

OCTA KUALI PROPOSAL GUIDE FOR DEPARTMENT RESEARCH ADMINISTRATORS

Instructions for creating a New Contract proposal for OCTA in Kuali Research

Last Updated 03/20/23

Tips – What to do and know BEFORE initiating a proposal for OCTA in Kuali Research

- 1. Confirm Contract Type and OCTA Procedure to Follow.** All clinical study agreements for OCTA must be submitted as a New Contract proposal in [Kuali Research](#). To submit CDA/NDA's and Contract Amendments for OCTA, complete OCTA's [online intake form](#). You can find links and training resources on how to submit contracts to OCTA on our [website](#). For questions or to join **OCTA's Email List** for OCTA specific updates, send an email to OCTA@health.ucsd.edu.
- 2. Confirm Proposed Project is Within OCTA's Scope.** In order for your New Contract proposal to be approved for negotiation by OCTA, it must meet all of the following criteria. If you are unsure, please gather the information below from the sponsor and/or PI. If you are still unclear or have questions as to whether OCTA can negotiate your agreement, please contact OCTA@health.ucsd.edu *before* submitting the proposal.
 - a. The owner and author of the Protocol is a for-profit company. There can be no UC PI intellectual contribution or co-authorship of the Protocol.
 - b. The study must be 100% funded by a for-profit entity(ies). The study cannot be supported in whole or in part by government or non-profit funds.
 - c. The proposed study activity is research involving human subjects covered by 45 CFR Part 46

- 3. Collect all Mandatory Documents and Information.** Collect all information and documentation from the Sponsor and/or PI, prior to sitting down to complete your proposal.

Documents you will need to upload:

- a. **Sponsor Protocol**
- b. **ICF** (Note: A draft or sponsor version is fine. If an ICF does not apply, the project is not human subjects research)
- c. **Draft Sponsor Contract** in MS Word format. If sponsor sent a PDF, ask for an editable version so OCTA can make edits during its review, as needed. (If sponsor is requesting UCSD to prepare a template, leave a Note in the Attachments section)
- d. **Draft Budget/Payment Schedule** in Word or Excel format (if not already contained in the Contract document)
- e. **PI Exception Documentation (if applicable):** PDF copy of the approved PI Exception
 - i. To determine if a PI Exception applies, start a proposal in KR and add the PI. When completing the Compliance Questionnaire, the PI Eligibility question below will appear if the PI is not automatically eligible. If this is the case, documentation of an approved PI Exception (PIE) is required to be submitted as part of your proposal. The PI must request a PIE following the new electronic process in OnBase* before continuing with the proposal submission.

- ii. ***Tip:** For resources to help navigate the new electronic PI Exception (PIE) process, click [here](#). You must attach a copy of the approved PIE as an attachment to the proposal, **before** routing to OCTA for approval. If you do not, you will receive the following error message:

- iii. ***For questions about the new electronic PIE process in OnBase, contact piexceptions@ucsd.edu.**

Information you will need to have on hand:

- a. Full name and email for the following contacts: (Some required for OCTA and others for OFC Financial Set-Up)
 - Main Department Study Contact(s) (please include a Rady Children's contact, if applicable)

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<ul style="list-style-type: none"> • Budget Negotiator (For central budget services like OCAA just put “OCAA Budget Services”) • Dept/RSC Invoicing Contact(s) (*required for OFC Financial Set-up) • DBO/MSO (*required for OFC Financial Set-up) <p>b. If you’ve submitted to the IRB, the IRB number. If you have not submitted to the IRB, details of when you intend to submit (you will need to later email OCTA with the IRB number, once you have one).</p> <p>For questions, email OCTA@health.ucsd.edu.</p>
<p>4. Elect OCAA Budget Negotiation Services (Optional). The PI (or a delegated member of the PI’s study team or Lead Department) is responsible for negotiating the budget for a proposal. Industry initiated and funded studies handled through OCTA have the option of electing OCAA budget negotiation services. If you would like to request OCAA budget development and negotiation services, you select “yes” that an external sponsor is providing the protocol (which should always be the case for a contract submitted to OCTA) and then select “I request OCAA budget services” in response to the OCAA budget services question in the Kuali Research Compliance Questionnaire. For questions, contact OCAA@health.ucsd.edu.</p>
<p>5. Complete Mandatory Conflict of Interest Disclosure. Conflict of Interest disclosures must still be made directly to the COI Office through Kuali COI. For more information (including a link to Kuali COI) and to request training, please visit the Kuali COI Blink Page. For questions, email info-coi@ucsd.edu.</p>
<p>6. Avoid Locking Yourself Out of Proposal. Always click Close when exiting the proposal to avoid creating a lock on the proposal. To clear a lock: Log out and back into Kuali. Open the proposal in edit mode. Click Close. Visit the Kuali Research Blink Page for Help Desk support information.</p>

Navigate to ucsd.kuali.co and sign in with your AD credentials. If you are a new user, please request access .	
Click Research Home – Click Common Tasks (Clipboard Icon with Checkmark) – Select Create Proposal	
A. Create Proposal Screen	
Kuali Field or Action	What Information to Enter
1 Proposal Type	New
2 Lead Unit	Enter the name of the Lead Department/Unit responsible for the proposed study.
3 Activity Type	Clinical Research
4 Project Dates	<enter/select today’s date> and <enter/select a date that is exactly one (1) year and 1 day earlier from today’s date> (e.g. 1/7/2020 – 1/6/2021 = 1 year)
5 Project Title	Copy and paste the Protocol Title directly from the Sponsor Protocol (preferred) or enter it exactly as it appears on the Sponsor Protocol.
6 Sponsor	This field should reflect the name of the entity UCSD is contracting with for the proposed OCTA study. <i>Check the first page, first paragraph (i.e. recitals) of the Sponsor’s draft contract to confirm what entity is entering into the contract with UCSD.</i> This will typically be the industry sponsor who is responsible for the conduct of the study but when a CRO is used for contracting, it may be a CRO or similar coordinating entity. Note: Selection of a non-profit or federal sponsor will route the proposal to OCGA. If this happens and the study is industry initiated and funded, please contact OCTA@health.ucsd.edu for assistance.
7 Sponsor deadline	<enter/select a date that is three (3) months from today’s date> (Note: This is a required Kuali field, but OCTA contracts do not have firm sponsor deadlines and the date entered here will not direct OCTA workload management or priorities)
8 Sponsor Deadline Type	Internal Deadline
9 Anticipated Agreement Type	Contract
10	Click Save or Save and Continue and document the Proposal # that is generated in the upper left hand corner for future reference in the proposal creation process and when contacting OCTA about this proposal.

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<p>Note: If you select an activity type other than “Clinical Research” or an Anticipated Agreement Type other than “Contract” or a “Sponsor” that is not a for-profit entity and click save, the system may trigger a notice to you and OCGA that your proposal request has been received by OCGA. To override this and ensure the proposal is routed to OCTA for approval, you must promptly correct your selections in line with this guide and click save.</p>		
<p>B. Basics Panel - Proposal Details Subpanel</p>		
	Kuali Field or Action	What Information to Enter
1	Sponsor	<p>a. This field should reflect the name of the entity UCSD is contracting with for the proposed OCTA study. <i>Check the first page, first paragraph (i.e. recitals) of the Sponsor’s draft, to confirm what entity is signing the contract with UCSD.</i></p> <p style="margin-left: 20px;">a. If the industry sponsor of the study is entering into the proposed research contract with UCSD, enter the name of the industry sponsor in the Sponsor field.</p> <p style="margin-left: 40px;">i. Example Sponsor: Pfizer, Inc. Prime Sponsor: (leave blank)</p> <p style="margin-left: 20px;">b. If an entity other than the industry sponsor of the study (e.g. a CRO, Academic Coordinating Center, or Consortium Group) is the contracting party that is entering into the proposed research contract with UCSD (on behalf of the sponsor) and is signing the contract in the CRO, Academic Coordinating Center, or Consortium group name, enter the name of this other entity in the Sponsor field. The name of the industry sponsor of the study will go in the Prime Sponsor Field.</p> <p style="margin-left: 40px;">i. <u>*Example 1</u> (contracting with a CRO): Sponsor: PPD, Inc. Prime Sponsor: Pfizer, Inc.</p> <p style="margin-left: 40px;">ii. <u>*Example 2 Industry Flow Through</u> (contracting with and payment flowing through a non-profit entity for an industry study) Sponsor: Public Health Institute Prime Sponsor: AstraZeneca, Inc.</p> <p style="margin-left: 20px;">c. *For Industry Flow Through Contracts in Example 2: If the entity listed in the “Sponsor” field of KR is a non-profit, the proposal will automatically route to OCGA, once submitted. If the proposal is intended for OCTA, you must take the additional step of emailing OCTA@health.ucsd.edu so OCTA can review and confirm acceptance of the Proposal and work with OCGA to get the proposal approved in KR. If you do not contact us, OCTA will have no knowledge of the submitted Proposal.</p> <p style="margin-left: 20px;">d. *Note: A CRO, Academic Coordinating Center, or Consortium Group should only be named in the Sponsor field if they are the entity entering into the contract with UCSD. If the contract</p>

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		<p>is with an Academic Coordinating Center, Consortium Group or some other non-profit/academic entity, in order for the study to qualify as industry initiated please make sure the proposed Protocol was developed and authored by a for-profit industry sponsor in addition to being 100% funded with for-profit industry funds, before submitting to OCTA. There are limited exceptions to this rule (e.g. Public Health Institute-COG Work Orders). If unsure, please contact OCTA@health.ucsd.edu for assistance.</p> <p>e. Note: If you cannot locate the name of the Sponsor or Prime Sponsor you are trying to add, please email OCTA@health.ucsd.edu with the full name and address of the entity you are trying to add. OCTA will request a Sponsor Code. Please do not select "Sponsor Code Pending". Once OCTA provides you with the Sponsor Code, you can complete the proposal and submit it for approval.</p>
2	Prime Sponsor	If you entered the name of a CRO, Academic Coordinating Center, Consortium Group, or other entity in the Sponsor field per the instructions above, enter the name of the industry sponsor in the Prime Sponsor field. Otherwise, leave this field blank.
3	Click Save or Save and Continue	
C. Basics Panel – Sponsor & Program Information Subpanel		
	Kuali Field or Action	What Information to Enter
1	Sponsor Proposal ID	Copy and paste the Sponsor Protocol number directly from the Sponsor Protocol or enter it exactly as it appears on the Sponsor Protocol. (NOTE: On rare occasions, a Sponsor Protocol may not have a Protocol Name or #. If this is the case, copy and paste the name of the investigational Study Product or if unsure leave this field blank but leave a note in the Notes tab of the Attachments panel alerting OCTA to this fact.)
	Keywords	<i>Follow WalkMe prompts to select a COVID-19 related Keyword if applicable to your study proposal.</i>
2	Click Save or Save and Continue	
D. Access Panel (Optional)		
	Kuali Field or Action	What Information to Enter
1	Add User button	Click to add other people to a proposal that may require access rights (view only or edit) during the proposal preparation process. Follow prompts. Click here for more information about access roles.
2	Click Save or Save and Continue	
E. Key Personnel Panel – Personnel Subpanel		
	Kuali Field or Action	What Information to Enter

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1	Add Personnel button	<p>a. Enter and search for the Principal Investigator by name. Assign the role of “Principal Investigator”. Do not add any other persons or sub-investigators. Click Save.</p> <p>b. Note: After you click Save, if a PI does not have a title code that makes he/she automatically eligible to serve as a PI, you will see a PI Eligibility Question appear in the Compliance Questionnaire which will alert you to the need for the PI to request a PI Exception, if one has not already been approved. It is the PI’s responsibility to provide a copy of the approved PI Exception.)</p> <p>c. Note: The addition of the PI to the Key Personnel section will trigger a notice to the COI Office. It is the PI’s responsibility to complete a financial disclosure statement through Quali COI. The PI must be cleared by COI before the contract can be executed by OCTA.)</p>
2	Click Save or Save and Continue	
F. Compliance Panel		
	Kuali Field or Action	What Information to Enter
1	Add compliance entry button	
2	Type	Human Subjects
3	Approval Status	Pending (Even if IRB approved, must select Pending to meet system requirements)
4	Protocol Number	<p>a. <enter UCSD IRB Number (numbers only)> (e.g. 804691)</p> <p>b. Note: OCTA strongly prefers an IRB number. If you do not have an IRB number, leave blank but must leave a comment per instructions below.</p>
5	Comments	<p>a. Use this field to explain why you have not submitted to the IRB yet and indicate when you will submit. If you provided an IRB number, you can leave this blank.</p> <p>b. Note: When you obtain the IRB number you must notify OCTA by emailing OCTA@health.ucsd.edu or notify the contract officer you are working with. It is your responsibility to provide OCTA with the IRB number once you obtain it and to notify OCTA of any status updates – such as, when the IRB provides notice of approval.</p>
6	Type	Export Control (If any of the Export Control Research Questions was answered “Yes”)
7	Approval Status	Pending
8	Comments	Use this field to explain the circumstances that are triggering Export Control compliance review.
9	Click Save or Save and Continue	
G. Attachments Panel		
	Kuali Field or Action	What Information to Enter

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<p>1</p>	<p>Click Internal Tab – Click +Add (Individual Docs) or Upload & Add (Multiple Docs)</p>	<p>OCTA requires the following attachments:</p> <ol style="list-style-type: none"> a. Sponsor Protocol (usually a pdf) <ol style="list-style-type: none"> i. Type: Other Sponsor Attachment (non S2S submissions) ii. Status: Final iii. Description: enter Sponsor Protocol b. Informed Consent Form (ICF) <ol style="list-style-type: none"> i. Type: Other Sponsor Attachment (non S2S submissions) ii. Status: Final iii. Description: enter ICF iv. Note: The ICF may not be included as part of the Sponsor’s initial site package. Please request it and be proactive about letting your sponsors know to provide this ASAP. If Sponsor cannot provide an ICF, please explain the circumstances in the description and provide a copy of the Investigator’s Brochure (if applicable to your study). OCTA will review and consider on a case-by-case basis. If an ICF does not apply to the study because subjects are not being consented, it is not human subject research and does not fall within OCTA’s scope to negotiate. c. Draft Contract from Sponsor – Word format <ol style="list-style-type: none"> i. Type: Draft Agreement ii. Status: Final iii. Description: (If it contains the draft budget, please note this here so that OCTA is not looking for a separate draft budget) d. Budget/Payment Schedule – Word or Excel format (if not already contained in the Contract) <ol style="list-style-type: none"> i. Type: Budget Documents ii. Status: Final iii. Description: (Can leave Blank) e. If applicable: PI Eligibility Document or PI Exception Request Form <ol style="list-style-type: none"> i. Type: PI Exception Documentation ii. Status: Final (Select complete if you have attached a completed, signed, and approved PI Exception Request Form or a Document that explains and confirms the PI’s Eligibility) iii. Description: (If uploading a PI Exception Request Form can leave this blank. If uploading a document to confirm the PI’s Eligibility, enter “PI Eligibility Document”).
<p>2</p>	<p>Click Notes tab - Click +Add Note button</p>	<ol style="list-style-type: none"> a. Topic: Main Department Study Contact <ol style="list-style-type: none"> i. Note: Add the main Department Study Contact for this proposal who OCTA should regularly communicate with about the study, <i>if different from the proposal aggregator</i>. You can add as many Department Study Contacts, as applicable. OCTA will include these people as Department Contacts on the Award, will include them on correspondence regarding the contract

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		<p>negotiation (as applicable) and contact them with any questions.</p> <p>ii. For studies taking place at Rady Children’s Hospital, it is helpful to include the contact information for any Rady point person for the study (e.g. Rady coordinator)</p> <p>iii. Text: enter <First Name Last Name> enter <email address for that person> (e.g. Leslie Knope lknope@health.ucsd.edu.)</p> <p>b. Topic: Budget Negotiator:</p> <p>i. List the name of the budget negotiator or alternatively, indicate if you have requested OCAA budget negotiation services.</p> <p>ii. Text: enter <First Name Last Name> enter <email address for that person> (e.g. Carly Smith csmith@health.ucsd.edu)</p> <p>c. Topic: Study Invoicing Contacts:</p> <p>iii. List both the primary contact responsible for sending study invoices to the sponsor, and an alternate. Helpful to denote if person is an RSC or Department Fund Manager.</p> <p>iv. Text: enter <First Name Last Name> enter <email address for that person> (e.g. Carly Smith csmith@health.ucsd.edu)</p> <p>e. Topic: DBO/MSO</p> <p>i. List the Department Business Officer or Management Service Officer responsible for the Lead Unit listed on the proposal. (If unsure, consult your fund manager or other financial or administrative contact or the PI)</p> <p>ii. Text: enter <First Name Last Name> enter <email address for that person> (e.g. Max Lee mxl009@health.ucsd.edu)</p>
3	Click Save or Save and Continue	
H. Budget Panel		
	Kuali Field or Action	What Information to Enter
1	Click +Add Budget	<p>a. Budget Name: (Suggestion: <Sponsor Name Protocol Number>) (e.g. Pfizer C17TP001)</p> <p>b. Select Start a Summary Budget</p> <p>c. Click Create Budget</p>
2	Start and End Dates	a. The Start and End Dates auto populate based on the Project Dates entered in the Basics panel – Proposal Details subpanel. If the time span entered in the Proposal Details subpanel exceeds 1 year, you will

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		<p>see more than one budget period/row. You want the Project Dates entered in the Proposal Details subpanel to equal 1 year and you should only see 1 budget period/row with the same dates as you entered in the Proposal Details subpanel.</p> <p>b. If you need to adjust the Project End date entered in the Proposal Details subpanel, Click return to proposal and modify the Project End Date accordingly and Click Save.</p> <p>c. When you return to the Budget click the Reset to period default button and the Budget Table will reset based off of the Project Dates entered in the Proposal Details subpanel.</p>
3	Direct Cost	OCTA does not use this figure. Enter \$1.00 to meet KR system requirements or if your department prefers, enter the estimated total direct costs for this study. These numbers will be updated to reflect the negotiated and agreed upon budget at the time of Award.
4	F&A Cost	OCTA does not use this figure. Enter \$1.00 to meet KR system requirements or if your department prefers, enter the estimated total direct costs for this study. These numbers will be updated to reflect the negotiated and agreed upon budget at the time of Award.
5	Total Sponsor Cost	Click the Recalculate with changes button and the Total Sponsor Cost field will populate with the sum of the total Direct Cost + F&A Cost entered above. Click Save
6	Click Budget Settings link	<p>Update Settings –</p> <p>a. Budget Status: Complete</p> <p>b. Unrecovered F & A Rate Type: TDC</p> <p>c. F & A Rate Type: TDC</p> <p>d. Submit Cost Sharing: uncheck the box (Note: Cost sharing should not apply in an industry initiated clinical trial. To view the F&A Rate that will apply to your proposal, click the Rates panel and scroll down to TDC which is 30%).</p> <p>e. Click Save and click Return to proposal.</p>
7	Open Actions drop-down	<p>a. Confirm the Budget Status is Complete. If not, select Complete Budget in the drop-down.</p> <p>b. Select Include for Submission (the table should turn green and you will see “(for submission)” under the Budget Name).</p> <p>c. <u>Note:</u> you will receive an error message when submitting the proposal if you have not marked the Budget as both Complete and Include for Submission.</p>
8	Click Save or Save and Continue	
I. Questionnaire Panel – Contact Tab		
	Kuali Field or Action	What Information to Enter
1	Full Name	<p>a. Enter the First Name and Last Name of the Sponsor/CRO/Academic Coordinating Center contact that OCTA should email with UCSD’s proposed edits to the contract.</p> <p>b. If you have more than one contact, please include additional contacts under the Notes tab of the Attachments panel (especially if the</p>

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		contract is with a different entity than the industry sponsor and you have an industry Sponsor contact).
2	Email address	Enter the email address for the person above.
3	Click Save or Save and Continue	
J. Questionnaire Panel – Space Tab		
	Kuali Field or Action	What Information to Enter
1	Will existing on campus space be used?	<ol style="list-style-type: none"> a. Select Yes or No. b. If Yes, list the on-campus space to be used. Provide details including any involvement of third party service providers.
2	Will new space be required?	<ol style="list-style-type: none"> a. Select Yes or No. b. If Yes, please describe the required new space. (<u>Note</u>: this will trigger Department Chair and DBO approvals in the approval routing workflow)
3	Will existing off-campus space be used?	<ol style="list-style-type: none"> a. Select Yes or No. b. If Yes, describe the off-campus space. Provide details including any involvement of third party service providers.
4	Click Save or Save and Continue	
K. Supplemental Information panel		
	Kuali Field or Action	What Information to Enter
1	COA Org Code	<ol style="list-style-type: none"> a. Enter the code for the lead department or division responsible for the conduct of the Study. Please make sure you have the correct Org Code. Contact your department’s Fund Manager to confirm, including to get the new seven digit code for KR and Oracle. b. Otherwise click the magnifying glass and enter the name of the Lead Unit/Division in the Account Description field and click Search. c. Select the appropriate org code. d. Click Save or Save and Continue.
2	<p><u>Note</u>: At this point, OCTA recommends that you run Data Validation before moving on to PI Certification to ensure a complete and accurate proposal package for the PI to review and certify. The only error you should see is “The Investigators are not all certified. Please certify xxxx”. To run Data Validation:</p> <ul style="list-style-type: none"> • Select Data Validation at the top of the screen • Click red button in upper right corner that say Turn On • To turn it off, you click this same button which will be green and say Turn Off (it’s recommended that you turn it off after successfully running the validation and clearing any errors, otherwise it will continue to run in the background and slow down your computer) 	
L. Key Personnel Panel – Personnel Subpanel (To Notify PI to Certify the Proposal)		
	Kuali Field or Action	What Information to Enter
1	Notify <PI Name> button	<ol style="list-style-type: none"> a. Click this button to send an email to the PI with a link to the proposal requesting the PI to certify. This will require the PI to answer the Compliance Questions and certify at the end. (<u>Note</u>: This is the recommended process to follow to certify the proposal) b. If your PI is unable to certify and delegates this authority to you, you can complete the Compliance Questions and certify on his/her behalf by clicking the black triangle next to the PI’s name and navigating to

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		<p>the Compliance Questions tab. After answering all questions click Save. (<u>Note</u>: The name of the person who completes the certification will be recorded in Kuali as the person who provided certification of the proposal. It is strongly recommended that only the PI complete the Compliance Questions)</p> <p>c. You will know the certification has been successful because next to the PI's name you will see "Certification Completed and Answered By xxx" with a date and time stamp.</p> <p>d. NOTE: If the PI completes the certification, please review the PI's answers to ensure they appear to be accurate and align with the required responses in the "Compliance Questionnaire" tab below, to ensure a proposal that meets OCTA's criteria, is properly routed to OCTA for approval.</p>
<p>2</p>	<p>Compliance Questionnaire Tab *OCTA assumes all answers are reasonably accurate. If unsure, please do your due diligence before responding.</p> <p>This section provides guidance on some of the key Compliance questions that impact proposal routing to OCTA and may disqualify a proposal from OCTA review. It does not address all of the questions on the Compliance Questionnaire.</p>	<p>a. Human Research Questions. For a study to route to OCTA for review and approval, the answer to the following questions must be Yes and the Sponsor and/or Prime Sponsor fields (as applicable) must contain a for-profit entity:</p> <ul style="list-style-type: none"> i. Do any of the activities proposed involve obtaining specimens or data through intervention or interaction with a living individual, or identifiable information about a living individual, or use of human tissue samples (including stem cells and their derivatives), fluids or records, whether identifiable or not? Response = Yes <ul style="list-style-type: none"> o This question is confirming the proposal is human subjects research. If an answer of "Yes" is not true for your project, it does not fall within OCTA's scope. ii. Is this research covered by regulations for human subjects protection? Response = Yes <ul style="list-style-type: none"> o This question is confirming the proposal is human subjects research subject to IRB review. If an answer of "Yes" is not true for your project, it does not fall within OCTA's scope. iii. Does this project include a Clinical Trial? Response = Yes <ul style="list-style-type: none"> o This question is asking if the proposal is industry initiated and funded human subjects research to be processed through OCTA at the 30% CT rate. To route this to OCTA, it must be answered "Yes". iv. Has the external sponsor provided a study protocol for this project? Response = Yes <ul style="list-style-type: none"> o This question is asking if a for-profit company (i.e. industry) developed and authored the study Protocol. For OCTA contracts, a for-profit company must be the primary initiator/owner/author of a project. To route this to OCTA, it must be answered "Yes". • NOTE: If you or a PI incorrectly answer "No" to either of the last two questions in (iii) or (iv), the proposal will route to OCGA. If this happens by mistake, please contact OCTA@health.ucsd.edu for assistance. <p>b. Human Research Questions Continued.</p> <ul style="list-style-type: none"> i. Is this project covered by the NIH Genomic Data Sharing Policy? Response = No. This policy only applies to NIH funded

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		<p>research and OCTA cannot negotiate contracts for NIH funded research.</p> <p>c. OCAA Budget Services: If you answer “Yes” to “Has the external sponsor provided a study protocol for this project?” you will be prompted with another question which asks whether you would like to request budget development and negotiation services from the Office of Coverage Analysis Administration (OCAA). To request budget services, select “I request OCAA budget services”. If you do not want OCAA budget services, select “I do not want OCAA budget services”.</p> <p>d. Export Control Questions. If the answer to any of the Export Control questions is “Yes,” a Compliance line must be added for Export Control with a description of the circumstances. Please answer all Export Control questions accurately. Here are just a few examples of the types of Export Control questions that may trigger an answer of “Yes” in an industry initiated and funded clinical trial.</p> <ol style="list-style-type: none"> i. Example: If either the Sponsor (e.g. CRO or Academic Coordinating Center/Consortium) or Prime Sponsor is headquartered outside of the U.S., the answer to the first Export Control question should be “Yes” with an Export Control Compliance line added, indicating the foreign country where the entity is located. ii. Example: Will any element of the project be performed outside of the United States? iii. Example: Have you received resources (financial or non-financial) from any foreign parties/entities related or unrelated to this project?
3	Click Save or Save and Continue	

M. Summary/Submit Panel – Proposal Summary Tab

	Kuali Field or Action	What Information to Enter
1	Click through each tab for a Summary of the completed proposal	Review the information to ensure it is accurate and what you want to submit.
2	Submit for Review button	<ul style="list-style-type: none"> When ready to submit the proposal for approval routing, click the Submit for Review button. (Note: Data Validation will automatically run at this time, whether you have run it previously or not. If errors appear, you will need to fix them and click Submit for Review again) When the bar at the top of the screen under Routing is colored in blue and the text in the blue box at the top of the screen says “Document was successfully submitted”, you will know your proposal has been submitted and has entered routing approvals.
3	View Route Log	<ul style="list-style-type: none"> Click View Route Log to confirm the next stop(s) in the routing approval workflow. If any critical criteria are present (new space, cost-sharing, or PI Exception Request), Department Chair and DBO approvals will be

OCTA KUALI PROPOSAL GUIDE FOR DEPARTMENT RESEARCH ADMINISTRATORS

Instructions for creating a New Contract proposal for OCTA in Kualu Research

Last Updated 03/20/23

		<p>required. Note: It is your responsibility to monitor and ensure the Department approvals are obtained in a timely manner.</p> <ul style="list-style-type: none"> If no critical criteria are present, the proposal will route directly to the Sponsored Projects Office (OCTA) for review. If the proposal is complete and accurate, OCTA will approve. If the proposal is incomplete or does not follow these guidelines and requires modification, OCTA will return for editing with comment. Please make the needed edits and re-submit.
4	Recall	You can recall a proposal while it is in approval routing, to bring a proposal back to the aggregator for editing, by clicking Recall before a proposal has been approved.
5	Click Close to exit the proposal	Always click Close to exit the proposal properly and avoid creating a lock on the proposal. (Note: To clear a lock. Log out and back into Kualu. Search and Open the proposal in edit mode. Click Close. By opening the proposal again and following the proper closing process, it should clear the lock. If the lock remains, contact the Help Desk.

Post- Proposal Submission Tips

- 1. Post-Approval Email Confirmation.** You should receive an email notification from Kualu upon OCTA approval of your proposal.
- 2. Reference PD# on all Pre-Award Communications with OCTA.** Please save this email and reference the Proposal # (also known as Proposal Development or PD #) in all pre-award communications to OCTA regarding the Study.