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.

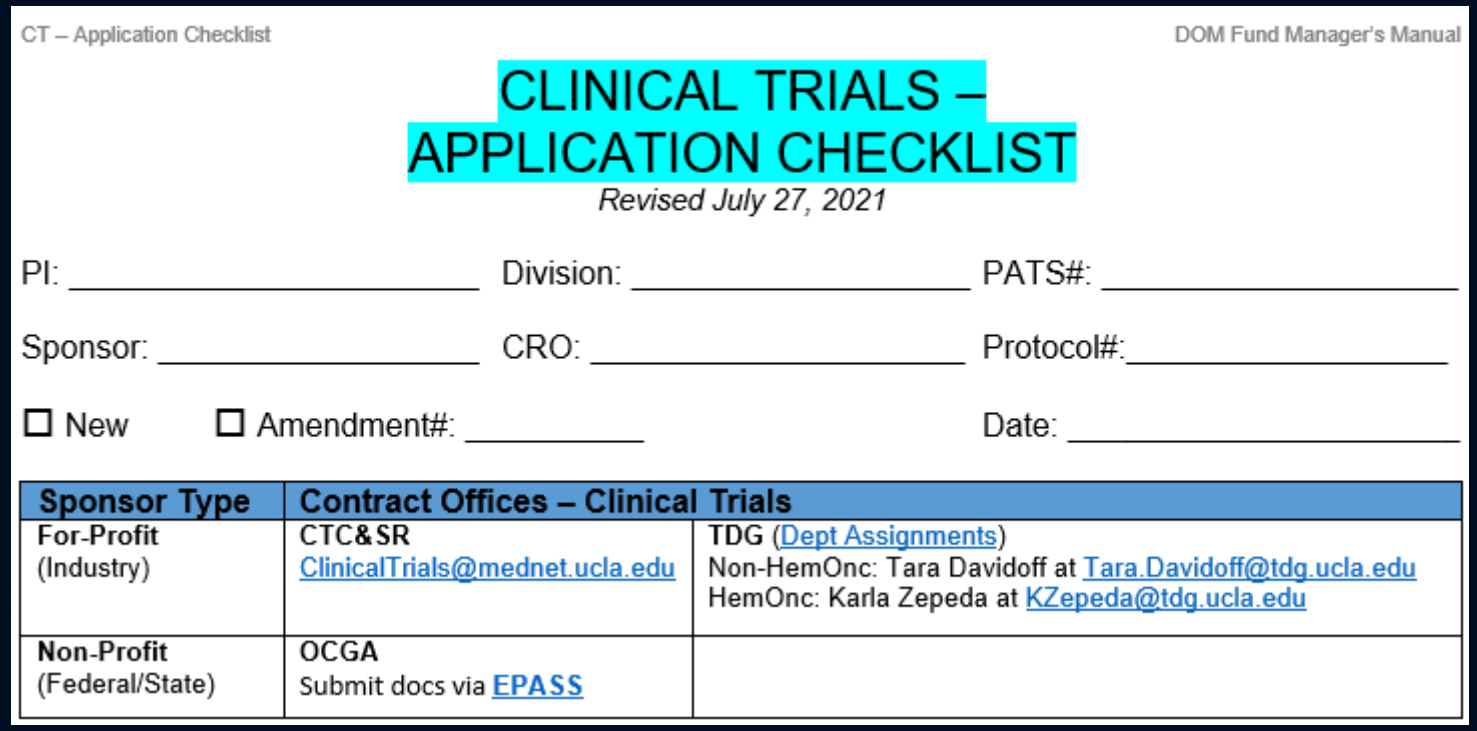
1. Clinical Trials Contracts and Strategic Relations (CTC&SR) – *CTC&SR Team Assignments*
2. Technology Development Group (TDG) - *TDG Contract Officer by Dept/Div*
3. Office of Contracts and Grants Administration (OCGA) - *OCGA Contract Officer by Division*

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** ClinicalTrials@mednet.ucla.edu	**TDG** (Dept Assignments) Non-HemOnc: Tara Davidoff at Tara.Davidoff@tdg.ucla.edu HemOnc: Karla Zepeda at KZepeda@tdg.ucla.edu
Non-Profit (Federal/State)	**OCGA** Submit docs via EPASS	

CTC&SR (For-Profit Clinical Trials)

After receipt of notification there is 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.

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 (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
  - 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

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 #: XXXXX
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	
☐	☑	**PI Exception Required?** (Check Requirements and Look up Eligibility). If yes, attach approval form (Sample Approval Form).
☐	☑	**On Campus Space?** Indicate location: Building: Room:
☑	☐	**Off Campus Space?** Indicate location: 12345 Santa Monica Blvd, LA, CA 90025
☐	☑	**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.
☐	☑	**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.
☐	☑	**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:
☐	☑	**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).
☐	☑	**Do you anticipate program income?** If yes, specify Source: Estimated Amount:

7. Additional Forms Required

Yes	No	
☐	☑	COI (Disclosure Requirements) 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).
☐	☑	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.
☑	☐	Non-Government Sponsor/Prime Sponsor? If yes and project is *Research*, 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
☐	☑	Industry Sponsored Non-Clinical Proposal? If yes, attach Industry Sponsored Research Checklist.
☑	☐	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
	Date		Date
	Date		Date

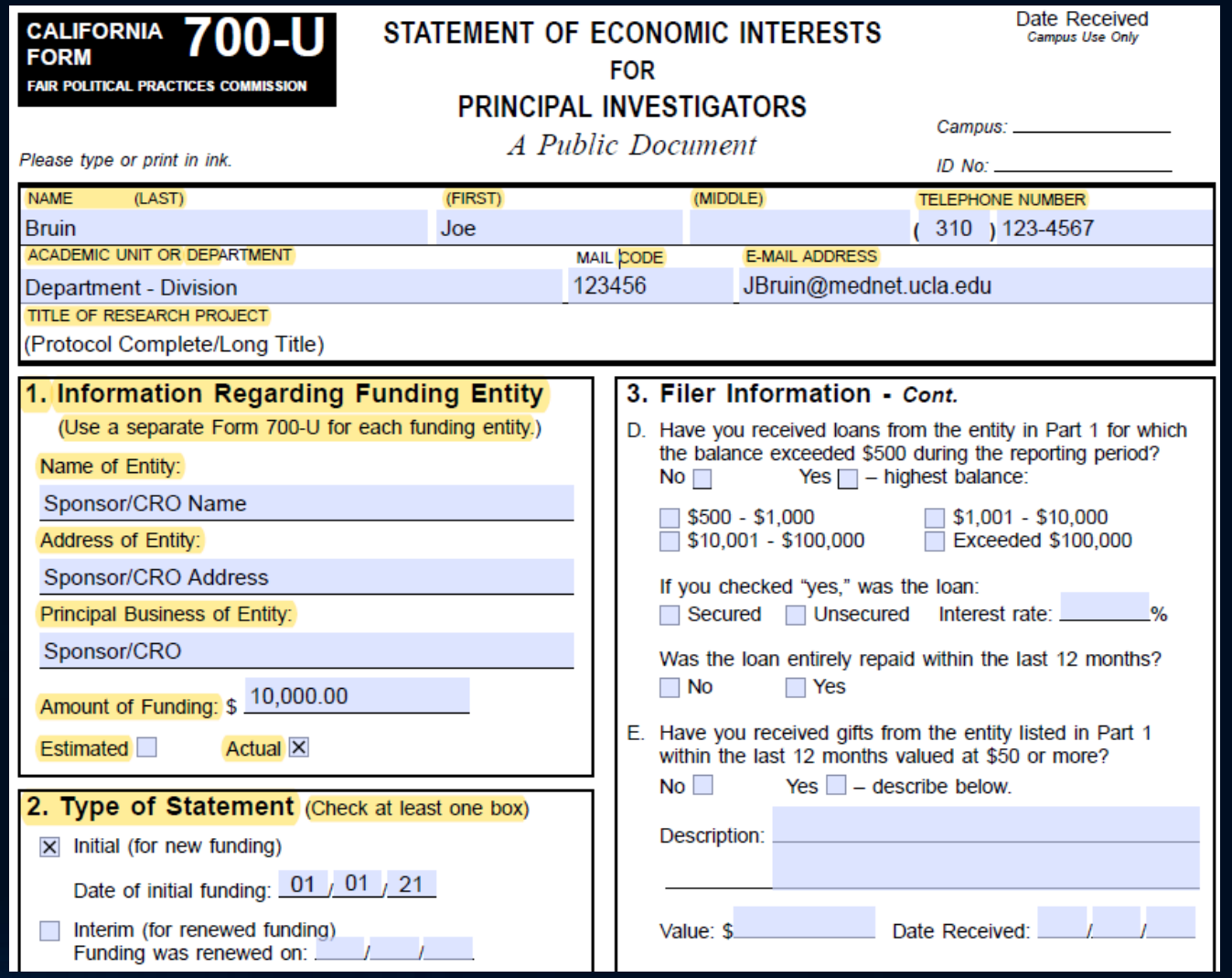
Contract Formation – Form 700U (CTC&SR, TDG, OCGA)

- 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
A Public Document

Date Received
Campus Use Only

Campus: _____
ID No: _____

Please type or print in ink.

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)

1. Information Regarding Funding Entity
(Use a separate Form 700-U for each funding entity.)

Name of Entity:
Sponsor/CRO Name

Address of Entity:
Sponsor/CRO Address

Principal Business of Entity:
Sponsor/CRO

Amount of Funding: $ 10,000.00

Estimated ☐ Actual ☒

2. Type of Statement (Check at least one box)

☒ Initial (for new funding)
Date of initial funding: 01 / 01 / 21

☐ Interim (for renewed funding)
Funding was renewed on: ___ / ___ / ___

3. Filer Information - *Cont.*

D. Have you received loans from the entity in Part 1 for which the balance exceeded $500 during the reporting period?
No ☐ Yes ☐ – highest balance:

☐ $500 - $1,000 ☐ $1,001 - $10,000
☐ $10,001 - $100,000 ☐ Exceeded $100,000

If you checked "yes," was the loan:
☐ Secured ☐ Unsecured Interest rate: _____%

Was the loan entirely repaid within the last 12 months?
☐ No ☐ Yes

E. Have you received gifts from the entity listed in Part 1 within the last 12 months valued at $50 or more?
No ☐ Yes ☐ – describe below.

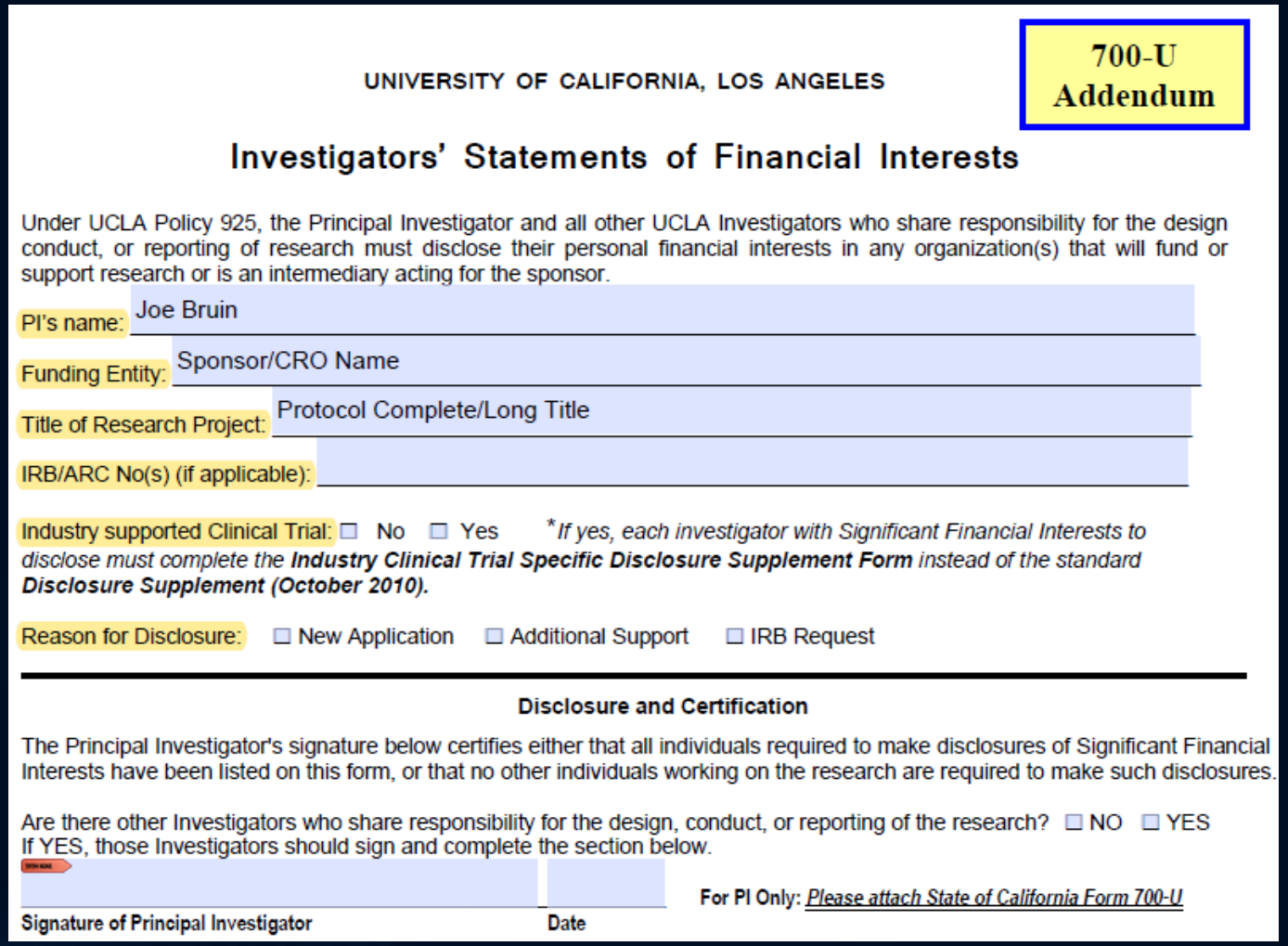
Description: _____

Value: $_____ Date Received: ___ / ___ / ___

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



700-U Addendum

UNIVERSITY OF CALIFORNIA, LOS ANGELES

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

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.

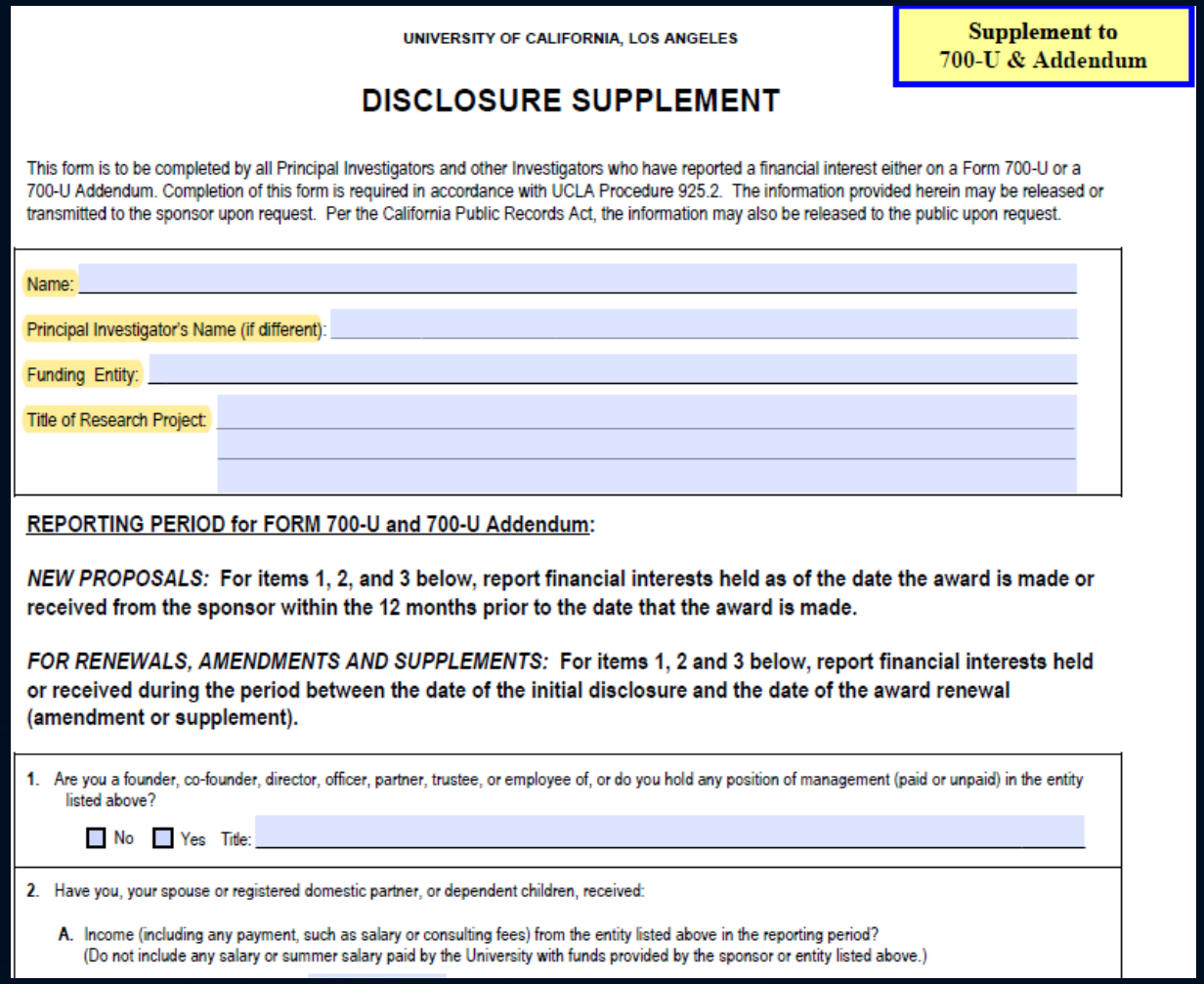
Signature of Principal Investigator **Date**

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



UNIVERSITY OF CALIFORNIA, LOS ANGELES

Supplement to 700-U & Addendum

DISCLOSURE SUPPLEMENT

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).**

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?

   ☐ No ☐ Yes Title: _____

2. Have you, your spouse or registered domestic partner, or dependent children, received:

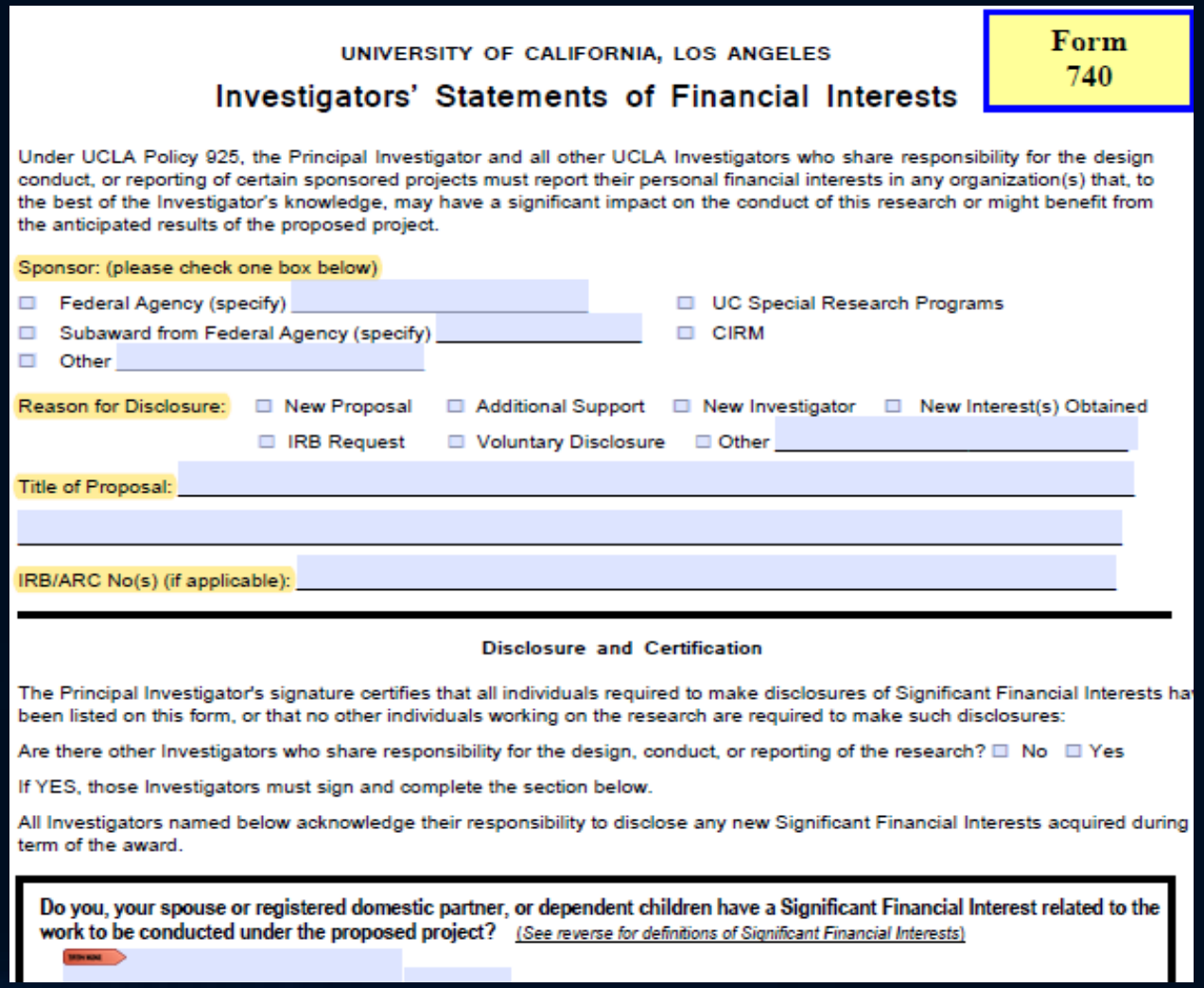
   A. Income (including any payment, such as salary or consulting fees) from the entity listed above in the reporting period? (Do not include any salary or summer salary paid by the University with funds provided by the sponsor or entity listed above.)

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)



UNIVERSITY OF CALIFORNIA, LOS ANGELES

Investigators' Statements of Financial Interests

Form 740

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):

Disclosure and Certification

The Principal Investigator's signature certifies that all individuals required to make disclosures of Significant Financial Interests ha 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.

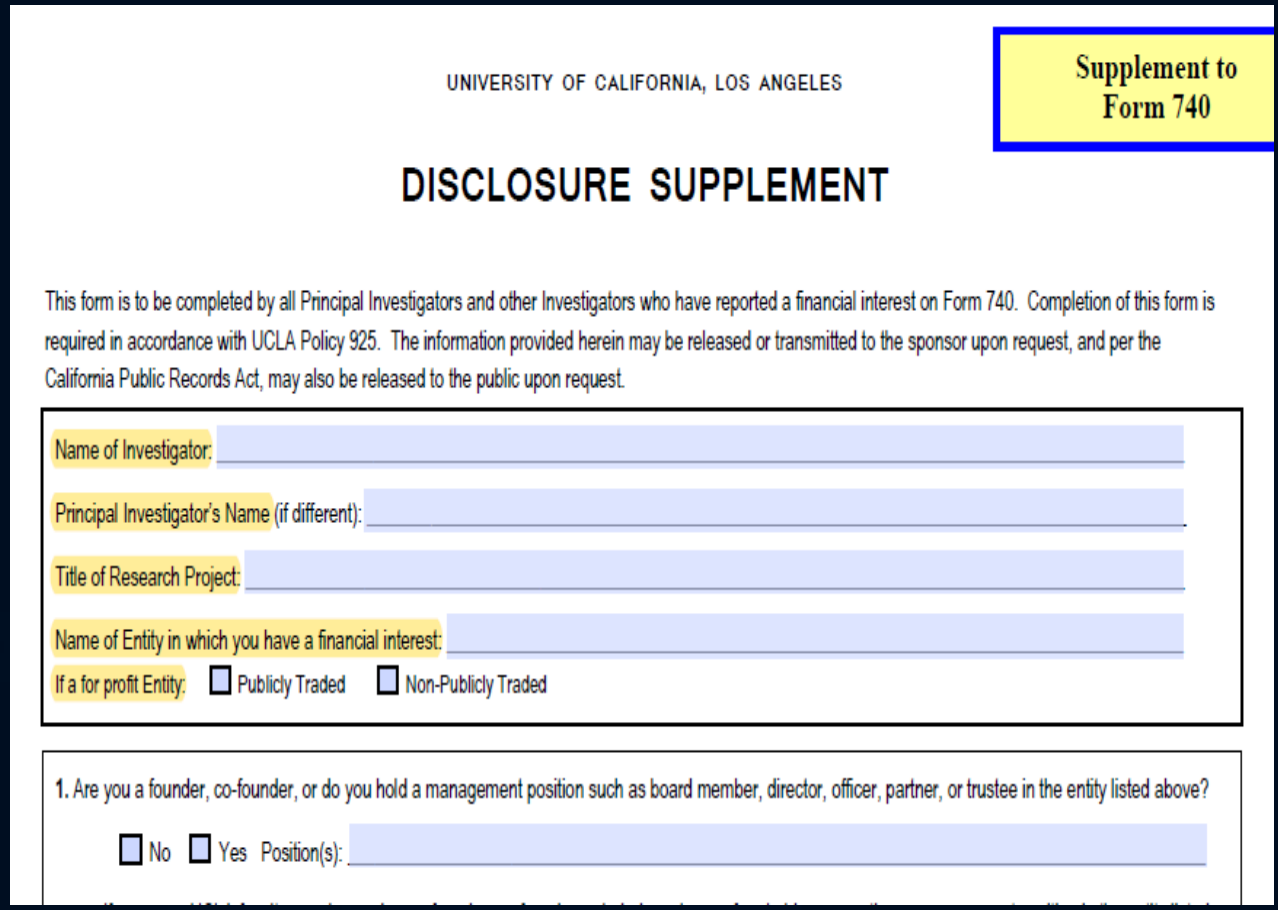
All Investigators named below acknowledge their responsibility to disclose any new Significant Financial Interests acquired during term of the award.

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)*

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



UNIVERSITY OF CALIFORNIA, LOS ANGELES

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:

Principal Investigator's Name (if different):

Title of Research Project:

Name of Entity in which you have a financial interest:

If a for profit Entity: ☐ Publicly Traded ☐ Non-Publicly Traded

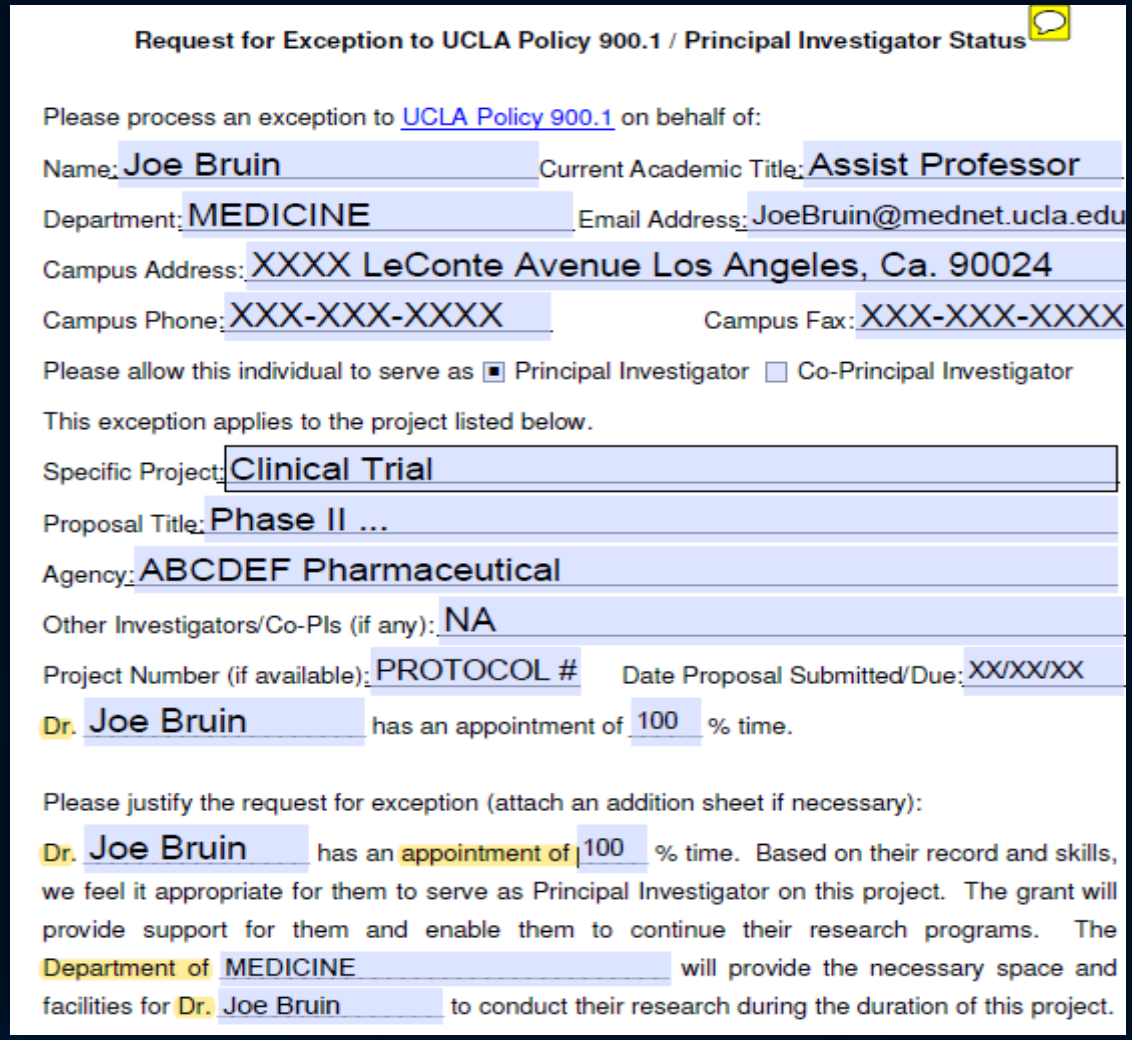
1. Are you a founder, co-founder, or do you hold a management position such as board member, director, officer, partner, or trustee in the entity listed above?

☐ 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* or *EXPANDED* (for DOM), a PI Exception Form is necessary
- Route PI Exception Form 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.

Contract Formation – *All* Clinical Trials

- Budget – draft/final & justification (for non-profit)
- DOM PI Responsibilities (PDF) | DocuSign (go to Templates (annual-*valid for 1 year*)
- IRB Approval Notice (obtain from Study Team)
- NCT # (obtain from Study Team)
- Informed Consent Form (ICF) (obtain from Study Team)
- Protocol (obtain from Study Team/OnCore)

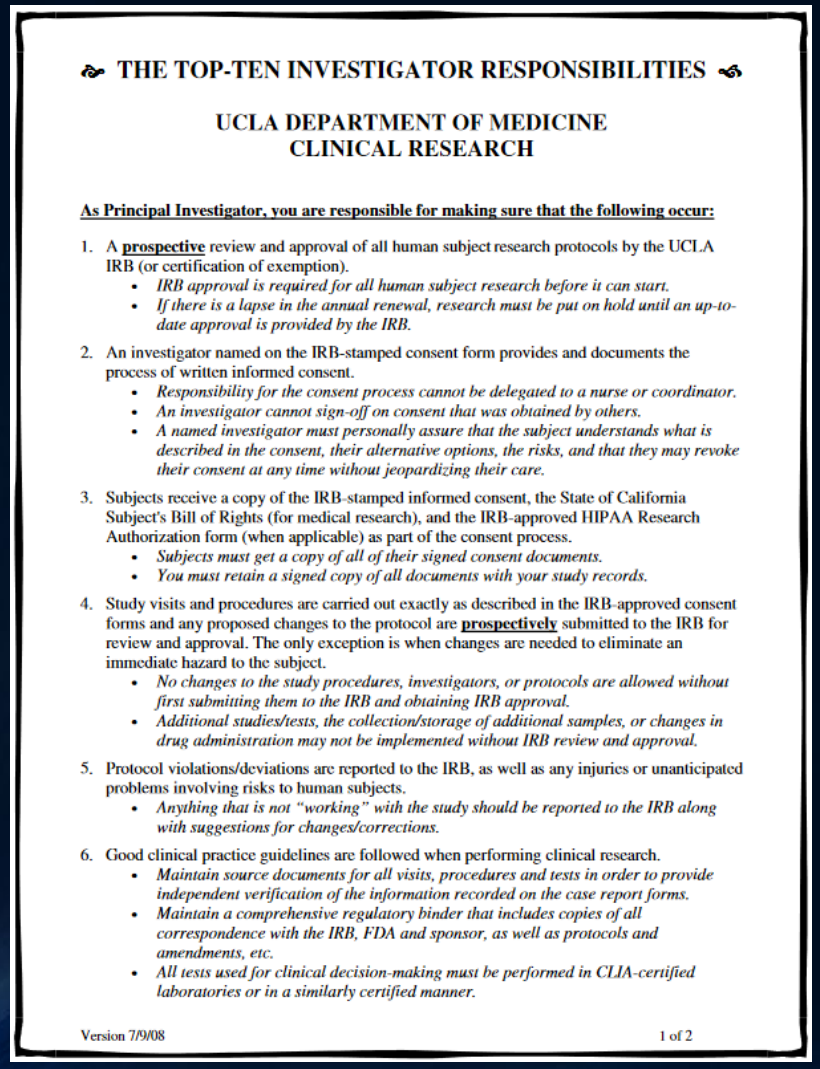
Pre-Award Budget Process (For-Profit)

- 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 (FCA) 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 within OnCore: Financial Console.

Pre-Award Budget Process (Non-Profit)

- 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 with study protocol

Contract Formation - DOM PI Responsibility Form



THE TOP-TEN INVESTIGATOR RESPONSIBILITIES

UCLA DEPARTMENT OF MEDICINE
CLINICAL RESEARCH

As Principal Investigator, you are responsible for making sure that the following occur:

1. A **prospective** review and approval of all human subject research protocols by the UCLA IRB (or certification of exemption).
   - *IRB approval is required for all human subject research before it can start.*
   - *If there is a lapse in the annual renewal, research must be put on hold until an up-to-date approval is provided by the IRB.*
2. An investigator named on the IRB-stamped consent form provides and documents the process of written informed consent.
   - *Responsibility for the consent process cannot be delegated to a nurse or coordinator.*
   - *An investigator cannot sign-off on consent that was obtained by others.*
   - *A named investigator must personally assure that the subject understands what is described in the consent, their alternative options, the risks, and that they may revoke their consent at any time without jeopardizing their care.*
3. Subjects receive a copy of the IRB-stamped informed consent, the State of California Subject's Bill of Rights (for medical research), and the IRB-approved HIPAA Research Authorization form (when applicable) as part of the consent process.
   - *Subjects must get a copy of all of their signed consent documents.*
   - *You must retain a signed copy of all documents with your study records.*
4. Study visits and procedures are carried out exactly as described in the IRB-approved consent forms and any proposed changes to the protocol are **prospectively** submitted to the IRB for review and approval. The only exception is when changes are needed to eliminate an immediate hazard to the subject.
   - *No changes to the study procedures, investigators, or protocols are allowed without first submitting them to the IRB and obtaining IRB approval.*
   - *Additional studies/tests, the collection/storage of additional samples, or changes in drug administration may not be implemented without IRB review and approval.*
5. Protocol violations/deviations are reported to the IRB, as well as any injuries or unanticipated problems involving risks to human subjects.
   - *Anything that is not "working" with the study should be reported to the IRB along with suggestions for changes/corrections.*
6. Good clinical practice guidelines are followed when performing clinical research.
   - *Maintain source documents for all visits, procedures and tests in order to provide independent verification of the information recorded on the case report forms.*
   - *Maintain a comprehensive regulatory binder that includes copies of all correspondence with the IRB, FDA and sponsor, as well as protocols and amendments, etc.*
   - *All tests used for clinical decision-making must be performed in CLIA-certified laboratories or in a similarly certified manner.*

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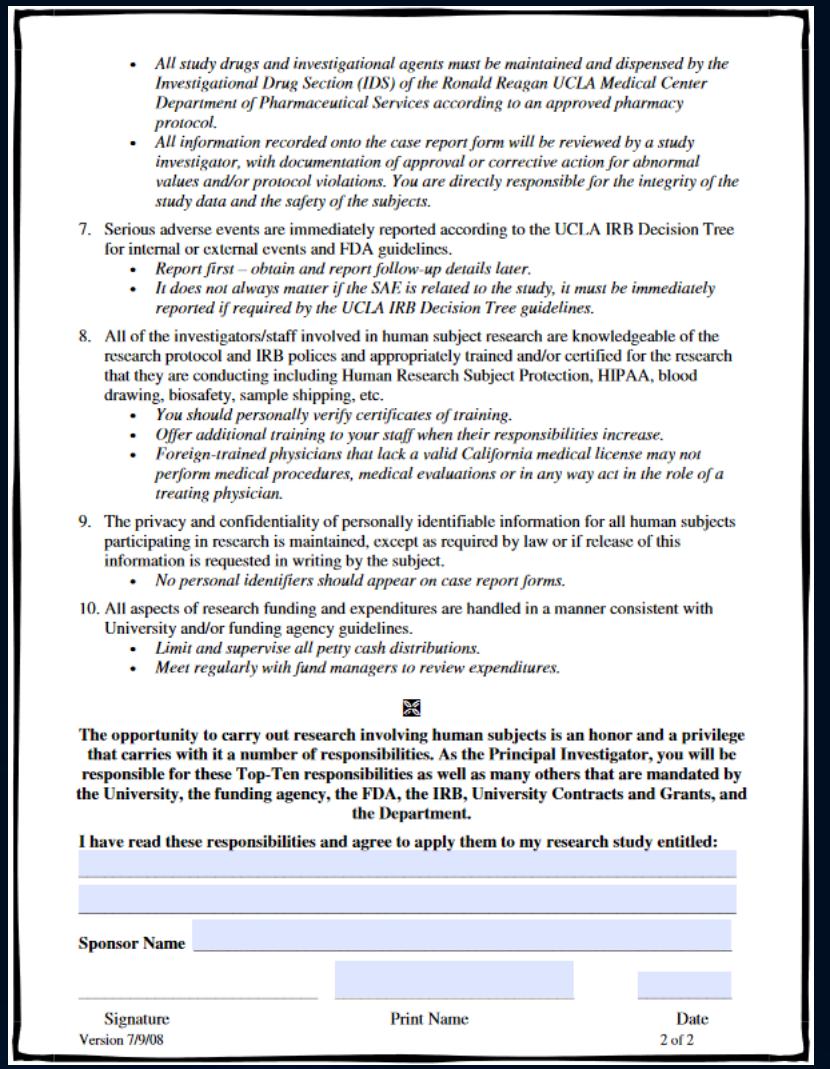

- *All study drugs and investigational agents must be maintained and dispensed by the Investigational Drug Section (IDS) of the Ronald Reagan UCLA Medical Center Department of Pharmaceutical Services according to an approved pharmacy protocol.*
- *All information recorded onto the case report form will be reviewed by a study investigator, with documentation of approval or corrective action for abnormal values and/or protocol violations. You are directly responsible for the integrity of the study data and the safety of the subjects.*

7. Serious adverse events are immediately reported according to the UCLA IRB Decision Tree for internal or external events and FDA guidelines.
   - *Report first – obtain and report follow-up details later.*
   - *It does not always matter if the SAE is related to the study, it must be immediately reported if required by the UCLA IRB Decision Tree guidelines.*
8. All of the investigators/staff involved in human subject research are knowledgeable of the research protocol and IRB polices and appropriately trained and/or certified for the research that they are conducting including Human Research Subject Protection, HIPAA, blood drawing, biosafety, sample shipping, etc.
   - *You should personally verify certificates of training.*
   - *Offer additional training to your staff when their responsibilities increase.*
   - *Foreign-trained physicians that lack a valid California medical license may not perform medical procedures, medical evaluations or in any way act in the role of a treating physician.*
9. The privacy and confidentiality of personally identifiable information for all human subjects participating in research is maintained, except as required by law or if release of this information is requested in writing by the subject.
   - *No personal identifiers should appear on case report forms.*
10. All aspects of research funding and expenditures are handled in a manner consistent with University and/or funding agency guidelines.
    - *Limit and supervise all petty cash distributions.*
    - *Meet regularly with fund managers to review expenditures.*

The opportunity to carry out research involving human subjects is an honor and a privilege that carries with it a number of responsibilities. As the Principal Investigator, you will be responsible for these Top-Ten responsibilities as well as many others that are mandated by the University, the funding agency, the FDA, the IRB, University Contracts and Grants, and the Department.

I have read these responsibilities and agree to apply them to my research study entitled:

Sponsor Name

Signature Print Name Date

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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) 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)
  - 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!