CHAPTER #6
Budgets and Contracts

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CHAPTER #6: Budgets and Contracts

6.1 Assistance with Coverage Analysis and Budgets
In-Service training for Coverage Analysis aims to provide departments with hands-on instructions and application of the Coverage Analysis process based on the specific needs of the department. Training sessions include an overview of the Coverage Analysis requirements and how to complete the Qualifying Clinical Trials (QCT) Form, Billing Grid and the Bridge Database. It also includes information on the requirements listed in the Medicare National Clinical Trials Policy, tools available on the CTSC website for developing the Coverage Analysis, and guidance on the existing policies and procedures related to clinical trial billing. For scheduling, contact Suzan Bruce skbruce@ucdavis.edu

In-Service training is available for internal industry-sponsored budgets. For more information contact Julie Calahan (916-734-2547).

Also see http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html

6.2 CTSC SOP # 4, #5, #6, #7, #8, #13
The purpose of these SOPs is to provide guidance to research personnel on how to complete a clinical trial Coverage Analysis, budgets, and to receive institutional and Departmental approvals. Reference: http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/sops/index.shtml

The flow chart below explains how Coverage Analysis and Billign Grid are used for trial management.

[Flow chart image]
6.3 Complete Coverage Analysis

Introduction to Clinical Research Billing

Clinical research billing compliance has become a major focus area of compliance professionals in recent years. Clinical research is highly regulated by federal regulations and state laws, as well as IRB’s. The Research Billing Compliance Program at UCDHS was developed to ensure appropriate billing practices for covered versus non-covered services related to research protocols. The program performs reviews of selected protocols for accurate regulatory and billing practice activity. This review process ensures that research costs are accounted for and billed appropriately according to the research study documents.

The Centers for Medicare and Medicaid Services (CMS) coverage rules for clinical research services are stated in the National Coverage Determination (NCD 310.1) Policy, most recently revised in July 2007. According to this policy, Medicare will reimburse for additional costs incurred by the participants in qualifying clinical trials. These additional (expanded) costs may include administration of the investigational item (e.g., chemotherapy infusion), clinically appropriate monitoring (e.g., additional labs to monitor for side effects of the investigational medication), and diagnosis, prevention, and treatment of complications. In order to receive the reimbursement for expanded services, the study has to “qualify.” The NCD specifies the qualification process for clinical trials, including covered indications, limitations of coverage, and other requirements. Medicare coverage for clinical trials is limited to items and services that are reasonable and necessary and within the scope of a Medicare benefit category. If services are only being obtained for data collection and not reasonable and necessary, the service is non-covered, and therefore, should be paid for by the study budget.

CMS contracts with local intermediaries to administer the Medicare Program. As of August 2013, the local Medicare contractor (intermediary) for California is Noridian. At the local level, in the absence of a national coverage policy, each Medicare contractor has the discretion to determine which items and services are reasonable and necessary and therefore covered as a Medicare benefit. Some coverage determinations are issued in a document called a Local Coverage Determination. National Coverage Determination always has higher importance than Local Coverage Determination. The local contractor (Noridian) also determines approval for coverage when providers request recognition as participants in device trials. Providers must adhere to device coverage instructions in the CMS manual. Specific claims processing instructions can be found in the Medicare Claims Processing Manual and in the NCD 310.1.

If your study enrolls patients with a Medicare Advantage Plan, be aware of special requirements for copays and claims processing. For a Medicare patient in a qualifying clinical trial device study, the claims go to the Medicare Advantage Plan. For a Medicare patient in all other qualifying clinical trial studies (drug, etc.), the claims go to regular Medicare (Fee for Service). It is critical that research staff communicate with the registration staff when a Medicare Advantage enrollee is receiving a research service. The correct insurance plan code must be chosen during registration to route the claims and adjust the proper co-payment amounts. For updated information on the Medicare Advantage Plan billing see: https://www.cms.gov/Medicare/Coverage/Coverage-with-Evidence-Development/Downloads/Mandatory-Clinical-TrialIdentifierNumberQsAs.pdf
Claims issued to Medicare (and in some instances, to other insurance providers) must carry special identifiers to show that the claim was issued for research-related services and procedures. These identifiers are **V70.7 or Z00.6 diagnosis code, Q0/Q1 modifiers and Clinicaltrial.gov number**. Investigators and clinical research coordinators are responsible for providing sufficient documentation in Electronic Medical Records for billers to add these identifiers to the claims. Claims that miss one or the other identifiers may be rejected by Medicare and returned back to the study team for corrections.

For updated information on the use of “Q” modifiers in coverage analysis, see the Clinical Trials Newsletter v8, May 2012 ([http://intranet.ucdmc.ucdavis.edu/ctsc/area/ctnewsletters/](http://intranet.ucdmc.ucdavis.edu/ctsc/area/ctnewsletters/)).

For best practices for providing billing documentation in EMR, see Chapter * of this Guidebook, CTSC SOP#13 and website: [http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/sops/index.shtml](http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/sops/index.shtml)

**What is Coverage Analysis?**

The NCD necessitates a priori delineation of what clinical trial services/procedures can be billed to Medicare, and which could only be billed to the study. Such delineation can be expressed in a Medicare Coverage Analysis (MCA) or simply Coverage Analysis (CA).

In order to bill the third-party payors, a clinical study must meet qualifying criteria. Coverage Analysis is a process of determining when a clinical study qualifies for Medicare coverage and lists these services in a Billing Grid. The grid identifies which clinical study-related procedures and services can be paid by the third party payor, including Medicare, and which should only be paid by the study sponsor. At UC Davis Medicare coverage criteria are used and extended to all insurance companies. Insurance policies vary in their coverage of clinical studies; therefore, it is important that the study participant confirm coverage with his/her individual insurance company.

The Coverage Analysis consists of two steps: 1) Qualification and 2) Enumerating qualified services in a Billing Grid. Qualification can be completed in the Bridge (See Chapter 8). In addition, templates for QCT (Qualifying Clinical Trial) Form and a Billing Grid are located on the CTSC webpage ([http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html](http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html)).

Coverage Analysis process is outlined in CTSC Clinical Trial SOP #4 ([http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/sops/index.shtml](http://intranet.ucdmc.ucdavis.edu/ctsc/area/clinicaltrials/sops/index.shtml)).

A Coverage Analysis is mandatory for all studies that include billing of patient care services in the UC Davis Health System. The Principal Investigator is ultimately responsible for ensuring that the Qualifying Clinical Trials (QCT) Form and Billing Grid (which together make up the Coverage Analysis) are accurate. Both forms must be approved by the Principal Investigator. The Department may keep a paper copy on file (in the Study Financial Binder) for audit purposes.

**Final Coverage Analysis is required to be uploaded into the Bridge database. (CTSC SOP#4, #13, Chapter 8).**
Qualification Process

The first step in Coverage Analysis is to determine if the study qualifies. It is a process for Principal Investigators to attest to Medicare that a clinical study meets certain Medicare qualifying criteria. When the study meets this criterion, it is a “qualifying clinical trial.” This means that Medicare (and by extension, other insurance companies) will cover associated routine and expanded patient care during the clinical study. Routine care is also called “standard of care” and defines procedures/services that would be performed absent a clinical study. Expanded care includes additional services such as clinically necessary monitoring of the effects the investigational drug or device, administration of the clinical study article (drug or device), procedures for prevention, diagnosing, and treatment of side effects or complications resulting from the patient’s participation in the clinical study (Medicare Clinical Trial Policy, NCD 310.1).

Medicare will not cover items and services that are paid for by the sponsor, promised free in the informed consent document, not ordinarily covered by Medicare, and studies that are solely for data collection or analysis.

<table>
<thead>
<tr>
<th>What types of services are covered in a clinical trial?</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Qualified Trial</strong></td>
<td><strong>Non-Qualified Trial</strong></td>
</tr>
<tr>
<td>Conventional or Standard of care (SOC)</td>
<td>Conventional or Standard of care (SOC)</td>
</tr>
<tr>
<td>Services to monitor effects of investigational drug/device</td>
<td>N/A</td>
</tr>
<tr>
<td>Services to administer investigational drug/device (e.g., infusions, surgery)</td>
<td>N/A</td>
</tr>
<tr>
<td>Services to prevent, diagnose, and treat complications</td>
<td>Treatment of complications</td>
</tr>
<tr>
<td>Protocol related services and items must be billed with clinical trial modifiers and diagnosis codes for Medicare patients</td>
<td>Services and items must <strong>not</strong> be billed with clinical trial modifiers</td>
</tr>
</tbody>
</table>

Information about the qualification process can also be found in the Clinical Trials Newsletter v3, June 2011 [http://intranet.ucdmc.ucdavis.edu/ctsc/area/CTNewsletters/](http://intranet.ucdmc.ucdavis.edu/ctsc/area/CTNewsletters/)
**Device Trials**

CMS determines Medicare coverage of devices based on which category the FDA assigns the device. Devices are either designated as a Category A or B IDE. Effective January 01, 2015, CMS Coverage Analysis Group began reviewing all IDE trials for approval. Once CMS approves the trial, it gets listed on CMS web site. This process is streamlining the approval process for all parties involved. Prior to enrolling any Medicare patients in an IDE study the local Medicare contractor (Noridian) has to be notified.

For IDE trials with an FDA and CMS approvals Noridian requires:

1. Notice of participation in the trial,
2. IDE designator assigned by the FDA

A cover letter including the PTAN of the facility, the names of the Principal Investigator, study doctors and their NPIs has to accompany the submission.

Such notice is necessary to input into the Noridian claims payment systems to assure proper processing of our provider’s claims related to such trial. For further information on this process, visit the CMS website: [http://www.cms.gov/Medicare/Coverage/IDE/index.html](http://www.cms.gov/Medicare/Coverage/IDE/index.html)

A device flowchart detailing the process for filing for Medicare approval of devices is located in the Coverage Analysis section of the CTSC Budgeting and Billing Website ([http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html](http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html)).

For assistance in this process contact Suzan Bruce [skbruce@ucdavis.edu](mailto:skbruce@ucdavis.edu)

**Billing Grid Process**

If the study qualifies for Medicare coverage, the clinical events specified in the protocol are listed in the Billing Grid (Excel spreadsheet). Each procedure is reviewed in detail to determine which would be reimbursed by Medicare and why. Preparation of the Billing Grid requires knowledge of CPT codes and Medicare coverage guidelines. Each CPT code listed in the Billing Grid is reviewed for national and local coverage policies. Many hospital procedures, especially surgical, may contain multiple “bundled” codes. Without identifying all individual codes in a bundle, it may not be possible to estimate true cost of the procedure. Use the Coverage Analysis Checklist to identify potential “hot spots” for bundled codes.

**Note:** Many lab procedures, specifically those sent to outside labs, may also be bundled. For budget purposes, add research costs for all procedures in the bundle Contact Pathology Client Services at (916)734-7373 for the estimate.
A "Preliminary Billing Grid" is prepared based on the Medicare and billing policies. A CTSC Coder will help to analyze the protocol to identify all billable services. In case of industry-sponsored studies, a sponsor may decide to pay for a service/procedure regardless of Medicare rules. This should be reflected in a Clinical Trials Agreement and the negotiated budget. Once the budget is approved and the CTA is signed, the Billing Grid for this study should be updated to reflect the changes. At this point, it is called “Final Billing Grid.” In contrast, investigator-initiated studies funded by a grant or department funds only have one version of billing grid, “Preliminary.”

Note that the Billing Grid needs to include the study objective. This statement is important to support qualification of the trial.

See Clinical Trials Newsletter v 9, June 2012 for further information (http://intranet.ucdmc.ucdavis.edu/ctsc/area/ctnewsletters/)

Coverage Analysis documents, including the Qualifying Clinical Trials (QCT) Form, Checklist and a template of the Billing Grid, are located on the Clinical Translational Science Center (CTSC) website http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html

6.4 Prepare internal budget for Industry-Funded Studies

A preliminary Billing Grid based on the Medicare medical policies is a foundational document for a sound budget for both industry- and investigator-initiated studies.

6.4.1 Unified Budget Template (UBT)

The Internal Budget identifies study costs based on labor costs and research rates for procedures as identified in the Coverage Analysis Billing Grid. To develop a sound internal budget, UC Davis uses an Excel template called the Unified Budget Template (UBT), found at: http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html.

The template consists of following components:

1. Invoiceable fixed costs, including start-up, recurring, and close-out costs
2. Per patient costs

6.4.2 Invoiceable Fixed Costs.

These costs are based on the anticipated time and expense to conduct these activities. The Unified Budget Template provides time brackets as guidelines.
A Note on Invoiceable Fixed Costs

To create realistic budgets, pay attention to the following costs occurring during the start-up, maintenance, and close out phases of the trial.

Start-up

- **Time for logistical assessment**: Be sure to include time for the logistical assessment and workflow implementation of the protocol. For example, are multiple departments have to be coordinated in order for the trial to be a success? Will someone be spending their time communicating and coordinating (scheduling) with other departments before or after subjects are on-site?

- **IRB documents and communication**: The IRB charges a set amount for initial review of every Industry-Sponsored trial. This amount goes straight to the IRB and does not account for any of the time for the site personnel to actually prepare the IRB documents. For example, a study with four consents will take longer to prepare than a study with only one consent. Also remember to account for time spent communicating with the IRB, including responding to concerns, providing further information, and providing clarifications.

- **Ancillary committees**: Make sure to account for time spent on applications for ancillary committees such as the Conflict of Interest Committee or the Radiation Use Committee.

- **Budget development**: Preparing an internal budget using the UBT is time consuming. Have you accounted for study budget preparation? Negotiating a budget with a Sponsor can also take a fair amount of time. Is there time in the budget for negotiation with the Sponsor?

- **Training**: Does the Sponsor require training on the electronic data capture system? Is there special training that is required by the Sponsor?

- **Investigational Drug Service**: The IDS has initial setup fees that vary depending on the complexity of the study. Contact IDS@ucdmc.ucdavis.edu for a quote.

Recurrent

- **IRB documents and communication**: The IRB charges a set amount for continuing review of every Industry-Sponsored trial. This amount goes straight to the IRB and does not account for time to prepare the continuing review of modify IRB documents when the Sponsor updates the protocol or consent. Add the time for regulatory maintenance to your budget.

- **Serious Adverse Event (SAE) reporting**: Reporting SAEs to the IRB and Sponsor can be time-consuming. Budget time to provide initial and follow up SAEs to both the IRB and Sponsor.

- **Site Monitoring**: Having a Sponsor representative on site can occupy the coordinator for days. Include this time in the budget.

- **IDS**: IDS charges an annual inventory fee, which is provided with the initial quote.
Close-out

- **Institutional Review Board (IRB):** The IRB does not charge a close-out fee but the study must be closed out with the IRB which entails paperwork. Budget time for preparing close out documents.

- **Storage of study records:** The study records must be securely stored, and there may be a fee if an outside facility is used.

- **Sponsor visit:** The Sponsor typically visits the site to close-out the study and ensure everything is in order. Budget time for this.

- **Financial closure:** Once the IRB closes the study, the closure will be updated in the Bridge. From this update, EMR will be notified and the study status will become inactive (complete) in EMR. Notify the billing office when your study is closed. This will ensure correct closure of sponsor accounts and patient care charges.

- **IDS:** The IDS has close-out fees that vary depending on the complexity of the study, and provided with the initial quote.

### 6.4.3 Per patient costs.

These costs are composed of protocol-related procedures and hospital services. Only those hospital procedures and services that are not paid by insurance are included in the UBT. To determine what is payable by the study and what is payable by insurance, refer to the Coverage Analysis and incorporate correct line items in the per-patient grid.

Research discounts are applied to the costs of research procedures and services. Discounts and the Master prices could be found in UCD Epic Cost Query tool, located at: [https://ctsc-prod.ucdmc.ucdavis.edu/ucdr/epiccer/2016/epicRCosts.aspx](https://ctsc-prod.ucdmc.ucdavis.edu/ucdr/epiccer/2016/epicRCosts.aspx)
6.4.4 Radiology Costs and Research Procedure Request Form

All research protocols/studies that involve radiological services must be reviewed and approved by the Radiology research team prior to study initiation.

The Department of Radiology supports and encourages clinical research at UCDMC. If your protocol contains any radiology services, contact the Department of Radiology prior to starting your study or even at the protocol preparation step.

Radiology will establish the exact process for study procedures, provide research cost estimations for radiological exams, obtain test transfers, and assist with completing imaging or feasibility questionnaires. This is especially important if study-specific imaging deviate from the standard radiology procedures, i.e., require an unusual contrast agent. It is not uncommon for radiology services not to be clearly detailed in the text of the protocol, potentially resulting in additional unanticipated charges at the point of service.

To minimize the impact of unanticipated charges, submit your study information to Radiology.

1. Research protocol
2. Imaging Acquisition Guidelines (if available)
3. Research Procedure Request Form

Send to: research-radiology-som@ucdavis.edu

The Research Procedure Request Form and Instructions may be found at: http://www.ucdmc.ucdavis.edu/clinicaltrials/StudyTools/StudyTools.html

6.4.5 Pathology Costs and Client Services (Lab)

The UC Davis Health System Department of Pathology and Laboratory Medicine is fully accredited by the College of American Pathologists (CAP), licensed by the State of California, the Clinical Laboratory Improvement Act (CLIA), Foundation for the Accreditation of Cellular Therapy (FACT), and American Association of Blood Banks (AABB). It performs over 3,000 tests. To find what tests is offered by the department of Pathology, see Laboratory Test Directory, accessible only via intranet: https://www.testmenu.com/ucdavis
Laboratory Licenses (such as CLIA) and Accreditations can be found here: [http://www.ucdmc.ucdavis.edu/pathology/services/clinical/licenses/](http://www.ucdmc.ucdavis.edu/pathology/services/clinical/licenses/)

**Anatomic Pathology** provides autopsy, cytopathology, neuropathology and surgical pathology. **Clinical Pathology** provides apheresis, hematopathology, molecular/Cytogenetics, Point of Care Testing and Transfusion Medicine. It also includes the UC Davis Medical Center Clinical Laboratory, a full-service anatomic and clinical pathology laboratory, offering one of the most extensive routine and esoteric testing menus in and beyond the Northern California region.

Some of the pathology services may require additional information prior to receiving the specimen. This is especially important for microbiology samples that may need to grow for a period of time under certain lab conditions. To ensure that clinical trial protocol specimens are processed correctly and in the timely manner, contact Pathology Client Services at (916) 734-7373, option 1, prior to beginning of the study.

For blinded studies, or those studies where results of laboratory testing are not recorded in EMR, complete the Research Checklist as well as Secured Fax and/or Secured Print Forms as well as and FAX to the Client Services. Next, the Requisition Form specific for the study will be created by the Pathology Client Services. Complete the Requisition Form for every sample. The Requisition Form **MUST** accompany the sample to the laboratory.
If the study is entirely bypassing the EMR (i.e., studies from the Davis Main Campus), obtain the Research Account number from Patient Financial Services and write it on the Requisition Form.

If the study is in the EMR, but one particular lab is bypassing the EMR, a “dummy patient account” is generated in the EMR Research Study File. This account number should be written on the Requisition Form.


### 6.4.6 Investigational Drug Services costs


### 6.5 Negotiation of the External Budget with Industry Sponsor

External budgets are negotiated with Industry Sponsors based on Fair Market Value. The external budget should cover costs included in the internal budget using the UBT. Formats for sponsor budgets vary widely, with each sponsor requiring their own template. External budgets are often expressed as “invoiceables” and “per patient cost,” and include institutional overhead rate. Only studies that meet a “clinical trial” definition may be negotiated at Health System Contracts – Clinical Trials with 26% overhead rate. If it is not clear as to whether a project meets the definition of a clinical trial, contact Health System Contracts–Clinical Trials prior to budget negotiations [http://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/](http://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/).

As of the time of publication, the Principal Investigator and the department are responsible for preparing a preliminary UBT, negotiating a final (external) sponsor budget and submitting to the Department Chair for signature. The negotiated budget (external budget) will become part of the contract packet, submitted to the SOM Dean’s Office for approval and forwarded to Health System Contracts-Clinical Trials, where the Budget Analyst will review for policy compliance and approve the final internal cost budget.

The negotiation may be a quite protracted affair. Be patient, respectful and stand your ground!

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**External Budget tips:**

- Remove CRC or Principal Investigator specific hours from the Sponsor Budget
- Don’t use term “cost,” instead, use “fee”
- Don’t agree to payment terms “Due upon site initiation.” Instead, use “Due upon contract execution”
- When negotiating, add a phrase on top of the Sponsor Budget: “Agreement pending contract office review”
- Make any changes in External Sponsor Budget by redlining the initial budget provided by the sponsor
- If the Sponsor indicated “SOC,” make a note that it was the Sponsor’s decision
- The Sponsor should agree to pay 100% of screening visit
- The Sponsor budget becomes part of the legal documents
6.6 Prepare Budget for Grant or Department Funded Clinical Trials

This process pertains only to those studies that involve patient care services at UC Davis Hospital and Clinics

Once the research team develops the description of the study (clinical trial protocol), it is strongly encouraged that the team contacts CTSC Clinical Trial Resource group. CTSC will review the protocol to ensure compliance with clinical research billing requirements and prepare correct budgets for patient care costs and other research activities. The Clinical Trial Resource group will provide analysis of:

- **The billing grid of patient care services/procedures** involved in the protocol (called Coverage Analysis). Analysis of these services and which procedures may be billed to insurance during the clinical trial is essential and required at the time of IRB submission. A CTSC Clinical Research Billing Analyst will prepare the Coverage Analysis (CA) document to delineate items that can be billed to Medicare or another third party payer versus those that are not covered by the insurance and must be paid out of the study budget. Understanding of clinical research billing ensures correct budgeting to account for hospital/clinical charges.

- **Hospital/clinic costs** for study-related procedures and services that are not covered by insurance and therefore must be paid by study budgets. A CTSC Analyst will help to assess the cost based on the completed CA. Costs are also available from the Clinical Trials Budgeting and Billing website ([http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html](http://www.ucdmc.ucdavis.edu/clinicaltrials/BudgetingBilling/index.html)).

- **Operational Feasibility** to assess potential scheduling conflicts, operating room availability, radiology research procedures, IDS pharmacy role, microbiology research procedures, etc.

- **Regulatory assessment** of trial activities required to comply with FDA, ICH GCP, IRB, and Medicare regulations. This may include assessment for regulatory compliance, and data quality monitoring and quality assurance support.

- **Other Clinical Trial Expenses** such as fees for language translation, investigational drug pharmacy, shipping, sample and record storage, and advertising. Use the worksheet in CTSC SOP#6 as guidance to identify other possible items that have budgetary implications.

The CTSC Clinical Trial Resource group will prepare a proposal to summarize the assessment and to detail the potential costs of services recommended. The CSTC analysis does not replace the budgets as required by the granting agency guidelines. It should be used as an estimate only and does not represent commitment of funds or resources.

The Unified Budget Template **is not used** for grant and department funded studies. However, the costs identified by the CTSC need to be included in budgets prepared in accordance with granting agency guidelines. For department sponsored studies, CAO and Chair need to agree to expend funds for clinical trial costs as identified.
6.7 Clinical Trials Contracts

Clinical studies meeting the definitions of clinical trials are negotiated by Health System Contracts-Clinical Trials Office [Clinical Trials Contracts] http://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/

6.7.1 Confidentiality (Non-Disclosure) Agreements

This activity is required for industry-initiated and industry-sponsored clinical studies. In many instances a Sponsor sends a Confidential Disclosure Agreement (CDA) prior to sharing a protocol or confidential documents. If a Principal Investigator receives a CDA directly, forward the CDA to Clinical Trials Contracts for negotiation. Clinical Trials Contracts reviews CDAs in great detail and ensures that it complies with the University rules for confidentiality, data retention and information ownership. UC Davis Principal Investigators are highly discouraged from signing the CDAs without the review, because it puts confidentiality obligations on them personally. CDAs are not always required by Sponsors, because some may already have Master Confidentiality Disclosure Agreements with the University.

6.7.2 Clinical Trial Agreements (CTA)

**Clinical trial agreements handled at the Clinical Trials Contracts have the following characteristics:**

- Involve prospective testing in Human Subjects and always require Institutional Review Board (IRB) review (this does not include cadaver or animal studies, nor does it include retrospective chart reviews)
- Examine the efficacy, safety or benefits of a Food and Drug Administration (FDA) reviewed medical intervention involving a drug, device, treatment or diagnostic (this would typically not include studies which involve the effects of beverages, foods or exercise on health, for example)
- Fully funded, directly or indirectly, by a for-profit entity (agreements which are partially or fully funded by non-profit, state or federal entities cannot be reviewed by this office)

Clinical Trials Contracts negotiates industry funded clinical trial agreements for the Health System

Before submitting a clinical trial packet to Clinical Trials Contract, the budget should be fully negotiated with the Industry Sponsor and approved by the responsible individuals from the Department. Below is a sample process map to use when negotiating the budget and preparing for submission to Clinical Trials Contracts.
Clinical Trial Packet

Once the budget is approved, the department prepares the clinical trial packet and routes to the SOM Dean’s Office for approval. The complete list of forms is available online (http://www.ucdmc.ucdavis.edu/healthsystemcontracts/clinicaltrialscontracts/requestforms.html)

<table>
<thead>
<tr>
<th>Clinical Trial Packet Documents</th>
<th>Links</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC Davis School of Medicine Grant/Contract Transmittal Form</td>
<td>Mandatory <a href="http://www.ucdmc.ucdavis.edu/medresearch/medsp/forms.html">http://www.ucdmc.ucdavis.edu/medresearch/medsp/forms.html</a></td>
</tr>
<tr>
<td>Sponsored Programs Data Sheet for Contract and Grant Proposals</td>
<td>Mandatory <a href="http://research.ucdavis.edu/resources/forms/#contract-grant-administration">http://research.ucdavis.edu/resources/forms/#contract-grant-administration</a></td>
</tr>
<tr>
<td>State of California Financial Disclosure Form 700-U (Statement of Economic Interests). Required for both Principal Investigators (PI) and co-PIs.</td>
<td>Mandatory, requires ORIGINAL signature</td>
</tr>
<tr>
<td>Federal Financial Disclosure Form 800 (Statement of Economic Interests) for Government Sponsored Programs and Projects involving Human Subject Research. Required for both PI and co-PI.</td>
<td>Mandatory <a href="http://research.ucdavis.edu/resources/forms/#Forms-FinancialConflictsofInterest">http://research.ucdavis.edu/resources/forms/#Forms-FinancialConflictsofInterest</a></td>
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<tr>
<td>Clinical Trial Packet</td>
<td>Links</td>
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<td>-------------------------------------------------------------------------------------</td>
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<tr>
<td>Statement of Economic Interests Supplemental Form (required if positive disclosure on 700U or 800)</td>
<td>Mandatory, if applicable <a href="http://research.ucdavis.edu/resources/forms/#Forms-FinancialConflictsofInterest">http://research.ucdavis.edu/resources/forms/#Forms-FinancialConflictsofInterest</a></td>
</tr>
<tr>
<td>Principal Investigator Statement to Exception to California Policy on Eligibility to Submit Proposals (Form 105A)</td>
<td>Mandatory, if applicable <a href="http://research.ucdavis.edu/resources/forms/#contract-grant-administration">http://research.ucdavis.edu/resources/forms/#contract-grant-administration</a></td>
</tr>
<tr>
<td>IRB Packet (without protocol)</td>
<td>Mandatory</td>
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<tr>
<td>Sponsor Protocol</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Sponsor Clinical Trials Agreement</td>
<td>Mandatory</td>
</tr>
<tr>
<td>Sponsor Budget</td>
<td>Mandatory</td>
</tr>
</tbody>
</table>

**Receipt and Assignment**

Once the contract packet is received it is assigned to an analyst for review, CTA negotiation and final execution. The analyst will work with the department contact if there are missing elements or delays with negotiations.

Conflict of Interest (COI) documents are reviewed and submitted to the Conflict of Interest Committee for approval. COI review may be concurrent with contract negotiation, but must be approved prior to IRB approval and prior to institutional signature on the contract.

**Initial Review**

The analyst will review the contract for consistency with UC policy, state and federal law, using the budget, protocol and internal forms as necessary. The analyst may also seek consultation with Risk Management, UCDHS Legal, IRB, UCOP or other sources as necessary to complete the initial review.

**First Comments to Sponsor**

The analyst will send a marked copy of the agreement to the sponsor with a copy to the Principal Investigator and the Department. Where reasonable, the analyst will keep the Principal Investigator and the Department copied on correspondence with the Sponsor or provide reasonable updates on the agreement.
**Contract Negotiation**

The analyst may need to consult with the Department, Principal Investigator, IRB, Legal, Risk Management, Innovation Access, UCOP and other sources during the negotiation process in order to move the agreement forward and ensure compliance with UC policies and applicable laws.

**End of Negotiation and PI Approval**

Once there is agreement between the analyst and the sponsor, the analyst will send the agreement to the Principal Investigator and the Department contact for final review and approval. If changes are requested, the analyst will negotiate any remaining issues with the sponsor. The contract will be held at this point until the Principal Investigator has approved or the Department contact certifies Principal Investigator approval.

**Sponsor/Institutional Execution**

Once approved by the Principal Investigator, the contract will be sent for signature, typically starting with the PI signature of acknowledgement to the contract. After the Principal Investigator signs the contract and all administrative requirements are met, the Director of Health System Contracts signs the agreement on behalf of the UC System. Typically the Sponsor signs last and the agreement is then fully executed. However, the contract will not be AWARDED until the **IRB has approved the project**.

**Contract Award**

With the fully executed CTA and the IRB approval the Clinical Trials Contracts notifies Extramural Accounting (EA). EA will open an extramural account and assign the Office of the President (OP) fund number. This enables the Department to open the DaFIS and Research Account to begin the study.

**Contract Maintenance**

After the contract is executed, Clinical Trials Contracts will be responsible, upon request from the Department, to negotiate and execute amendments to the project period, budget, or other required changes to the contract as agreed between the sponsor and the PI and department. Such requests must originate from the department, rather than directly from the sponsor.