

Class is meant to *supplement* other training, not as all inclusive training. This session will *not* be recorded, but this PowerPoint can found:

<https://medschool.ucla.edu/research/research-infrastructure/administrative-support/department-of-medicine-office-of-research/fund-management-training>

# Clinical Trials

## Pre-Award: Documents

UCLA DEPARTMENT OF MEDICINE  
OFFICE OF RESEARCH ADMINISTRATION  
ZOOM TRAINING

# Summary

- Pre-Award Clinical Trial Intake
  - UCLA Central Pre-Award offices
  - Determine which office needs appropriate forms - CT Application Checklist
- Review of Internal Documents & Required Forms
  - Budget –Process and Forms
- Best Practices

# Pre – Award Clinical Trial Intake

CLINICAL TRIALS

# UCLA Central Pre-Award Offices

- Responsibility for handling agreements related to sponsored research and other sponsored project activities is distributed across various UCLA administrative offices based on the sponsor and the nature of the transaction. In some cases, multiple offices may share responsibility for different aspects of the negotiation and administration of the transaction/agreement.
- There are **3 offices** on campus that support investigators with our clinical research awards.
  1. [Clinical Trials Contracts and Strategic Relations \(CTC&SR\)](#) – [CTC&SR Team Assignments](#)
  2. [Technology Development Group \(TDG\)](#) - [TDG Contract Officer by Dept/Div](#)
  3. [Office of Contracts and Grants Administration \(OCGA\)](#) - [OCGA Contract Officer by Division](#)

# CT Application Checklist – Internal Documents

CLINICAL TRIALS

# DOM CT Application Checklist

- Minimum Documents are required to **initiate an agreement negotiation**
- Receipt of complete Minimum Documents *with* PI signature **begins the review process**
- The **sponsor/funding type** (for-profit vs non-profit) & **type of submission** (new vs amendment vs NCTE) will determine which Minimum Documents are necessary

CT – Application Checklist DOM Fund Manager's Manual

## CLINICAL TRIALS – APPLICATION CHECKLIST

*Revised July 27, 2021*

PI: \_\_\_\_\_ Division: \_\_\_\_\_ PATS#: \_\_\_\_\_

Sponsor: \_\_\_\_\_ CRO: \_\_\_\_\_ Protocol#: \_\_\_\_\_

New       Amendment#: \_\_\_\_\_      Date: \_\_\_\_\_

Sponsor Type	Contract Offices – Clinical Trials	
For-Profit (Industry)	CTC&SR <a href="mailto:ClinicalTrials@mednet.ucla.edu">ClinicalTrials@mednet.ucla.edu</a>	TDG ( <a href="#">Dept Assignments</a> ) Non-HemOnc: Tara Davidoff at <a href="mailto:Tara.Davidoff@tdg.ucla.edu">Tara.Davidoff@tdg.ucla.edu</a> HemOnc: Karla Zepeda at <a href="mailto:KZepeda@tdg.ucla.edu">KZepeda@tdg.ucla.edu</a>
Non-Profit (Federal/State)	OCGA Submit docs via <a href="#">EPASS</a>	

# CTC&SR (For-Profit Clinical Trials)

After [Fund Manager notification](#) is received of a new/Amended contract, you must initiate the routing of the appropriate documents. To do this, you must retain information on study details surrounding the project and that information is supplied by our PIs/Study Teams to complete routing of internal docs.

To initiate [CTC&SR](#) review, Departmental Administrators/Fund Managers should submit the following documents to [CTC&SR Intake Team](#) at [ClinicalTrials@mednet.ucla.edu](mailto:ClinicalTrials@mednet.ucla.edu).

## To Route-

- [EPASS](#) (Extramural Proposal Approval and Submission Summary)
  - *Remarks:* New – include NCT#  
Amendment – include brief summary of amended changes
- [Conflict of Interest \(COI\) Disclosure Forms](#) for [non-government](#) Sponsor +/- CRO
  - [Form 700-U](#)
  - [Form 700-U Addendum](#)
  - [Form 700-U Disclosure Supplement](#) (*if applicable*)
- [PI Exception Form](#) (*For PIs who are not [Policy 900](#) PIs*)

## Docs available in OnCore-

- Sponsor Draft Contract (Word doc)/Budget (Received from Study Team)
- After contract is executed Sponsor Certified Final Budget/Contract and UCLA internal matrix

# TDG (For-Profit Supported Basic & Applied Research, MTAs)

- To initiate **TDG** review, Departmental Administrators/Fund Managers should submit the following documents to [TDG Contract Officer](#)
  - [EPASS](#) (Extramural Proposal Approval and Submission Summary)
    - *Remarks:* New – include NCT#  
Amendment – include brief summary of amended changes
  - [Conflict of Interest \(COI\) Disclosure Forms](#) for Sponsor +/- CRO [*Note: typically non-government sponsors*]
    - Non-government sponsor: [Form 700-U](#) & [Form 700-U Addendum](#) & [Form 700-U Disclosure Supplement](#) (*if applicable*)
    - Federal PHS agency (i.e. NIH): [eDGE](#) date on third page of [EPASS](#)
    - Non-PHS Federal agency (i.e. DOD): [Form 740](#) & [Form 740 Disclosure Supplement](#) (*if applicable*)
  - [PI Exception Form](#) (For PIs who are *not* [Policy 900 PIs](#))
  - [Industry Sponsored Research \(ISR\) Proposal Checklist](#)
  - [Proposal Budget](#)
  - [Health Systems Data Oversight Committee \(HDOC\)](#) – submitted by PI
  - Sponsor Draft Contract (Word doc)/Budget (Study Team)
  - After contract is executed Sponsor Certified Final Budget/Contract and UCLA internal matrix



# OCGA (Non-Profit Clinical Trials)

- To initiate [OCGA](#) review, Dept Administrators/Fund Managers should submit the following documents via [EPASS](#):
  - [EPASS](#) (Extramural Proposal Approval and Submission Summary)
    - *Remarks*: New - (include NCT#)  
Amendment - (include brief summary of amended changes)
  - [Conflict of Interest \(COI\) Disclosure Forms](#) for Sponsor [*Note: typically Federal sponsors*]
    - Federal PHS agency (i.e. NIH): [eDGE](#) date on third page of [EPASS](#)
    - Non-PHS Federal agency (i.e. DOD): [Form 740](#) & [Form 740 Disclosure Supplement](#) (*if applicable*)
    - Non-government sponsor: [Form 700-U](#) & [Form 700-U Addendum](#) & [Form 700-U Disclosure Supplement](#) (*if applicable*)
  - [PI Exception Form](#) (*For PIs who are not [Policy 900](#) PIs*)
  - Sponsor Guidelines
  - [Budget – draft](#)/final & justification (for non-profit)
  - Final Proposal (science, agency required signatures, biosketches, etc.)
  - Brief description of proposal aims/abstract
  - [Subaward](#): [Required Forms](#) & [Checklist](#) (*if applicable*)


# Contract Formation – EPASS (CTC&SR,TDG,OCGA)

Items you need to complete EPASS ([Instructions](#))

- Sponsor (& CRO if applicable) Name and Address, Contact Name, Phone and email, ([NCT](#))#, Protocol Title, Protocol #, Budget (to determine #s on your EPASS)

Sections #1-9 to be completed by preparer:

PATS #: \_\_\_\_\_ EPASS ID: 45322

 **UCLA RESEARCH**  
**EXTRAMURAL PROPOSAL APPROVAL AND SUBMISSION SUMMARY**  
**"EPASS"**

[Print](#)  
[Reset](#)

**1. Principal Investigator(s)/Co-PIs (Not Co-Investigators)**

	First Name	M.I.	Last Name	Employee ID	Email Address	Extension
PI:	JOE		BRUIN	123456789	JBRUIN@MEDNET.UCLA.EDU	1234
Other Co-PI/Multiple PI:						
Other Co-PI/Multiple PI:						
Fellow (if Individual Fellowship):						

*Named individuals must sign certification below. Attach additional pages if needed.*

**2. Department or Organized Research Unit (ORU)**

Administering Department Name: DEPT - DIVISION FS Code (Dept. Code): 1234  
Account #: XXXXXX Cost Center: XX Recharge ID: TWXX  
Dept. Contact Name: FUND MANAGER NAME Extension: 1234 Email Address: FM@MEDNET.UCLA.EDU  
If your department/unit has a single e-mail address for all proposal/award related correspondence, enter it here: N/A  
Have the services of any campus Center or ORU been used in the development of this proposal?  
If yes, select: Not Applicable  
If "Other Center/Institute" is selected above, please specify name, or if multiple Center(s)/Institute(s) please add additional selection(s) here: \_\_\_\_\_

**3. Proposal Identification**

Proposal Title: (Protocol Complete/Long Title)  
Is this COVID-19 Subject Matter?  Yes  No  
Project Begin Date: 6/1/2021 Project End Date: 2026 (5-7 years CTC&SR) (TDG&OCGA ACTUAL)

**4. Award/Proposal/Program Type**

Award Type: Contract Proposal Type: New  
Program Type: CT Drug Special Program Type: Not Applicable  
If this EPASS relates to an existing Award or Master Agreement, select an Action Type: Not Applicable  
Current Sponsor Award/ ID#: Sponsor protocol #(RUN123)

**5. Sponsor Information** (Entity which will provide funding directly to UCLA)

Sponsor Name: CRO Name  
Sponsor Due Date: 06/30/2028 Time (Pacific): 12:00am  
Deadline Type: Electronic  
Sponsor Guidelines and/or FOA/RFA/RFP:  
 Yes  No  
Attached:  URL (Section 9)  Name/No. #  
Contact (if known): John Smith  
Email Address: John.Smith@cro.com  
Phone #: XXX-XXX-XXXX

**Prime Sponsor Information** (Complete this section when UCLA is a subrecipient)

Prime Sponsor Name: SPONSOR Name  
Prime Sponsor Due Date: Time (Pacific):  
Prime Sponsor Guidelines and/or FOA/RFA/RFP:  
 Yes  No  
Attached:  URL (Section 9)  Name/No. #  
Contact (if known):  
Email Address:  
Phone #:

**6. Proposal Checklist - Carefully Review and Answer All Questions**

Yes	No	
<input type="checkbox"/>	<input checked="" type="checkbox"/>	PI Exception Required? (Check Requirements and Look up Eligibility). If yes, attach approval form (Sample Approval Form).
<input type="checkbox"/>	<input checked="" type="checkbox"/>	On Campus Space? Indicate location: Building: Room:
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Off Campus Space? Indicate location: 12345 Santa Monica Blvd, LA, CA 90025
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Outgoing Agreements? If yes, attach Subrecipient/MCA Commitment Form(s) or FDP Expanded Clearinghouse Subrecipient Letter(s) of Intent with applicable attachments, and Subrecipient vs. Contractor Determination Checklist for each subaward. See Outgoing Subaward Forms for details and forms.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Does this project involve activities outside the U.S. and/or partnership with foreign collaborators, whether or not funded? If yes, list country(ies) in the Remarks section, and see Export Control questions below.
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Is any mandatory Cost Sharing/Matching proposed in this application? (Cash, unfunded effort, or in-kind contributions - do not include salary cap differential.) Voluntary Cost Share is discouraged under UC Policy. If Yes, Mandatory Cost Share Amount:
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Is any unfunded effort proposed in this application? In accordance with UC Policy, "unfunded effort", must be reported in ERS.(Do not include salary cap differential here).
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Do you anticipate program income? If yes, specify Source: Estimated Amount:

**7. Additional Forms Required**

Yes	No	COI (Disclosure Requirements)
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Sponsor/Prime Sponsor is Federal Public Health Service (PHS) or agency that has adopted the PHS regulations? If yes, provide names of other investigators on page 3 (See UCLA Policy 926).
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Sponsor/Prime Sponsor is Federal (other than PHS), CIRM or special research programs managed by the UC Research Grants Program Office (RGPO)? If yes, attach COI Form 740 & Supplement to Form 740 (if applicable). See UCLA Procedure 925.3.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Non-Government Sponsor/Prime Sponsor? If yes and project is <i>Research</i> , attach Form 700-U, 700-U Addendum and 700-U Supplement, as applicable, unless sponsor is exempt. See UCLA Procedure 925.2.
Yes	No	Industry Sponsored Research
<input type="checkbox"/>	<input checked="" type="checkbox"/>	Industry Sponsored Non-Clinical Proposal? If yes, attach Industry Sponsored Research Checklist.
<input checked="" type="checkbox"/>	<input type="checkbox"/>	Industry Sponsored Clinical Trial? If yes, view the Clinical Trials Contracts & Strategic Relations Checklist to determine additional required attachments.

**8. Funds Requested**

1st Budget Period

Direct Costs (\$): 439,905 Excluded Direct Costs (\$): 2,500 F&A Costs (\$): 113,725 Total Costs (\$) 553,630

All Project Periods (complete only when multiple budget periods are involved)

Direct Costs (\$): 22,976 (TDG&OCGA) Excluded Direct Costs (\$): 2,500 (TDG&OCGA) F&A Costs (\$): 5,324 (TDG&OCGA) Total Costs (\$) 28,300 (TDG&OCGA)

F&A: F&A Rate (%): 26 F&A Base Type: TDC If Other, specify:

**9. Remarks**

NCT#

**10. Accepts Responsibility**

**Approvals: Includes Certifications**

*The Investigator(s) certifies to the following: (1) that the information submitted within this application is true, complete and accurate to the best of their knowledge; (2) that any false, fictitious, or fraudulent statements or claims may subject the Investigator(s) to criminal, civil or administrative penalties; (3) agrees to accept responsibility for the scientific conduct of the project and to provide the required progress reports if a grant is awarded as a result of the application; and (4) that you are not currently debarred, suspended or ineligible to receive federal or non-federal funds; (5) all Clinical Trials based upon FDAAA 801, will be registered in ClinicalTrials.gov. When multiple Investigators are proposed in an application this assurance must be obtained by all named Investigators.*

Principal Investigator (Required)	Date	Chair/ORU Director/Dean/Medical Center Director (Required)	Date

# Contract Formation – Form 700U (CTC&SR, TDG, OCGA)

- Original 700-U need to be routed to the appropriate central office. Electronic versions of these forms may be routed. Long are the days that we forward the original wet signature versions to the central offices, now they may be routed via [DocuSign](#) using a UCLA email address! These forms are a State requirement.
- Form 700-U series is applicable to [non-government](#) sponsors  
(view [Conflict of Interest \(COI\) Disclosure Forms](#))
- You may visit DOM Pre-award for a [Demo on how to use DocuSign](#).

# Contract Formation – Form 700U (CTC&SR, TDG, OCGA)

Complete Form 700u for Sponsor +/- CRO

- Preparer to fill out **Header** section
- Preparer to fill out **Section 1. Information Regarding Funding Entity**
- Preparer to fill out **2. Type of Statement**
  - Amount of funding must reflect EPASS total
  - Date of Initial or Interim must match date on EPASS
- Preparer to route form to PI to complete **Sections 3 & 4** and signature
  - Follow-up with PI, if you haven't heard back in 1 week
  - Double check form to ensure all questions answered including PI signature and date.
- If PI selects **YES** in **Section 3**, a **Positive Disclosure Supplement Form** is required

CALIFORNIA FORM 700-U FAIR POLITICAL PRACTICES COMMISSION		STATEMENT OF ECONOMIC INTERESTS FOR PRINCIPAL INVESTIGATORS <i>A Public Document</i>		Date Received <i>Campus Use Only</i>
Please type or print in ink.			Campus: _____	ID No: _____
NAME (LAST)	(FIRST)	(MIDDLE)	TELEPHONE NUMBER	
Bruin	Joe		( 310 ) 123-4567	
ACADEMIC UNIT OR DEPARTMENT		MAIL CODE	E-MAIL ADDRESS	
Department - Division		123456	JBruin@mednet.ucla.edu	
TITLE OF RESEARCH PROJECT (Protocol Complete/Long Title)				
<b>1. Information Regarding Funding Entity</b> (Use a separate Form 700-U for each funding entity.)			<b>3. Filer Information - Cont.</b>	
Name of Entity: Sponsor/CRO Name			D. Have you received loans from the entity in Part 1 for which the balance exceeded \$500 during the reporting period? No <input type="checkbox"/> Yes <input type="checkbox"/> – highest balance:	
Address of Entity: Sponsor/CRO Address			<input type="checkbox"/> \$500 - \$1,000 <input type="checkbox"/> \$1,001 - \$10,000 <input type="checkbox"/> \$10,001 - \$100,000 <input type="checkbox"/> Exceeded \$100,000	
Principal Business of Entity: Sponsor/CRO			If you checked "yes," was the loan: <input type="checkbox"/> Secured <input type="checkbox"/> Unsecured    Interest rate: _____%	
Amount of Funding: \$ 10,000.00			Was the loan entirely repaid within the last 12 months? <input type="checkbox"/> No <input type="checkbox"/> Yes	
Estimated <input type="checkbox"/> Actual <input checked="" type="checkbox"/>			E. Have you received gifts from the entity listed in Part 1 within the last 12 months valued at \$50 or more? No <input type="checkbox"/> Yes <input type="checkbox"/> – describe below.	
<b>2. Type of Statement</b> (Check at least one box)			Description: _____	
<input checked="" type="checkbox"/> Initial (for new funding)			Value: \$ _____ Date Received: ____/____/____	
Date of initial funding: 01 / 01 / 21				
<input type="checkbox"/> Interim (for renewed funding)				
Funding was renewed on: ____/____/____				

# Contract Formation – 700U Addendum (CTC&SR, TDG, OCGA)

Complete Form 700U Addendum for Sponsor +/- CRO

- Preparer to fill out **Header** section
  - Select Yes or No for **Industry Supported Clinical Trial**
  - Select **Reason for Disclosure**
    - New Application: New Contract
    - Addt'l Support: Amended Contract
- Route to *all* PIs listed on ICF as Co-Is
  - PI to check yes or no, sign & date
  - Follow-up with PI , if you haven't heard back in 1 week
  - Double check form to ensure all questions answered by all PIs prior to submission

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700-U  
Addendum

### Investigators' Statements of Financial Interests

Under UCLA Policy 925, the Principal Investigator and all other UCLA Investigators who share responsibility for the design conduct, or reporting of research must disclose their personal financial interests in any organization(s) that will fund or support research or is an intermediary acting for the sponsor.

PI's name: Joe Bruin

Funding Entity: Sponsor/CRO Name

Title of Research Project: Protocol Complete/Long Title

IRB/ARC No(s) (if applicable):

Industry supported Clinical Trial:  No  Yes \*If yes, each investigator with Significant Financial Interests to disclose must complete the **Industry Clinical Trial Specific Disclosure Supplement Form** instead of the standard **Disclosure Supplement (October 2010)**.

Reason for Disclosure:  New Application  Additional Support  IRB Request

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#### Disclosure and Certification

The Principal Investigator's signature below certifies either that all individuals required to make disclosures of Significant Financial Interests have been listed on this form, or that no other individuals working on the research are required to make such disclosures.

Are there other Investigators who share responsibility for the design, conduct, or reporting of the research?  NO  YES  
If YES, those Investigators should sign and complete the section below.

Signature of Principal Investigator: \_\_\_\_\_ Date: \_\_\_\_\_ For PI Only: Please attach State of California Form 700-U

# Contract Formation – 700U Disclosure Supplement Form (CTC&SR, TDG, OCGA)

Complete Disclosure Supplement for PI (when applicable)

- Preparer to fill out **Header** section
- Route to *all* PIs that checked having a positive disclosure
  - PIs to complete form, sign & date
  - Follow-up with PI, if you hadn't heard back in 1 week
  - Double check form to ensure all questions answered by PI prior to sending

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**DISCLOSURE SUPPLEMENT**

**Supplement to  
700-U & Addendum**

This form is to be completed by all Principal Investigators and other Investigators who have reported a financial interest either on a Form 700-U or a 700-U Addendum. Completion of this form is required in accordance with UCLA Procedure 925.2. The information provided herein may be released or transmitted to the sponsor upon request. Per the California Public Records Act, the information may also be released to the public upon request.

Name:	
Principal Investigator's Name (if different):	
Funding Entity:	
Title of Research Project:	

**REPORTING PERIOD for FORM 700-U and 700-U Addendum:**

**NEW PROPOSALS:** For items 1, 2, and 3 below, report financial interests held as of the date the award is made or received from the sponsor within the 12 months prior to the date that the award is made.

**FOR RENEWALS, AMENDMENTS AND SUPPLEMENTS:** For items 1, 2 and 3 below, report financial interests held or received during the period between the date of the initial disclosure and the date of the award renewal (amendment or supplement).

<p>1. Are you a founder, co-founder, director, officer, partner, trustee, or employee of, or do you hold any position of management (paid or unpaid) in the entity listed above?</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes Title: _____</p>	
<p>2. Have you, your spouse or registered domestic partner, or dependent children, received:</p> <p>A. Income (including any payment, such as salary or consulting fees) from the entity listed above in the reporting period? (Do not include any salary or summer salary paid by the University with funds provided by the sponsor or entity listed above.)</p>	



# Contract Formation – Form 740 (TDG & OCGA)

## Complete Form 740 for Sponsor

- Preparer to fill out **Header** section
- Route to all PIs provided feedback by PI/Study Team
  - PIs to complete form, sign & date
  - Follow-up with PI, if you haven't heard back in 1 week
  - Double check form to ensure all questions answered by PI prior to submission

Note: Form 740 series is applicable to **non-PHS Federal agencies** (view [Conflict of Interest \(COI\) Disclosure Forms](#))

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**Form 740**

### Investigators' Statements of Financial Interests

Under UCLA Policy 925, the Principal Investigator and all other UCLA Investigators who share responsibility for the design, conduct, or reporting of certain sponsored projects must report their personal financial interests in any organization(s) that, to the best of the Investigator's knowledge, may have a significant impact on the conduct of this research or might benefit from the anticipated results of the proposed project.

**Sponsor:** (please check one box below)

Federal Agency (specify) \_\_\_\_\_  UC Special Research Programs

Subaward from Federal Agency (specify) \_\_\_\_\_  CIRM

Other \_\_\_\_\_

**Reason for Disclosure:**  New Proposal  Additional Support  New Investigator  New Interest(s) Obtained

IRB Request  Voluntary Disclosure  Other \_\_\_\_\_

**Title of Proposal:** \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

**IRB/ARC No(s) (if applicable):** \_\_\_\_\_

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**Disclosure and Certification**

The Principal Investigator's signature certifies that all individuals required to make disclosures of Significant Financial Interests have been listed on this form, or that no other individuals working on the research are required to make such disclosures:

Are there other Investigators who share responsibility for the design, conduct, or reporting of the research?  No  Yes

If YES, those Investigators must sign and complete the section below.

All Investigators named below acknowledge their responsibility to disclose any new Significant Financial Interests acquired during term of the award.

**Do you, your spouse or registered domestic partner, or dependent children have a Significant Financial Interest related to the work to be conducted under the proposed project?** (See reverse for definitions of Significant Financial Interests)

Yes  No

# Contract Formation – Form 740 Disclosure Supplement (TDG & OCGA)

Complete Disclosure Supplement for PI (when applicable)

- Preparer to fill out **Header** section
- Route to *all* PIs that checked having a positive disclosure
  - PIs to complete form, sign & date
  - Follow-up with PI, if you hadn't heard back in 1 week
  - Double check form to ensure all questions answered by PI prior to sending

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**Supplement to  
Form 740**

## DISCLOSURE SUPPLEMENT

This form is to be completed by all Principal Investigators and other Investigators who have reported a financial interest on Form 740. Completion of this form is required in accordance with UCLA Policy 925. The information provided herein may be released or transmitted to the sponsor upon request, and per the California Public Records Act, may also be released to the public upon request.

Name of Investigator:	<input type="text"/>
Principal Investigator's Name (if different):	<input type="text"/>
Title of Research Project:	<input type="text"/>
Name of Entity in which you have a financial interest:	<input type="text"/>
If a for profit Entity:	<input type="checkbox"/> Publicly Traded <input type="checkbox"/> Non-Publicly Traded


1. Are you a founder, co-founder, or do you hold a management position such as board member, director, officer, partner, or trustee in the entity listed above?

No  Yes Position(s):

# Contract Formation – PI Exception Form (CTC&SR, TDG & OCGA)

Complete PI Exception Form (when applicable)

- How to check if PI Exception Form is needed
  1. Go to [ORA Online Resource Center – Investigator Directory Search](#)
  2. Search for PI (Last Name, First Name)
  3. If PI Category indicates *EXCEPTION REQD*, a PI Exception Form is necessary
- Submit Form via DocuSign to Vice Dean for signature and CC: Dept Chair.
- Note: PI Name, Department and Effort will populate throughout form.

Request for Exception to UCLA Policy 900.1 / Principal Investigator Status 

Please process an exception to [UCLA Policy 900.1](#) on behalf of:

Name: Joe Bruin Current Academic Title: Assist Professor  
Department: MEDICINE Email Address: JoeBruin@mednet.ucla.edu  
Campus Address: XXXX LeConte Avenue Los Angeles, Ca. 90024  
Campus Phone: XXX-XXX-XXXX Campus Fax: XXX-XXX-XXXX

Please allow this individual to serve as  Principal Investigator  Co-Principal Investigator

This exception applies to the project listed below.

Specific Project: Clinical Trial  
Proposal Title: Phase II ...  
Agency: ABCDEF Pharmaceutical  
Other Investigators/Co-PIs (if any): NA  
Project Number (if available): PROTOCOL # Date Proposal Submitted/Due: XX/XX/XX

Dr. Joe Bruin has an appointment of 100 % time.

Please justify the request for exception (attach an addition sheet if necessary):

Dr. Joe Bruin has an appointment of 100 % time. Based on their record and skills, we feel it appropriate for them to serve as Principal Investigator on this project. The grant will provide support for them and enable them to continue their research programs. The Department of MEDICINE will provide the necessary space and facilities for Dr. Joe Bruin to conduct their research during the duration of this project.

# For Profit - Budget Process

- Patient Care **Budgets** are created with a quorum of several Departments. Study Teams are best equipped to understand and validate research related services provided in association with each study. Coding and financial expertise through the **Centralized Research Billing Partners (CRBP)** and **Department of Financial Services**, as well as **Financial Coverage Analysis (CRF)** work together with Study teams to develop study budget calendars.
- A **released version of the Budget** is negotiated by Study Team or DOMCTP.
- Budget is uploaded onto OnCore for certification. Fund Managers have access to the Budget in **OnCore: Financial Console**.

# Non-Profit Budget Process

- Budget Preparation (work with PI to complete)
  - SF424 Budget
  - PHS 398 Budget
  - Center Grant Budget
- Budget Justification (work with PI to complete)
  - Review and ensure any **effort** on Justification matches budget
  - Review and ensure any **amount** indicated on Justification matches budget
- Tip: DOM CTP offers support to calculate Patient Care Costs- send your requests to [DOMCTP@mednet.ucla.edu](mailto:DOMCTP@mednet.ucla.edu) with study protocol

# Contract Formation – *All* Clinical Trials

- Budget – draft/final & justification (for non-profit)
- IRB Approval Notice (obtain from Study Team)
- Informed Consent Form (ICF) (obtain from Study Team)
- Protocol (obtain from Study Team/OnCore)

# Best Practices

## CLINICAL TRIALS

# Recap & Tips

- **Collect the Necessary Information**
  - Review your [DOM CT Application Checklist](#) to prepare intake forms as soon as you are notified of a new study
  - Improve turn around times by being proactive and ask for the information from Study Team/PI needed to prepare your forms (*Sponsor & CRO (if applicable) Name and Address, Sponsor Contact Name, Phone and Email, NCT#, Protocol Title, Protocol #, Budget*)
  - Ensure *weekly* follow-up on forms that have been routed for signature(s)
- **Don't know where to begin or who to contact?**
  - Contact **DOM Clinical Trial Program** ([DOMCTP@mednet.ucla.edu](mailto:DOMCTP@mednet.ucla.edu)) for:
    - Guidance on submitting CT application documents
    - Updates on internal budget inquiries including negotiations



# Links from Today's Class

- Sponsor Specific Guidance & Required Forms
  - [CTC&SR](#) (submit internal docs to Intake Team [clinicaltrials@mednet.ucla.edu](mailto:clinicaltrials@mednet.ucla.edu))
  - [TDG](#) (submit internal docs to [TDG Contract Officer](#))
  - [OCGA](#) (submit internal docs via [EPASS](#))
  - [Forms](#)
- DOM Clinical Trials Fund Manager Manual Chapters
  - [CT Application Checklist](#) (DOM)

# Survey Link

<https://forms.gle/QaMyquTmKtNDEj1k8>

We appreciate if you would take a few moments to complete a short 7 question anonymous survey to help us improve your training experience. Thank you!