IU-CTO – Kuali Coeus Proposal Routings

Logic Update

Proposal Guidance

Supplemental Guidance

Reminders

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IU –CTO – Kuali Coeus Proposal Routing Logic Update

- Ability to route proposals to the IU-CTO where the main sponsor is a non-profit entity but the prime sponsor (funding source) is a commercial sponsor
- EXAMPLE 1: University pass through (i.e. Sponsor = UCLA [non-profit entity], prime sponsor = Eli Lilly [commercial sponsor], and “clinical trials” box checked)
- EXAMPLE 2: Consortium Study (i.e. Sponsor = HCRN, prime sponsor = Eli Lilly, and “clinical trials” box checked)
- Screen Shot:

Proposal Development Document

Doc Nbr:	53357708	Status:	Approved Post-Submiss
Initiator:	mali	Created:	01:53 PM 09/08/2016
Sponsor/S2S:	HOOSIER CANCER RESEARCH NETWORK/None	PI:	O'Neil, Bert Howard

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

expand all | collapse all

Document Overview

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Document Overview			
* Description:	Phase II Randomized, Double-Blind Study of mFOLFIRINOX plus Ramucirumab versus mFOLFIRINOX plus placebo in Advanced Pancreatic Cancer Patients	Explanation:	New CTA Protocol Study #GI14-198
Organization Document Number:			

Required Fields for Saving Document

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Required Fields for Saving Document			
Proposal Number:	92145	Sponsor Code:	062359 HOOSIER CANCER RESEARCH NETWORK
Proposal Type:	New	Project Start Date:	10/08/2016
Lead Unit:	IN-HEMO - HEMATOLOGY/ONCOLOGY	Project End Date:	10/07/2021
Activity Type:	Service/Other		
Project Title:	Phase II Randomized, Double-Blind Study of mFOLFIRINOX plus Ramucirumab versus mFOLFIRINOX plus placebo in Advanced Pancreatic Cancer Patients		

Institutional Fields Conditionally Required	
Award ID:	
Original Institutional Proposal ID:	
Revision Type:	
Clinical Trial?:	Yes

Sponsor & Program Information

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Sponsor & Program Information			
Sponsor Deadline Date:	10/08/2016	Sponsor Deadline Time:	
Sponsor Deadline Type:	Target	Notice of Opportunity:	
Sponsor Name:	HOOSIER CANCER RESEARCH NETWORK	CFDA Number:	
Prime Sponsor ID:	056120 LILLY USA, LLC	Opportunity ID:	
NSF Science Code:		Sponsor Proposal ID:	GI14-198
Sponsor Div Code:		Does this proposal include subaward(s)?:	No
Anticipated Award Type:		Sponsor Program Code:	
Agency Routing Identifier:		Prev Grants.Gov Tracking ID:	
Opportunity Title:			
Program Guidelines URL:			

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IU-CTO – Kuali Coeus Proposal Guidance

- The IU-CTO, in conjunction with ORA, has recently updated the Kuali Coeus Proposal Training Guide for routing Commercial Clinical Trials .
- The guidance has been posted in the Kuali Coeus training site at the following link: http://researchadmin.iu.edu/EO/eo_kc_grants.html
- This guide will be posted to the new IU-CTO website on the Additional Resources Page

Training Guides

Quick Start Guides are documents that provide a brief overview of functionality. The guides are often used as a quick reference point or cheat sheet.

Quick Start Guides:	Guide Details:	Release Date:
Proposal Routing in Kuali Coeus Grants	13 pages	04-25-2016
Getting Started and Navigating	2 pages	10-21-2015
Approver View for Routing and Approval	4 pages	10-21-2015
Proposal Routing for Commercial Clinical Trials in Kuali Coeus Grants	11 pages	04-25-2016
Creating a New Rolodex Entry	1 page	08-24-2011
Proposal Budget	2 pages	03-30-2011

Formal Classroom Guides are documents that provide very detailed information regarding system functionality. The guides are used during formal classroom training.

To view the schedule and register for a class, visit the Kuali Coeus Training Sessions page.

- Important Reminders:
  - To route a proposal to the IU-CTO, always click the “clinical trials” box
  - For new CTA, activity type will always be “service/other”
  - For CTA Amendments the proposal type will always be either:

    “**revision/supplemental**” (if there are supplemental funds associated with the Amendment)

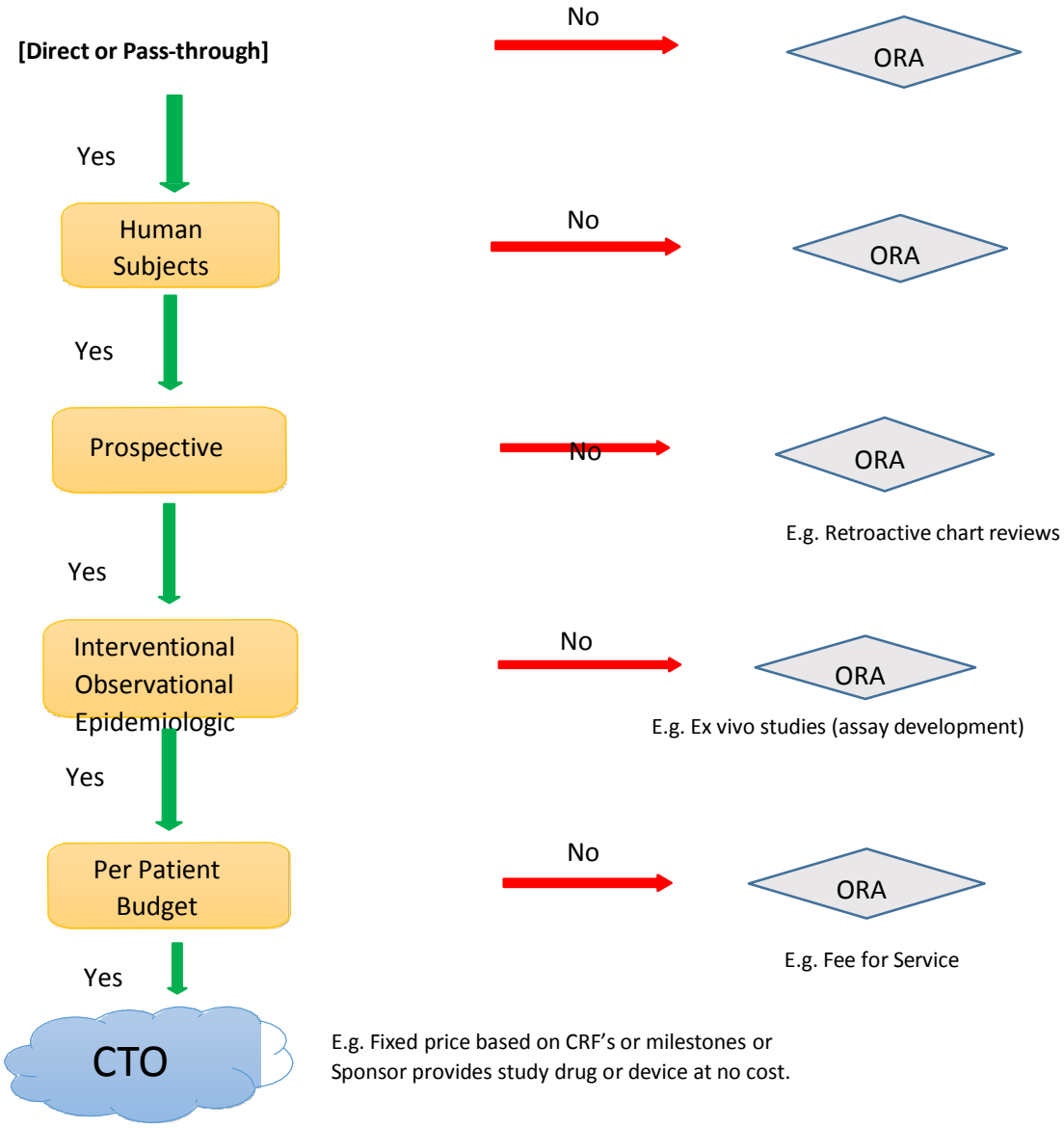
    OR

    “**revision/other**” (if there are **NO** supplemental funds associated with the Amendment)
  - For proposal types “new” or “revision/supplemental” please make sure the budget versions tab is complete and an internal budget is attached to your proposal

IU-CTO – Kuali Coeus Proposal Supplemental Guidance

- The IU-CTO has recently created a supplemental guidance for Kuali Coeus Proposals to outline what types of proposals get routed to the IU-CTO and what types of proposals get routed to ORA

Clinical Trial Contract Routing Guidelines



- The flow chart begins with the funding source. The first check is if the funding source is directly from a commercial sponsor or a pass through a non-profit entity but is funded by a commercial sponsor
- The next check is if the study involves human subjects (the IU-CTO only does contracts for Human Subjects Clinical Trials)
- The following checks involves the design of the clinical trial and the payment structure. We are looking for prospective clinical trials that are interventional, observational, or epidemiological
- A way to think about study design is ex-vivo versus in-vivo

Kuali Coeus Proposal Supplemental Guidance:

Agreement Types that must be routed to CTO through Kuali Coeus Proposal:

1. Clinical Trial Agreement
2. Clinical Trial Agreement Amendment
3. Subcontract Agreement

All other agreement types (CDAs, SSUAs, FUA, etc.) must be sent to CTO Inbox

AT

(cto@iu.edu)

Clinical Trial Agreement Proposal:

Must include:

- Final Version of the Study Protocol
- Draft Budget
- Internal Budget
- Draft Clinical Trial Agreement

Clinical Trial Agreement Amendment Proposal:

Must include:

- Draft Budget (if supplemental funds associated with amendment)
- Internal Budget (if supplemental funds associated with amendment)
- Draft Clinical Trial Agreement

Subcontract Agreement Proposal:

Must include:

- Scope of work
- Final Version of the Study Protocol
- Draft Budget
- Internal Budget
- Draft Clinical Trial Agreement
- Appropriate contact information for the Sub-Site

IU-CTO - Reminders

- **The Conflict of Interest (COI) forms must be renewed after August 15, 2016. Investigators will be required to complete a current form to ensure compliance with this annual requirement. The COI form can be found at the following website:** *http://researchcompliance.iu.edu/coi/coi_disclosure.html)*
- Visit the IU-CTO Process Map: (https://indianaclinicaltrialsoffice.iu.edu/investigators-study-coordinators/about-process-map/)
- Please note: the IU-CTO always strive for the Contract Negotiation, Budget Negotiation, IRB Submission, and OnCore Entry to occur simultaneously
- **Always remember to contact the IU-CTO at CTO@IU.EDU with any questions!!! Our office is always happy to assist!**