This session will *not* be recorded, but this PowerPoint can be found [here](https://medschool.ucla.edu/research/researcher-resources/administrative-support/department-medicine-office-research-administration/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
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>
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<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>
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<td>TDG (Dept Assignments) 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></td>
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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 (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)
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:

![EPASS Form](image-url)
### Proposal Identification

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

### Award/Proposal/Program Type

- **Award Type:** [Contract]
- **Program Type:** CT Drug
- **If this EPASS relates to an existing Award or Master Agreement, select an Action Type:** New [x]
- **Current Sponsor Award ID:** Sponsor protocol #R123

### Sponsor Information

- **Sponsor Name:** CRG Name
- **Sponsor Due Date:** 06/30/2028
- **Deadline Type:** Electronic
- **Sponsor Guidelines and/or FOA/RF/A/RFP:** [ ] Yes [x] No
- **Attached:** [ ] URL (Section 9) [ ] Name/No.
- **Contact (If known):** John Smith
- **Email Address:** John Smith@crc.com
- **Phone #:** XXX-XXX-XXXX

### 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 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

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- COI Disclosure Requirements
- Sponsor/Prime Sponsor in 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 in Federal (other than PHS), CIRM 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.
- Non-Government Sponsor/Prime Sponsor? If yes, 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.

- Industry Sponsored Research
- Industry Sponsored Clinical Trial? If yes, view the Clinical Trials Contracts & Strategic Relations Checklist to determine additional required attachments.

8. Funds Requested

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<th>1st Budget Period</th>
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<tr>
<td>Direct Costs ($)</td>
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<td>Excluded Direct Costs ($)</td>
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<td>F&amp;A Costs ($)</td>
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<td>Total Costs ($)</td>
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<tr>
<th>All Project Periods (complete only when multiple budget periods are involved)</th>
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<tbody>
<tr>
<td>Direct Costs ($)</td>
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<tr>
<td>Excluded Direct Costs ($)</td>
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<tr>
<td>F&amp;A Costs ($)</td>
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<tr>
<td>Total Costs ($)</td>
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</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 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/COU Director/Dean/Medical Center Director (Required) |
| Date |
| | |
| | |

| Approval Date:

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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
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
  - 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
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
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)
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
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.
Contract Formation – All Clinical Trials

- Budget – **draft/final & justification** (for non-profit)
- **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) 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
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 for certification of compliance.
   - IRB approval is required for all human subject research before it can start.
   - If there is a lapse in the usual renewal, research must be put on hold until an appropriate 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 co-investigator.
   - An investigator cannot sign-off on consent forms obtained by others.
   - A named investigator must personally ensure 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 IRB (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 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 change in the study procedures, protocols, or materials are allowed without first submitting them to the IRB and obtaining IRB approval.
   - Additional radiographs, the collective 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 data used for clinical decision-making must be performed in CIJA certified laboratories or in a similarly certified manner.

All study drugs and investigational agents must be maintained and dispensed by the Investigational Drug Service (IDS) of the Ronald Reagan UCLA Medical Center Department of Pharmaceutical Services according to an approved pharmacy protocol.

All information recorded on the case report form will be reviewed by a study investigator, with documentation of approval or corrective action for abnormal value and/or protocol violations. You are directly responsible for the integrity of the study data and the safety of the subjects.

Some 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.
- Does not always mean if the AEs is related to the study; it must be immediately reported if required by the UCLA IRB Decision Tree guidelines.

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, bisulphite, sample shipping, etc.

- You should personally verify certificate 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.

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.

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.
- Monitor 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:

[Space for study title]

Sponsor Name: [Space for sponsor name]

Signature: [Space for signature]

Print Name: [Space for print name]

Date: [Space for date]

Version 7/98

1 of 2
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)
  • 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/QaMyquTmKtNDEj1k8

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!