. Depending on the degree of revision, shorter review timelines may be possible.

**Are there any costs associated with requesting data from the Archive?**

There are no costs associated specifically with requesting or accessing data that are available in the Archive.

**What do I do if the data I’m seeking isn’t in the Archive?**

If the data you are seeking is within the Archive’s scope (see [ID Scope](#)), but are not available for request in the Archive, then the data are still being prepared for data sharing. Although the Archive contains limited data from NCTN or NCORP trials that are not within the Archive’s scope, it may not be possible to make additional out-of-scope data available via the Archive. You can contact an Archive administrator [NCINCTNDataArchive@mail.nih.gov](mailto:NCINCTNDataArchive@mail.nih.gov) with any questions about data from a specific trial.

**Can I use data from the Archive to develop a product or invention?**

Any product or invention developed using Archive data must adhere to all terms of the Data Use Agreement (DUA). Among other activities prohibited by the DUA, Archive data cannot be embedded in a product that is intended for use beyond the DUA’s effective date (3 years) and Archive data cannot be made accessible

to anyone not included as an Other Approved User in the DUA, including through access to a product in which Archive data are embedded. The complete terms to which projects using Archive must comply can be found in the sample Data Use Agreements on the [Archive homepage](#).

## **V) Questions and Comments**

For questions or comments about the NCTN/NCORP Data Archive or any requests placed through the system, including inquiries regarding the status of a data request, please contact [NCINCTNDataArchive@mail.nih.gov](mailto:NCINCTNDataArchive@mail.nih.gov).