

Kuali Protocols NEW Form Guide – Emergency Use

v05.2021

This form guide is meant as a tool for investigators, HRPP staff, and IRB members and provides information about the Kuali Protocols NEW form. This information is meant as a tool only and should be considered guidance. Please contact the HRPP if you are unsure how to answer a specific question.

Question ID	Question	Options	Guidance
General Information			
N/A	Principal Investigator	User list	Start typing the value and options will appear. Select desired option.
N/A	Lead Unit	Unit list	This is the IU unit under which the research will be conducted. Typically, this is the PI's division or department. For non-IU PIs, enter "External Organization." Start typing the value and options will appear. Select desired option.
N/A	Study Title		Enter Study Title
Protocol Type			
0100	Select your protocol type.	<ul style="list-style-type: none"> Exempt Expedited/Full Board Request to rely on a non-IU IRB Not Human Subjects Research Humanitarian Use Device (HUD) Emergency Use (This is rare. Contact the HRPP at irb@iu.edu before selecting.) 	If you are unsure of your protocol type, visit the protocol decision tree for more information.
Research Personnel			
	Personnel List <i>Select +Add Line to list each person</i>	List	This Personnel list is for Research Personnel Only. For individuals who need access to the protocol but are not research personnel, add them to the Permissions tab. For NEW studies and amendments changing the PI, you must click on the pencil icon to complete all required information in the person record.
N/A	Person	User list	
N/A	Email Address	Auto-filled based on person selected	
N/A	Researcher Role	<ul style="list-style-type: none"> Principal Investigator (PI) Co-PI Key Personnel Site-specific PI Other Research Staff 	
N/A	<i>IF Researcher Role = Principal Investigator (PI)</i> Home Unit	Unit list	
N/A	IU Faculty/Staff or Student?	<ul style="list-style-type: none"> Yes No 	

Kuali Protocols NEW Form Guide – Emergency Use

v05.2021

Question ID	Question	Options	Guidance
N/A	<i>If IU Faculty/Staff or Student = No</i> List the institution	Free text	
N/A	Permission Type	<input type="checkbox"/> Full Access <input type="checkbox"/> Read-Only	This is auto-populated based on Researcher Role.
0142	Training		Will display applicable CITI training courses for person and note if active or expired.
N/A	People Attachments <i>Select +Add Line to list each attachment</i>		For Expedited/Full Board or Request to rely on non-IU IRB protocol types, attach a CV for the Principal Investigator.
	Attachment	Drag & drop a file	
	Name	Free text	
	Attachment Type	<ul style="list-style-type: none"> • Curriculum Vitae • Conflict of Interest • CITI or Other Training Documentation • Non-affiliated investigator agreement • Site Specific Personnel List • Other 	
	Comments	Free text	
Emergency Use			
0146	State the name of the investigational product used.	Free text	
Protocol Attachments			
	Protocol Attachments <i>Select +Add Line to add each attachment</i> <i>Select Replace to replace an existing document</i>	List	
N/A	Attachment Type	<ul style="list-style-type: none"> • Assent Form • Data Collection Instrument • HIPAA Authorization Form • Informed Consent Statement • Investigator Brochure • Protocol • Recruitment Materials • Reliance Documentation • Study Information Sheet • VA – Security/Privacy Checklist • Other 	

Kuali Protocols NEW Form Guide – Emergency Use

v05.2021

Question ID	Question	Options	Guidance
	Attachment	Drag & drop a file	
	Description	Free text	