

# 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		
<ul><li>U Sign Out</li></ul>					

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	trouting	Sort by 🗸
Common Tasks			Proposal	Proposal #1 – PI: admin, admin – Sponsor: NIH – Title: Demo – Lead Due date: 12/20/19 Last action: Admin, System; 11/25/19 10:11 AM	
<ul> <li>Reports</li> <li>Configuration</li> </ul>			Proposal	Proposal #3 – PI: admin, admin – Sponsor: National Institutes of Hea Due date: 11/30/19 Last action: Admin, System; 11/25/19 10:29 AM	
Conniguration	All Clear!		Proposal	Proposal #4 – PI: admin, admin – Sponsor: NIH – Title: Proposal Tes Due date: 12/20/19 Last action: admin, admin; 12/09/19 10:07 AM	
			Proposal	Proposal #5 - PI: admin, admin - Sponsor: NIH - Title: Demo - Lead Due date: None Last action: admin, admin; 12/13/19 1:30 PM	unit: 000001
		0-0 < >	Proposal	Proposal #6 - PI: admin, admin - Sponsor: NIH - Title: Test Proposa Due date: 12/21/19 Last action: Admin, System; 12/19/19 1:52 PM	
					1-5 of 23 < 💙
	Negotiations				Sort by $\sim$
@ Help D	Negotiation         Show activities         Last action: Alam, Javed; 3/09/20 10:00 AM	n-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	COI	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 Overview	▼ hide		U
		Document Overview			
🕜 Help	<u>ہ</u> ک	* Description:	new data use agreement	Explanation:	ß
(i) About		Organization Document Number.			

#### 7. In the Negotiation section:

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

🕝 Common Tasks	Negotiation 8	3						Ø
GƏ All Links	* Negotiation Status:	Progress	~	Negotiation Dates: Start:	01/27/2021	End:		
II. Reports		select Complete In Progress	•					
🔅 Configuration	* Negotiator:	Suspended Terminated		Negotiation Age in Days: 0				
	* 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										
	KcPerson Lo	ookup₀			KCF	Person ld:	00				* required field
\$					Fit	st Name: er Name: Address:					
					Offic	te Phone:					
						Active:  Yes  No  Both	۹ 🕮				
							0				
	One item retrieved.				Cam	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
ს ල Ⅲ >	Export options: CSV   s	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.

	Negotiation	-					0
	* Negotiation Status:	In Progress	~	Negotiation Dates: Start:	01/27/2021	End:	
	* Negotiator:	grants-no Grants Office	۹	Negotiation Age in Days: 0			
	* Agreement Type:	select	~	Anticipated Award Date:			
⑦ Help	Document Folder:	Select Clinical Trial Agreement					
<ol> <li>About</li> </ol>	* Negotiator: Neg	cto Clinical Trials	۹				
Logout	* Neg	otiation Association Type: select		~	Negotiation Associatio	n ID:	
<b>.</b>							

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

G All Links	
II. Reports	Negotiation Thide
🄹 Configuration	Negotiation 8
	* Negotiation Status: In Progress V Negotiation Dates: Start: 01/27/2021
	Negotiator: Cto Negotiation Age in Days: 0     Clinical Trials
	* Agreement Type: Data Use Agreement
⑦ Help	Document Folder:
(i) About	Negotiation Attributes.
ப் Logout	Negotiation Association Type:) select     Negotiation Association ID:
💿 Alam, Jawed	select Award Institutional Proposal
Switch Apps	Activities & Attachments

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:	۵ 🕮	Prime Sponsor:	۹ 💷
⊘ Help 🖸	Sponsor Award ID:		Subaward Organization:	9 🛍
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.

Activities & Attachments	▼ hide				
	$\sim$				
Thide Add Activity		_	$\bigcirc$		0
* Location:	Clinical Trials Office Y		* Activity Type: Review Initial Agrmt	~	Number of Days: 0
* Activity Start Date: 0	1/27/2021	<b>a</b>	Activity End Date:		Create Date:
Follow-up Date:		a	Last Update:		Last Update By:
		2			
* Activity Description: O	chsner for the study noted above.	6 unrestrict			
	* Location: * Activity Start Date: 0 Follow-up Date:	Clinical Trials Office     Clinical Trials Office     Activity start Date     O1/27/2021     Follow-up Date:     Please review the draft DUA from			

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:
		Please review the draft DUA from Ochsner for the study noted above.	& unrestrict				
⊘ Help     ☑	Attachments: * File: Choose File Ochsner Data Draft.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			(	e
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:		Last Update By:
	* Activity Description:	Please review the draft DUA from Ochsner for the study noted above.	& unrestrict		
	Attachments: * File: C	hoose File No file chosen	* Description:		add
	1 💥 Ochsn	er Data Use Agreement _ Draft.docx [	view Ochsner DU	A template	delete unrestrict
⑦ Help	2		# oud activity reset		

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

Agreement Type $\rightarrow$ Routing Docs $\downarrow$	СТА	CTA Amendment	DUA	CDA	ΜΤΑ
Agreement	х	х	х	х	х
Payment Schedule	х	If amended			
In-House Budget	х	If amended			
Protocol	х	lf 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
	Reports	* Activity Start Date:	01/27/2021	Activity End Date:		Create Date:
<b>\$</b>	Configuration	Follow-up Date:		a Last Update:		Last Update By:
		* Activity Description:	Please review the draft DUA from Ochsner for the study noted above.	R unrestrict		
		Attachments: * File:	thoose File No file chosen	* Description:		add
		1 🐺 Ochsr	er Data Use Agreement _ Draft.docx 💽	view Ochsner DU	A template	delete unrestrict
<u>ا</u> (2	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		▼ hide Add Activity						0
훋 Common Tasks		* Location:	select	•]	* Activity Type:	Accept Version for Execution	~	Number of Days:
GÐ All Links		* Activity Start Date:			Activity End Date:			Create Date:
il. Reports		Follow-up Date:			Last Update:			Last Update By:
Configuration								
		* Activity Description:		🔏 unrestrict				
		Attachments: * File:	Choose File No file chosen		* Descriptio	n:		add
					# add activity reset			
🔿 Help								
	ك	► show Activities (1) ► show Activity Constitutes (1)	tory (1)					
i About		Show All Attachments (1)						
ப் Logout		▶ show Notifications (0)						
💿 Alam, Jawed	ß	Medusa	► show					
Switch Apps								
6 O-ll				send noti	fication 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 Trials	e Search sloyee Search office e Search e Search
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	• hids
⑦ Help	Ø	Show Add Activity Show Activities (1)	0
(i) About		Activity/Location History (1)	
ப் Logout		Show Hotifications (1)	
💿 Alam, Jawed	ø	Medusa	▶ show
🗰 Switch Apps			send notification save reload close cancel

		> show     Activities (1)       > show     Activity/Locati       > show     All Attachment       > hide     Notifications (	ls (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.
(U) Logout	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.