

# **Coordinator Training**

**OCR Guide to Assisting Study Coordinators**

# ORA vs OCR

**What goes to Office of Research Administration (ORA) versus the Office of Clinical Research (OCR)?**

## **ORA**

- Non-Profit(government) Sponsored/Supported Research
  - Bench Research Included

## **OCR**

- Industry-Sponsored/Supported Research
  - Trials on Human Subjects

# How to get a Contract to OCR

- ✓ Portal on OCR website (CDA)
- ✓ KC - Kuali Coeus (IU Grant & Contract System)
- ✓ E-mail to [OCR@iu.edu](mailto:OCR@iu.edu)

# CDA Submission

To protect confidential information exchanged between Indiana University and third parties, the execution of a **Confidential Disclosure Agreement (CDA)** is required

Principal Investigators **CANNOT** do their own CDA

<https://ocr.iu.edu/investigators-study-coordinators-2-2>





# **Routed Contracts**

**Clinical Trial Agreement (CTA)**

**Work Order/Statement of Work**

**Subcontract-In**

**CTA/Subcontract-In Amendment**

increase in overall budget  
change in Principal Investigator

# Routing through KC (Creating Proposal Development Document)

## **CTA, Work Order, Statement of Work or Subcontract-In**

- ✓ Draft/template of contract
- ✓ Budget (draft)
- ✓ Protocol
- ✓ ICF

## **Amendment**

- ✓ Draft/template of contract
- ✓ Budget

# **Non-Routed Contracts**

**Subcontract-Out**

**Subcontract-Out Amendment**

**CTA and Subcontract-In Amendment**

decreasing overall budget  
language/address change  
budget change with invoiceable items only  
(no increase in overall budget)

# Non-Routed Contracts

## Submitting Non-Routed Contracts

Submit via e-mail to [OCR@iu.edu](mailto:OCR@iu.edu)

- ✓ Draft/template
- ✓ Sponsor contact name and e-mail
  - ✓ Details of the Contract
- ✓ Subcontract - include subcontract intake form