

OSP Contracting: A Deeper Dive

OFFICE OF SPONSORED PROGRAMS

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February 22, 2024



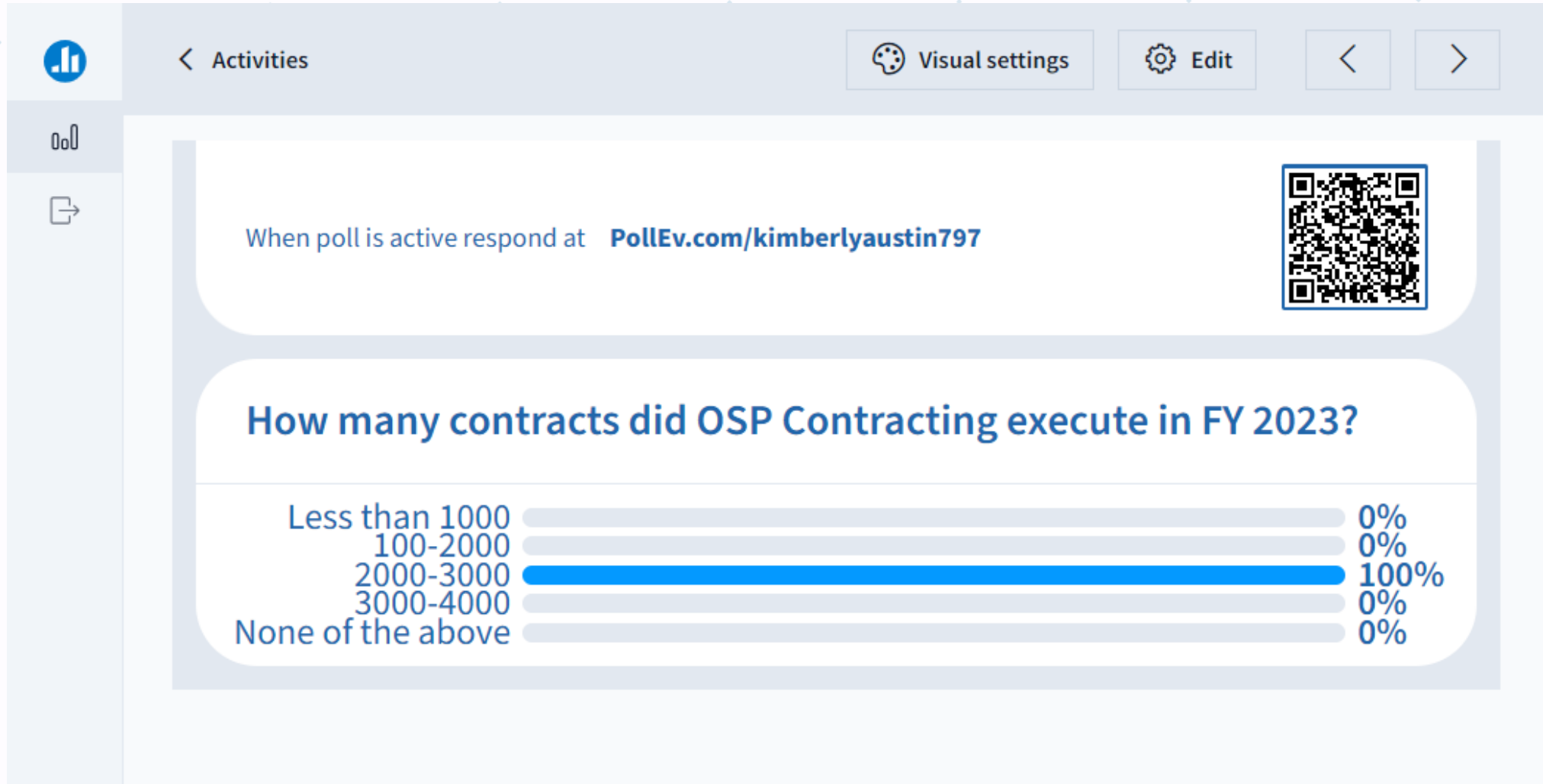
RESEARCH

OBJECTIVES:

- 1) Overview of the Office of Sponsored Programs
- 2) Contract Types
- 3) Contract Negotiation Process: Submission to Execution
- 4) Tips for Working with OSP Contracting
- 5) Coming in 2024/Resources



OSP Trivia




OSP Contracting... TRIVIA!

The screenshot shows a mobile application interface for a poll. At the top, there is a navigation bar with a back arrow, the text "Activities", and buttons for "Visual settings" and "Edit". Below the navigation bar, there is a sidebar with three icons: a bar chart, a list, and a share icon. The main content area displays the poll details: "When poll is active respond at", the poll name "PollEv.com /kimberlyaustin797", and the instruction "Send 121472 and your message to 22333". A QR code is located to the right of the poll details. The poll question is "How many CTAs did OSP Contracting finalize in FY 2023?". Below the question, it states "Nobody has responded yet." and "Hang tight! Responses are coming in."

Activities

Visual settings Edit

When poll is active respond at **PollEv.com /kimberlyaustin797** Send **121472** and your message to **22333**



How many CTAs did OSP Contracting finalize in FY 2023?

Nobody has responded yet.

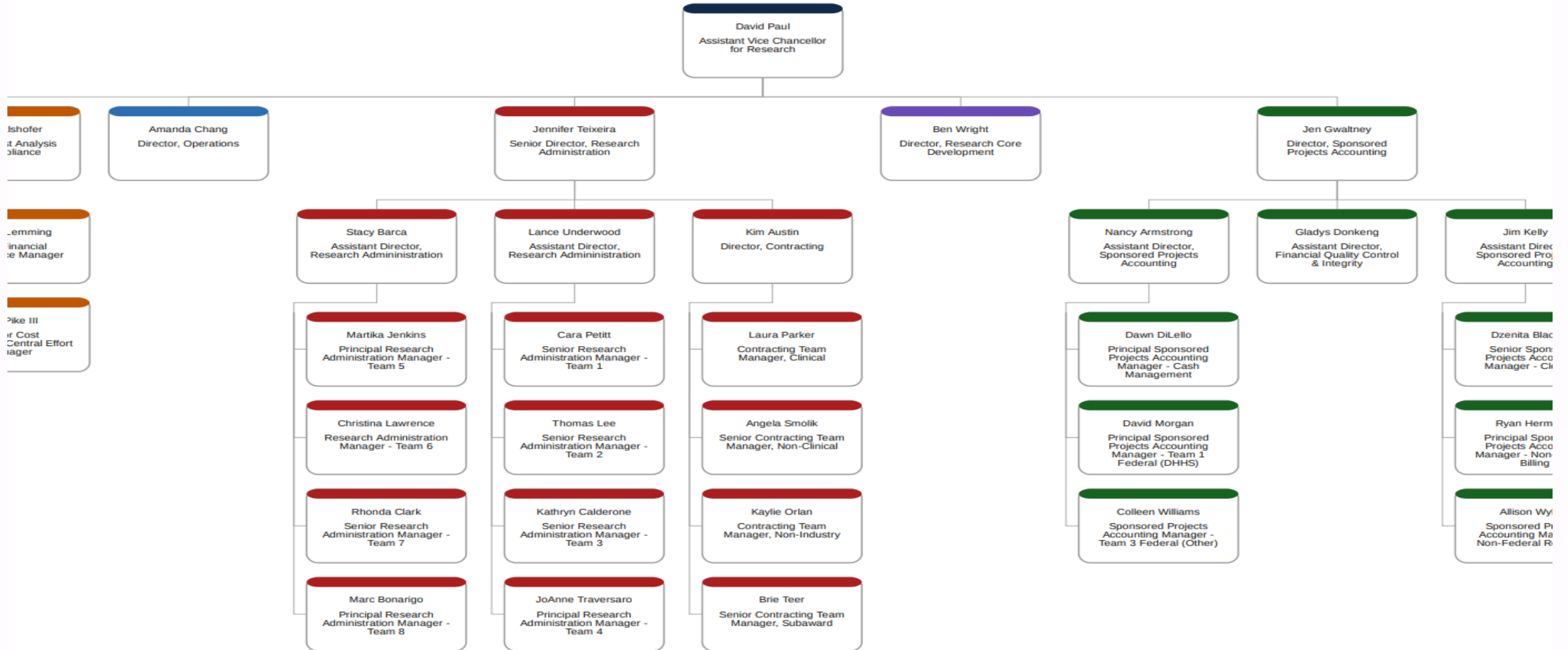
Hang tight! Responses are coming in.

Office of Sponsored Programs Overview

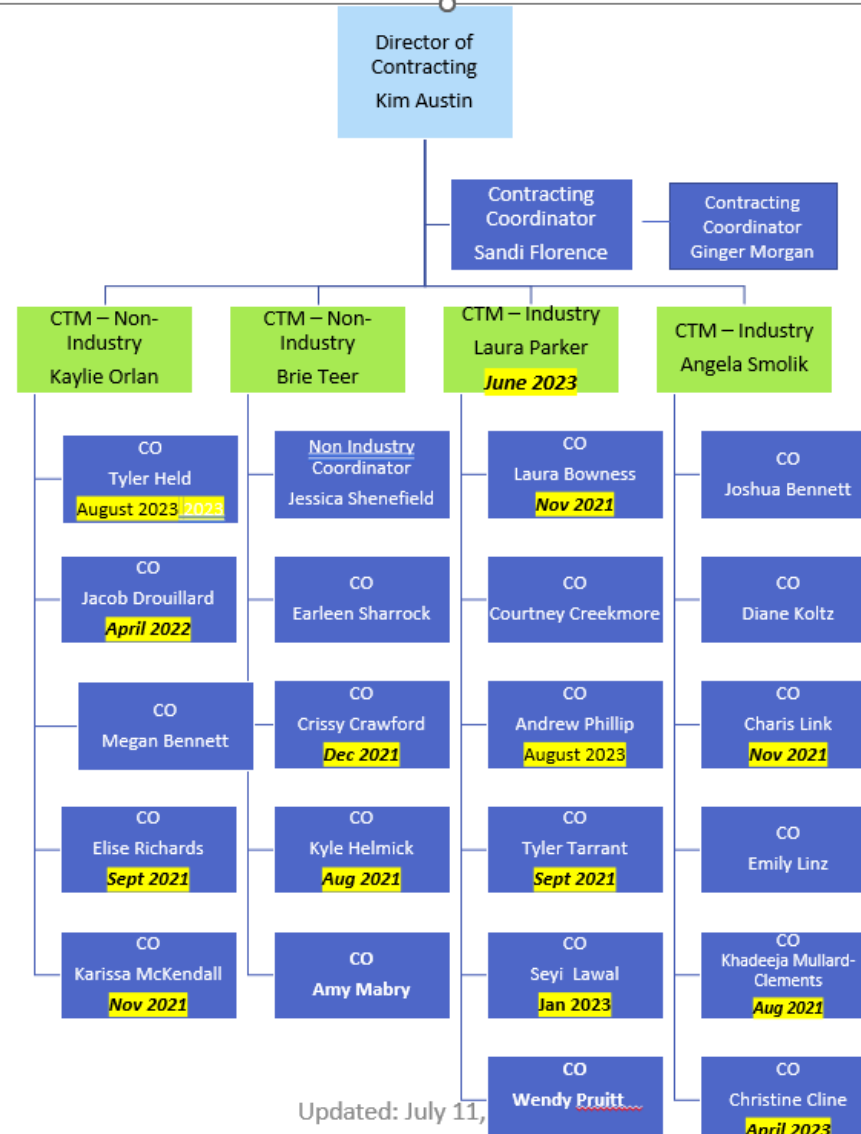


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OSP Contracting- Organizational Structure



OSP Contracting- Organizational Structure



Updated: July 11,

Overview of Contract Types





Activities

Visual settings Edit

What is the average time to execute a CTA?

- Less than 30 business days
- 30-60 business days
- 60-90 business days
- More than 90 business days
- None of the above



Log in to Poll Everywhere

To present live activities, please log in to your Poll Everywhere account in a separate window.

[Launch log-in window](#)

Confidential Disclosure Agreement (CDA)

- A contractual agreement which outlines the terms under which such confidential information will be exchanged
- Required if confidential information will be disclosed in order for the University and an external partner to evaluate a potential collaboration (clinical trial, sponsored research agreement, etc.).

Clinical Trial Agreement (CTA)

- A legally binding contract between an external sponsor and the University which outlines each party's responsibilities and obligations for the clinical trial.
- Required for sponsor-initiated protocols and investigator-initiated protocols.

Collaboration Agreement

- A contractual agreement used to outline the research obligations of each party in pursuit of a common research objective.
- Each party to the Agreement funds its own costs.

Data Use Agreement (DUA)

- A contractual agreement used to define how access to and/or exchanged data may be used.
- Required when transferring (incoming or outgoing) human subject data that includes at least one of the 18 HIPAA identifiers and no other agreement governs the transfer and use.

Material Transfer Agreement (MTA)

- A contractual agreement which governs the transfer of tangible materials between two entities when the recipient intends to use it for their own research purposes.
- Required when the University desires to send or receive tangible material such as reagents, cell lines, plasmids, vectors, chemical compounds, mouse models, and software for research purposes.
- If funding associated with transfer or the material includes PHI, the MTA comes to OSP Contracting; otherwise it goes to Office of Technology Transfer (BLUE)

The Contract Negotiation Process: From Submission to Execution



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Confidential Disclosure/Nondisclosure Agreements (CDA/NDA)

Submission:

Confidential Disclosure/Nondisclosure Agreements (CDA/NDA)	
- CDA for Clinical Purpose	CRMS
- CDA for Non-clinical Purpose	ALICE

Negotiation:

- Can be bilateral or unilateral disclosure
- Usually fairly quick negotiation process
- If needed by a certain date, please include this in the RRF

Clinical Trial Agreements (CTA)

Submission:

Clinical Trial Agreements (CTA), including:

- Investigator Initiated Trials (IIT) and any applicable Outgoing Subcontracts	CRMS/ALICE
- Task/Work Order under a Master CTA	CRMS
- Incoming Clinical Subcontract	CRMS
- CTA Amendments	CRMS/ALICE

Negotiation:

Negotiation time varies greatly by agreement, based in part on:

- Responsiveness of sponsor
- Number of prior agreements with the Sponsor
- Overall workload/volume
- Escalation to other offices (OTC, COI, etc.)

DUAs/MTAs/Collaboration Agreements

- DUAs/MTAs/Collaboration Agreements are submitted in ALICE
- DUAs and MTAs have an additional form to be completed at intake to ensure Contracting Officer has all of the information necessary information
- Negotiation times vary significantly depending on the specifics of the agreement

Working with OSP: Tips and Tricks



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Tell us about you!



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Tell us more!



Communication

- New Auto Emails are sent to PI, Dept contact and Budget Contact when the status of the Agreement changes
- If you want to be copied on correspondence, put yourself as the Dept Contact in ALICE as only ONE department contact receives the automated emails
- General submission questions, please email OSPContracting@unc.edu

Submit All Required Documents

Ensure all required documents are uploaded in ALICE:

- Draft Contract (in Word format)
- Protocol
- Draft Informed Consent Form
- Draft Budget

Ensure IPF is submitted and Certified:

- IPF Can be submitted at anytime, but is required prior to Project ID setup
- PI must certify the IPF in RAMSES
- To help expedite the process, you can email OSPContracting@unc.edu with the IPF number once certified

Coming in 2024!



Coming in 2024!

- Contract Lifecycle Management (CLM)
- Monthly Presentations at OVCR Project Manager Meeting
- Continued Process Improvement and Transparency

We want to hear from YOU!



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Resources



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New OSP Website

OSP | Office of Sponsored Programs

Search this site...



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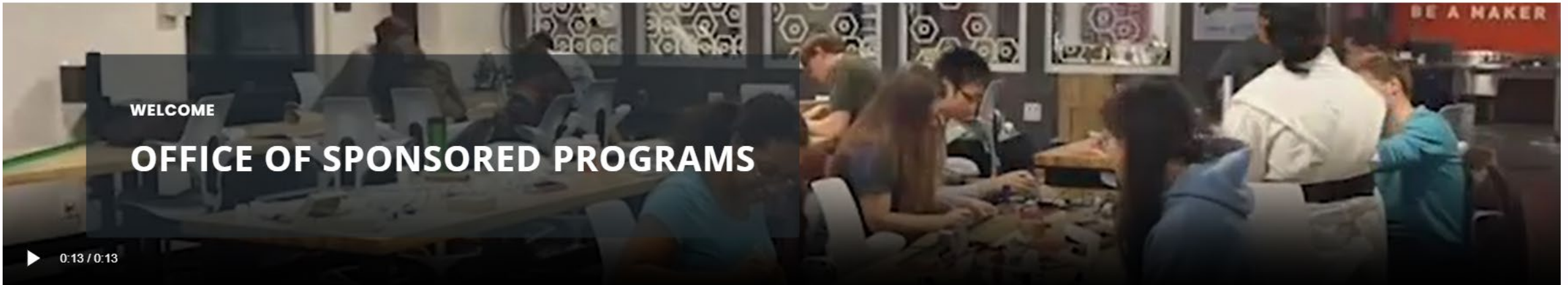
Compliance ▾

Core Facilities ▾

Resources ▾

Training & Events ▾

Quick Info



RESEARCH BY THE NUMBERS

\$1.1B
FY2023

\$1.2B
FY2022

\$1.1B
FY2021

OSP.unc.edu/contracting

[Home](#) / [Contracting](#) / Industry and Non-Industry

Industry and Non-Industry

The Industry and Non-Industry Contracting team is responsible for reviewing and executing agreements with industry for sponsored projects, including sponsored research and clinical trial agreements. The team is also responsible for all (*industry, federal, non-profit*) data use/transfer and research confidentiality agreements as well as other unfunded agreements to support [UNC's research community](#).

Please reference the information on this page to help you determine the type of agreement you need to process and method for their submittals to the Industry Contracting team for review. Please also contact OSPContracting@unc.edu for any additional assistance.

[Contracting Agreements](#) [Systems for Contracting](#) [Forms](#) [Resources & Guidance](#) [Training](#)

Industry Agreements

Agreement Types and Subtypes	Routing System	Instructions
Clinical Trial Agreement (CTA) , including: <ul style="list-style-type: none">Incoming Clinical SubcontractTask/Work Order under Master Clinical AgreementInvestigator Initiated Trial (IIT)CTA AmendmentACTA	CRMS	CRMS CTA Amendments: <ul style="list-style-type: none">If you have an existing CTA record in CRMS, please access that CRMS number, click <i>Submission</i> tab, click <i>OIC</i>, and select <i>Non-CTA Agreement Request Form</i> to submit there.If you do not have an existing CRMS record, you can submit the amendment in



Contact Information

Please reach out with questions or suggestions!

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Questions?

