Office of Clinical Trials Administration (OCTA)

Contract Negotiation Services for Industry Sponsor-Initiated and Funded Clinical Trials

Our Team
Director
Work Leader & 4 Contract Officers
Project Analyst

Human Subjects Research
(45 CFR Part 46)

Industry Initiated
(For-Profit Company)

Industry Funded
(For-Profit Company)

OCTA Contracts
# OCTA vs OCGA

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<td>• Clinical Trial Agreements</td>
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<td><em>For-profit Industry Initiated and Industry Funded</em></td>
<td><em>Investigator or Non-Profit Initiated Non-Industry or Mixed Funding</em></td>
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<td>• Incoming Lab Service Agreements*</td>
<td>• Sponsored Research Grants, Contracts, Incoming Subawards, Basic Research</td>
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<td>• Related CDA/NDA’s</td>
<td>• Material Transfer Agreements, CDA/NDA’s, Data Use Agreements, and other Unfunded Agreements</td>
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<td>• Related Contract Amendments</td>
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*OCTA only handles certain incoming lab service agreements. Please contact OCTA@health.ucsd.edu to confirm, before submitting.

*This is not meant to be an exhaustive list, included for comparison purposes only.
Let’s Re-Cap

Industry Authored Protocol for Human Subjects Research

100% Funded by Industry Sources

OCTA
Submitting Contracts to OCTA

Web-Based JotForm
- Confidentiality Agreements (CDA/NDA)
- Contract/Budget Amendments

Kuali Research*
- Clinical Trial Agreements
- Other Agreement Types Within OCTA’s Purview

*To Login and Submit, must have a UCSD Single Sign On
- Must complete required fields (*) and attach draft CDA/NDA or Amendment
- Form is dynamic, requesting required information based on previous answers.
JotForm Work-Flow

Dept. Preparer Completes & Submits CDA/NDA or Amendment Review Request

Automatically Assigned to a Contract Officer

Training or Access Inquiries: email OCTA@health.ucsd.edu or call 858-822-2940
Close Up: Kuali Research

For access and online training: (1) email researchadmin@ucsd.edu and/or (2) email OCTA@health.ucsd.edu for OCTA’s proposal submission guide.
OCTA Kuali Work-Flow

Dept Preparer Completes Proposal & Submits for Approval

Subject to OCTA Review & Approval

Once **approved**, a contract proposal is automatically assigned to a contract officer’s queue for negotiation.
Completing and Submitting a Proposal in Kuali Research

• Not sure? It’s best to ask questions **BEFORE** completing and submitting a Proposal in Kuali.

• The goal is parallel processes – IRB Review, Budget Negotiation, and Contract Negotiation should occur simultaneously. Don’t hold Kuali Proposal submission for budget negotiation.

• Preferable to obtain an IRB number before submitting a Proposal in Kuali.

• Need to attach draft documents from Industry Sponsor:
  • Draft CTA
  • If not included in CTA, separate draft payment schedule and/or budget
  • Protocol
  • Informed Consent Form (ICF)*

*While preferred, a proposal submission may be accepted without the ICF provided that an IRB number has been provided.
Budget Services Update

• As of July 9, 2018, budget services for industry sponsor initiated clinical trials is now serviced by the Office of Coverage Analysis Administration (OCAA).

• OCAA offers full concierge services to execute your study budgets and to enhance your experience with the study sponsor. They will develop a detailed budget and negotiate the figures with the sponsor to ensure the sponsor covers the full cost of conducting the study at UCSD.

• Please Visit OCAA Clinical Trial Budget Service Request Form:
  • https://ucsd-actri.jotform.com/200906572342047
  • Alternatively, OCAA concierge services for new proposals may be requested through Kuali submission.
Let’s Re-Cap

Contract Negotiation:
CTA’s & More
CDA/NDA’s
Amendments

Industry Initiated
Industry Funded

Kuali

Not Sure? Just Ask

Protocol
OIA (IRB)
Contract
Velos
Questions? More Information?

Office of Clinical Trials Administration (OCTA)

Altman Clinical and Translational Research Institute (ACTRI), 2nd Floor, East Wing

The OCTA team is currently working remotely with access to email and voicemail. If you call, please leave a voicemail.

Main Inbox: OCTA@health.ucsd.edu
Main Line: 858-822-2940

Visit OCTA’s Website: https://medschool.ucsd.edu/vchs/research-services/octa/Pages/default.aspx

(Hint: Type “UCSD OCTA” into Google)

- Staff Assignments
- Staff Contact Information
- General Information
Please complete the SURF Evaluation

We want to hear from you!