QUICK START GUIDE



Kuali Coeus: The Clinical Trial Process

Industry/Commercial Clinical Trials at Indiana University

Industry/Commercial clinical trials are routed to the Office of Clinical Research (OCR) while clinical trials supported by federal funds or foundations/non-profits are routed to the Office of Research Administration (ORA). Both types use the Kuali Coeus routing and awards systems. Correctly completing the forms ensures the documents reach the correct office. The system looks at three variables to determine where it routes; *the Clinical Trials Checkbox, the Sponsor field, and the Prime Sponsor field*.

For more complete information on completing and submitting a Kuali Coeus Proposal Development Document, please see the documentation *How to Submit a Proposal*. For more information about industry/commercially sponsored clinical trials, contact the Office of Clinical Research: <u>OCR@iu.edu</u>.

Variable 1: The Clinical Trial Checkbox:

The Proposal Development document opens to the Proposal tab which contains the required items for saving the form.

Approver View Proposal S2S Key Personnel Special Review Custom Data Abstracts and Attachments Questions Budget Versions Permissions Proposal Actions Medusa

The clinical trials checkbox is located on the *Institutional Fields Conditionally Required* subpanel. A clinical trial is generally a project which involves testing of a sponsor's device or drug on participants. The checkbox should be checked if the project is a clinical trial regardless of funding source. Additionally, variables 2 or 3 are needed for the document to route to OCR.

Institutional Fields Conditionally Required	8
Award ID:	<u> </u>
Original Institutional Proposal ID:	<u>()</u>
Revision Type:	select
Clinical Trial?:	
Sponsor & Program Information	

Variable 2: The Sponsor

In addition to the Clinical Trial Checkbox being marked, if the Sponsor is an industry/commerical entity and no federal funds are involved, the document will route to OCR. If the Sponsor is NOT an industry/commerical entity (example below), the document could still route to OCR if Variable 3 is met.

Required Fields for Saving Document	
Required Fields for Saving Document	?
Proposal Number: 136771	* Sponsor Code: 052457 Supervision Code: UNIVERSITY OF CHICAGO
* Proposal Type: New	* Project Start Date: 02/01/2022
* Lead Unit: BL-PHYS - PHYSICS 🛄	* Project End Date: 01/31/2027
* Activity Type: Research	

Variable 3: The Prime Sponsor

In addition to the Clinical Trial Checkbox being marked, if the Prime Sponsor is an industry/commercial entity and no federal funds are involved, the document will route to OCR. If the Prime Sponsor is NOT an industry/commercial entity (example below), the document will route to ORA.

Sponsor & Program Information	▼ hide	<u>`</u>			
Sponsor & Program Information					
Sponsor Deadline Date:	06/02/2021		Sponsor Deadline Time:	5:00 PM	
Sponsor Deadline Type:	Target 🗸		Notice of Opportunity:	No Guidelines Available	
Sponsor Name:	UNIVERSITY OF CHICAGO	_	CFDA Number:	47.049	
Prime Sponsor ID:	018500		Opportunity ID:		
NSE Science Code:	select		Sponsor Proposal ID:		
Sponsor Div Code:			Does this proposal include subaward(s)?:		