

Kuali Protocols NEW Form Guide – Amendment

v05.2021

This form guide is meant as a tool for investigators, HRPP staff, and IRB members and provides information about the Kuali Protocols Amendment 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
Amendment Request			
4000	Select your Protocol Type	<ul style="list-style-type: none"> • Expedited/Full Board • Exempt • Request to rely on a non-IU IRB • Humanitarian Use Device (HUD) 	If unsure, click Protocol Type in left hand navigation bar to review Protocol Type in the main form.
4012	Amendment Number	Free text	Assign an amendment number in the format AXXX (e.g. A007)
IF 4000 = Expedited/Full Board			
4001	Select the type of changes being made.	<input type="checkbox"/> Personnel update <input type="checkbox"/> Investigator’s Brochure update which does not result in any changes to other study documents or Kuali Protocols information <input type="checkbox"/> Other changes	
4002	<i>IF 4001 = Personnel update</i> Does this amendment include a change in PI?	<ul style="list-style-type: none"> • Yes • No 	If Yes, upload the new PIs CV to their person record in the Personnel List.
4003	<i>IF 4002 = Yes OR 4001 = Other changes</i> Select the appropriate status of the study.	<ul style="list-style-type: none"> • Open to Enrollment – No subjects consented to date • Open to Enrollment – Enrollment continues • Closed to Enrollment – Research interventions continue • Closed to Enrollment - Clinical Follow-up Only (Remaining research activities are limited to accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care) • Data Analysis Only (Remaining research activities are limited to analysis of identifiable information or biospecimens) • FOR HRPP PURPOSES ONLY. HRPP initiated administrative amendment. 	
4004	<i>IF 4000 ≠ Expedited/Full Board, OR 4001= Other changes OR 4002 = Yes</i> Describe the changes being made.	Free text	

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Question ID	Question	Options	Guidance
4005	IF 4000 ≠ Expedited/Full Board, OR 4001= Other changes OR 4002 = Yes Why are these changes being made (i.e. what is the rationale for these changes)?	Free text	
IF 4001 = Other changes			
4006	IF 4003 = Open to Enrollment – Enrollment continues, Closed to Enrollment OR Data Analysis Only Will any previously enrolled subjects be informed of these changes?	<ul style="list-style-type: none"> • Yes • No 	
4007	IF 4006 = Yes Explain which subjects will be informed and which subjects will not.	Free text	
4008	IF 4006 = Yes Select how subjects will be informed of the changes.	<input type="checkbox"/> Subjects will be re-consented <input type="checkbox"/> Subjects will be informed in writing (e.g. a letter) but will not sign a revised Informed Consent Statement <input type="checkbox"/> Subjects will be verbally informed <input type="checkbox"/> Other	
4009	IF 4008 = Other Describe the other method of informing subjects of the changes.	Free text	
4010	IF 4006 = Yes Describe the timing of notification or re-consent.	Free text	
4011	IF 4006 = No Explain why subjects will not be informed.	Free text	
This is the end of the Amendment form. Make changes to the form responses and/or attachments below to reflect the changes being made with this Amendment.			