STANDARD OPERATING PROCEDURES			
KUALI PROTOCOLS – PERSONNEL AND PERMISSIONS			
NUMBER	**APPROVED BY**	**EFFECTIVE DATE**	**PAGE**
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I.   Introduction

This procedure establishes the process for managing protocol access in Kuali Protocols (Kuali). Access to a given protocol is controlled two ways in Kuali: Personnel Section and the Permissions tab.

The purpose of this guidance is twofold:
- Clarify the difference between Research Personnel and Administrative Contacts; and
- Establish process for adding users to the Permissions tab.

This procedure is intended for all IRB submissions, including potential and actual human subjects research (HSR) under the oversight of LSU Health Sciences Center – New Orleans (HSC) Human Research Protection Program (HRPP), and HSR for which HSC or its affiliates are relying on an external IRB for oversight.

II.   Definitions

All definitions are in the context of Kuali for HRPP/IRB purposes.

Protocol Form: The original IRB application for the study in Kuali, which includes the Personnel Section.

Submission Forms: Post-approval applications available for submission after initial IRB Approval (e.g., Amendment, Renewal, Reportable Event and Closure).

Protocol: Includes the entire IRB Protocol record for a study in Kuali, including the original Protocol Form (for studies initially submitted after the implementation of Kuali) and Submission Forms, with tabs across the top screen, an action menu on the right side of the screen, and "jump to" navigation on the left side of the screen.

Personnel Section: Where Principal Investigators, Sub-Investigators, and additional Research Personnel are listed in the Protocol Form. Although individuals listed in this section will appear

in the Permissions tab, their level of access can only be modified in the Personnel Section of the main Protocol Form (via a traditional amendment).

Research Personnel: Individuals who are considered "key personnel" or "engaged" in the conduct of HSR as the term is defined by regulations. All HSC and non-HSC individuals who qualify as research personnel must be listed in the Personnel Section of the Protocol Form.

Permissions Tab: This is a tab within the IRB Protocol that allows individuals who are not Research Personnel (i.e., Administrative Contacts) to be granted access to the Protocol. The submitter is automatically added to the Permissions tab and granted Full Access permission. No amendment is necessary to modify those directly added to this tab, as their access can be modified directly from the Permission tab.

Administrative Contacts: Individuals who are not Research Personnel and are added to the Permissions tab. They might include Site Administrators, Administrative Coordinators, or temporary persons like regulatory officials doing a review.

Level of Access: The same two levels of access are available for selection in the Personnel Section and Permissions tab:

- **Read-Only**: Gives the user the ability to view the Protocol and download attachments and approval letters but does not allow the individual to take actions on the study (e.g., editing/submitting applications).
- **Full Access**: Gives users 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. Full Access individuals can edit the Permissions tab and modify the access level of Administrative Contacts and Research Personnel.

III.   Procedure Statements

The procedure is reflective of current Kuali features and designated use by the HSC HRPP. This document outlines the difference between Research Personnel and Administrative Contacts and clarifies appropriate use the Permissions tab.

A. Research Personnel

All individuals considered Research Personnel must be listed in the Personnel Section of the Protocol Form. In short, Research Personnel should never be added to Permissions tab. HSC considers Research Personnel to be those who are either "key personnel" or "engaged" in the conduct of HSR as the term is defined by regulations:

1. **Key Personnel:** Any individual with full or partial responsibility for the design, conduct, OR publication/presentation of research results.

2. **Engaged:** The Office for Human Research Protections (OHRP) considers an institution "engaged" in HSR when its employees or agents, for the purposes of a research project, obtain:

- Data about the subjects of the research through intervention or interaction with them;
- Identifiable private information about the subjects of the research; or
- The informed consent of human subjects.

Therefore, individuals who intervene or interact with human subjects, or access subjects' identifiable data for research purposes, are considered engaged in research.

B. **Administrative Contacts**

The Permissions tab should only be used to add individuals who are not considered Research Personnel, such as:

- **Performance Site Administrators**: Individuals at an organization who need access to view research protocols conducted at their organization for administrative purposes (financial, reporting, auditing responsibilities, etc.).
- **Administrative Coordinators**: Individuals at an organization who need Full Access to initiate or edit submissions for IRB review.

C. **Level of Access**

The submitter/PI is responsible for correctly adding all Research Personnel to the Personnel Section, listing applicable Administrative Contacts to the Permissions tab, and designating the appropriate level of protocol access.

Only individuals that initiate the Protocol Form (i.e., submitter) or have Full Access permission as designated in the Personnel Section or Permissions tab can take "Submit" and "Resubmit" actions.

IV. **Procedures**

A. **Research Personnel**

The submitter identifies all Research Personnel and lists them in the Personnel Section of the Protocol Form, designating their access level and other required fields as listed in the Personnel table.

Individuals listed in the Personnel section will also display in the Permissions tab (**permission type in black**); however, Research Personnel can only be modified by submitting an amendment and updating the Personnel section as traditional done. Research Personnel cannot be edited from the Permissions tab.

Submitter Notes:

- The submitter is not automatically added the Personnel Section; instead, they are automatically granted Full Access permission as an Administrative Contact upon initiating the Protocol Form.
- If the submitter is also considered Research Personnel, they need to add themselves to the Personnel Section.
    - In this case, the submitter's contact 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 Research Personnel (where their contact and permission can only be edited from the Personnel Section).
    - To avoid duplicate notifications, the submitter can remove their duplicate contact from the Permissions tab.
- If the submitter is an Administrative Contact only (e.g., activities are limited to editing and submitting applications through Kuali), they do not need to add themselves to the Personnel Section and will still receive all notifications and Full Access to the protocol as an Administrative Contact.

B. Administrative Contacts

The submitter identifies applicable Administrative Contacts (see Performance Site Administrative Contacts below) and adds them directly to the Permissions tab, designating their applicable access level. The submitter and anyone with Full Access permission can edit the Permissions tab; therefore, designating full access permission should be done with intention.

In summary, Administrative Contacts:

- Are not Research Personnel.
- Can be directly added to the Permissions tab by Full Access individuals.
- Have their level of Access is determined by the submitter/PI.
- Will not appear in the Protocol.
- Will receive all Protocol notifications.
- Do not require an Amendment (their permission and contact can be edited directly from the Permission Tab (**permission type in blue**).

C. Performance Sites – Administrative Contacts

It is now the submitter's responsibility to add all Administrative Contacts, including Performance Site Administrative Contacts, to the Permissions tab as detailed below.

- Protocol Form: Upon adding any of following institutions to the Performance Site section of the Protocol Form, the submitter will immediately navigate to the Permissions tab and list the respective Administrative Contact.
- Submission Forms: Upon submitting a post-approval form, the submitter will review the Performance Site section of the Protocol Form and crosscheck the

Permissions tab, ensuring the applicable Performance Site Administrative Contact is listed. If they are missing, the submitter will list the contact, thereby ensuring they receive all protocol 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 you respond "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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V.   Related Information

Related Policy Documents

A.   HSC Policies

1.   P & P # 5.03: Research Personnel Definition, Roles & Training

Related HSC Guidance

B.   HRPP Kuali Quick Guides

1.   HRP-2801: Overview of New Protocol Submission

C.   Website Guidance

1.   Training Requirements

Kuali Research Knowledge Base

D. [KR Protocols](#)

1. [Document Permissions](#)

VI. **Images**

A. Protocol Tab and Personnel Section:

B. Personnel Section – Selecting the "Level of Access"

C. Example - Protocol Personnel Displaying in Permissions Tab (Cannot Edit from this Tab)

Protocol Tab

Protocol Personnel Table

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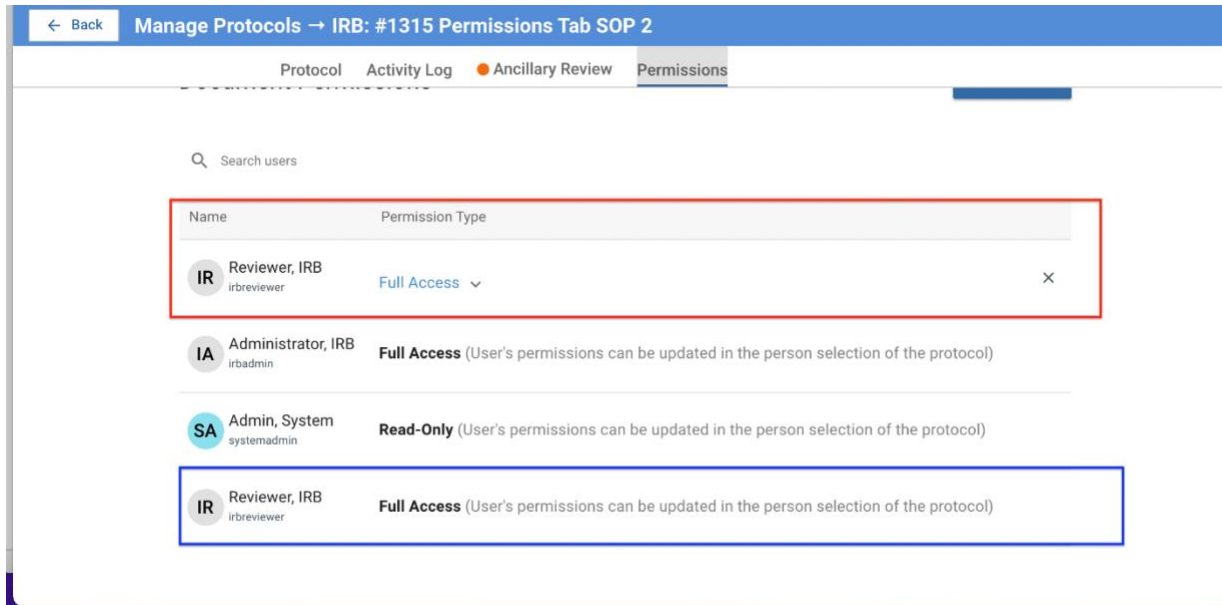|	NAME	EMAIL ADDRESS	PROTOCOL ROLE	AFFILIATION TYPE
◉	Administrator, IRB	irbadmin@test.co	Principal Investigator	HSC [faculty (including gratis), staff, students or employees of LSUHSC-NO]
◉	Admin, System	systemadmin@test.co	Sub-Investigator	HSC [faculty (including gratis), staff, students or employees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

Permissions Tab

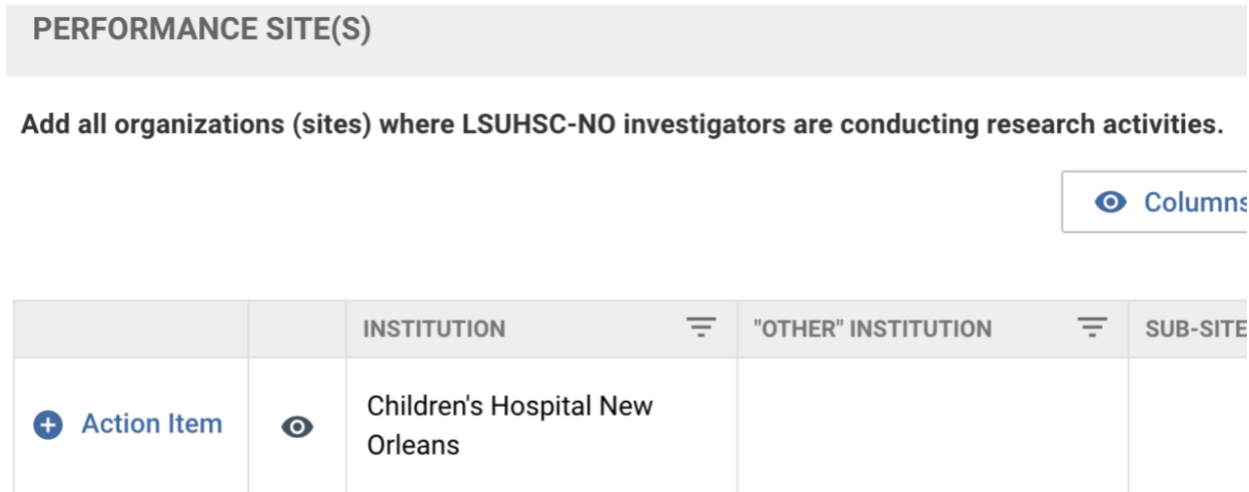Protocol   Activity Log   ● Ancillary Review   Permissions

🔍 Search users

Name	Permission Type	
IR Reviewer, IRB irbreviewer	Full Access ˅	✕
IA Administrator, IRB irbadmin	**Full Access** (User's permissions can be updated in the person selection of the protocol)	
SA Admin, System systemadmin	**Read-Only** (User's permissions can be updated in the person selection of the protocol)	
IR Reviewer, IRB irbreviewer	**Full Access** (User's permissions can be updated in the person selection of the protocol)	

D. Example - Permissions Tab: Submitter automatically added as Administrative Contact and added themselves to Personnel Section (displays twice in Permissions tab)

E. Adding an Administrative Contact based on Performance Site section

Protocol Tab

Permissions Tab

VII.   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

Version Number	Version Date	Summary of Changes
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
1.6	1.25.2023	Clarified difference between Researcher Personnel and Administrative Contacts; Submitter/PI now responsible for adding Administrative Contacts (including site admin) to Permissions tab.