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LSU Health	PERMISSIONS TAB IN KUALI			
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1 PURPOSE

This procedure establishes the process for adding administrative contacts to Kuali through the "Permissions" tab.

2 CONSIDERATIONS

- 2.1 **Protocol Personnel** are those listed in the "People" section (Protocol Personnel Table) of the main Protocol form. Only those designated as "research personnel" are listed here by the submitter of the protocol. Although all protocol personnel will appear in the Permission tab, they cannot be edited from this tab (**permission type in black**). Protocol Personnel can only be modified by submitting an amendment and updating the Protocol Personnel table as traditionally done.
- 2.2 Administrative Contacts are those automatically or directly added to the Permissions Tab. They will be granted "Full Access" permission and can only be modified from the Permissions tab (permission type in blue). No amendment is necessary to modify Administrative Contacts.
 - 2.2.1 Automatic addition: Previously, users submitting a protocol were automatically added to the Protocol Personnel table. Now, when a user submits a protocol, they are automatically added to the Permissions tab with "Full Access" permission, allowing them to continue to make changes and access the protocol as an administrative contact. If the submitter's participation is limited to initiating or editing submissions for this protocol, no further action is needed, and they will NOT appear in the Protocol Personnel table. If the submitter is also "research personnel," they will need to add themselves to the Protocol Personnel table as a researcher. In this case, the contact for this user will display twice in the Permissions tab: once as an Administrative Contact (where their permission and contact can be edited directly from the Permission Tab) and once as Protocol Personnel table).
 - 2.2.2 *Direct Addition*: Those previously designated as "Site Administrators" will now be directly added to the Permissions tab by IRB Staff and will not appear in the Protocol Personnel table.
- 2.3 **The Permissions tab is an administrative function reserved for IRB Staff use.** However, any protocol personnel or administrative contact with "Full Access" permission is granted access to edit the Protocol, Permissions tab, as well as the permission type of administrative contacts and protocol personnel. Therefore, unless you are IRB staff, please do not touch the Permissions tab.

3 PROCEDURES

3.1 Submitter of KR Application Responsibilities

- 3.1.1 The submitter identifies all research personnel and lists them in the Protocol Personnel table, designating their level of permission (read-only or full access) as applicable.
 - 3.1.1.1 Note: The submitter is no longer automatically added the Protocol Personnel table; instead, they are granted full access as an administrative contact upon initiating a protocol. If the submitter is also considered "research personnel" as defined <u>here</u>, they need to add themselves to the Protocol Personnel table. If the submitter is not engaged in HSR (e.g., activities are limited to editing and submitting applications through Kuali Research (KR)), they do not need to add themselves to the protocol and will still receive all notifications and full access to the protocol as an administrative contact.

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3.1.2 The submitter and anyone with "full access" permission does not edit the Permissions tab. The Permissions tab is for IRB staff use only due to its nuanced function (understanding who an administrative contact is and that those directly added to this tab are not research personnel); however, anyone with "full access" permission can see and edit this tab and the permission type of others. Therefore, to avoid confusion and enhance ease of review, do not click on this tab. The study team can access all relevant content and functions in the main Protocol form.

3.2 LSUHSC IRB Administrative Responsibilities

- 3.2.1 Receives initial or post-approval KR Protocol Submission
- 3.2.2 Reviews the Performance Site section for ALL protocol types
 - 3.2.2.1 Exception: Not Human Subjects Research (NHSR) protocols Performance sites do not display and administrative contact addition is not applicable for this protocol type except as noted below*
- 3.2.3 If the following institutions are listed, IRB staff adds the respective administrative contact to the Permissions tab and designates their permission type as "Full Access."
 - 3.2.3.1 Note: The same process is followed for post-approval submissions if the administrative contact is not currently listed, ensuring they receive all study-related notifications.

Institution	Administrative Contact	Permission Type	Notes
University Medical Center – New Orleans	UMC Research	Full Access	
Children's Hospital New Orleans	CHNOLA Research	Full Access	*Additional Protocol Type - NHSR*: Add to NHSR Protocols where the user responded "yes" to the question, "Will the project be conducted at Children's Hospital?"
Franciscan Missionaries of Our Lady Health System (FMOLHS)	FMOLHS Research	Full Access	
LSU Healthcare Network (LSUHN)	LSUHN Research	Full Access	
Touro Infirmary	Touro Research	Full Access	
East Jeff General Hospital	EJGH Research	Full Access	
West Jeff Medical Center	WJMC Research	Full Access	

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4 **DEFINITIONS**

- 4.1 Administrative Contact Those added automatically or directly to the Permissions Tab and granted "Full Access" permission. This tab allows those who are not Protocol Personnel to be granted access to the study in KR without having to be listed in the Protocol form. Administrative contacts are given "Full Access" permission and will receive all notifications related to the protocol once they are given permission. The protocol will also display in their "Manage Protocols" dashboard.
 - 4.1.1 Those initiating protocols are automatically listed in the Permissions tab. If their activities go beyond submitting/initiating protocols and are considered "research personnel," they need to add themselves to the Protocol Personnel table. If they are solely an administrative coordinator, they should not be listed in the Protocol Personnel table and will only display in the Permissions tab.
 - 4.1.2 For direct addition by IRB Staff, administrative contacts will never be found in the Protocol Personnel table, as they are not research personnel. IRB Staff adds administrative contacts directly to the Permissions tab after the protocol is submitted for review. These contacts were previously designated as "Site Administrators," which is no longer a role type, and the process for adding contacts to the Permissions tab is based on this SOP.
- 4.2 **Protocol Personnel** Those designated as research personnel by the submitter/PI of the KR application and listed in the Protocol Personnel table. Their permission level and role type is determined by the submitter/PI at the time of submission. Although Protocol Personnel will appear the Permission tab, their permission type can only be modified in the main Protocol form.

4.3 Permission type:

- 4.3.1 "Read-Only" access allows individuals to view the study in KR Protocols and download attachments and approval letters but does not allow the individual to take actions on the study (e.g., editing/submitting post-approval submissions).
- 4.3.2 "Full Access" allows individuals the same document permissions as "Read-Only" access as well as the ability to create submissions, such a renewals and amendments, respond to revisions requested (editing the protocol), and take other actions in the system.

5 HISTORY

Version Number	Version Date	Summary of Changes
1.0	4.22.2022	N/A
1.1	3.22.2022	Addition of Admin Contact - LSUHN Research
1.2	3.31.22	Admin Contact Update – FMOLHS
1.3	5.18.2022	Addition of Admin Contact – Touro Research
1.4	5.18.2022	Clarified Post-Approval Submission Review Process – addition of admin contacts to permissions tab when not present.
1.5	8.01.2022	Addition of Admin Contact – EJGH Research

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6 PICTURES

6.1 Protocol Personnel – "People" section of main Protocol form

PROTOCOLS	kuali	Reviewer, IRB
← Back Manage Prote	cols → IRB: #1315 Permissions Tab SOP 2	
	Protocol Activity Log Permissions	
Pages Expand Navigation	Detentify all research personnel involved in the project by completing the table(s) below. If you are initiating this protocol and your participation is limited to initiating/editing submissions, do not list yourself in the table. You automatically have full access to the protocol as an administrative contact. The PI listed in this application is automatically listed in the Protocol Personnel Table, but you will need to edit this entry to add any missing required fields (e.g., affiliation type). THE PI'S DEFAUL LEVEL OF ACCESS IS FULL; DO NOT EDIT THIS OR THEY WILL NOT BE ALL CERTIFY AND SUBMIT THE PROTOCOL FOR REVIEW! List all other researcher personnel, their roles, level of access, affiliation type, and any other required fields, as applicable, in the table below. Definitions of research personnel roles are described here. Training requirements for LSUHSC (HSC) research personnel are described here. You will not be able to add personnel not currently listed as Users in KR. Instructions are provided below for registering individuals as KR Users.	 Notify PI To Submit Admin Notes & Files Abandon Submit Print
PROTOCOL DOCUMENT REFERENCEREVIEW TYPE QUESTIONNAIRESSUBMISSION	Protocol Personnel Table Click '+Add Line' to enter a protocol personnel. Repeat this process until all research personnel are listed. Click '+Add Line' to enter a protocol personnel. Repeat this process until all research personnel are listed. Columns + Add Line Add Line Add Line Add Line Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table Table T	
	Administrator, IRB irbadmin@test.co Principal Investigator	

6.2 Protocol Personnel – Selecting the "Level of Protocol Access"



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6.3 Example: Protocol Personnel Displaying in Permissions Tab (Cannot Edit from this Tab)

Protocol Tab

Protocol Personnel Table

	NAME -	EMAIL ADDRESS	PROTOCOL ROLE	AFFILIATION TYPE
Ø	Administrator, IRB	irbadmin@test.co	Principal Investigator	HSC [faculty (including gratis), staff, students or employees of LSUHSC-NO]
0	Admin, System	systemadmin@test.co	Sub-Investigator	HSC [faculty (including gratis), staff, students or employees of LSUHSC-NO]
0	Reviewer, IRB	irbreviewer@test.co	Regulatory Coordinator	HSC [faculty (including gratis), staff, students or employees of LSUHSC-NO]

Permissions Tab

Protocol	Activity Log Ancillary Review Permissions 	
Q Search users		
Name	Permission Type	
IR Reviewer, IRB	Full Access 🗸	×
IA Administrator, IRB	Full Access (User's permissions can be updated in the person selection of the protocol)	
SA Admin, System systemadmin	$\ensuremath{\textbf{Read-Only}}$ (User's permissions can be updated in the person selection of the protocol)	
IR Reviewer, IRB	Full Access (User's permissions can be updated in the person selection of the protocol)	

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6.4 **Permissions Tab** – Example of Submitter automatically added as Administrative Contact and adding themselves to Protocol Personnel Table (showing up twice in Permissions tab)

← Back Ma	nage Protocols \rightarrow IRB	: #1315 Permissions Tab SOP 2	
	Protocol	Activity Log • Ancillary Review Permissions	
	Q Search users		
	Name	Permission Type	
	IR Reviewer, IRB	Full Access 🐱	×
	IA Administrator, IRB	Full Access (User's permissions can be updated in the person selection of the protocol)	
	Admin System		
	SA systemadmin	Read-Only (User's permissions can be updated in the person selection of the protocol)	
	Reviewer, IRB	Full Access (User's permissions can be undated in the person selection of the protocol)	
	irbreviewer		

6.5 Example: Adding an Administrative Contact based on Performance Site

Protocol Tab

PERFORMANCE SITE(S)

Add all organizations (sites) where LSUHSC-NO investigators are conducting research activities.

O Columns

		INSTITUTION	Ŧ	"OTHER" INSTITUTION	$\overline{\pm}$	SUB-SITE
 Action Item 	0	Children's Hospital New Orleans				

JOINT CHNOLA-LSUHSC DOCUMENTS

Visit this page to use the most up to date forms appropriate for your study (e.g., consent, assent, HIPAA) when following the instructions listed in the Supporting Documents Section. The applicabl templates must be used for research conducted at Children's Hospital.

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Permissions Tab

ols → IRB: #1361 Updated LSUHN Application KD							
Protocol	Activity Log 🛛 🗕 Ancilla	ry Review Permissions					
	Document Peri	+ Add User					
	Q Search users	Q Search users					
	Name	Permission Type					
	CHNOLA Research	Role & Permissions Read-Only Full Access			Cancel Add		
) a curra ant Darmia	Protocol Activity Log	Ancillary Review	Permissions			
L	ocument Permis	ssions			+ Add User		
	Q Search users						
	Name	Permission Type					
	KR Rome, Kadie	Full Access 🐱			×		
(LR LSUHN Research	Full Access 🐱			×		
	CR CHNOLA Research CHNOLA.Research	Full Access 🐱			×		
	IR Reviewer, IRB	Full Access (User's perm	issions can be updated	in the person selection	on of the protocol)		