

QUICK START GUIDE



Kuali Coeus: The Clinical Trial Process

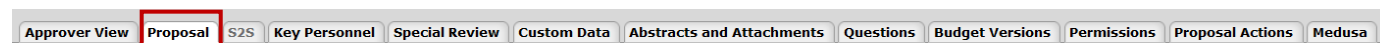
Industry/Commercial Clinical Trials at Indiana University

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: OCR@iu.edu.

Variable 1: The Clinical Trial Checkbox:

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

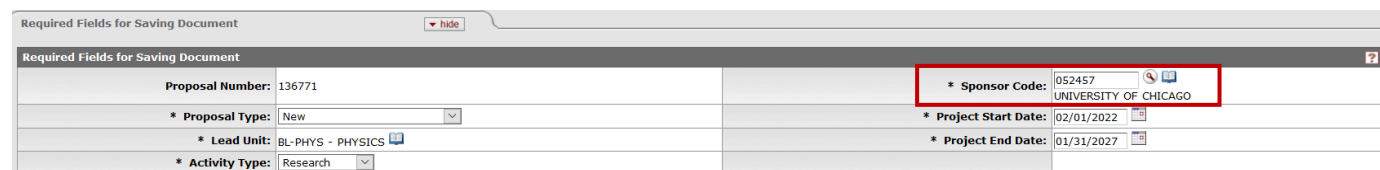


The clinical trials checkbox is located on the *Institutional Fields Conditionally Required* subpanel. A clinical trial is generally a project which involves testing of a sponsor's device or drug on participants. The checkbox should be checked if the project is a clinical trial regardless of funding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



Variable 2: The Sponsor

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



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.

