INITIATING CLINICAL TRIAL CONTRACT REVIEW WITH DGSOM – CLINICAL TRIAL CONTRACT UNIT ("CTCU") - USEFUL INFORMATION AND FORMS

What to submit to CTCU:

These documents are the required for your Contract Officer to review & sign a Clinical Trial Agreement ("CTA"). The department/division is responsible for getting documents to CTCU. The highlighted documents must be submitted to start the CTCU review process. All documents are required prior to contract signing. An explanation of these documents follows the list.

1. Goldenrod
2. Protocol
3. Clinical Trial Agreement
4. Financial Disclosure form - Statement of Economic Interests for Principal Investigators – "Form 700U" and Industry Clinical Trials Supplement if necessary
5. Financial Disclosure form - Investigators' Statement of Financial Interests – "Form 700U Addendum" for persons other than the PI who are responsible for the design, conduct or reporting of the trial, and Industry Clinical Trial Supplement if necessary
6. Informed consent
7. IRB approval
8. Budget
9. Principal Investigator Exception Letter when necessary
10. For **Department of Medicine Investigators**, please also submit the **DOM** "**Other Support Form**" & "**Top Ten Investigator Responsibilities**" Form

The minimum documents should be forwarded to your Contract Analyst.

Explanations:

1. Goldenrod http://www.research.ucla.edu/ocga/forms/goldrod2.pdf

The Goldenrod is UCLA's internal submission and approval form. The form contains a summary of important trial information. Once the form is completed it is circulated to: the PI, his/her Chair or Dean, his/her MSO, the Medical Center Director for their review and approval to move forward. CTCU will accept a draft signed by the PI in order to get started in reviewing the CTA.

2. Protocol – The official current protocol should be provided.

3. Clinical Trial Agreement – The written understanding between the university and the funding source and/or drug or device provider. There are many companies with whom UCLA may already have master agreement. Contact your Contract Analyst or Officer to find out if a master agreement or template exists. If you have the electronic version it should be forwarded directly to your assigned Contract Analyst. You Contract Officer can also assist in drafting an agreement if the sponsor does not have a standard agreement.

4. Statement of Economic Interests for Principal Investigators – "Form 700" and Industry Clinical Trials Supplement if necessary

The original Form 700U must be sent to CTCU. **California law requires this disclosure and an original complete form** signed by the Principal Investigator must be provided whenever new funds are being provided. An academic peer committee reviews disclosures. For more information about the committee go to: http://www.research.ucla.edu/researchpol/coi.htm

To obtain the Form 700U go to: http://www.research.ucla.edu/researchpol/forms/Form700U.pdf

To complete the Industry Clinical Trials Supplement smart form online go to:
http://www.research.ucla.edu/researchpol/CT_Disclosure_Supplement/profile.asp

NOTE – *If contracting through a Contract Research Organization (CRO) then forms are required for both the CRO and the underlying sponsor of the study.*

5. Investigators' Statement of Financial Interests – "Form 700U Addendum" for persons other than the PI who are responsible for the design, conduct or reporting of the trial, and Industry Clinical Trials Supplement if necessary.

The original Form 700U Addendum must be sent to CTCU. Remember the PI must also sign this form in addition to the other investigators on the study. An academic peer committee reviews disclosures. For more information about the committee go to: http://www.research.ucla.edu/researchpol/coi.htm

To obtain the forms go to: http://www.research.ucla.edu/researchpol/forms/700-U_Addendum_Dec2007.pdf

To obtain the supplement go to: http://www.research.ucla.edu/researchpol/CT_Disclosure_Supplement/profile.asp

NOTE – *If contracting through a Contract Research Organization (CRO) then forms are required for both the CRO and the underlying sponsor of the study.*

6. Informed consent

7. IRB approval- the university policy requires that the Institutional Review Board approval be in place prior to execution of the Clinical Trial Agreement. For more information about the IRB go to: http://ohrpp.research.ucla.edu/

8. Budget - for contract review purposes a draft may be provided but the final approved budget must be provided to your Contract Officer before the Clinical Trial Agreement may be signed.

9. Principal Investigator Exception letter – If the PI is not eligible to serve as a PI pursuant to UCLA policy APPM 900 (go to http://www.adminvc.ucla.edu/appm/_entry_900.html) then it is necessary to have their Chair or Dean approve them as a principal investigator on each trial. Generally investigators with an academic title code of 1, 2, or 3 are eligible all others require a letter of approval.

10. DOM Other Support form – the Department of Medicine requires that principal investigators track their percent of effort on research projects. This form must be completed prior to the clinical trial receiving its fund number.

REMEMBER: 1 through 5, are the minimum documents required to open a proposal file and begin the contracting process at CTCU.