

# Using the Kuali Negotiation Module to Submit Research Agreements for Review

If you are unable to log into Kuali or do not have access to the Negotiation Module, please contact the Clinical Trials Office at <u>CTO@lsuhsc.edu</u>.

### **INITIAL SUBMISSION & REVIEW**

- 1. Sign into Kuali:
  - a. Individuals WITH an LSUHSC email account: https://lsuhsc.kuali.co/
  - b. Individuals WITHOUT an LSUHSC email account: https://lsuhsc.kuali.co/auth/kuali
- 2. On the main page, click **Research Home**.

KUALI	Kuali				
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		Research Home	Conflict of Interest	Protocols	
		<b>±</b>	••		
e Alam, Jawed		Users	Groups		
じ Sign Out					

3. You will be directed to your Dashboard. Click **Common Tasks** on the sidebar menu. If the sidebar is not fully displayed, click on the arrow at the bottom of the sidebar to un-collapse the menu.

KUALI RESEARCH	Dashboard				Show/hide cards
Dashboard					
Q Search Records	Proposals routing to me	Sort by 🗸	Proposals not	routing	Sort by 🗸
<ul> <li>Common Tasks</li> <li>All Links</li> </ul>			Proposal	Proposal #1 – PI: admin, admin – Sponsor: NIH – Title: Demo – Lead ur Due date: 12/20/19 Last action: Admin, System; 11/25/19 10:11 AM	it: 000001
1. Reports			Proposal	Proposal #3 – PI: admin, admin – Sponsor: National Institutes of Health Due date: 11/30/19 Last action: Admin, System; 11/25/19 10:29 AM	- NIH – Title: Demo – Lead
Conngulation	All Clear!		Proposal	Proposal #4 – PI: admin, admin – Sponsor: NIH – Title: Proposal Test – Due date: 12/20/19 Last action: admin, admin; 12/09/19 10:07 AM	Lead unit: 000001 Compliance
			Proposal	Proposal #5 - PI: admin, admin - Sponsor: NIH - Title: Demo - Lead un Due date: None Last action: admin, admin, 12/13/19 1:30 PM	it: 000001
		0-0 < >	Proposal	Proposal #6 - PI: admin, admin - Sponsor: NIH - Title: Test Proposal - Due date: 12/21/19 Last action: Admin, System; 12/19/19 1:52 PM	Lead unit: 000001
					1-5 of 23 < >
	Negotiations				Sort by ${\scriptstyle\checkmark}$
O Help D	Negotiation         Negotiation #5 - Negotiator: Jawed Alam - Agreement Type: Non-I           (Overdue)         Show activities         Last action: Alam, Jawed; 3/09/20 10:00 AM	Disclosure Agreement - 3/09/20			

#### 4. Click Create Negotiation.

KUALI RESEARCH	Common Tasks						
<ul> <li>Dashboard</li> <li>Q Search Records</li> </ul>	Quick Links	соі	Institutional Proposal	Negotiation	Proposal Development		
<ul> <li>Common Tasks</li> <li>All Links</li> <li>Reports</li> <li>Configuration</li> </ul>	Action List     Doc Search     Current & Pending Support     Person Training     View 525 Submissions     Locks	My Disclosures	Create Institutional Proposal Create Proposal Log Search Institutional Proposals Search Proposal Logs	All My Negotiations Create Negotiation Search Negotiation	All My Proposals Create Proposal Search Proposals		
	Protocols Manage Protocols						

5. On the Negotiation Document page, the **Negotiation ID** and **Initiator** of the Negotiation will be listed in the top right-hand corner.

KUALI RESEARCH	Kuali Research	
<ul> <li>Dashboard</li> <li>Search Records</li> </ul>	Negotiation Document o	Doc Nbr: 3447 Status: INITIATED Negotiator Username: Negotiation ID: 8 Initiator: jalam Created: 05:50 AM 01/27/2021
Common Tasks	Negotiation	
Ge All Links	₩ Unsaved changes will be lost.	expand all [ collapse all

6. In the Document Overview section, enter a **Description** of the document such as *"new data use agreement."* An **Explanation** is not required but may be completed if you wish.

Fields marked with an asterisk require an entry. Other fields are optional.

	Document Overv	ew	▼ hide				Ĭ
	Document Ove	view					
⑦ Help	* Description:		new data use agreement	$\supset$	Explanation:	æ	
(i) About	Organization Docu	ment Number.			$\smile$		

#### 7. In the Negotiation section:

a. Click on the down arrow for Negotiation Status and select from the available options.

🕝 Common Tasks	Negotiation 8	0
GÐ All Links	* Negotiation Status: Progress V Negotiation Dates: Start: 01/27/2021	
IL Reports	select Complete * Negotiator: 1h Progress Negotiation Age in Days: 0	
Configuration	Suspended Terminated	
	* Agreement Type: select  Anticipated Award Date:	
	Document Folder:	

b. Click on the look-up button for **Negotiator**. In the context of Kuali Negotiations, the Negotiator is the primary reviewer of the agreement in the Office of Research Services (ORS), the Office of Innovation and Partnerships (OIP), or LCMC Health/UMC as described in the table below.

Agreement Type	<b>Responsible Office</b>	Negotiators
Material Transfer Agreement (MTA)	OIP	"Innovation Partnership"
Non-Disclosure Agreement (NDA)	OIP	"Innovation Partnership"
Data Use Agreement (DUA)	СТО	"Clinical Trials"
Clinical Trials Agreement (CTA)	СТО	"Clinical Trials"
Other Research Agreements	СТО	"Clinical Trials"

🔅 Configuration	Negotiation 8
	* Negotiation Status: In Progress Negotiation Dates: Start: 01/27/2021
	Negotiation Age in Days: 0
	* Agreement Type: Select   Anticipated Award Date:
⑦ Help	Document Folder:

- c. You will be directed to the Person Lookup page. Type in the name of the Negotiator.
  - i. Only one negotiator may be listed.
    - For CTO, type "Clinical" as the first name and/or "Trials" as the last name.
    - For OIP, type "Innovation" as the first name and/or "Partnership" as the last name.
  - ii. Click search.
  - iii. Select the correct person from the table that appears at the bottom of the page by clicking "return value."

K	Kuali Researc	h									
	KcPerson Lo	ookup₀					lon			,	required field
•					KcF La Fir	st Name st Name st Name					
					Us Email	Address:					
					Offic	Active: O Ves O No O Both					
					н	Active: Tes O No O Botti	<b>Q</b>				
					Came	uus Codeu					
	One item retrieved.				Camp	search clear cancel					
0	Return Value	KcPerson Id	Full Name	User Name	Email Address	Directory Department	Directory Title	Office Location	Office Phone	School	Active
(i)	return value	cto	Clinical Trials	cto	CTO@lsuhsc.edu						Yes
() (5) Ⅲ >	Export options: CSV   sp	preadsheet   XML									

- d. The **Negotiator** field will be populated with the individual selected.
- e. Click on the down arrow for Agreement Type and select from the available options.

Configuration	Negotiation 8	Θ
	* Negotiation Status: In Progress V Negotiation Dates: Start: 01/27/2021	
	Negotiator: grants-no     Grants Office     Negotiation Age in Days: 0	
	Agreement Type: select      Anticipated Award Date:	
🔿 Help	Document Folder:	
<ol> <li>About</li> </ol>	* Negotiator: Cto S Neg Clinical Trials	
U Logout	* Negotiation Association Type: select  V Negotiation Association ID:	

f. Click on the down arrow for Negotiation Association Type and select "None".

GƏ All Links	
il. Reports	Negotiation
🔅 Configuration	Negotiation 8 o
	* Negotiation Status: In Progress V Negotiation Dates: Start: 01/27/2021
	Negotiator:     Clinical Trials     Negotiation Age in Days: 0
	* Agreement Type: Data Use Agreement V Anticipated Award Date:
⑦ Help 🖸	Document Folder:
(i) About	Negotiation Attributes.
ப் Logout	Negotiation Association Type: select      Negotiation Association ID:
🕤 Alam, Jawed 🛛	select Award Institutional Proposal
III Switch Apps	Activities & Attachments Propagal Log Subaward

g. When "None" is selected, additional fields will appear. Although entries are not required, we ask that you enter the Title of the associated project, the PI name, the Admin Person name, and the Sponsor. Use the look-up function to retrieve the PI name, Admin name, and Sponsor.

	Negotiation Attributes:			
	* Negotiation Association Type: None	~	Negotiation Association ID:	
	Title:	æ	Lead Unit:	9
	Principal Investigator Employee:	۹	Principal Investigator Non-Employee:	۹ 💷
	Admin Person:	۹		
	Sponsor:	۹ 🕮	Prime Sponsor:	9
@ Help 12	Sponsor Award ID:		Subaward Organization:	9 🕮
(i) About	Activities & Attachments			

- 8. In the Activities & Attachment section:
  - a. Click on the **Show/Hide** button to reveal the various subsections.
  - b. Click the Show/Hide button for Add Activity to reveal additional fields.
  - c. Select the Location where the activity will take place. For instance, initial review of MTAs and NDAs would occur in OIP whereas initial review of CTAs, DUA and other research agreements would occur in CTO.
  - d. Click on the down arrow for Activity Type and select from the available options. For example, if submitting a new DUA for initial review, select *Review Initial Agrmt*.
  - e. Select the Activity Start Date, typically the day of submission.
  - f. Provide the Activity Description. If a hospital is involved, include the hospital information here.

Dashboard	Activities & Attachments	
Q Search Records		
🙆 Common Tasks	Hole Add Activity	0
🕤 All Links	Location: Clinical Trials Office     Activity Type: Review Initial Agrmt	Number of Days: 0
1. Reports	Activity start Date: 01/27/2021 Activity End Date:	Create Date:
🔅 Configuration	Follow-up Date:	Last Update By:
	* Activity Description: Please review the draft DUA from Ochsner for the study noted above.	

g. Choose the Attachment and provide a brief Description of the attachment.

🕝 Common Tasks	► hide Add Activity						0
👄 All Links	* Location:	Clinical Trials Office 🗸		* Activity Type:	Review Initial Agrmt	~	Number of Days:
il. Reports	* Activity Start Date:	01/27/2021		Activity End Date:			Create Date:
🔅 Configuration	Follow-up Date:			Last Update:			Last Update By:
	* Activity Description:	Please review the draft DUA from Ochsner for the study noted above.	& unrestrict				
© Help ₽	Attachments: * File: Choose File Ochsner DataDraft.docx						

h. Click the add button to attach the Document. If add is not clicked, the document will not be attached.

Dashboard	Activities & Attachments	▼ hide			
Q Search Records					
😧 Common Tasks	► hide Add Activity	· · · · · · · · · · · · · · · · · · ·		· · · · · · · · · · · · · · · · · · ·	0
G All Links	* Locatio	Clinical Trials Office	* Activity Type:	Review Initial Agrmt V	Number of Days: 0
1. Reports	* Activity Start Dat	01/27/2021	Activity End Date:		Create Date:
🔅 Configuration	Follow-up Dat	21	Last Update:		Last Update By:
	* Activity Descriptio	Please review the draft DUA from Ochsner for the study noted above.	₿ [unrestrict]		
	Attachments: * File	Choose File No file chosen	* Description:		add
		hsner Data Use Agreement _ Draft.docx	View Ochsner DU/	A template	delete unrestrict
			add activity reset		

i. Repeat Steps 8g-h to attach additional documents.

Agreement Type $\rightarrow$	СТА	СТА	DUA	CDA	ΝΛΤΛ
Routing Docs $\checkmark$	CIA	Amendment	DUA	CDA	IVITA
Agreement	х	х	х	х	х
Payment Schedule	х	If amended			
In-House Budget	х	lf amended			
Protocol	х	If amended			
Compliance Approvals	х				
Material Transfer Initiation Form					Х

j. Once all documents have been attached, click the add activity button to register the activity in the negotiation. If add activity is not clicked, the Negotiation will not contain any activities for ORS or OIP to complete.

	Dashboard	Activities & Attachments	▼ hide			
۹	Search Records					
2	Common Tasks	► hide Add Activity		_		0
G	All Links	* Location:	Clinical Trials Office	* Activity Type:	Review Initial Agrmt 🗸	Number of Days: 0
11.	Reports	* Activity Start Date:	01/27/2021	Activity End Date:		Create Date:
\$	Configuration	Follow-up Date:		Last Update:		Last Update By:
		* Activity Description:	Please review the draft DUA from Ochsner for the study noted above.	unrestrict		
		Attachments: * File:	hoose File No file chosen	* Description:		add
		1 💥 Ochsn	er Data Use Agreement _ Draft.docx view	Ochsner DU/	A template	delete unrestrict
3	Help 🗹			* add activity reset		

- 9. Next:
  - a. An empty Add Activity section will appear for creation of a new activity (see Subsequent Review section below).
  - b. The current number of **activities** and **attachments** associated with the **Negotiation** will be updated.
  - c. Click send notification.

Q Search Records	( Mad Add Activity )
🖄 Common Tasks	* Location: select   * Activity Type: Accept Version for Execution   Number of Days:
co All Links	* Activity Start Date: Create Date: Create Date:
1. Reports	Follow-up Date: Last Update : Last Update By:
Configuration	* Activity Description:
	Attachments: * File: Choose File No file chosen * Description: add
⊘ Help 🗹	Show Activities (1)
About	Stow         Activity/cocoder: #Story (1)           Stow         All Attachments (1)
U Logout	Show Notifications (6)
🕤 Alam, Jawed 🛛 🖸	Medusa Is show
III Switch Apps	send notification ) save close cancel

- 10. You will be directed to a new page containing the Notification Editor section.
  - a. Click the look up button for **Employee Search** to access the Person Lookup page and select the individual(s) to whom the email notification should be sent (as in Step 7b-c).
    - i. Note: For notifications to CTO use the person name "Clinical Trials" so that the email notification will be sent to a central mailbox, <u>CTO@lsuhsc.edu</u>.
    - ii. For notifications to OIP, use the person name "Innovation Partnership" so that the email notification will be sent to a central mailbox, <u>oip@lsuhsc.edu</u>. [Also include both Patrick Reed and Katie Kuhn as recipients. See step 10c below.]

- b. Click the add button and the name of the individual will be displayed. If the add button is not clicked, the individual will not be displayed and the email notification will not be sent to this individual.
- c. Repeat this process to add additional recipients, if necessary. You must click the add button after each recipient is selected. For documents being sent to OIP, please also include both Patrick Reed and Katie Kuhn as recipients.
- d. Click **send** to send the email notification.
- e. DO NOT edit the Subject or Message in the Notification. The message text requires HTML coding.

Q Search Records			
🖄 Common Tasks	Notific	ation Editor	▼hide
G All Links	Notif	ication Recipie	ents
1. Reports			
🏚 Configuration	Add: 1 Notif	Clinical Triats	rch & e Search & bloyee Search & office determined and the search & ge
⑦ Help		Subject	Negotiation Requires Your Actic
About			
ப் Logout		Message	Hello,
🕤 Alam, Jawed			A document associated
Switch Apps			
< Collapse Menu			send cancel

11. You will be returned to the main Negotiation page. In the Activities & Attachments section, the Notification subsection will be updated to indicate a new notification. you can click on **show** to visualize the notification and recipients. When finished, click **save** and then **close**.

		Activities & Attachments	• hidg
⑦ Help	ß	>show Add Activity >show Activities (1)	0
(i) About		Activity/Location History (1)	
ப் Logout		Show Lotifications (1)	
💿 Alam, Jawed	Ø	Medusa	) show
Switch Apps			send notification save reload close cancel
Collance Menu			

		Show Activities (1) Show Activity/Locati Show All Attachment	ion History (1) ts (1) 1)		
		Date Created	Recipients	Subject	Message
<ul> <li>Help</li> <li>About</li> </ul>	ß	2020-09-14 16:19:03.0	aclesi, gdomi1	Negotiation Requires Your Action	Hello, A document associated with the following Negotiation requires your action: Negotiation ID: 17 Document Number: 3894 Project Title: Covid-19 Principal Investigator: Kadie Rome Sponsor Name: None given. Please click on the link to the ID number to access the Negotiation and carry out the requested activity with the associated document. Thank you.
<ul> <li>Logout</li> <li>Alam, Jawed</li> </ul>	ß	Medusa		► show	
<ul> <li>Switch Apps</li> <li>Collapse Menu</li> </ul>					send notification save reload close

## SUBSEQUENT REVIEW & NEGOTIATIONS

- 12. Once CTO or OIP has completed its initial review, it will follow the procedures described above to:
  - a. Create a new Activity (for instance, *Review Revised Agrmt*) in the same Negotiation instance;
  - b. Attach the reviewed agreement (with revisions as appropriate);
  - c. Send an email notification to the PI or original submitter.

#### 13. Negotiations:

- a. **MTAs & NDAs:** Except in extenuating circumstances, OIP will negotiate directly with the other party(ies).
- b. **CTAs, DUAs & Other Agreements:** The CTO is responsible for reviewing, and having the Sponsor review, any changes to the agreement and budget.
- 14. The Negotiation instance will be updated with additional activities, notifications and attachments until the agreement has been fully executed.