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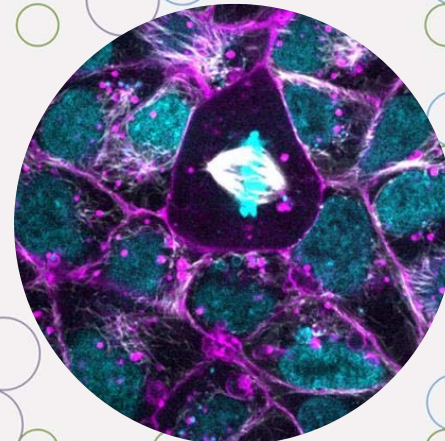
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Negotiating Contract Terms

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- Established 2003 by Paul G. Allen
- South Lake Union, Seattle, WA
- 500 employees++
- \$150 MM annual budget

hard problems
complexity
foundational biology



big science
team science
open science



data
knowledge
tools



What words come to mind when you think of an “industry sponsor”?

What words come to mind when you think of an “academic sponsor”?

Impact of Sponsor Type on Negotiation

Industry Sponsors

- Deliverable focused
- Abundant legal language
- Take it or leave it/hard negotiation

Academic/Federal Agencies

- Relationship focused
- Protect both institutions
- Generate good science
- Tax-payer focused

Lawyers – They should be helping you.

What is a lawyer's role in the context of sponsored research agreements?

- Redline things (contracts, T&Cs, etc.)
- Negotiate things
- Identify and assess legal and business risks
- Advise on contract strategy
- Partner with other teams to support their goals*

Inside vs. Outside lawyers

- Organization as the client
- Billable hours
- Institutional knowledge

Contracting Concepts

What is a Contract (K)?

- “Meeting of the minds”
- Risk allocation device:
 - What happens when stuff goes wrong?
- Set of promises
- Document governing a business relationship

What are lawyers looking for during K review?

- Do the terms reflect both parties’ understanding?
- Can the client accept these terms?
- Is the language in the K legally effective?
 - Ambiguity/interpretation
 - Legal significance
- Is the tone appropriate?*

Contracting Concepts Cont'd

Examples

- Words with legal significance: “shall or will”; “indemnification”; “intellectual property”
- Ambiguity: “reasonable best efforts”
- Tone:
 - Certain phrases seem harsh: “sole discretion”
 - Redlines vs. questions
 - When to ask for a call

Hypothetical #1

Flow down of sponsor terms and institutional policies

Hypothetical #1

A year ago, an investigator submitted an NIH grant application with US University. The application complies with all NIH policies and was reviewed by both institutions. The application was recently funded and your institution will be a subrecipient to US University. You receive a non-standard subaward agreement for execution and review the terms. You notice that the agreement references Department of Defense and NIH policies.

What are your concerns (if any) with this subaward?

Our concerns and lessons learned

- Diligence at time of application
 - How is the institution funded?
 - How do they interpret federal policies?
 - What is the history of collaboration with these investigators?
- Utilize standard contract templates (FDP)
- Prime flow down of terms are based on institutional discretion

Hypothetical #1 New Information

Your sponsored programs office reaches out to US University to inquire about the agreement terms. US University explains that their agreements are subject to DoD terms. Your sponsored programs officer requests a call to try to negotiate elimination of unfavorable terms. US University refuses to take the call. The Notice of Award indicates that you are already four months in to the first period of the grant.

What is your approach to this situation?

Our approach

- Use a light pen and try to “carve out” rather than replace
 - Example: foreign travel
 - OK to accept DoD terms because the award did not include foreign travel
 - Clarify that no other DoD terms apply
- Phone call with all stakeholders (including investigators)
- Be prepared for a deep dive in to new policies
 - Utilize your research administration network!

Hypothetical #2

International Contracts

Hypothetical #2

Your investigator is submitting a large multi-project grant application with four international subrecipients. One of the subrecipients is located in China and three others are located in the United States and Europe. Your investigator identified the China site because he has worked extensively with the PI on other projects. They have even shared data and materials previously, which will help this application.

Given the recent federal government scrutiny of foreign collaboration, how would you approach the application for this proposal?

Hypothetical #2 New Information

The application was successful! You've been asked to draft the agreement with the Chinese site.

1. What risks are specific to this agreement?

2. What special terms do you include in the subaward agreement?

Risks & Special Terms/Mitigation

- Risk: Export Control violations Mitigation: Review K language; perform EC screenings
- Risk: Debarment Mitigation: Perform screening
- Risk: Violations of NIH Policy Mitigation: Review flow down terms and include FDP foreign party addendum
- Risk: Legal enforceability clauses Special Terms: Dispute Resolution and Choice of Law
- Risk: Performance site approvals Special Terms: Draft language requiring sub to get pre-approval for any new sites/PIs

Hypothetical #3

Dueling redlines?

Hypothetical #3

You open your email in the AM and see that you received a contract back from Pharmaceutical Company X. You open the document and it is a mess – there are a lot of redlines and several comments. To make your morning more fun, the person who sent them to you is Company X's attorney.

You try to review the redlines, and most of them just don't make sense. Also the comments are pretty curt in tone and the explanations are very formal and written in legalese.

What do you do (assuming you don't have easy access to legal advice)?

Your Choices

1. Start a redline duel and try to respond to each deletion, change and comment in redline form based on what you think the edits mean.
2. Try to get legal advice somehow (help!).
3. Pause and re-read the changes and comments with the following questions in mind:
 - Have other commercial parties agreed to your terms in the past – if yes, then why does Company X seem to care more about these things?
 - Does Company X's lawyer understand how clinical research works?
 - Are any of the changes beneficial to both parties?
 - Can you ask questions that will help resolve the redlines?
4. Find something else to work on today, because this is ridiculous.

Hypothetical #3 New Information

Later that week you were able to make some progress on the redline, and you are down to a few key provisions (indemnification, and intellectual property). The PI for this award pings you and asks where the agreement is at in the process. The PI is concerned that there will be recruitment delays if you don't have the agreement finalized this week.

How do you communicate with your investigator?

How to explain legal risk

In the science community- legal agreements and negotiations seem to be perceived as a “necessary evil.”

- Disconnect between PI’s concerns and institution’s concerns (explain that while PI might not be worried, institution is and that’s something we can’t change)
- Gap in understanding what the legal terms mean (explain why the term is there and why it is important)
 - Example: indemnification
- What if the PI won’t listen? (Is there someone in your org who can approve the requested deviations from policy? Put it on the PI to ask for that)

— **Any stories or questions
you'd like to share?**

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THANK YOU

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