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.

 PROJECTS	STUDIES	DMSPs	GDSPs 111	ICs 21		
Open Pro	ojects					
Keyword S	iearch	۹				Create a New Project
All						

STEP 2: Complete the Project Information

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

*	Project	Title	
*	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.

* PI			
abid			٩
Abid Rehman	NIA IRP LG RRS	abid.rehman@nih.gov	^
Abid Reza	NCI CCR CGB	abid.reza@nih.gov	
Abidemi Ola	NIAID VRC CTP	abidemi.ola@nih.gov	
Eissa Alzabidi			
Mahnoor Abid	NIAID DIR LHIM MIS	mahnoor.abid@nih.gov	
Mahrukh Abidi	NCI OD CBIIT OD	mahrukh.abidi@nih.gov	
Matteo Abideni		matteabi@gmail.com	
PI Branch	NO BOTD OTED CTOID		•

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

ail	
d.reza@nih.gov	
e	
one	
240 858 7909	
nch	
CCR CGB	

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

o Organism

* Organism Type			
None			
	م		
None			
Human			
Non-Human			
Both Human and Non-Human			
Mouse			
Rat			
Model 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

Parent	³ arent Protocol					
* Prote	scol ID					
	Select the Parent Protocol/Project from the dropdown list. Text input will					

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

Parent	Protocol		
0	000081 *		*
* Prote	1	C	٦
	000144		•
	000176		į.
* Stud	000193		
	000194		
	000199		
* Abbr	000211		
	000218		Ŧ

 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.

× v

• For more information about the selected protocol, click the "①" button



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

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Protocol		Study Title	Close Window
Protocol ID			
		Data Deposited	
Abbreviated Title			
		Soudy registered	Ţ
Principal Investigator		Descriptions (Newlorith	
		Mpomery study to	
Primary Branch		Omenium	
	*	Human	•
Study Status		lournal Mandate	
N/A	*	No	Ŧ
21A		Lead Investigator	
GDS Answer		Non-compliance letter sent	
No	*	No	¥
GPA Review		Associated Project IDs	
тво			
GSR		Cell Line	
- None	*	No	٣
GDSP Submitted		CTEP	
nu		No	*
IC Submitted	T.	Audit	
10			
Source			
		Exception Request	
		Exception Granted	Ţ
Activity			
Type your message here		Po	st
			_
04/19/2021 13:43:33			
		art	
PI Branch			
			_
Delete		Save (Ctrl	s)

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

* Study	/ Title
*Abbre	eviated 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.

o ZIA number

LA		

- 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

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

STEP 3: Establish Collaborator Access

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

Collaborator Access		
Collaborators (Read Access)	Collaborators (Edit Access)	

- 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.

o Consider including your Protocol Coordinator from the Protocol Support Office

STEP 4: Select Save

Submit
Required information Project Title PI Protocol ID Study Title Abbreviated Title

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.

 IC DMSP 1			
IC			
		-	Create a New IC
IC ID	Project Title for Data to be submitted	Certification Date	Status

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 were collected with or without consent (Yes/No)

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

* Certification Date	*Name of Institution	
* Organization of GPA	* Organization of SD	
v		Ŧ
* Original Study Name		
* Project Title for Data to be submitted		
Kathy Test 3	×	•
Data are made available through		
Controlled-access	,	*
Controlled-access		
Check the box above if the genomic summary results (GSR) from this study are only to be made	e available through controlled-access.	

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

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

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

Data are made available through	
Controlled-access	*
	٩
Unrestricted	
Controlled-access	
Delection Commente	

Note: Human studies are controlled access

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

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

*Sensitive study populations are considered those that may have heightened privacy risks or have other restrictions on the use of the data, e.g., populations from isolated geographic regions, affected with rare or potentially stigmatizing traits and/or diseases, or populations with data restrictions. [#]The Trans-NCI Genomic Data Sharing Working Group has adopted the following definition of rare disease – a disease that affects **less than 200,000 persons** in the United States, that has been <u>set forth</u> 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.

Consent Group Approvals	
Consent Group	
	New
	New
No records in Consent Group using that filter	•

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.

*IC	
CCR_IC0348308 X	•
*Collaborating Site Name	
*Data Use Limitations	
None	•
Data Use Limitation Modifiers	
Submit Required information Collaboration Site Name Data Vise Limitations	

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

In case you selected "Other" for the Data Use limitation field,

* Data Use Limitations	
Other	*
	٩
None	
General Research Use	
Health/Medical/Biomedical	
Disease-Specific	
Other	

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

* Specify Other			

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

Submit
Submit

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.

NATIONAL	an infra-resignated reportery. To the National Institutes of Health (NIH), U.S. Department of Health and Human Services (HHS):	Ramaprasad Srinivasan 👻
PROJECTS DMSP	The submission of data to the NIH-designated data repository is being made with Institutional approval from NCI , along with appropriate institutional approvals from	
Yes	collaborating sites, as listed here:	
* Is the individua	NCI	
Yes		•
Controlled-a		
Check the box al	The NCI hereby assures that submission of data from the study entitled	
Principal Investig	to an NIH-designated data repository meets the following expectations, as defined in the <u>NIH Genomic Data Sharing (GDS) Policy</u> (NIH Guide	
Ramaprasad Si	 Notice Number NO1-OD-14-124): The data submission is consistent, as appropriate, with applicable national, tribal, and state laws 	
Save	and regulations as well as relevant institutional policies.Any limitations on the research use of the data, as expressed in the informed consent documents,	Delete
Annroue and Sign	Type signature Draw signature	
approve and only.	Full name	
Consent Group		
	This constitutes your electronic signature and has the same legal impact as signing a printed version of this document.	
Consent	Close Accept and complete	O BACK TO TOP

- Enter your name.
- Click the "Accept and Complete" button.

STEP 5: Review and Approval

- GPA review and approval
 - \circ $\;$ 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.

DMSP 👔			
DMSP			
		_	Create a New DMSP
Project ID	Investigator / Project Lead	DMSP ID	Status

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

DMSP ID	Investigator / Project Lead	
	Kathleen Calzone	Ŧ
Status	Project / Project Title(s)	
None *	Kathy Test 3 X	Ŧ
	*ZIA Number(s)	
	ZIA12345	
	Organism Type	
Data Type Related Tools, Data Standards Data P Software and/or Code	reservation, Access, Access/Distribution/Reuse Other Elements & Timelines Considerations	
Labratory data types produced by project	Approximate Amount of Data	-
Clinical data types produced by project	Measurement of Data	
	None	Ŧ
Data Generated From	Data Files to be Produced	
Number of Research Participants/Specimens/Experiments	Raw Data Transformation by	
Number of Datasets Generated	Data Made Available to Share	
	List of Data to be Preserved and Shared	
	Considerations influencing Preserved and Shared Data	
	Data types shared to facilitate interpretation of the data	
Save		

STEP 2: Complete the Data Type fields

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

Data Type	Related Tools, Software and/or Code	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements
Labratory data types pr	roduced by project		Approximate Amou	nt of Data	
Clinical data types prod	luced by project		Measurement of Da	ta	
			None		v
Data Generated From			Data Files to be Pro	duced	
Number of Research Pa	rticipants/Specimens/Experime	nts	Raw Data Transform	nation by	
Number of Datasets Ger	nerated		Data Made Available	e to Share	
			List of Data to be Pr	eserved and Shared	
			Considerations influ	iencing Preserved and Shared Data	
			Data types shared to	o facilitate interpretation of the data	
Save					

• Select Save before moving to the next tab.

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

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

Data Type	Related Tools, Software and/or Code	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements
Will specialized tools be	e required to access or manipul	ate the data?			
None					•
Specialized Tools Requi	ired to Access				
Specify how to access s	pecialized tools				
Data Format					
Save					

• Select Save before moving to the next tab.

STEP 4: Complete the Data Standards fields

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

Data Type	Related Tools,	Data Standards	Data Preservation, Access,	Access/Distribution/Reuse	Other Elements
Software and/or Code		Note: Please use the NCI CDE resource list to identify the CDEs that	Considerations		
Select all Common Dat	ta Elements (CDEs) that will be u	sed. Justify if not used	will be used https://cdebrowser.nci.nih.gov/cdeb rowserClient/cdeBrowser.html#/sear ch		
State additional comm	non data standards to be applied	to the data & metadata			

• Select Save before moving to the next tab.

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

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

Data Type	Related Tools, Software and/or Code	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements						
Name of repository(ies) where scientific data and metadata will be archived											
Describe how the scientific data will be findable and identifiable											
When and how long dat	a will be available to other user	s?									
Save											

• Select Save before moving to the next tab.

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

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

Actors affecting subsequent access, distribution, or reuse of scientific data Human data protection method Lata are made available through Genomic Summary Results are made available through	Data Type	Related Tools, Software and/or Code	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements
ata are made available through Genomic Summary Results are made available through	actors affecting subse	equent access, distribution, or re	use of scientific data	Human data pro	tection method	
	Data are made available through			Genomic Summ	ary Results are made available through	

• 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.

Data Type	Related Tools, — Software and/or Code —	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements
Other elements					
None					v
Save					

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

Data Type	Related Tools, — Software and/or Code —	Data Standards	Data Preservation, Access, & Timelines	Access/Distribution/Reuse Considerations	Other Elements
Other elements					
Other					v
* Specify other elemen	ts				
Save					
Required inform	nation Specify other elements				

• 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.

NIH NATIONAL CANCER INSTITUTE										
PROJECTS	STUDIES	DMSPs	GDSPs 111	ICs 22						
		≡ CCR_DMSP000	01007						0	
		Attachments Ed	it Management and Sha	ring Plan.pdf						
_		DMSP ID				Investigator / Project Lead				
		CCR_DMSP000100	7			Kathleen Calzone		×	¥	
		Status				Project / Project Title(s)				
		Ready for SRC Review	v		Ψ	Kathy Test 3		×	٣	

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

PROJECTS	S STUDIES	DMSPs	GDSPs 🏨	ICs 🙋				
	CCR_DMSP00010	07						
	Attachments Edit	nagement and Sharir	g Plan.pdf					
	DMSP ID					Investigator / Project	Lead	
	CCR_DMSP0001007					O Kathleen Calz	one	×
	Status					Project / Project Title	(a)	
	Ready for SRC Review					Kathy Test 3		×
						*ZIA Number(s)		
						ZIA12345		
						Organism Type		
						× Human		
	Data Type	Related Tool Software and/or	s, Data Code	Standards	Data Prese & T	rvation, Access, Imelines	Access/Distribution/Reuse Considerations	Other Element
	Labratory data types pr	oduced by project				Approximate Amoun	t of Data	
	× Whole Genome Sec	uencing X Whole	me Sequencing			5		

• 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

NIH NATIONAL CANCER INSTITUTE									
PROJECTS	STUDIES	DMSPs	GDSPs 111	ICs 22					

- 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.