

Contracts and Negotiation

Sponsored Projects Administration

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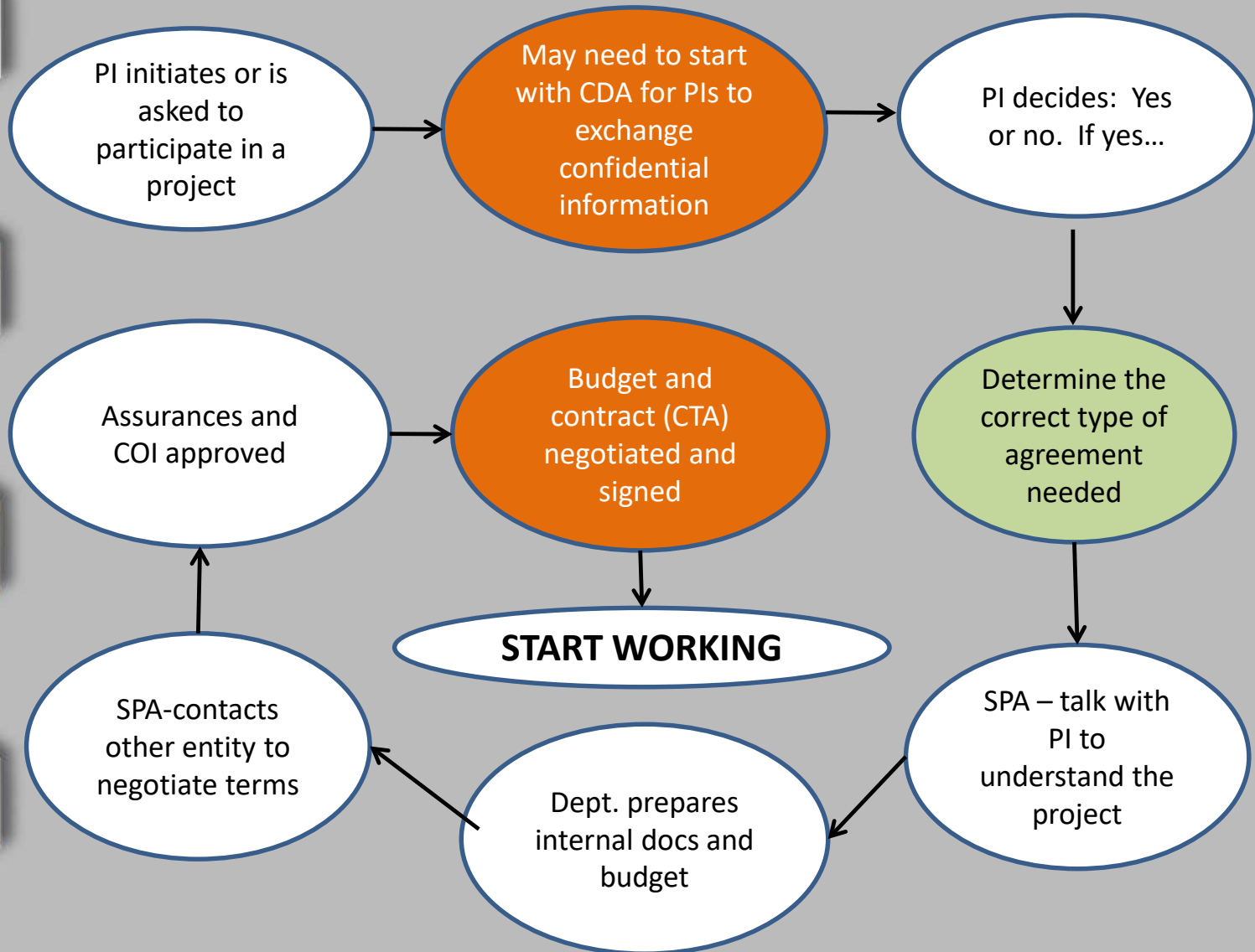
Sr. Clinical Research
Administrator

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Lifecycle of a Contract



Types of Contracts

- ❖ Confidential Disclosure
 - ❖ One party wishes to share confidential/proprietary information with another party.
 - ❖ May be two-way
- ❖ Material Transfer
 - ❖ One party wishes to obtain material or data from another party

Types of Contracts

Clinical Research vs. Clinical Trial

- ❖ Clinical Research

- ❖ aims to advance medical knowledge by studying people, either through direct interaction or through the collection and analysis of blood, tissues, or other samples.

- ❖ Clinical Trial

- ❖ Involves enrollment of humans who are prospectively assigned to an intervention that is biomedical or behavioral, to evaluation the effect of the

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Terms are different based on who wrote and owns the research plan:

Sponsor or
other research
entity wrote

UTH PI wrote

Jointly written

Types of Contracts

❖ Sponsored Research

- ❖ A contract between the University and a sponsor for the purposes of funding and conducting research at the University. An SRA may be supported by funding from any type of sponsor

❖ Collaboration

- ❖ University partners with another party to partner on a research project.
- ❖ Dependent on each other to complete

Types of Contracts

- ❖ Subcontract/Subaward
 - ❖ Overarching Prime Grant Award
 - ❖ Prime Grant terms and conditions pass through to subcontractor/subrecipient
 - ❖ Similar to a Collaboration Agreement
- ❖ Fee For Service
 - ❖ Work for hire
 - ❖ No ownership of data or results
 - ❖ No Publication rights
 - ❖ Need to negotiate a higher budget/profit

Types of Contracts

- ❖ Professional Services/Consulting
 - ❖ Faculty member provides guidance, expertise, analysis, writing
 - ❖ Salary/Fringe of faculty member only
- ❖ Salary Reimbursement
 - ❖ Payment for grad student or post-doc salary/benefits only.

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Confidentiality

Indemnification

Subject Injury

Data Rights and Intellectual Property

Publication

Budget and Payment Terms

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Confidentiality

“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.”

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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.

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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

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Data Rights and Intellectual Property

Any inventions or improvements, innovations, **suggestions, ideas, work product**, results, reports, **documents**, case report forms, **source documents, notations or clinical activities**, and **all reports and records** necessary for the evaluation and reconstruction of the Study), data correction forms, workbooks, monitoring logs, **schedules, correspondence, regulatory documents**, and **all other clinical information made or developed by Institution**, during the course of this Study shall be promptly disclosed to Sponsor in writing and **shall become, be and remain the sole and exclusive property of Sponsor**. Institution and Investigator hereby assign and shall ensure that all Research Staff assign all right, title, and interest in and to such Study IP, and all intellectual property rights with respect thereto

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Publication

Neither any and all data resulting from the Study, nor any other Information, will be presented or published in any form or media by the Institution, Investigator or Research Staff without the prior written consent of Sponsor.

When something goes wrong

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:

SYNCARDIA SYSTEMS, INC.,¹

Debtor.

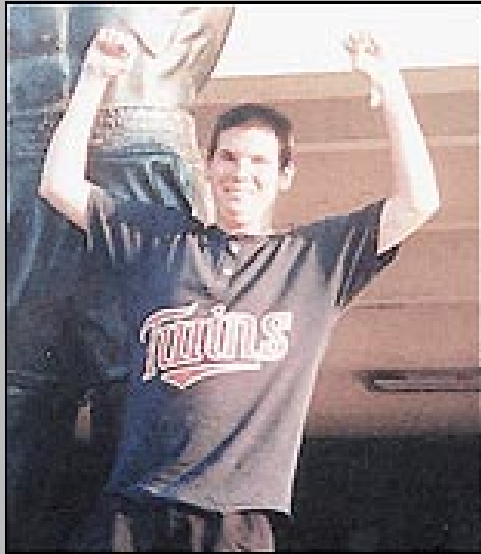
Chapter 11

Case No. 16-11599 (MFW)

Ref. Nos. 9, 175

Bankruptcy is a small issue that impacts UTH as far as receiving payment. We may have to remove patients from study and close.

When something goes very wrong



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

When something goes wrong

Breaching Confidentiality:

- ❖ Publishing confidential information in a written document, newspaper, online article, or other such publication.
- ❖ Orally disclosing the information to another person.
- ❖ Revealing the information through non-verbal communication.
- ❖ Showing other persons a product or item that is not intended to be seen yet.
- ❖ Providing information for formulas, recipes, construction plans, and other instructions for production.

When something goes wrong

Conflict of Interest:

- ❖ Increased risk of bias or poor judgement

Case Study: Janet's Suspicions



*Administrators
and the Responsible
Conduct of Research*

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 employees

Protecting Yourself

“See something, say something”:

- Conflicts of Interest
- Coercing patients to enroll
- Sharing confidential information
- Falsification/Fabrication of study data
- Negligence, malfeasance

Make sure you know your responsibilities:

- Understand what your responsibilities are to report questionable activities.

Ask questions

The Process

Send all agreements to SPA:

Preaward@uth.tmc.edu

Grants & Contracts Team

- Subawards
- MTAs

Industry Engagement Team

- Collaboration
- Sponsored Research
- Professional Services
- Fee for Service

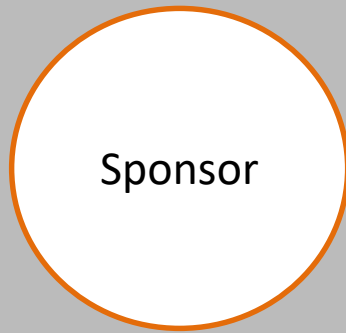
CRF@uth.tmc.edu

- Confidentiality
- Clinical Trial
- Data Use

What is Negotiation?

- ❖ Process by which UTHealth and Sponsors work together to find solutions
- ❖ Involves:
 - Analysis
 - Willingness to listen
 - Communication
 - Problem solving
 - Mutual exchange of information
 - Objectivity
 - Detachment

The Players and Their Goals

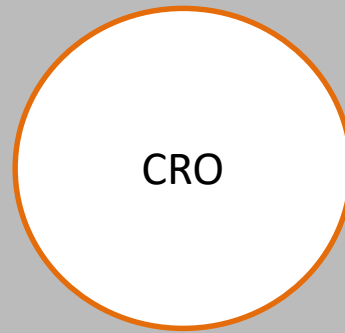


Obtain FDA approval of drug or device as fast as possible

Beat their competitors

Make Money

Improve patients' lives



Provide the best drug development and study management services

Beat their competitors

Make Money



Improve patients' lives / cure disease

Make money to invest in overall research program and advancements

Publish, expand our own knowledge, disseminate knowledge

Negotiation Strategies

❖ Accommodating

- Outcome is not as important as the relationship
- Objective is to improve the relationship

❖ Competitive

- Outcome is more important than the relationship
- Relationship may not be ongoing

❖ Collaborative

- Outcome and relationship are equally important
- Focus is on trust, openness, and collaboration
- Negotiation points are treated as a mutual problem to be solved together

Steps to a Successful Negotiation

- ❖ Actively and adequately prepare
- ❖ Separate people from the problem
- ❖ Focus on interests, not positions
- ❖ Insist on using objective criteria

Adapted from Fisher, Ury, and Patton, [Getting To YES: Negotiating Agreements Without Giving In](#)

Preparation

- ❖ Analyze
 - Gather information
 - ❖ **KNOW YOUR PROTOCOL or PROJECT**
 - ❖ know your costs ahead of time
 - Anticipate points of discussion
 - Evaluate strengths and weaknesses (ours and theirs)
- ❖ Plan
 - Rank priorities
 - Determine realistic objectives
 - Identify acceptable alternatives
 - Identify key players and strategic allies
- ❖ Identify what you want
 - Know your overall goal
 - Outline your needs, wants, and expectations

Separate People from the Problem

- ❖ Be aware of tension between industry and academia
 - Industry emphasizes profit and commercialization
 - Academia emphasizes advancement of science and education
- ❖ Facilitate a mutual exchange of information
 - Clarify terms
 - Listen attentively
- ❖ Remember it's not personal
 - Empathize with the other party's position
 - Remain objective

Focus on Interests

- ❖ Interests v. positions
 - Position: what you've decided
 - Interest: what causes you to decide
- ❖ Identify shared interests
 - Why has the Sponsor reached out to you?
 - Why are you agreeing to take on the study?
- ❖ Invent options for mutual gain
 - Focus on the shared interests identified
 - At the end of the day, we're partners, not adversaries

Use Objective Criteria

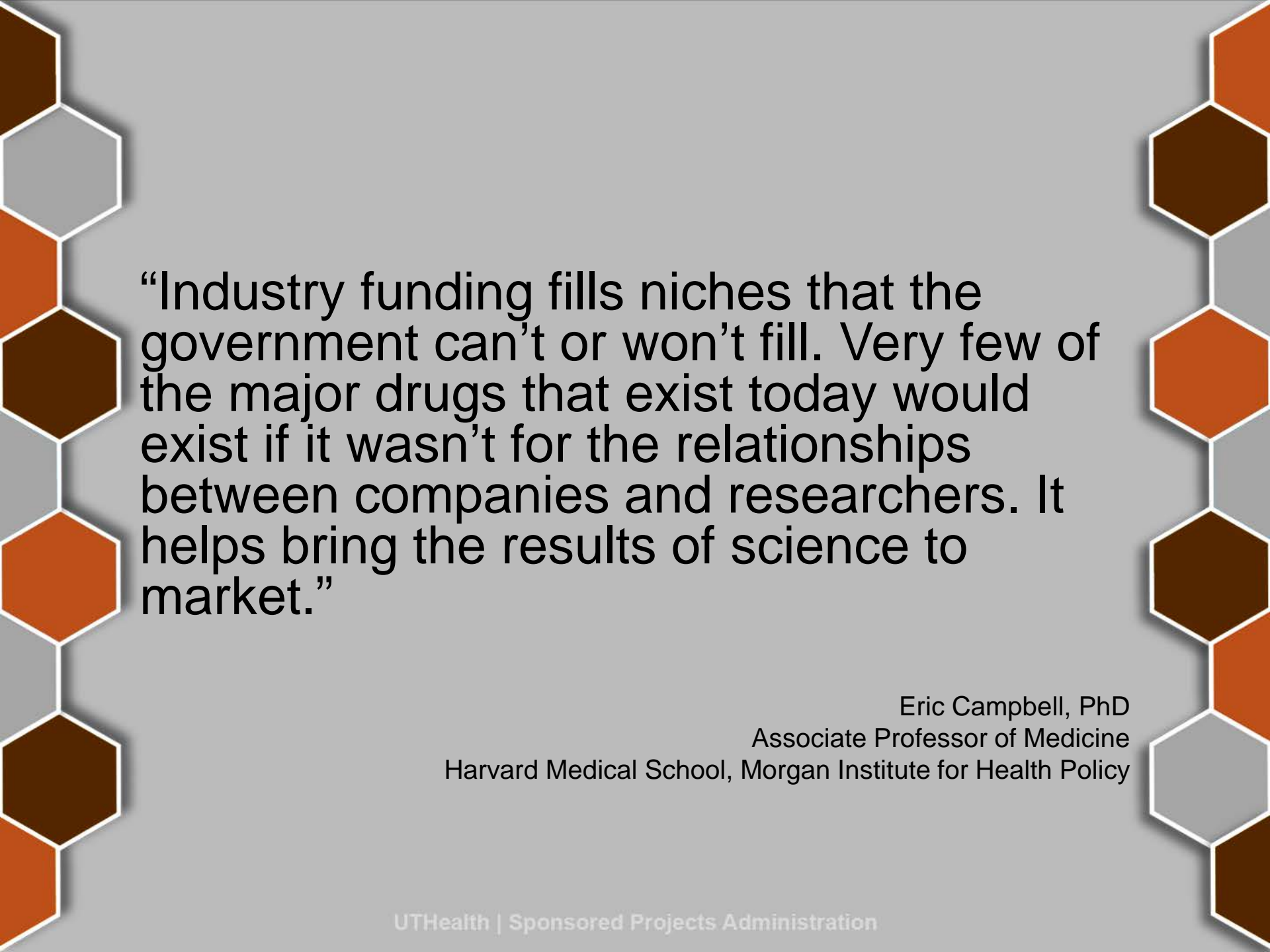
- ❖ Approach each issue as a search for objective criteria
 - Identify Sponsor's rationale behind their position
 - Use Sponsor's rationale to support your position
- ❖ Keep an open mind
 - Make concessions when appropriate
 - Threats and acting defensive get you nowhere
- ❖ Don't be manipulated
 - Recognize tactics that are designed to make you uncomfortable or hurry you through the negotiation
 - Take phone calls and send email responses when you are fully prepared for the negotiation
 - **KNOW YOUR PROJECT AND COSTS**

Budget and Payment terms

- Always negotiate
- Never accept less than our costs, and never reduce costs to match what sponsor offers to pay.
- Always include indirect costs
- Arrange a large up-front payment
- No more than 20% at end of project
- Don't be afraid to say "no"

Recap

- ❖ Negotiation is a skill that can be learned with practice
- ❖ Preparation is key
- ❖ Steps to success:
 - Preparation
 - Separating people from the problem
 - Focusing on shared interests
 - Using objective criteria



“Industry funding fills niches that the government can’t or won’t fill. Very few of the major drugs that exist today would exist if it wasn’t for the relationships between companies and researchers. It helps bring the results of science to market.”

Eric Campbell, PhD
Associate Professor of Medicine
Harvard Medical School, Morgan Institute for Health Policy