Grants 101

Sponsored Projects
Contracts and Subcontracts
Why do they matter?

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Sponsored Projects Administration

UTHealth | Sponsored Projects Administration
The University of Texas Health Science Center at Houston
Agenda

- Why do contracts and subcontracts matter to you?
- Where can you find help?
- What’s the process?
- How can we work together?
Contracts are everywhere

[License Agreement]

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Contracts Involving UTHealth: Institutional Policy

- Agreements are negotiated to conform to:
  - UTHealth/UT System policy
  - Applicable regulations and guidelines

- Authorized Institutional Official executes agreements
  - SPA is signature authority for sponsored projects

- Parties are UTHealth and Sponsor
  - PI is NOT party to the agreement
  - PI reviews and signs as “read & understood”
  - UTHealth is responsible for work performance

- Required internal documentation
  - Review & Approval form or Transfer form; RCOI; assurances
Why do contracts matter?
Protecting the Patient

Jesse Gelsinger, 19 years old

1999 - First person known to have died from experimental gene therapy

Lawsuit against Univ. of Pennsylvania

- PI was heavily invested in the company, Genova, Inc.
- University failed to disclose death of monkeys in the informed consent
- University failed to disclose SAE of two other enrolled patients.

Settled for an undisclosed amount
Why do contracts matter? Protecting You

All agreements are between sponsor and UTHealth only:

- UTHealth does not allow its employees to be named as individual parties to an agreement.
- UTHealth maintains adequate liability and malpractice insurance that covers its employees.
- Agreements indemnify all study personnel
Who Negotiates Contracts at UTHealth?

- **Contracts | SPA**
  - Sponsored projects agreements

- **Office of Legal Affairs**
  - Consultant agreements
  - Professional service (in)
  - Data Use Agreements (out)

- **Office of Technology Management**
  - CDAs when UT CI is shared
  - IP, licensing, patent issues
Clinical Trials: The Players

**Sponsor**
- Obtain FDA approval of drug or device as fast as possible
- Beat their competitors
- Make Money
- Improve patients’ lives

**CRO**
- Provide the best drug development and study management services
- Beat their competitors
- Make Money

**Study Site**
- Improve patients’ lives / cure disease
- Make money to invest in overall research program and advancements
- Publish, expand our own knowledge, disseminate knowledge
SRA/CRA/MTA: The Players

Other Academic Institutions/Funding Agencies

- Improve patients’ lives / cure disease
- Make money to invest in overall research program and advancements
- Publish, expand our own knowledge, disseminate knowledge

Industry

- Obtain FDA approval of drug or device as fast as possible
- Beat their competitors
- Make Money
- Improve patients’ lives

UTHealth

- Improve patients’ lives / cure disease
- Make money to invest in overall research program and advancements
- Publish, expand our own knowledge, disseminate knowledge
Types of “Sponsored Projects” Contracts

* Confidential Disclosure
* Clinical Trial
* Data Transfer/Data Use Agreements
  • Material Transfer
  • Sponsored/Collaborative Research
  • Subcontract
  • Fee For Service
  • Salary Reimbursement
When and how does SPA get involved in contracts?

Highly dependent on the type of contract
Close coordination with department & PI

Examples:
- a subcontract attached to a grant proposal (sub in & sub out)
- sponsor sends a CDA or a CTA
- investigator contacts us after conversation with sponsor
- other offices (OTM, legal, etc)
What does SPA need to know about a project?

**Work Scope!**

- The more information we have, the better we can match the agreement terms.
- Any materials/data being exchanged?
- What do YOU want the project to look like?
- What does the Sponsor want the project to look like?
- Any material/data being exchanged?
- Who wrote the workscope?

Internal forms help us gather information:

- Review & Approval Form/Transfer Form
Internal Forms

[Review & Approval Form]

Review & Approval Form

Project Information:

Project Type:
- Instruction
- Research
- Scholarship/Fellowship
- Service
- Construction/Equipment
- Other

Proposal Type:
- New
- Continuation
- Renewal
- Resubmission
- Supplement
- Transfer

Award Type:
- Contract/CTA
- Coop Agreement
- Grant
- Subcontract

Research:
- Basic
- Clinical Research
- Clinical Trial
- N/A

Funding Source:
- Federal
- State
- Local
- Foundation/Not For Profit
- Industry/For Profit
- Other

Protocol/Research Plan:
- Developed by:
  - UTHealth
  - Sponsor
  - Joint
  - N/A

Short Title: (20 Characters Max)

Existing Grant/Award #

Existing FMS Project #

[Transfer Form]

Transfer Form

Materials/Data will be sent:
- to UTHealth
- from UTHealth
- Transferring:
  - Material
  - Data
  - Both

UTHealth Information

PI Name: ___________________________ Department: _________________________

Outside Organization Information

PI Name: ___________________________ Phone: _____________________________ Email: ___________________________

Organization Name: ___________________________
Material Transfer Agreements, Subcontracts, Sponsored/Collaborative Research Agreements, Other Agreements
Send contracts to: preaward@uth.tmc.edu

Confidential Disclosure Agreements, Data Use Agreements, Clinical Trial Agreements
Send contracts to: crf@uth.tmc.edu

Confidential disclosures (CDAs) do not need an R&A form
Other Agreements (SRA/CTA) do need a completed and signed R&A form
Material/Data Transfer Agreements need a Transfer form
- When negotiations complete, PI must provide “Read and Understood”
- We work to ensure we have the proper paperwork to get the contract signed or the project set up (R&A/transfer form; RCOI; assurances; coverage analysis for CTAs, Intellectual property concerns; etc)
- Post award finance will set up the account once contract signed and IRB issues approval
Protecting UTHealth

Confidentiality (CDA, then restated in CTA)
Indemnification
Subject Injury
Data Rights and Intellectual Property
Publication
Budget and Payment Terms
Bankruptcy is a small issue that impacts UTH as far as receiving payment. And, we have to remove patients from study and close.
Protecting UTHealth

Terms are different based on who wrote and owns the protocol:

- Sponsor wrote protocol
- Study Site/UTH PI wrote protocol
Protecting UTHealth

Confidentiality (CDA, then restated in CTA)

“Institution shall not disclose any data, records or other information provided by Sponsor, or generated by Study site as a result of this Study without the prior written consent of Sponsor. Such Information shall remain the confidential and proprietary property of Sponsor.”

Indemnification

Sponsor shall indemnify, defend, and hold harmless Study Site, and its officers, directors and Study Staff, including Investigator from and against any and all liabilities, damages, losses, claims, and expenses (“Losses”) arising out of (i) bodily injury to or death of any subject enrolled in the Study, which injury or death is caused by administration of Study Drug or properly performed procedure in accordance with the Protocol, to the extent that such Losses do not arise out of or in connection with Study Site’s (A) failure to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including good clinical practices, issued by any regulatory authority or IRB; or (B) negligence or willful misconduct.
Subject Injury
Sponsor shall reimburse study site for any injury to properly enrolled and consented subjects directly resulting from the administration of the study drug provided that:
- Study site immediately notifies sponsor of any injury that occurs
- Subject complied with protocol and all written and verbal instructions
Sponsor shall pay for any injury to properly enrolled and consented subjects resulting from the conduct of the study.
Confidential Disclosure Agreements

- A CDA is typically the first step in a clinical trial
- If you are sharing any of your scientific/academic confidential information, a mutual CDA is needed (OTM)
- Send agreement to crf@uth.tmc.edu
- No internal documentation needed
- Specialist will review and negotiate contract
- Specialist will obtain PI concurrence
- Institutional Official will sign agreement
- Fully executed agreement is sent to PI
Material Transfer Agreements

- Needed for ALL transfers in or out of the University
- Send agreement transfer form to preaward@uth.tmc.edu
- Specialist will:
  - Review and negotiate terms, if necessary
  - Obtain PI concurrence
  - Obtain Institutional Official signature
  - Copy of the fully executed agreement sent to PI

DO NOT SHIP MATERIALS WITHOUT AN EXECUTED MTA
Sponsored/Clinical Trial Agreements

- CTAs to crf@uth.tmc.edu; SRAs to preaward@uth.tmc.edu
- Specialist will:
  - Review and negotiate contract
  - Be liaison between UTHealth, PI & Sponsor
  - Obtain PI concurrence upon completion
  - Obtain Institutional Official signature
- Department (PI/Coordinator/Administrator) will:
  - Complete Review and Approval form
  - Submit protocol to CPHS/AWC
Subcontracts Out

- Grants & Contracts team receives NOGA and notifies PI
- Specialist:
  - Drafts subcontract
  - Submits to PI/departmental admin for concurrence
    - Should review budget and scope of work
  - Obtains subcontractor signature
  - Obtains Institutional Official signature
- Fully executed agreement is sent to PI & PAF Team

Subcontracts In

- Grants & Contracts team processes sub-in proposal
- Subcontracting agency (typically another university) sends subcontract to preaward@uth.tmc.edu
- Specialist compares subcontract to proposal and reviews/negotiates terms
- Specialist will obtain PI concurrence
- Institutional Official will sign agreement
Sponsored Projects Administration

Overview
Sponsored Projects Administration (SPA), as part of Finance and Business Services, supports UTHealth faculty, staff, and students in the acquisition and administration of programs funded from sources outside the University. SPA is the central point of coordination and tracking for sponsored projects and is UTHealth’s authorized representative for grants, contracts, and other agreements from government agencies, private industry, and non-profit foundations.

SPA is comprised of the Grants & Contracts Administration, Clinical Research Finance, and Systems & Reporting. SPA guides faculty and administrators in completing external applications; reviews and approves sponsored project budgets and applications; negotiates terms for government and non-profit grants, cooperative agreements, contracts, and subcontracts; establishes accounts and sets up budgets; processes budget revisions, no-cost extension requests, and grant transfers; provides assistance with external online grants/contracts systems; and negotiates the University’s federal indirect cost rate.

News (Sponsored Projects)

December 14, 2017 »
NSF have published a new edition of their Proposal & Award Newsletter

December 07, 2017 »
Cayuse 424 v6.0 (including FORMS-E) arrives Dec 9th

NIH Grants

Mon, 18 Dec 2017 11:22:07 EST
Notice of Change to Award Information in RFA-AI-17-040 “Cooperative Centers on Human Immunology (U19 Clinical Trial Optional)”

Mon, 18 Dec 2017 11:33:51 EST
Notice of Participation of National Institute of Allergy and Infectious Diseases (NIAID) on PAR-18-333 “Understanding the Early Development of the Immune System (R01 - Clinical Trial Not Allowed)”

Tue, 19 Dec 2017 12:31:18 EST
WE AGREED THAT YOUR CONTRACT WAS TOO COMPLICATED SO WE REDRAFTED IT TO COVER YOUR NEW RESPONSIBILITIES...
Contact Information

Sponsored Projects Administration
7000 Fannin Street, Suite 1006
Houston, TX  77030

713-500-3999
preaward@uth.tmc.edu
crf@uth.tmc.edu

http://go.uth.edu/SPA

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