If you do not have a microphone on your computer, or using remote desktop to join this meeting, please also call in to participate in class discussions:

Call one of the “Join by Telephone” dial-in number provided in your invite (646-876-9923).
Enter the Meeting ID (968 5919 6077) followed by #.
Enter your Participant ID followed by #.

This session will not be recorded, but this PowerPoint can found [https://medschool.ucla.edu/ora/fund-management-training](https://medschool.ucla.edu/ora/fund-management-training)
Summary

• Pre-Award Clinical Trial Intake
  • UCLA Central Pre-Award offices

• 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
  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.

<table>
<thead>
<tr>
<th>Sponsor Type</th>
<th>Contract Offices – Clinical Trials</th>
</tr>
</thead>
<tbody>
<tr>
<td>For-Profit (Industry)</td>
<td>CTC&amp;SR <a href="mailto:ClinicalTrials@mednet.ucla.edu">ClinicalTrials@mednet.ucla.edu</a></td>
</tr>
<tr>
<td>Non-Profit (Federal/State)</td>
<td>OCGA Submit docs via EPASS</td>
</tr>
</tbody>
</table>

CLINICAL TRIALS – APPLICATION CHECKLIST
Revised July 27, 2021
CTC&SR (For-Profit Clinical Trials)

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

- **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)*

- Sponsor Draft Contract (Word doc) & Draft Budget

- Certified Final Budget and Sponsor Contract uploaded into OnCore System by negotiating party
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 (Non-HemOnc: Tara.Davidoff@tdg.ucla.edu & HemOnc: KZepeda@tdg.ucla.edu)
  - 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) & Draft Budget
  - Final Budget (sent to TDG by negotiating party)
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 / Justification**
  • Final Proposal (science, agency required signatures, biosketches, etc.)
  • Brief description of proposal aims/abstract
  • **Subaward:** **Required Forms & Checklist** *(if applicable)*

UCLA Department of Medicine - Office of Research Administration
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:
### Proposal Identification

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

### Award/Proposal/Program Type

- **Award Type:** Contract [ ]
- **Program Type:** CT Drug [ ]
- **Proposal Type:** New [ ]
- **Current Sponsor Award #:** [SPONSOR ID#]
- **Action Type:** Not Applicable [ ]

### Sponsor Information

- **Sponsor Name:** [CRO Name]
- **Sponsor Due Date:** 06/30/2028
- **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

### Principal Investigator Information

- **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.

### Proposal Checklist - Carefully Review and Answer All Questions

- **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 Clearance 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

- If COI is required, please provide names of other investigators on page 3 (See UCLA Policy 928).
- If Sponsor/Prime Sponsor is Federal (other than PHS), CRIR or special research programs managed by the UC Research Grants Program Office (UGPO), if yes, attach COI Form 740 & Supplement to Form 740 (if applicable). See UCLA Procedure 925.3.
- If Non-Government Sponsor/Prime Sponsor is yes, then project is Research, attach Form 700-U, 700-U Addendum and 700-U Supplement, if applicable, unless sponsor is exempt. See UCLA Procedure 925.2.

8. Funds Requested

<table>
<thead>
<tr>
<th>1st Budget Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Costs ($)</td>
</tr>
<tr>
<td>Excluded Direct Costs ($)</td>
</tr>
<tr>
<td>F&amp;A Costs ($)</td>
</tr>
<tr>
<td>Total Costs ($)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>All Project Periods (complete only when multiple budget periods are involved)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Direct Costs ($</td>
</tr>
<tr>
<td>Excluded Direct Costs ($)</td>
</tr>
<tr>
<td>F&amp;A Costs ($)</td>
</tr>
<tr>
<td>Total Costs ($)</td>
</tr>
</tbody>
</table>

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

9. Remarks

NCT#

10. Accepts Responsibility

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. All Clinical Trials based upon FDAAA 807, will be registered in ClinicalTrials.gov. When multiple Investigators are proposed in an application, this assurance must be satisfied by all named Investigators.

<table>
<thead>
<tr>
<th>Principal Investigator (Required)</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chairman/Dean/Chief Medical</td>
<td>Date</td>
</tr>
<tr>
<td>Chairman/Dean/Chief Medical</td>
<td>Date</td>
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<tr>
<td>Chair/Dean/Chief Medical</td>
<td>Date</td>
</tr>
<tr>
<td>Chair/Dean/Chief Medical</td>
<td>Date</td>
</tr>
</tbody>
</table>
Contract Formation – **Form 700U** (CTC&SR, TDG, OCGA)

- Original 700-U (with wet signatures) need to be routed to the appropriate central office, in addition to routing the electronic versions. Fund Managers *MUST* forward the original wet signature versions to the central offices! It is a State requirement.

- Note: Form 700-U series is applicable to non-government sponsors (view [Conflict of Interest (COI) Disclosure Forms](#))

- Note: Form 700-U is the *only* form that requires wet signatures
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
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
    - Add’tl 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
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
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**)

*UCLA Department of Medicine - Office of Research Administration*
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

**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 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: Assistant 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:** XXXX/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
• DOM PI Responsibility Form (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)**, 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

UCLA Department of Medicine - Office of Research Administration

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 is required for all human subject research before it can start.
   - IRB approval is required for all human subject research.
   - If there is a lapse in the usual renewal, research must be put on hold until an appropriate renewal is approved by the IRB.

2. An investigator named on the IRB-stamped consent form provides and documents the process of written informed consent.
   - Responsibilities for the consent process cannot be delegated to a novice or coordinator.
   - An investigator cannot sign-off on consent that was obtained by others.
   - A named investigator must personally ensure that the subject understands what is described in the consent, their alternatives, 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 IRB 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/assessments of additional samples, or changes in drug administration may 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 change/correction.

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.

7. Serious adverse events are immediately reported according to the UCLA IRB Decision Tree for internal or external events and FDA guidelines.
   - Reports first - obtain and report follow-up details later.
   - It does not always matter if the SME 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 policies 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 certification 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 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 disbursements.
    - More 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 those 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: ________________________________

Version 7/9/98
1 of 2

Version 7/9/98
2 of 2
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](mailto:TDGContractOfficer@mednet.ucla.edu))
  - **OCGA** (submit internal docs via [EPASS](mailto:EPASS@mednet.ucla.edu))
  - **Conflict of Interest Disclosure Forms Matrix**

- **DOM Clinical Trials Fund Manager Manual Chapters**
  - **CT Required Documents Checklist** (CTC&SR)
  - **CT Application Checklist** (DOM)
  - **CT Subcontract Checklist** (CTC&SR)
  - **CT Budget Template**
  - **Budget Preparation**
    - **SF424 Budget**
    - **PHS 398 Budget**
    - **Center Grant Budget**
  - **Budget Justification**
Survey Link
https://forms.gle/QaMyquTuMKTmKtNDEj1k8

We appreciate if you would take a few moments to complete a short 5 question anonymous survey to help us improve your training experience. Thank you!