UCLA Technology Development Group

NUTS AND BOLTS

INDUSTRY RESEARCH CONTRACTS &
MATERIAL TRANSFERS

Today's Agenda

WHO Technology Development Group

WHAT Agreements Types managed by TDG

HOW The Contract Process

WHY Common Issues That Could Delay the Process

UCLA Technology Development Group

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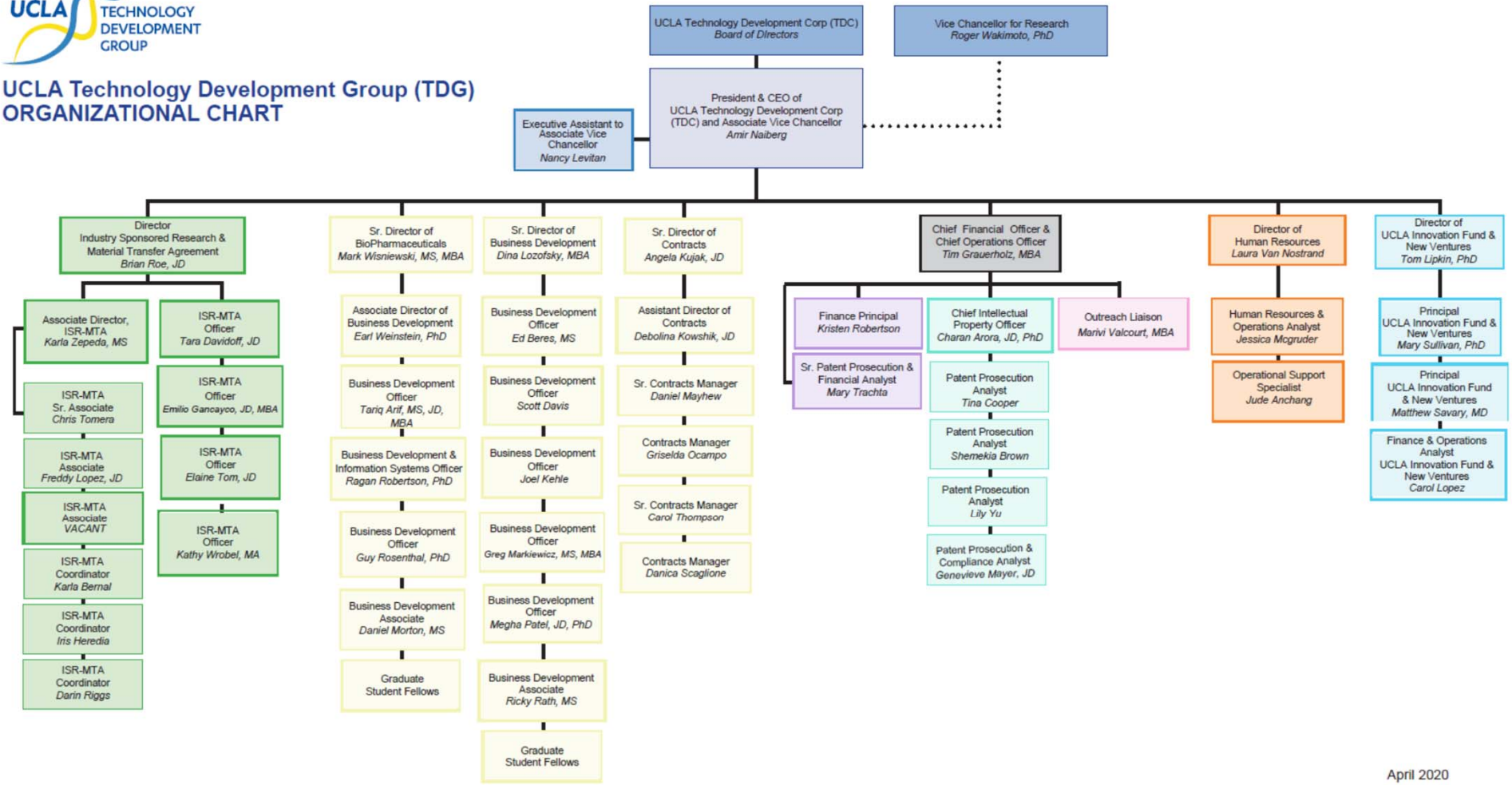
Part One: Who Are We?

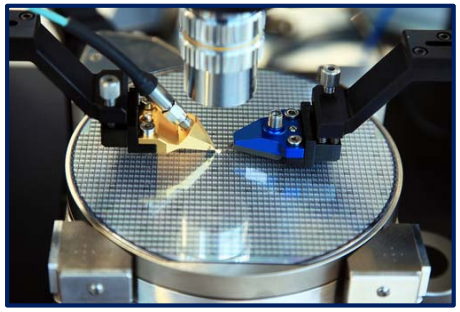
UCLA TECHNOLOGY DEVELOPMENT GROUP

UCLA Technology Development Group (TDG)
ORGANIZATIONAL CHART



April 2020

What Does TDG Do?



MANAGE INVENTIONS

- Manage invention disclosures
- Develop patent strategy
- File patent applications
- Market inventions
- Negotiate licenses

FACILITATE SPONSORED RESEARCH & MATERIAL TRANSFER

- Draft, negotiate and execute research related agreements
- General Support on IP-related matters

RELATIONSHIP MANAGEMENT

- Existing companies
- Investors & entrepreneurs
- Commercialize research through startups

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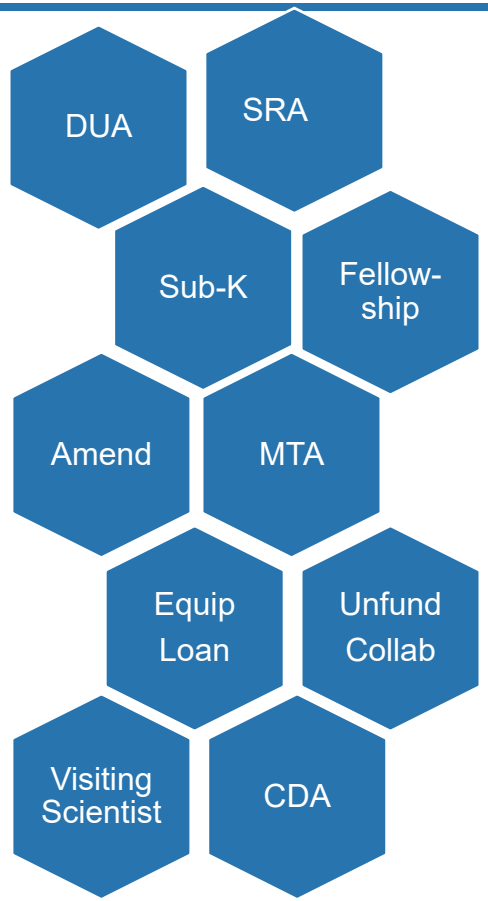
What Does TDG Do?

2,036 total contracts
FY2019

Research Related Contracts

$41.65 Million
FY2019



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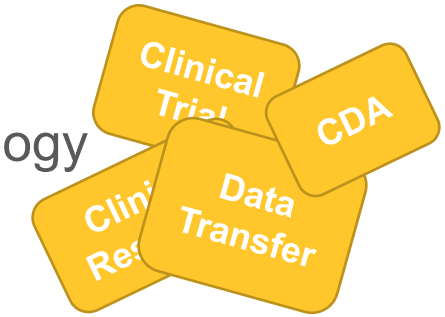
What Does TDG Do?

DO: Give us a call we are here to help.

DON'T: Rely on the contract title.

- Each entity has their own nomenclature or terminology
- Sponsor may have provided incorrect contract



NEVER: Appropriate for PI to personally sign the contract.

- If contract intent is to cover activity at UCLA

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Part Two: Agreement Types Managed by TDG

Material Transfer Agreements

WHAT are MTAs?

HOW to use OnlineMTA

Material Transfer Agreements

Agreements for receipt or transfer of tangible items (including both incoming and outgoing MTAs)

Government, Not-for-profit, For profit entities

Types of MTAs

- Unfunded research collaboration agreements with both for-profit and non-profit entities (one-way or two-way material exchange, etc.)
- Data transfer agreements/data use agreements
- Software transfer/access agreements

Material Transfer Agreements

TDG processes ***approx. 1500*** MTAs each year

What is OnlineMTA?

A web portal that allows administrators and Faculty to submit MTA requests and related information and documents online and to receive information on the status of such matters.

http://mta.research.ucla.edu/

Material Transfer Agreements

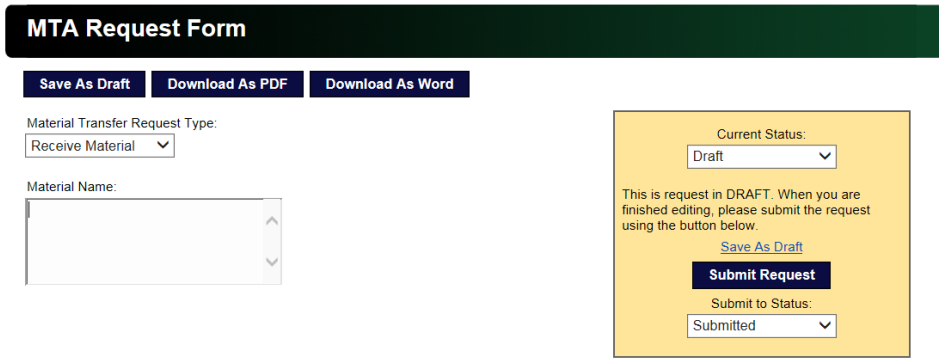
How do I use OnlineMTA?

Log on to OnlineMTA **http://mta.research.ucla.edu/**

Create an Account (for new users)

Initiate a new request – Material name, sending or receiving

Complete & submit request form



Material Transfer Agreements

Completing and Submitting an OnlineMTA request form

Fill out the request form

PI, provider/recipient, name and description of the material, statement of work, IRB, ARC, etc.

Attach required documents to the request form

Form 700-U, Form 700-U Addendum, Form 700-U Supplement, PI Exception Letter, etc.

Submit the request form

The appropriate TDG Team Member will be assigned

TDG will review all documents and information that is included in, or attached to, the OnlineMTA request.

Material Transfer Agreements

OnlineMTA Quick Tips:

- Must be a UCLA employee
- Add research staff (including PI) as a Subscriber
- Upload the contract and any related research approvals

https://tdg.ucla.edu/ucla-researchers-innovators/receipttransfer-materials-data/receipttransfer-materials-or-data

Help!

contact the onlineMTA Help Desk
uclamta@tdg.ucla.edu

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Sponsored Research and Other Industry Agreements

TYPES of agreements handled by TDG

HOW to distinguish between Sponsored Research & Clinical Trial

WHAT documents we need from you

Agreement Types

Unfunded Research Support

- Equipment Loan
- Transfer of Material, Information, Software, etc.

Other Agreements

- Agreements to Cover Conversations/Meetings (NDA/CDA)
- Agreements to Host Visitors to Perform Research in Lab (Visiting Scientist/ Scholar)

Extramural Research Funding

- For-Profit Research Sponsor (subcontracts, including SBIR and STTR)

Extramural Research Funding

Distinguishing TDG from other Admin units

Extramural Research Funding

Distinguishing TDG from other Administrative Units

What is the Intended Purpose of Funding?

- Is it unrestricted funding with no applicable terms and conditions?
- Is it intended to sponsor research activity?

Who is the Party Directly Providing Funding to UCLA?

- Non-Profit Research Sponsor: OCGA
- For-Profit Research Sponsor: TDG or Clinical Trials
- Unrestricted Gift: Development

Sponsored Research vs Clinical Trial

UCLA's Definition of Clinical Trial

- 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

- Conducted under an industry-developed or investigator-developed protocol

- Financial support provided by for-profit entity only (no non-profit direct or non-profit sourced/prime funds)

Sponsored Research vs Clinical Trial

When is it a Clinical Trial?

- **Meets** the UCLA definition
- **Only** Industry funding (no federal or other prime sponsor)
- **Prospective** enrollment of human subjects
- **Administered** drug, device, or diagnostic must be the focus of the study and not just a tool

→ 26% Indirect Cost Rate

Sponsored Research vs Clinical Trial

When is it Sponsored Research?

- **Direct Sponsor** to UCLA is a for-profit entity

  Either sole source of funding or prime funding from government, foundation or other entity

- **"Clinical Research"** that does not meet the UCLA definition

  Retrospective chart reviews, analysis of existing medical data and records, laboratory research and animal studies

56% On campus Indirect Cost Rate
26% Off campus Indirect Cost Rate

Required Internal Documents

Information and internal documents is available on our website:

- EPASS
- Financial Disclosure forms
- ISR Checklist
- Budget
- Scope of Work

https://tdg.ucla.edu/ucla-researchers-innovators/industry-sponsored-research

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Brief Pause for Questions on Part 2

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Part Three: The Contract Process

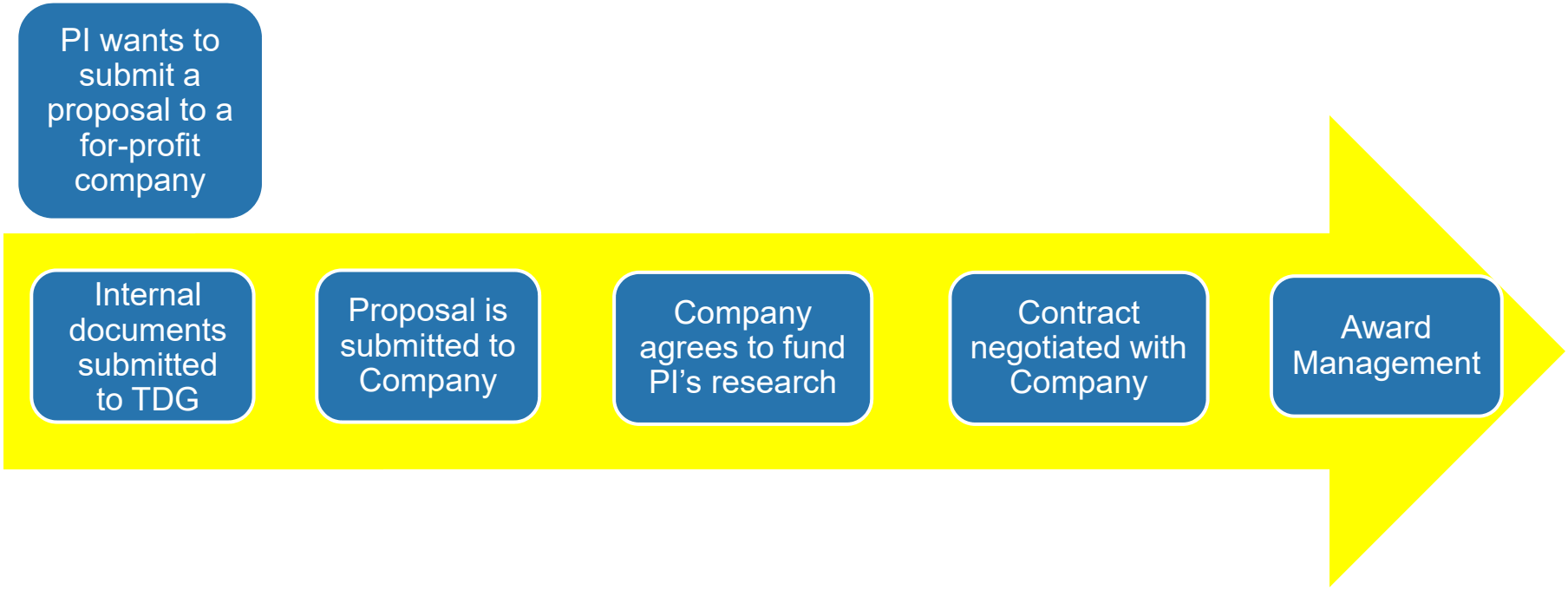
The Contract Process

WHAT does the contract process look like

COMMON issues that can delay the process

The Contract Process

When Sponsor Requires Formal Proposal



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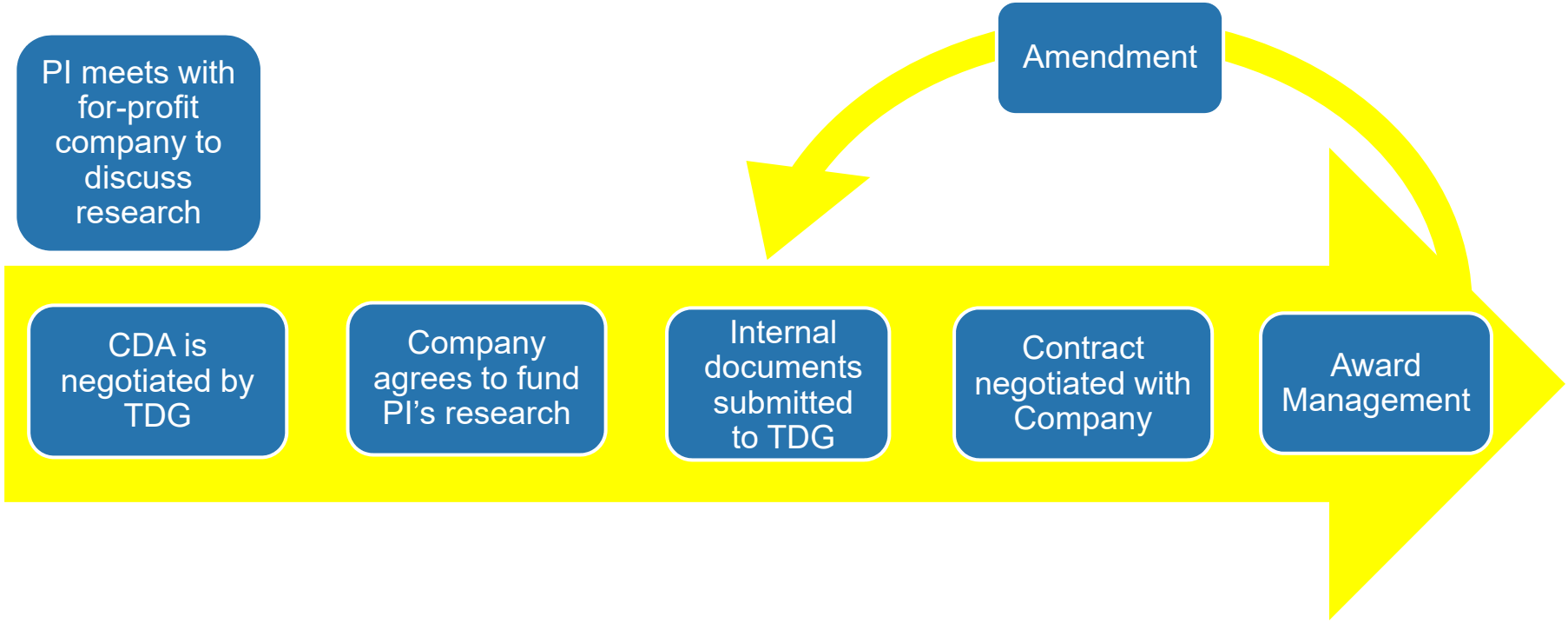
The Contract Process

When Sponsor Agrees to Fund Without Formal Proposal



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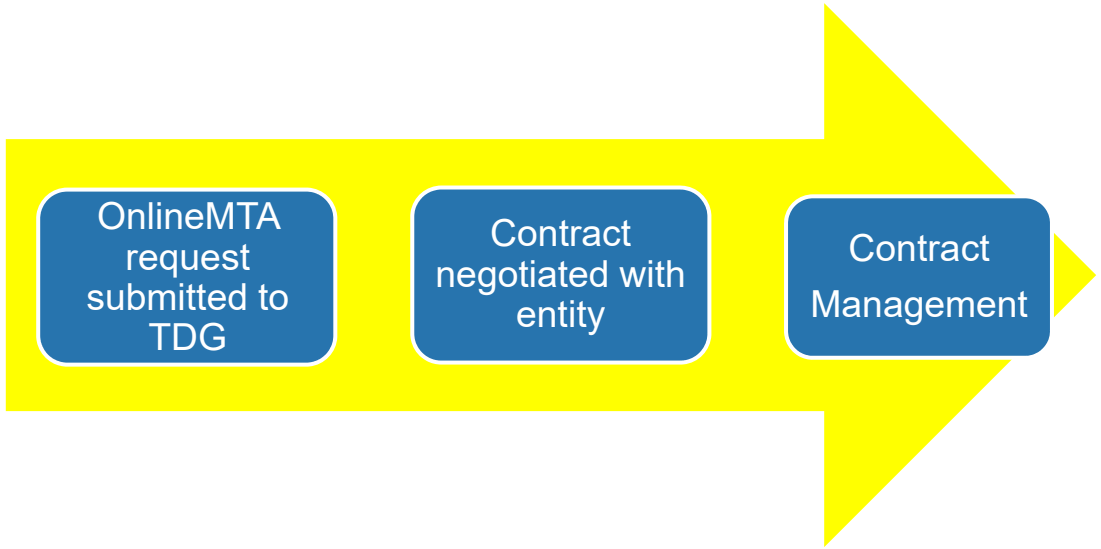
The Contract Process

When Request Received to Send or Receive “Material(s)”

PI wants to receive/send research material



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Brief Pause for Questions on Part 3

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Part Four: Common Issues That Could Delay the Process

Common Issues That Can Delay the Process

- Research Compliance Issues
- Export Control
- Budgets
- Conflicts of Interest
- Contractual Terms - Balancing Company Interests with Academic Interests
- Federal Government Scrutiny Regarding Foreign Influence in Research
- Third Party Access to or Use of UCLA Health Data

Common Issues That Can Delay the Process

Research Compliance Issues

Can The Contract Be Signed?:

- **Yes, but…**
- Before we sign, **if applicable**, the appropriate oversight must be completed specific to the requirements of the relevant Research Compliance Department

Who Are The Research Compliance Departments?:

- **To name a few…**
  - Research Safety and Animal Welfare Administration (RSAWA)
  - Office of the Human Research Protection Program (OHRPP)
  - Environmental Health and Safety (EH&S)
  - Office of Compliance Services (Information Privacy & Security)

Common Issues That Can Delay the Process

Export Control

What Is It?

- Federal regulations that restrict the movement of certain kinds of information, equipment and money out of the United States.

How Does it Affect Your Agreement?

- We have to make sure transfers comply with Federal and applicable law

Why Do We Care?

- Potential problems may arise:
  - Conduct of research in certain situations with unlicensed foreign students/employees
  - Shipment of certain information/technology to (i) embargoed or targeted-sanctions countries, or (ii) individuals on restricted lists

Common Issues That Can Delay the Process

Export Control

How Does UCLA Comply?

- Maintain an open academic research environment performing “fundamental research”.
- Work with Research Policy and Compliance to scrutinize information/technology prior to use/transfer → can we manage?
- Inform contracting parties of our responsibilities as an institution and keep PIs aware of their obligations.
- Crafting appropriate contract language to reflect compliant management plan

Need or Want More Information?

- Visit our Office of Research Policy and Compliance website:

http://ora.research.ucla.edu/RPC/Pages/nsreg.aspx

Common Issues That Can Delay the Process

Conflict of Interest: UC Policy Informed by Specific Regulation

- Federal Regulations and California Law state that a financial conflict of interest in research may exist when an individual or institution has financial interests in the outcome of the research that might compromise the integrity of the research
- UCLA Policy provides the mechanism for the review of such interests in order to determine whether a financial conflict of interest exists and, if so, whether action must be taken to manage the conflict before the pending transaction may proceed
- Goal is **not** to stall or prevent project from proceeding, but to utilize a standard review process to document potential conflict and deploy consistent standards for conflict management

Common Issues That Can Delay the Process

PI and all other UCLA Investigators who share responsibility for the design, conduct or reporting of research must disclose their personal financial interests in any organization(s) that will **fund** or **support** research or that is an intermediary acting for the entity funding or supporting the research.

- Sponsored Research ("Fund"). Financial Disclosure Forms Required:
  - Any time a new award is requested or proposal is to be submitted
  - When changes to financial interest(s) occur, or
  - When a new Investigator is added to a project for which disclosure is required

- Material Transfer ("Support"). Any request to receive materials from a non-academic or non-governmental provider must be accompanied by Financial Disclosure Forms unless the provider has been deemed exempt by the Office of the President.**

*** Material transfer where fee required not subject to CIRC review*

Common Issues That Can Delay the Process

Conflict of Interest: What you can do to help

- Make sure requisite financial disclosure documents are prepared in full, signed, and submitted as early as possible

  → ***CIRC only meets once per month***

- CIRC submission deadlines can be found:

  https://rpc.research.ucla.edu/wp-content/uploads/circ-meetings-case-submission-deadlines.pdf

- Where financial interest identified, contract cannot be signed without completed CIRC review

Common Issues That Can Delay the Process

Research Budget

- **Full cost** of the research must be covered by Sponsor, including salary for investigator and research staff as well as appropriate indirect costs

- **Incorrect** Indirect cost rate - “Clinical Research” does not receive 26% rate for “UCLA Clinical Trial”

- **Non negotiable** Indirect Cost rate is determined by periodic federal audit

Common Issues That Can Delay the Process

Research Budget: *What you can do to help?*

- **Contact** your Industry Contract Officer for assistance if budget and/or indirect cost questions come up in early discussions with a potential sponsor

- **Assist** investigator to make sure budget included with proposal paperwork includes all applicable costs of the proposed project

Common Issues That Can Delay the Process

Balancing Company Interests With Academic Interests in Final Contractual Terms

Do we need a contract?

- Our intent is not to insert an arbitrary legal process – we want to protect the Investigator and UCLA
- Executing a contract binds two parties to an understanding and confirms a specific outcome
- TDG will work with other party to address those terms and conditions that are necessary and appropriate for the proposed activity
- If a simple template or letter is a viable option, or if it can be determined no contract is needed, that is the direction we will take

Common Issues That Can Delay the Process

Balancing Company Interests With Academic Interests in Final Contractual Terms

Fair consideration for university research results and resources

Academic Freedom
Publication and use of research results

First right to negotiate for a commercial license

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Principles Regarding Rights to Future Research Results In University Agreements with External Parties

University of California, Office of the President, August 26, 1999

1. **Open Dissemination of Research Results and Information**

   Agreements with external parties shall not abridge the ability of University researchers to disseminate their research methods and results in a timely manner. The most fundamental tenet of the University is the freedom to interpret and publish or otherwise disseminate research results in order to support the transfer of knowledge to others and maintain an open academic environment that fosters intellectual creativity.

2. **Commitment to Students**

   Agreements for research relationships with external parties shall respect the University's primary commitment to the education of its students.

3. **Accessibility for Research Purposes**

   Agreements with external parties shall ensure the ability of University researchers to utilize the results of their research to perform future research.

4. **Public Benefit**

   Agreements with external parties shall support the ability of the University to make available for the public benefit in a diligent and timely manner any resulting innovations and works of authorship.

5. **Informed Participation**

   All individuals involved in research governed by a University agreement with an external party shall have the right and responsibility to understand the rights and obligations related to future research results embodied within the agreement.

6. **Legal Integrity and Consistency**

   Commitments concerning future research results made in agreements with external parties shall be consistent with all applicable laws and regulations and the University's contractual obligations to others.

7. **Fair Consideration for University Research Results**

   Agreements with external parties shall provide fair consideration to the University and the general public for granting commercial access to future University research results.

8. **Objective Decision-Making**

   When establishing or conducting University relationships with external parties, decisions made about rights to future research results shall be based upon legitimate institutional academic and business considerations and not upon matters related to the personal financial gain of any individual.

Common Issues That Can Delay the Process

Balancing Company Interests With Academic Interests in Final Contractual Terms

Protecting Academic Freedom

NO publication approval - company can review & comment

NO excessive publication delays

Freedom for PI to use research results for any future purpose

Common Issues That Can Delay the Process

Balancing Company Interests With Academic Interests in Final Contractual Terms

Protecting UC Interest in Research Results

"We funded the project so we should own the results"

- **Protect** UC's interest for benefit of people of California
- **Fully fund** costs of research (including salaries)
- **Reasonable consideration** commensurate with scope of support and context of proposed research

Common Issues That Can Delay the Process

Federal Government Scrutiny Regarding Foreign Influence in Research

What is It?

- U.S. government has expressed increasing concern that foreign entities have been seeking to exploit openness of U.S. academic environments, generally, to systematically target the acquisition of intellectual property generated by U.S.-funded research or otherwise benefit from that work.
- Government and institutions/universities are exploring practices and policies to to balance national security and economic/competitive interests with academic principles.

Policy is Evolving

- Office of the Vice Chancellor of Research and Research Policy and Compliance have established the ***Committee on International Engagements*** to manage UCLA response and compliance.
- TDG subject to these evolving policies and some contracts may a require review process that TDG does not control.

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Brief Pause for Questions (so far) on Part 4

Common Issues That Can Delay the Process

Projects Involving THIRD PARTY Access to UCLA HEALTH DATA

Internal assessment of request for Health Data is needed

WHAT is "Health Data"?

Any information pertaining to the health, care, and treatment of UCLA Health patients or health plan members which:

1) Results in a report used in treatment or monitoring of a patient;
2) Generates a claim or a bill for services that are provided; or
3) Is used for operations, financial management, population health activities or quality metrics.

- Additional information and link to the Online Request Form to initiate Committee(s) review:

https://www.ctsi.ucla.edu/researcher-resources/pages/third_party

Third Party Access to UCLA Health Data

What is **NOT** "Health Data"?

Prospectively-collected clinical research data and related research results if collected/created exclusively for sponsored research under an IRB approval and collected pursuant to a patient authorization or consent;

- Governed by existing law and UC policy, not HD guidelines

- If the clinical research data appears in the patient's medical record (in whatever form), it will then be HD within the scope of the guidelines

- Clinical trial data is excluded from Health Data, only to the extent acquired under the IRB-approved clinical trial. Other health data associated with CT participants will be considered HD.

Third Party Access to UCLA Health Data

HEALTH DATA TIPS

- A **Third Party** is any for-profit or non-profit entity, including UCLA entities that are external to UCLA Health (e.g., UCLA Dentistry)
- Both sponsored research and material transfers may require DRS approval
- Any type of "Health Data" will require review by the DRS: Protected Health Information, Limited Data Set and De-identified data
- Retrospective Chart Review will always require DRS review; case report forms include health information from a patient's medical record.

Third Party Access to UCLA Health Data

TIPS to Avoid Delays

- After submission of internal proposal documents to TDG for review, submit request to the DRS via its online CTSI portal: https://ctsi.ucla.edu/researcher-resources/pages/third_party. Do NOT delay the DRS submission. The sponsored research or material transfer agreement cannot be signed until DRS review is complete. The process will take on average 3-6 months, but depending on a variety of factors, could be longer.
- Answer all questions on the DRS intake form or the request will not be reviewed.
- Department Chair approval in writing is required in order for the DRS review to proceed.
- IRB approval is required before DRS review, unless the PI has a cogent reason for delay and provides that information on the form.
- Respond quickly, accurately and comprehensively to any questions DRS asks in order to keep the request moving forward.
- Health information lacking certain 18 identifiers is said to be “de-identified” under HIPAA. Oftentimes the protocol states that HD will be de-identified, but is incorrect as defined by HIPAA. You will need to fill out a form that lists all 18 identifiers and respond whether or not they will be provided to the 3rd party at any time during the study. The list of 18 PHI identifiers can be found here: https://ohrpp.research.ucla.edu/hipaa/#identifiers

We Want to Help However We Can

Officer Department Assignments:

https://tdg.ucla.edu/ucla-researchers-innovators/industry-sponsored-research/department-assignments

Summary of Transaction Types and Requisite Paperwork:

https://tdg.ucla.edu/ucla-researchers-innovators/industry-sponsored-research/transaction-types

Forms and Related Policies:

https://tdg.ucla.edu/ucla-researchers-innovators/industry-sponsored-research/forms-and-related-policies

Material Transfer at UCLA:

https://tdg.ucla.edu/ucla-researchers-innovators/receipttransfer-materials-data/receipttransfer-materials-or-data

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Thank You

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