HSC Sponsored Projects Date Use/Share Agreements in Click



MA BEALTH SCIENCES THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES

Data Use Agreement (DUA) Process Flow

Data Use Agreement Procedure



NY BEALTHES THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES

DUA Questionnaire

- DUA's are initiated through the HSC Sponsored Projects Office. You will need to:
 - Complete the Data Use Questionnaire located: (WILL PROVIDE ONCE PILOT PERIOD IS COMPLETE)
 - You will then need to create a record in Click Agreements and upload the fully completed questionnaire under "Data Screening Questionnaire" It
 is highly important that all relevant questions are answered thoroughly. You can refer to the DUA Questionnaire reference guide for definitions
 and examples. Alternatively, you can work with your collaborator to ensure the most accurate information.
 - Once the record has been submitted, the DUA SPO Specialist will review the questionnaire to verify the need of a Data Use Agreement. If it is
 determined an agreement is needed, the SPO DUA Specialist will draft the agreement based on the information provided in the questionnaire. At
 this time, if you will be sharing/receiving human subject data, you are encouraged to submit your IRB protocol. The information you provide in the
 data questionnaire should be the same information you include in your IRB protocol.
 - The data use agreement will then be sent to Privacy and IT security for their reviews. If they have questions, they will contact you directly. Once their reviews are complete, they will advise the DUA SPO Specialist on whether to proceed or make suggested changes.
 - SPO will send to PI for final review/approval PI will approved in Click Agreements through an "ancillary" review
 - SPO will then send to the collaborator for review this will occur via email
 - Once the collaborator approves, SPO will obtain all signatures and send a fully executed copy to you
 - Once you receive the executed DUA, if you have not done so already and this involves human subject data, you will need to submit your IRB
 protocol and attach the executed DUA. Please remember, although you have an executed DUA, you CANNOT share/receive data until your IRB
 protocol has been approved.

The following slides will explain how to create a Click Agreements record for your DUA request.



Creating a New DUA Record (Logging in)



If you do not have a Click Account, you will need to take the CLICK Electronic Research Administration Lecture in Learning Central: Course HSC 135 in order to obtain an account.

If you do have a Click Account but have never used Agreements, you will need to request a user role by emailing <u>HSC-</u> <u>PreAward@salud.unm.edu</u>

Click Agreements URL: <u>https://era.health.unm.edu/Agreements</u>

If you encounters issues logging in, you can contact: Sean Gonzales, <u>Sgonzales@salud.unm.edu</u>, 505-272-3495 or <u>HSC-Preaward@salud.unm.edu</u>

MA BEALTH SCIENCES THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES

Creating a New DUA Record (Agreements)



MA HEALTH THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES

Creating a New DUA Record

	»	My Inbox		COI		Grar	its	Agreements
	Agreements	Home Help	Center Reports					
Agree	ments	All Agreements	Unassigned New	In Progress	Active	Evergreen	Archived	
Crea	le Agreement	Filter by 😧 ID Once you are tab, click on "(in the "Agreements" Create Agreement" to	ext to search for		Q + Add f	Filter 🗙 Clear All	1



Creating a New DUA Record



HEALTH SCIENCES

Creating a New DUA Record



NA HEALTH

Creating a DUA Record (General Info)



Creating a DUA Record (HS & AS Research)

Validate 🕰 Compare	You Are Here: Data Transfer - TEST - TEST -				
Agreement Upload	Editing: DUA0000574				
General Information Human Subjects and Animal Research	Human Subjects and Animal Research	If your DUA has human subjects, select "yes." If "yes" see below. If not, select "no" and move	is selected, the form will branch out – e on to the Question 2.		
Export Control Completion Instructions	 2. * Is this agreement tied to Animal Research? Ores No Clear 3. Describe the purpose of the exchange: The purpose of this exchange is to receive patient data for pregnant women, de-identified, in order to research correlations between the number of healthcare visits, reported diet, and family genetic history with the likelihood of developing pre-eclampsia. TEST - TEST - TEST - TEST - TEST RECORD 		Indicate if your project is "exempt" from HS research, had not yet been submitted (its encouraged to submit your IRB protocol at this time), is Pending, or if your IRB protocol related to this research has been approved. You will also need to indicate if you will be sharing or receiving PHI. If Yes, the		
	4. ★ Will Data be Incoming/Outgoing? Both Incoming Outgoing <u>Clear</u> 5. Upload data screening questionnaire: Data Questionnaire(0.01) ····	c. * Check the appropriate boxes below: UNM will receive from sponsor All PHI is de-identified Exchange will be mutual UNM will exchange with sponsor Indicate your response above. If it is unclear which option you should select, you can in the Data Use Questionnaire reference guide: (WEBSITE LINK HERE)			
	6. * Is the transaction related to a funded agreement? • Yes O No Clear				

NA HEALTH

Creating a DUA Record (HS & AS Research cont.)



Creating a DUA Record (Export Control)

E Validate O Compare «	You Are Here: 📸 Data Transfer - TEST - TEST		
Agreement Upload	Editing: DUA00000574	🕯 Go to forms menu 🔒 Print 👻 🔞 Hel	As PL you will need to answer the questions to the left
General Information	Export Control		regarding Export Controls. You should know if
Human Subjects and Animal Research			engagement in your project will includes these
Export Control	2. * Does This Project Involve Select Agents or Select Toxins Of Any Amount: Yes No Clear		components, especially if sharing/receiving data from a foreign collaborator and/or if a non US citizen will
Instructions	3. * Foreign National: O Yes No Clear		handling the data. If a question is unclear, you can request
	4. * Has Dual Citizenship: O Yes No Clear		assistance by emailing HSC-DUASPO@salud.unm.edu
	5. * Has Foreign Collaborators: O Yes No Clear		
	6. * Has Restrictions On Publications: O Yes No Clear		
	7. * Has Foreign Owned Funding: O Yes No Clear		If the response is "yes" to any of these question, you will be
	8. * Involves Foreign Travel: O Yes No Clear		prompted to complete an Export Control Exclusion Screening Form
	9. * Has Proprietary Information: Yes O No Clear		which can be downloaded by clicking on the arrow.
	10. * Contains FAR Clause 48 CFR 1852.223-74 - Drug and Alcohol-Free Workforce?: O Yes No Clear		You will then upload for SPO submission to the export control
	11. * Has Security File (TCP): O Yes No Clear		committee for review and clearance.
	12. * Download, complete and sign the Export Control Exclusion Screening Form (ECES) if any of the above were answ	ered Yes. 🛓	Click "save" and "continue"
	Attach Here:		
	None] ± Upload		
	© Exit	Continue	
HEALTH SCIENCE	es the university of Ne	EW MEX	XICO HEALTH SCIENCES

Creating a New Agreement

E Validate Compare

Agreement Upload

General Information

Human Subjects and Animal Research

Export Control

Completion Instructions

You Are Here: 📄 Data Transfer - TEST - TEST -

Editing: DUA00000574

Completion Instructions 💡

You have reached the end of the Agreement form. Read the next steps carefully:

1. Click Validate to verify that all required questions in this Agreement form are answered.

2. Correct any errors or omissions and refresh the error report.

3. When no errors are reported, click Finish to exit the form.

4. From the workspace, click Submit to send the Agreement for review.

You have successfully created your DUA record. Please allow 3 business days for initial review of request. If there are any questions with the data provided, the SPO DUA Specialist will reach out to you.

B Save

Finish

🕴 Exit

Whew, now we are done with the smartforms! Be Sure to click "Finish"! Instruction to submit are on the following slides

HEALTH SCIENCES

Click DUA Record Dashboard

This screen serves as a dashboard for your new record. You can:

- 1. View summarized data regarding the project
- 2. View the status of your DUA request
- 3. Complete actions as necessary
- 4. Assign PI Proxies if you are unavailable
- 5. Copy the agreement
- Manage relationships connecting your DUA to a funded agreement and/or IRB protocol

We will take a closer look at some of these items in the following slide.

Dashboard	Agreemer	its	COI	IRB	Grants	Contact Us			
Agreements	Help Cent	er Rep	orts						
Agreements > Data Tr	ansfer - TEST - TE	ST - TEST							🕑 Help
Pre-Submit Primary contact: Stacy Manager/Pi: Stacy Owner: 10/8/2 Received: 10/8/2 Effective: 2 Poster Steps Edit Agreeme	Catanach Catanach 1024 8:46 AM 1024 1:36 PM	UA00000574 Data T Greement: inal agreement inal agreement ontracting particular Pre-Submissio	ant: ransfe nt: AAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAAA	Unassigned	DER	- TEST	Agreement type: Data U https: Unfunc tesponsible lescription: Test - 1 igning Active	Ise Agreement led Agreements Office and Services HSC Test - Test	
Printer Versic	n i	Correspondenc	e Histor	v Contacte	Snanshote	Documente			
View All Correspor	ndence	Corresponde	ence To Do	y contacto	onuponoto	Documents			
A Submit		Filter by 😧	Due Date	Enter te:	d to search	٩	+ Add Filter × Clear All		\$
Manage Ancillary F	Reviews	ue Date	Ow	ner Typ	e Status	For Person	Summary	Date Modified	2
Assign PI Proxies						No data to	display.		
Ø Discard	(Corresponde	ence Comp	leted					
Copy Agreement		Filter by 🔞	Due Date	Enter te:	d to search	٩	+ Add Filter X Clear All		\$
		ue Date	Ow	ner Typ	e Status	For Person	Summary	Date Modified	
% Manage Relations	nips								

NO data to display.

DUA Dashboard (Main Functions)



DUA Record (Managing Relationships)

Once "manage relationships" is selected on the p screen, the following will pop-up (ensure pop-up on your browser). Click on the ellipsis below to fin you would like to relate	previous s are allowed nd the project	Lorende Makeage Kalatienships ⁴ as Statisscontoxic - Luchward - Municed Edge - -
Related Projects: ID Name PI First Name PI Last Name There are no items to display 2. Comments:	"Filter by" allows you to search for your project in multiple ways. If you know the record number, you can search by "ID" by changing the filter.	Select One or More Integration Projects Filter by Project Type Imn% Co Clar Description Project Type Imn% Co Clar Three are no items to display
3. Supporting documents: + Add Name Description There are no items to directory	Otherwise, you can search by "project type." To see funded	(BrAIST III) Radographic Status of Stubjects and Change in HISC-20037 Cobbangle at a Minimum of 2 Years After BirAIST ED0001572 (PENUT) Robin (Not Onlie Funding Austriand
There are no nems to display	projects, type fun% and it will bring up a selection. Find your project, check the box and click "ok'	Cisted and the second of the
MA HEALTH THE UNIVER	STLY OF	NEW MEXICO HEALTH SCIENCES

DUA Record (Finding Relationships)



HEALTH SCIENCES

DUA Review - Communications



HEALTH SCIENCES

DUA Review – Communications cont.



NO HEALTH SCIENCES

Department: How to Respond to an Ancillary Request (PI Approval)

	H SC-PreAward@salud.unm.edu To: ⊙ Stacy M Catanach Tue 10/8/2024 5:25 P	Ir	iternal Review	DuA00000574 Data Transfer - TEST - T	TEST - TEST			
	[[External - this message has been sent from outside the University]]	Primary Manage Owner: Created Receive	contact: Stacy Catanach hr/PI: Stacy Catanach Stacy Catanach 10/8/2024 8:46 AM d: 10/8/2024 2:34 PM d: 10/8/2024 2:35 PM	Agreement: Final agreement: Contracting party: AAAA TEMP PLACEHOLDER		Agreement type: Office: Responsible Department/Division/Insti Description:	Data Use Agreement Unfunded Agreements Of itute: Pre-Award Services HSC Test - Test - Test	fice
	Notification of Ancillary Review	Effectiv	1. 10/6/2024 5.25 PM 9:					
	To: Stacy Catanach Link: DUA0000057 PI: Stacy Catanach Title: Data Transfer - TEST - TEST - TEST Required: Yes	Expires Next	Steps Edit Agreement	Pre-Submission Unassigned Clarification Requested	In Review Clarification Requested	Signing	Active	
	Description: An Agreement submission has been assigned to you for ancillary review. Click the link above to access and		Printer Version	Ancillary Reviews				
<	Comments: Please review the attached DUA. Once approved, SPO will send to the collaborator for review/consideration. Thank you.	Vie ▲ Ass ① Unit 營 Mai	w All Correspondence lign Owner issign Owner hage Ancillary Reviews hage Access	Review type Organization Department	Person Stacy Catanach Stacy Catanach Laura Putz	yes yes no	Notice how you can view where the agreement is in the process	nts
	You will receive a notification similar to that above. You will click on the link under "Supporting Documents" to view the "draft" DUA.	Sut	mit Ancillary Review	Surespondence History Contacts Sn	apshots Documents			
_	Once you have reviewed, you will need to click on the link: DUA00000 To log in to Click (if not already logged in) and complete the Ancillary Review process. It will take you directly to the record.	T	o approve the d ee next slide, wi	raft DUA, you will Click "Submit ill appear. Please ensure your br	Ancillary Review. owser is set to all	" A new pop-u ow for pop-up	ıp window, ıs.	
	This method allows all approvals to remain transparent and viewable in the Click (Note: Unfortunately these notifications are restricted from being modified by the Vendor (Huron) and they will only provide minimal direction.							
	NM SCIENCES THE UNIVERSITY OF I	NEV	V ME	XICO HEA	LTH S	SCIEN	NCES	

Department: How to Respond to an Ancillary Request cont.

Submit Ancillary Review 1. * Select the review you are submitting: Required Organization Review Type Check the appropriate box for you as the reviewer ~ Stacy Catanach Department ~ Stacy Catanach Department yes 2. * Do you accept the proposed agreements? If you accept the proposed agreement, click "yes." • Yes O No Clear If you require changes, click "no" and proceed to the "Comments" section 3. Comments: < Agreement looks good - please proceed to sending to collaborator If you selected "no" to Question 2, please indicate the reason in the Comments section. Once you Click "ok" the review will be routed back to SPO to update your agreement. You will be sent another ancillary review to review the updated agreement. 4. Supporting documents: + Add Name There are no items to display Click "ok" to submit back to SPO Cancel THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES

Status of Agreement



HEALTH SCIENCES

DUA Executed – Now what?

Once the collaborator signs the DUA, SPO will route for internal signature. The DUA will require the HSC VPR signature.

Once this signature is obtained, SPO "activate" the DUA in Click Agreements.

A copy of the executed agreement will be sent to you and the IRB. You will be responsible for ensuring you have initiated your IRB protocol and attached the executed DUA. Please remember, not data can be shared/received without an approved IRB Protocol. The DUA Process within SPO is now complete. So what actions can you take in your record once it is active?

If a change is required (i.e. additional data elements need to be added) you can select "Create Amendment." This will trigger SPO to initiate the amendment.

If you have questions regarding the executed DUA, you can contact SPO by selecting "Contact Owner."

If you are going to be unavailable (i.e. sabbatical) you can assign a proxy to handle any concerns by selecting "Assign PI Proxies"

If you are going to initiate a similar agreement, you can select "Copy Agreement." By doing this, you will not have to enter all the same information again.

If you didn't have a funded agreement related to this DUA at the time of initiation but now do, you can relate it this DUA by selecting "Manage Relationships."

	AC	
Cre	eated by:	Emily Altman
Agi	reement Manager:	Emily Altman
Ow	ner:	Susan De Los Santos
Cre	eated:	4/19/2021 6:38 PM
Re	ceived:	4/23/2021 10:46 AM
Mo	dified:	4/28/2021 10:13 AM
Effe	ective:	4/23/2021
Exp	pires:	4/22/2022
Ne	ext Steps	
	View Agreer	nent
	View Agreen	nent
	View Agreer Printer Vers	nent
	View Agreen Printer Vers View All Corresp	nent iion ondence
	View Agreen Printer Vers View All Corresp Create Amendme	nent ion ondence
	View Agreen Printer Vers View All Corresp Create Amendme Contact Owner	nent ion ondence
	View Agreen Printer Vers View All Corresp Create Amendme Contact Owner Assign PI Proxies	nent ion ondence
	View Agreen Printer Vers View All Corresp Create Amendme Contact Owner Assign PI Proxies Copy Agreement	nent ion ondence ent

Streamers The University of New Mexico Health Sciences

DUA Record ("Other" Tabs)

Correspondenc	e History Contacts Sna	pshots Documents						The "Other" tabs	s on the DUA re	ecord dashb	board ref	lect the following:
orresponde	ence To Do											
Filter by Ø	Duo Data	rah (Correspondence	:Reflects corre	espondence	recorde	b
Filter by	Due Date	ch										
ue Date	Owner Type	Status For Perso						History: Reflects	all actions tha	t have occu	rred sinc	e inception of the
	Correspondence History	Snapshots Documents						record. Provides	a timeline of	events.		
	Filter by 😧 Activity 💌 Enter t	text to search	+ Add Filter × Clea	rAll								
	Activity	Author		- Activity Data				Contacts: Shows	all personnel e	entered rela	ated to th	is project
		Correspondence History Contacts	pshots	Documents			1 I					
	Thank you - yes Patient Name needs to be add	Owner					· – I	Snapshot: Provid	les a snapshot	of change n	nade in t	he record
orrespond	Clarification Requested	Name	Organization	E-mail		Phone	1 I I					
Filter by Ø	Can you please confirm the data elements you I	Stacy Catanach	Pre-Award Servic	es HSC scatanach@salu	d.unm.edu			Documents: Prov	vides links to d	ocuments t	hat have	been uploaded
-inter by •	Thanks	Contracting Party					through the record.					
ue Date	Submitted Ancillary Review	Name	Contact	E-mail		Phone						
	Managed Ancillary Reviews	AAAA TEMP PLACEHOLDER	Albert Einstein	AlbertEinsten@b	raniac.com	505-222-2222	- I					
		Agreement Manager/Principal Investig	pator									
		Name	Organization	Correspondence	History	Contacts	Snapsho	bocuments				\sim
		Stacy Catanach	Pre-Award Servi						Correspondence	History Co.	macts Sn	Documents
		Primary Contact		Version					Documents			
		Name	Organization	A Spanshot 0.2/0	01)				Project	ID N	lame	File (Final)
		Stacy Catanach	Pre-Award Servi	@ Shapshot. 0.3(0.	01)				_			
				Snapshot: 0.2(0.	01)							
												No dat
												ø page 1
									Data Screening Que	stionnaire		
									Data Questionna	aire(0.01)		

MA HEALTH SCIENCES THE UNIVERSITY OF NEW MEXICO HEALTH SCIENCES