

# NATIONAL RESEARCH INFORMATION MANAGEMENT SYSTEM (NRIMS)

# Step-By-Step Guide to make your Protocol Submissions for approval to conduct research in Uganda

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# CHAPTER 1

## **1.1 GENERAL INFORMATION**

This is an online platform that supports the National Regulatory Agencies; NDA/UNHRO/UNCST and Research Ethics Committees in the regulatory oversight of clinical research to be carried in the country.

The system provides efficient reviews of research and provides the researcher with an interface with the regulatory agencies in the data capture, data management, data validation, quality control and overall regulatory compliance to clinical research management processes

## **1.2 GETTING STARTED**

- To get started, access the NRIMS website on <u>https://nrims.uncst.go.ug/</u>
- To create an account and submit a protocol, follow the steps in SECTION 2, Section 2.1
- After Submitting your protocol, it will be reviewed and feedback will be given through your registered email address.

## CHAPTER 2

### 2.1 Using the system

Follow the steps below to create an account and submit a protocol to conduct research in Uganda. Take note of the red circles in each screenshot as they show important actions.

### 1. Click on "REGISTER/CREATE ACCOUNT" and fill in your information:



2. After registration, you will be taken back to the home page and asked to login. Click on "RETURNING USER/LOGIN" at the top, to Login:



- 3. Click on the drop-down arrow to answer "yes" or "No":
  - I) If "No", click "Proceed" to be redirected to seek for clearance to conduct research in Uganda from the UNCST

Does the study involve Human	n participant	s?
<ul> <li>a) Clinical investigations - any experiment or study on one or more persons, which involves a procedure or device.</li> <li>b) Social-behavioral studies which involve interaction with or observation of people.</li> <li>c) Basic scientific research to study biology of persons or organs and specimens thereof.</li> <li>d) Systematic collection, storage and analysis of data on humans.</li> </ul>	test product/ article such as a drug, t	reatment,
Please Select Proceed		

II) If "Yes", "Select Research Category" from the drop down. Select an option from the drop-down list and click on "Proceed" to be directed to a REC approval work space.

Does the study involve Human participants?
a) Clinical investigations - any experiment or study on one or more persons, which involves a test product/ article such as a drug, treatment,
procedure or device.
b) Social-behavioral studies which involve interaction with or observation of people.
c) Basic scientific research to study biology of persons or organs and specimens thereof.
d) Systematic collection, storage and analysis of data on humans.
Yes v
Select Research Category
Select from list
You will be re-directed to REC Approval
Proceed

4. You will be logged in and taken to the Research Ethics Committees (REC) page. Click on "Submit New Protocol":

← → C ☆ 🖷 nrimsuncst.	go.ug/recapproval/data/dashboard/				☆ 🖬 🛛 🐼
UNCST RESEARC	H ETHICS COMMITTEES onduct Research in Uganda				Welcome, Test Test 🗸
Click here to Apply for a Permit	Dashboard				
Uganda from UNCST	Submitted Protocols	Pending Submission 0	Scheduled for Revi	ew 0	Approved Protocols
My Halled Studies 0 My Revisions 0	Submit New Protocol				
My Closeout Reports	Find protocols.			Status:	Search
My Renewals	My Protocols			rui	
My Safety and Other Notifications	# Protocol Title	Type REC	Last Update	Status	Wëare
My SAEs 0					LICEOCOS

5. Fill in the protocol Information from the Dashboard, then click "Save and Next":

otocol Information	Protocol Details	Study Description	Study Population	Budget Stud	y Work Plan	Attached Files	Payments
-							
<ul> <li>Does the study if</li> </ul>	ivolve Human particip	ants? (All research in	volving Human part	ticipants REQUI	RES REC appro	val, else you wi	l be re-dire
to acquire a UN	CST approval)*						
to acquire a UN ⊙ Yes ○ No	CST approval)*						

6. After filling in the required fields, the Protocol Information tab turns green,

indicating completion of that section of the Dashboard.

Dashboard					
Protocol Information Protocol Details Study Description	Study Population	Registry	Budget	Study Work Plan	Attached Files
Payments					
Protocal Title	Author O Upd	ated At	35	5%	
lest brug	Test Test 2020	-02-18 09:37:	55		
Protocol Summary: *					
Characters limit: 250 words					

7. The percentage in Red, Shows your overall progress.

Protocol Information Payments	Protocol Details	Study Description	Study Popu	lation	Registry	Budget	Study Work Plan	Attached
Protocal Title Test Drug			Author Test Test	0 Upda 2020-0	<b>ted At</b> 02-18 09:37:	55		
Protocol Summary								

8. After all the Information has been filled with all the necessary documents attached, your overall progress will be at 100%, and the "Make Final Submission"

button will pop up under your overall progress. Click on it to make your submission. Please note that you will not be able to edit after this point.

rotocol Information	Protocol Details	Study Description	Study Popu	ulation F	legistry	Budget	Study Work Plan	Attached Files
ayments								
Protocal Title Test Drug			Author Test Test	⊘ Update 2020-02	<b>d At</b> 18 09:37:55	5	100% Make Final Submi	ssion
Type of Payment: Cash Deposit		Attach Proof of Payme Choose File No fil	ent: * le chosen		P	roof of	Payment Delet	•
NOTE: Undergraduat	le students may att:	sch proof of payment o	f research fe	es to the L	Iniversity.			

9. After making your final submission, you will be able to view or print your submission, or view the comments made by the Reviewer.

Click here to Apply for a Permit	Dashboard							
Uganda from UNCST	Submitted Pr	otocols	Pen	ding Submission S	cheduled for Review	A	pproved Protocols	
My Protocols		1		0	(	) 🛑 🚺	0	
My Halted Studies								
My Revisions	Submit New Protocol							
My Closeout Reports	Find protocols:				Sta	atus:		
My Renewals						4II	* Search	l
My Amendments 0	My Protocols							
My Safety and Other Notifications		Protocol Title	Туре	REC	Last Update	Status	Actions	
My SAEs 0	UNCST.70.ES.2020	Test Drug Test Test - Test	Clinical Trial	Test UNCST Research Ethics Committee	2020-02-18 10:01:48	Waiting for Committee	View Submission     View Comments	)
My Deviations		inc,					+ Print Submission	,

2.2 REVISION/UPDATING A SUBMISSION

Dashboard

This section indicates how to provide revisions to a protocol that been deemed by the REC Admin to be incomplete or does not meet minimum requirements.

Of a submission.

10. If your protocol is rejected by the REC admin, A button labeled "Update Submission" will appear and you will need to update your submission and resubmit your protocol.

Protocol Title	Туре	REC	Last Update	Status	Actions
NXT Tool Deng Luka -	Engineering and Technology	Test UNCST Research Ethics Committee	2020-02-17 16:27:07	completeness check	+ View Suberitation + Update Suberitation + Print Supersystem

11. Update the necessary requirements and click "Resubmit" when done.

Protocol Information Protocol Details Stud	ly Description Study Population Bud	get Study Work Plan Attached Files Pa	yments
Protocal Title NXT Tool	Author Deng Luka	© Updated At	
Add Team Members •			
Deng Luka - Principal Investigator, click to review			+
			Add Team Member
Add Collaborating Institutions * ® Yes O No			
Name of Institution*	Institutional Code	Data Sharing Agreement *	
		Choose File No file chosen	Add Rows
Elk Rapids			View File Delete

12. After resubmission, you will be redirected back to the protocols menu and you can view or print your protocol as it gets reviewed again.

Protocol Title	Туре	REC	Last Update	Status	Actions
NXT Tool Deng Loka -	Engineering and Technology	Test UNCST Research Ethics Committee	2020-02-20 15:54:59	Waiting for Committee	View Submission     View Comments     Print Submission

13. If your protocol gets approved, protocol status changes and a signed REC Approval Letter will be available for download, as shown below.

My Protocols						
	Protocol Title	Туре	REC	Last Update	Status	Actions
UNC5T.70.ES.2020	Test Drug Test Test - Test Inc,	Clinical Trial	Test UNCST Research Ethics Committee	2020-02-18 10:01:48	Approved, pending UNCST approval Download REC Approval Letter	View Submission     View Comments     Print Submission     Apply for Ammendments

## 2.3 MAKING AMENDMENTS

14. You'll be able to "Apply for Amendments" as well, if necessary, using the red button at the bottom.

1	Ay Protocols						
		Protocol Title	Туре	REC	Last Update	Status	Actions
	UNC5T.70.ES.2020	Test Drug Test Test - Test Inc <sub>9</sub>	Clinical Thal	Test UNCST Research Ethics Committee	2020-02-18 10:01:48	Approved, pending UNCST approval Download REC Approval Letter	View Submission     View Comments     Prove Comments     Apply for Announdments

15. After clicking on "Apply for Amendments", you will be redirected to fill in the changes to be made and attach the necessary documents highlighted in red.

transmission       Type       Language       Version       Date         se attach: cosal with Tracked Changes/Lean CopyCover letter/Froof of Payment       Image: State					Click to add N	ew Attachmer
se atlach: losal with Tracked ChangesClean CopyCover letterProof of Payment changes to Consent Form: Are changes required?: No Yes changes to data collection tool: Are changes required?: No Yes changes to protocol: Are changes required?: No Yes changes to protocol: Are changes required?: No Yes	Protocol	Туре	Language	Version	Date	
osal with Tracked Changes Clean CopyCover letterProof of Payment Changes to Consent Form. Are changes required?: No Yes Changes to data collection tool: Are changes required?: No Yes Changes to protocol: Are changes required?: No Yes re they changes to study districts? Please highlight districts : Outline	lease attach:					
Changes to Consent Form. Are changes required?: No Yes Changes to data collection tool: Are changes required?: No Yes Changes to protocol: Are changes required?: No Yes ve they changes to study districts? Please highlight districts : Confine	oposal with Tracked Chang	esClean CopyCove	r letterProof of Payment			
Yes         changes to data collection tool: Are changes required?:         No         Yes         changes to protocol: Are changes required?:         No         Yes         we they changes to study districts? Please highlight districts :	Changes to Consent Form:	Are changes required	2			
Changes to data collection tool: Are changes required?: No Yes Changes to protocol: Are changes required?: No Yes vie they changes to study districts? Please highlight districts :	O Yes					
Changes to data collection tool: Are changes required?: No Yes Changes to protocol: Are changes required?: No Yes vie they changes to study districts? Please highlight districts : Online						
No         Yes         Changes to protocol: Are changes required?:         No         Yes         ve they changes to study districts? Please highlight districts :         Online	Changes to data collection t	ool: Are changes requ	ired?:			
Changes to protocol: Are changes required?: No Yes ve they changes to study districts? Please highlight districts :	O NO O Yes					
Changes to protocol: Are changes required?: No Yes vie they changes to study districts? Please highlight districts :						
Changes to protocol: Are changes required?: No Yes ver they changes to study districts? Please highlight districts : Online						
Ves ve they changes to study districts? Please highlight districts :	Changes to protocol: Are ch O No	anges required?:				
Vie they changes to study districts? Please highlight districts :	○ Yes					
Are they changes to study districts? Please highlight districts :						
Online	Are they changes to study d	istricts? Please highlig	ght districts :			
Online						
Connec					Online	

16. Fill in all the information and click on the "Save" button to save your inputs, or "Make Final Submission" button to submit your amendments.

Are they changes to study districts? Please highlight districts :
Description of proposed changes:
Reason for Amendment/Modification:
Save Make Final Submission

17. After submission, you will be redirected to the "My Amendments" Section.

Click here to Apply for a Permit	Dashboard						
to Conduct Research in Uganda from UNCST	Find Ammendmnets:				Status:		_
My Protocols					All	*	Search
My Halted Studies	My Protocols						
My Revisions	Project Title					Status	
My Closeout Reports	Test Drug	Туре	Language	Version	Date	Submitted	
My Renewals		Payment	English	6	2019-06-28		
My Amendments 1		CoverLetter	English	9	2018-12-08		
My Safety and Other		CleanCopy	English	9	2018-05-15		
Notifications		TrachedChanges	English	9	2018-05-12		
My SAEs							
My Deviations						Online	

## 2.4 MAKING A CLOSEOUT REPORT

18. To make a Closeout Report, click on "My Closeout Reports", then "Click to submit Closeout Reports"

Click here to Apply for a Permit	Dashboard					
to Conduct Research In Uganda from UNCST	Click to submit Closeout Reports					
My Protocols	Find Closeout Reports:		S	itatus:		
My Hatted Studies				All	*	Search
	My Closeout Reports					
My Revisions						
My Closeout Reports	Project Title	Attachment	Submission Da	te Status	Actions	
My Renewals						
My Amendments 1	© Uganda National Council for Science and Tec	hnology - UNCST, 2020. All rights reserved				

19. Then click on "Click to add New Attachment"

Click here to Apply for a Permit	Dashboard		
to Conduct Research in Uganda from UNCST	Apply for Close Out Report		
My Protocols	Protocol Title	Author 📀	
My Hatted Studies		Test Test Updated At	
My Revisions			Click to add New Attachment
My Closeout Reports 0	Protocol	Attachment	
My Renewals		Save	

20. Note that a Closeout Report can only be submitted if you have a project nearing the end. Therefore, if you do not have one, the following message will be displayed.

Click here to Apply for a Permit to Conduct Research in	Dashboard	
Uganda from UNCST	×	New Attachment
My Protocols		
My Halted Studies	Select Protocol you are submitting to: *	
My Revisions	You dont have any project nearing end	
My Closeout Reports		
My Renewals	File (PDF) *: Choose File No file chosen	
My Amendments 1		

### **2.5 SUBMITTING RENEWALS**

21. To submit a Renewal, click on "My Renewals" and then, "Click to Submit Renewals".

Click here to Apply for a Permit	Dashboard					
Uganda from UNCST	Click to submit Renewals					
My Protocols	Find Renewals:			Status:		
My Halted Studies				All		*
My Revisions	My Renewals					
My Closeout Reports	Project Title	Enrolled No	Sample size	Submission Date	Status	Actions
My Renewals 0						

### 22. Fill in all the information required on the red tabs.

#### Dashboard »Annual Renual

Protocol Information	Status of Participants & Specimens	Literature & Challanges	Status of Future Plans/Activities	Payment
Select Protocol yo	u are submitting to: *			
Please Select P	rotocol		*	
Brief rationale for t	he Study: *			
General Research	Objective: "			
			ĥ	

23. When you're done, click on "Save" and then "My Renewals".



### 24. Your renewal will be added, and you can View, or edit it.

Click here to Apply for a Permit	Dashboard							
to Conduct Research in Uganda from UNCST	Click to submit Renewals							
My Protocols	Find Renewals:				Status:			
My Halled Studies					All			Search
My Halled Studies	My Renewals							
My Revisions 0								
My Closeout Reports	Project Title	Enrolled No	Sample size	Submission Date	:	Status	Actions	
My Renewals 1	Test Drug	4	5	20/02/2020 10:4	6:50	Pending	+ View Subm	Mission
My Amendments							+ Edit Sabin	

## 2.6 SUBMITTING SAFETY AND NOTIFICATIONS

25. To submit Safety and notifications, click on "My Safety and other Notifications", then "Click to Submit Notifications".

Click here to Apply for a Permit	Dashboard							
to Conduct Research In Uganda from UNCST	Click to submit Notifications							
My Protocols	Find Notifications:				Status:			Search
My Halted Studies	Safety and Other Notifications							
My Revisions								
My Goseour Reports	Project litle		Attachment	Submission Date		Status	Actions	
My Amendments	© Uganda National Council for Science and Te	echnology - UNCST, 2020. All ri	ights reserved					
My Safety and Other Notifications								
My SAEs 0								

### 26. Click "Click to add New Attachment"

	Author	
Protocal Title	Test Test Updated At	
		Click to add New Attachmen

27. Select your protocol and upload the file. Then scroll down and click "Save".

	Dashboard				
×				New Attachmen	nt
Γ	Select Protocol you are sut	mitting to: *			4
	Test Drug		•		I
File	(PDF) *:	Choose File No file chosen			+

28. Click "Save" to save it or "Make final Submission" to submit it.

Click here to Apply for a Permit	Dashboard		
to Conduct Research in Uganda from UNCST	Apply for Notifications		
My Protocols	Protocol Title	Author <sub>O</sub>	
My Hatted Studies	Protocal fillo	Test Test Updated At	
My Revisions	Changes have saved		
My Closeout Reports			Click to add New Attachment
My Renewals 1	Protocol	Attachment	
My Amendments 1	Test Drug	Click to view	
My Safely and Other Notifications		Save Make Final Submission	

## 2.7 APPLYING FOR SAES

29. To submit SAEs, click on "My SAEs", then "Click to submit SAEs"

to Conduct Research in Uganda from UNCST	Dashboard	
My Protocols	Click to submit SAEs	
My Halled Studies	Find SAEs:	
My Revisions		
My Closeout Reports 0	My Protocols	
My Renewals 1	# Protocol Title	Date of Birth Gender
My Amendments 1		
My Safety and Other Notifications	© Uganda National Council for Science and Tech	nology - UNCST, 2020. All rights reserved
My SAEs 0		

### 30. Fill in all the necessary information and click "Submit"

escribe the corrective action undertaken *	
haracters limit: 250 words	
Attach Evidence of corrective action (RDE only) *	
Choose File No file chosen	
Submit	

31. A "Make Final Submission" button will then appear. Click on it to Submit.



## 2.8 SUBMITTING DEVIATIONS

32. To submit Deviations, click "My Deviations", then "Click to submit

### Deviations"

Click here to Apply for a Permit to Conduct Research in Uganda from UNCST	Click to submit Deviations		
My Protocols	Find Deviations:		
My Halted Studies			
My Revisions	My Protocols		
My Closeout Reports	Project Title	Description of deviation	Root cause of deviatio
My Renewals			
My Amendments 1	© Uganda National Council for Sci	ance and Technology - UNCST, 2020. All r	ights reserved
My Safety and Other Notifications			
My SAEs 1			
My Deviations			

33. Fill in the necessary information and then click "Submit Details"

Characters limit: 250 words	
5. Measures to mitigate violation	
Measures (one per row)	
	Add More
$\frown$	
Submit Details	

34. A "Make Final Submission" Button will appear. Click on it to make submission.

	5. Measures to mitigate violation			
	Measures (one per row)			
				Add More
Q	WERTYUI Delete			
		Submit Details	Make Final Submission	

### 2.9 APPLYING FOR A PERMIT TO CONDUCT RESEARCH IN UGANDA

35. To apply for a Permit, click on the orange button at the top left corner.

Click here to Apply for	a Permit	Dashboard					
My Protocols 1		Submitted F	Protocols		Pending Submission	Scheduled fo	r Review 0
My Halted Studies	0						
My Revisions 0		Submit New Protocol					
My Closeout Report	is 🧿	Find protocols:					Status:
My Renewals 0							All
My Amendments		My Protocols					
My Safety and Othe Notifications	e		Protocol Title	Туре	REC	Last Update	Status

36. You will be asked to login to UNCST Research Management System, (Use the same Log in information) and You will be redirected to the Research page.

Click here to Apply for a Permit	Dashboard
to Conduct Research in Uganda from UNCST	Apply for a Permit to Conduct Research in Uganda from UNCST, Login here
My Protocols	Username *
My Halted Studies	Retype Password *
My Revisions	Login
My Closeout Reports 🧿	
My Renewals	© Uganda National Council for Science and Technology - UNCST, 2020. All rights reserved

37. The side bar labeled "Status" Shows your information progress. All the "Pending" processes should be filled to complete your application. However, the processes visible on the screen are your user information. Click on "Update Submission" at the bottom left.

	A NATIONAL CO	OUNCIL FOR SCIENCE A for permission to conduct rese	ND TECHNO earch in Uganda	LOGY - UNCST	👤 Helo, hel 👻
Welcome Test Te	est		/	Status	
Tel:0712345678 Email: testt96004@gmail.com				Home	
Organisation of affiliation: Organisation email:				User account details Pending	Logoul
				Password & Photo Completed	Apply for REC Approval
Dear Test, Welcome to Uganda National Counci	il for Science and Technology app	plication for permission to conduct research in U	ganda.	Personal details Pending	
Please make sure that all processes required fields, please make a final e	marked "pending" are filled in o submission of your application by	rder to complete your application. After completin y clicking make final submission at the top right t	ng all the hand comer.	Education background Pending	
				Employment Pending	
My Submissions					
Project Title	Status	Remarks			
Test Drug.					
Update Submesson					
					Let's talk

38. Additional processes will pop up on the "Status" bar. Click on the icon headed "Edit"

Main	features of t	he research project					Status
Project	Title	Research Type	Sponsor	Duration	Edit	Delete	Home
	Test Drug RefNo:	Degree Award	Testi	(	2	Ш.	User account details Comp
					$\smile$		Password & Photo Pend
							Personal details Comp
							Education background Comp
							Employment Comp
							Research details Pond
							Research experience Pane
							Research attachments
							Estimated cost

39. Then fill in all the necessary information...

Research projec	t details, ed	it record				
Project tittle	Research	Тура	Sponsor	Duration	Edit	Delete
Test Drug	Degree A	ward	Test1	1 Month	20	1
Neino, h3570E3	,					
Research project	eiget tittle abier	Gun method	distance.			
Research details le pr	ojeci utue, cojet	uve, meuto	oology			
Title of the research pro	oject: *	Test Drug				
					4	
Objectives of the resear	rch project: *	Type your	objectives here			
Category		Select fro	m list		•	
Brief outline of research	methodology"	Type your	research methods	ology here	_	
					li	

40. Click "Update Details" when you're done.

District Country/ Mun	icipality Sub County/ Parish Duration Town Council (Months) Add Rows
Description of study population (Age sex, tribe etc): "	group, Type your description here
Sponsor (s): *	Testi
Sample Size *	5
Total study duration in months: *	1 Month *
	Update Details

41. "Research Details" from the status bar will turn green. Click on "Research experience", and then "Click to Add Publication"

Research experience			Status		
Publication	Edit	Delete	Home		
Research experience			User account details	Completed	Logout
			Password & Photo	Pending	View submission
Research experience, with list of public Click to add publication	ations, if any : (list no more than 10 pu	blications) start with the current	Personal details	Completed	Apply for REC Approva
			Education background	Completed	
			Employment	Completed	
			Research details	Completed	
			Desearch experience		

42. A window will pop up asking if there has been any research experience. Click "Save Details" after making your choice.



43. After filling in all the necessary information, a "Make final submission" Button will pop up under the "Apply for REC approval" Button on the right.

tatus		
Home		
User account details	Completed	Logout
Password & Photo	Completed	View submission
Personal details	Completed	Apply for REC Approva
Education background	Completed	

# CHAPTER 3

# **3.1 CONCLUSION**

Protocol Submissions are divided into sub sections and reviewed accordingly. Depending on the information provided in the submission, your protocol can be approved, rejected, or approved on a condition that a certain aspect of your protocol has to be changed.

Application for a permit to conduct research in Uganda is made granted by the Uganda National Council for Science and Technology (UNCST). Only when your submission has been approved can a permit be granted and only then can you be able to conduct research in the area(s) stated in your application.