Overview

Offices that review research and service-related contracts at UC Davis:

1. Sponsored Programs
2. UC Davis Health Clinical Trials Contracts Office
3. Business Contracts
4. InnovationAccess—MTA team
Sponsored Programs (SPO)

https://research.ucdavis.edu/proposals-grants-contracts/spo/

**SPO is responsible** for submitting proposals and accepting awards on behalf of the Regents for *projects* funded by federal and state agencies, foundations, and other public and private sources. The office is also responsible for drafting, negotiating, and executing awards and subawards for **collaborative research**.

* research and service (without recharge rates) projects

**SPO is not responsible** for processing most graduate student fellowships. Those should be processed by Graduate Studies.
### Sponsored Programs

- Proposals for extramural (outside) funding
- Extramural awards for research, training and public service
- Subawards
- Service (Other Sponsored Activity) agreements (if no approved rate)
- Confidentiality agreements in anticipation of research funding
- Teaming agreements in anticipation of proposal submissions
The following award/contract documents are handled by the **Awards** Team:

1. Collaborative research and service (without recharge rates) agreements between educational institutions, regardless of whether funding is provided
   * Also, Cooperative Research and Development Agreements (CRADA)
2. State of California agreements
3. Awards issued by Foundations
4. Federal Grants and Contracts
5. Any award issued using FDP, or FDP-like templates
6. Any award issued under a UCOP-negotiated Master Agreement. Sample Master Agreements:
   * **EXAMPLES:** Pacific Gas & Electric Company, and Lawrence Livermore National Security, LLC
The following are handled by the Negotiation Team:

1. All UCD master agreements
2. All awards from for-profit corporations that do not fall under a UCOP-negotiated Master Agreement.
   * Contracts from for-profit entities with federal flow-through (EXAMPLE: STTR, SBIR)
3. All CDA’s, NDA’s, teaming agreements, Intellectual Property Agreements (IPA’s), and MOU’s.

Email: Awards@ucdavis.edu or OR-SPO-Negotiation-Team@ad3.ucdavis.edu
Health Clinical Trials Contracts Office (CTCO)
UC Davis Health Clinical Trials Contracts Office (CTCO)

- The CTCO is a part of **Health Contracts**
- Health Contracts also houses **Health Affairs** and **Health Plan**
  - Health Affairs Contracts:
    - Non-research-related agreements only: Service agreements, Independent consultant agreements, Independent contractor agreements for professional services, Affiliation agreements, Training agreements, Facility transfer agreements, Intergovernmental Personnel Act (IPA) agreements, Expert witness agreements when primary to course and scope of faculty appointment, Facility use agreements and permits of less than one year, Data Use Agreements involving the disclosure of PHI.
  - Health Plan Contracts
    - Managed care contracts; Healthcare payer contracts; Serves as primary liaison between UC Davis Medical Center Managed Care Department and all contracted physicians, hospitals and ancillary providers; Provider customer service for all contracted payors including claims processing, credentialing, compliance and reimbursement methodologies.
The CTCO is responsible for the negotiation of *industry-funded* clinical trial agreements for UC Davis Health.

The clinical trial must be funded SOLELY by a for-profit company.
- agreements which are partially or fully funded by non-profit, state or federal entities cannot be reviewed by the CTCO – they must be handled by SPO.

The CTCO negotiates protocol-specific confidentiality agreements directly related to industry funded Clinical Trial Agreements as well as clinical service agreements.
• Definition of a clinical trial at the University of California:
  • “The controlled, clinical testing in human subjects of investigational new drugs, devices, treatments, or
diagnostics, or comparisons of approved drugs, devices, treatments, or diagnostics, to assess their
safety, efficacy, benefits, costs, adverse reactions, and/or outcomes. Such studies may be conducted
under an industry-developed protocol or an investigator-developed protocol.”

• Clinical Trials are now subject to a 26% indirect cost rate based on total direct
cost (TDC).

• Service agreements are still subject to indirect costs at 39% TDC.
• Average negotiation times for clinical trial agreements in 2019: 91.52 days
  • 49% of time with department
  • 45% of time with sponsor
  • 6% of time with contracts office

• Most negotiated provisions:
  • Definition of Study Data
  • Confidentiality
  • Inventions/Intellectual Property
  • Indemnification
  • Subject Injury
Business & Revenue Services Contracts
Business & Revenue Services Contracts

Procurement & Contracting Services

Accounts Payable and Card Services

Travel & Entertainment

Distribution Services

Repro Graphics

*B&RC is part of Procurement & Contracting Services, within Supply Chain Management
Business & Revenue Services Contracts

Business & Revenue Contracts is responsible for...

...REVIEWING, NEGOTIATING, and ESTABLISHING...

...legal, binding AGREEMENTS and CONTRACTS...

...for the provision of SERVICES and SERVICE-RELATED TRANSACTIONS
Business & Revenue Services Contracts

Types of Agreements

- Revenue Agreements (for which there are approved rates)
- Professional Agreements
- Consulting Agreements
- Equipment Rental Agreements
- Facility/Land Use Agreements (less than one year but more than one month)
- No Cost Agreements
- Reimbursement Agreements
- Fellowship Agreements
- Intergovernmental Personnel Act (IPA) Agreements

- Performance Agreements
- Affiliation Agreements
- Training Agreements
- Sponsorship Agreements
- Short Term Housing Agreements
- Executive Search Agreements
- Confidentiality Agreements (in anticipation of revenue or professional services Agreements)
- Work Study Agreements
- Student Recruitment Agreements
- Program Membership Agreements
Business & Revenue Services Contracts

Resources

• **Business & Revenue Contracts Website:**
  https://supplychain.ucdavis.edu/procure-contract/biz-rev-contracts

• **Business & Revenue Contracts Team Reference Manual**

• **KFS Purchase Agreement Document Help:**
  https://financeandbusiness.ucdavis.edu/systems/kuali/docs/purchasing/pa

• **How Do I Buy? Guide**
InnovationAccess—MTA team
InnovationAccess—MTA team

• Who is InnovationAccess?
  • InnovationAccess is a unit of the Office of Research: https://research.ucdavis.edu/industry/ia/
  • We are committed to protecting and commercializing UCD Intellectual Property (IP)
  • Intellectual property is also known as IP or tangible research property (TRP)
  • What is intellectual property: “a work or invention that is the result of creativity, such as grape varieties, plug in hybrid electric vehicles, strawberries, vaccines, disease treatments, etc. to which one has rights and for which one may apply for a patent, copyright, trademark, etc.”
  • What is tangible research property: “tangible items produced in the course of research including, but not limited to, biological materials, research notes and reports, laboratory notebooks, computer databases and software, circuit chips, equipment and engineering drawings”
InnovationAccess—MTA team

- The MTA team at UC Davis consists of:
  - One Senior IP Officer (University **Authorized Official** with delegated signing authority) – Jan Carmikle
  - One IP Officer – Byron Roberts (starts 4/8/2019)
  - One copyright & MTA Analyst (Marianne)
  - four MTA Analysts (Dianna, Vio, Ana, Bonnie)

*We make sure agreements comply with a host of policies including the U.S. Bayh-Dole Act, the 1986 Tax Report Act, UC Guidelines for the Dissemination of TRP, the Principles Regarding Future Research Results, etc.*

- The MTA team executes approximately 800-1000 legally binding agreements a year for the entire campus including Health Systems
- We also executed Data Sharing Agreements (DTAs) and Confidentiality/Non-Disclosure Agreements (CDA/NDAs)
InnovationAccess—MTA team

- Transferring Tangible Proprietary Materials and Information

  A Material Transfer Agreement (MTA) is a contract between the university and one or more outside entities, e.g., another university, a company, or a non-profit organization, to facilitate and govern the transfer of tangible proprietary research materials, as well as the transfer of any associated data and information. A typical MTA will include terms that specify:

  - Permitted research uses of the materials and substances created through the use of the materials
  - Publication procedures
  - Inventions and intellectual property rights
  - Confidentiality obligations
  - Other standard terms
• What to do when you receive a MTA/DTA/CDA?
  • Go to the UC Davis website and search MTA (bookmark it for future use)
  • Ask your researcher to fill out the internal request form (this is not an MTA)
  • Return the form along with the agreement to the email address on the form
  • The request will be assigned to the appropriate analyst who will work with the other party to make sure the agreement complies with guidelines & policies
  • We work on requests in the order they are received
  • If you have an **urgent** request, it is best to email or call your assigned analyst to let them know
  • We will communicate with the researcher if we have any questions
  • And we send out a final version as soon as its ready
  • The process could anywhere from 10 minutes to several years
  • Of course, we always want to get things done as quickly as possible
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<th>Grace Liu</th>
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<tr>
<td>Dianna Francis (MTAs)</td>
<td>Marque-Diane Vassar and Valerie Ody</td>
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<td>Senior Material Transfer Analyst</td>
<td>Clinical Trial Contract Administrator</td>
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