

T-20: TOP TEN TOUGH THINGS TO TACKLE AND THINGS TO TRY IN SPONSORED RESEARCH AGREEMENTS

CINDY KIEL, J.D., CRA
Assistant Vice Chancellor,
Research Services
Washington University in St. Louis
ckiel@wustl.edu
(314) 935-5825

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TOP TEN TOUGH THINGS TO TACKLE

1. TITLES/PARTIES/PURPOSE/SIGNATURE AUTHORITY. Supervision and Control over Employees, Conflicts, Non-compete terms, Taxes, Governing Policies & Joint Partnership
2. THE MONEY. Fixed Price/Cost Reimbursible/Fee Based/Payment Schedules
3. SCOPE OF WORK/STANDARD OF CARE/WARRANTIES.
4. RISK OF LOSS. Liability, Indemnification, Insurance, Equipment
5. PUBLICATION AND CONFIDENTIALITY

TOP TEN TOUGH THINGS TO TACKLE

6. INTELLECTUAL PROPERTY- Ownership and Rights to Data, Copyright, Trademark & Patents
7. CHOICE OF LAW/JURISDICTION/VENUE
8. TERMINATION AND DAMAGES
9. ADVERSE EVENTS
10. REPORTING (TECHNICAL & FINANCIAL)/AUDIT RIGHTS/MILESTONES

TOP TEN TOPIC #1

Title/Parties/Purpose

- **PURPOSE**: The Contract Title can define the nature of an agreement. Is this an MOU, MTA, Research Agreement, Service Agreement, Subagreement, Merchant/Commercial, Other?
- **DOs**: Use Legal Name: “The Washington University”, Use Title and Nicknames that reflect non-profit mission/purpose of agreement
- **DON'Ts**: No Partnership, Joint Venture, Work for Hire or Merchant/Commercial purpose nicknames.

WUSTL LEGAL NAME & INTRO EXAMPLE

- “Washington University, a benevolent corporation organized pursuant to special act of the General Assembly of the State of Missouri approved February 22, 1853, on behalf of, (Insert school or center name here if applicable), and having its principal offices at One Brookings Drive, St. Louis, MO 63130, USA, (*hereinafter* [*“University”*], [*“WU”*],[*“WUSTL”*], *etc.*).

SCENARIO

- You are negotiating with a company who has an SBIR award from the Department of Defense.
- The Company insists they are hiring your institution for work on a work-for-hire basis and they are the buyer and you are the seller.
- The scope of work states that you will be analyzing and developing smart materials that could be used in bullet proof vests

TOP TEN TOPIC #1 Title/Purpose TACTICS TO TRY:

- Dear Negotiator,
 - Please modify the text in the introductory paragraphs as indicated in the redlined agreement. In particular, we are requesting a change to insert our institution's legal name. Additionally, we have changed the title of the agreement and the listed purposes to better reflect the nature of the project and the role our institution will play as a non-profit educational 501(c)3 organization.

TOP TEN TOPIC #1

Personnel and policies

- Signatures and Signature Authority
 - Actual, Apparent Express & Implied
 - PI signatures on contracts
- Notices for changes – technical/contractual
- Control over employees
- Non-compete issues
- Joint ventures and partnerships
- Applicable laws and policies

TOP TEN TOPIC #2 THE MONEY

- Fixed Price : pay attention to scope of work, timelines, milestones and deliverables & time is of the essence requirements –treatment of residuals
- Fee for Service or Patient based Reimbursement:
 - Appropriate costing, Patient care costs, billing compliance
- Cost Reimbursable: pay attention to budget, appropriate rate of f&a applied.
- Penalties for late invoicing or financial reports

TOP TEN TOPIC #2 THE MONEY – Invoicing/Reporting

- Payment Schedules, timelines and project duration
- “Desk Audit”
- Report and Invoice Templates from Sponsor –submission deadlines
- Pre-payment requirements for less reliable sponsors
- Carryforward or separate auditable budget periods.

TOP TEN TOPIC #2 MONEY & TIME

Contract Term Dates

- DO: Double check to make sure dates make sense (i.e. backdating more than 1 year, effective date and contract terms are not incompatible, etc.)
- DO: Make sure the contract dates ARE backdated to cover any period of time that the project may have been on Preliminary status.
- DO: Make sure an end date is specified for accounting purposes.
- DON'T: confuse effective dates with project or budget term dates – especially in master contracts.
- DON'T: backdate contract if issues of background IP ownership are at stake.

SCENARIO

- You are negotiating with a state government agency. Your PI began work six months ago but the agency was really slow in getting the contract out the door. The agency refuses to backdate the contract past their fiscal year date and won't pay or reimburse you for the prior work. They got their funding from a federal block grant.

Top Ten Topic #2 – Contract Term Tactic to Try

Dear Negotiator,

Please note that the Effective date and the Contract dates did not coincide so we have modified the effective date language to make the contract term consistent. Also, please note that we have backdated the contract term to encompass and allow for the payment of pre-contract work that began July 1st 2009. Also, please indicate if the initial budget period will extend automatically or if you plan on initiating an agreement amendment to extend the budget dates. For accounting purposes, we will also need to know if you require separate accounting for the separate budget periods or if cumulative accounting for the duration of the project (with automatic carry-forward) will be allowed.

TOP TEN TOPIC #3 SCOPE OF WORK/STANDARD/WARRANTIES

- SCOPE OF WORK must be detailed enough to know what is being contracted/paid for. SOW impacts appropriate cost allocations, ownership of IP and level of institutional risk
- STANDARD OF CARE:
 - Strict,
 - highest professional standard,
 - industry standard, (geographic?)
 - best efforts,
 - reasonable,

SCENARIO

- You are negotiating with a health care company who is demanding that you strictly adhere to the research scope of work and protocol and that the work will be performed at the “highest professional standard” of care and that you keep their information “strictly” confidential.

Top Ten Tactic to Try #3

Dear Negotiator,

As a non-profit research institution, we apply reasonable standards of care as opposed to the standard proposed in the Agreement. As you know, research, even when conducted perfectly, can end up with results that were unanticipated. Additionally, we are not able to apply a "strict" standard of care in the Confidentiality or protocol provisions. The word "Strict" implies liability without fault on our part. Therefore, we request that the language be modified to "reasonable" standards. Alternatively, we could state that we will protect your information with the same level of care that we protect our own confidential information.

TOP TEN TOPIC # 3 WARRANTIES

- UNIFORM COMMERCIAL CODE:
 - Goods and Services (Commercial)
 - Particular Purpose
 - Merchantability
 - Safety and Efficacy
- WAIVER OF WARRANTIES
- BY SPONSOR
- BY INSTITUTION
- CERTIFICATIONS/REPRESENTATIONS

TOP TEN TOPIC #3 TACTIC TO TRY

Dear Negotiator,

As a Non-profit research enterprise, our university is not a merchant nor does it engage in the business of providing commercial goods or services, rather, we engage in cutting-edge research with inherent risks and deliverables and particular outcomes are never guaranteed either in an implied or express manner. The institution works "at cost" and no profits are anticipated by us. Thus, the Warranty requirements are not appropriate as set forth in this agreement. Indeed, we require a waiver of Warranties as set forth in the provision attached.

TOP TEN TOPIC #4 Risk of Loss

- Liability
- Indemnification
 - Third parties
 - Subcontractors/Consultants/Employees/Agents
- Defend
- Insurance
- Risk Analysis

SCENARIO

You are negotiating with a health company who wants you to participate in a multi-site clinical trial. They want you to indemnify and defend them for any adverse events or liabilities arising out of or relating to the study at your site. They want you to carry a minimum of 2 Million/5Million insurance coverage.

The study involves a new vaccine for H2N2
flu

Top Ten TACTIC to Try # 4

Dear Negotiator,

Because the vaccine and the protocol were both developed/designed by you and we are only following your directions, liability for any adverse events or harm should be born by your company instead of the Site and Company should indemnify Site instead of the other way around. In the end, you are the ones most like to reap a financial benefit from this study, not our institution so, you should also bear the larger burden relative to risk. Additionally, we are not willing to limit human participants ability to obtain medical relief in the event adverse events occur. As a non-profit entity (of the state of x) we are self insured up to the level of risk limited by state statutes.

TOP TEN TOPIC # 5 PUBLICATION AND CONFIDENTIALITY

- Publication
 - Academic Freedom & Institutional Policies
 - Ethical Concerns
 - Student Impact
 - Right to Review vs Right to Approve
 - Delays
 - Export Trade Controls
 - UBIT

TOP TEN TOPIC #5 Publication and Confidentiality

- Confidentiality
 - Sponsor's Information
 - Institutional Information
 - Research Results
 - The terms and conditions of the Agreement itself or that Agreement exists
 - Appropriately identified
 - Open records access laws
 - Classified vs. Secure vs. Proprietary (for what purpose?)
 - Internal vs External
 - Time

SCENARIO

- You are a University negotiating with the Department of Defense on a Federal Acquisition Regulation Contract that contains a security clause – DFAR 252.202-7000 that restricts publication rights on a project related to the development of robotic devices that could someday be used on Submarines for the manipulation of undersea objects.

TOP TEN TOPIC #5 Publication & Confidentiality Tactic to Try

Dear Negotiator,

The Director of DOD has indicated that security clauses such as this should not be inserted into contracts with institutions performing basic research (a copy of the directive is attached hereto). Including such a clause can lead to significant issues relative to student thesis and dissertation work, has a negative impact on our policy on academic freedom to publish and could result in project delays because we would have to apply for export trade licenses with the state department before we could begin work due to foreign students at our institution who might have access to project information.

TOP TEN TOPIC #6 Intellectual Property

- How is IP Defined?
- How is "Invention" Defined?
- How are Residuals defined?
- Clarity
- Ownership or Option for License or Right of First Refusal
- NERF (for what purpose? Safe Harbor?)
- Copyright
- Nature of Scope of Work –clinical trial/applied research, etc.

SCENARIO

- You are negotiating with a pharmaceutical company who wishes to own all outcomes, inventions, copyright, data, materials and know-how of a research study they are sponsoring related to the development and testing of hearing implants.

TOP TEN TACTIC #6 – IP – data/residuals

Dear Negotiator,

Our institutional policy requires that we retain ownership of project outcomes and data for compliance and record retention purposes, but we are willing to provide you with a royalty free right to use information that is identified as a deliverable under the scope of work for your company's purposes (so long as you indemnify us for any harm that might result from such use)

Top Ten Tactic # 6 – Patentable IP

Dear Negotiator,

This agreement requires payment from you to perform the scope of work attached whether or not the work results in patentable IP. Thus, your sponsorship does not include consideration for you to retain ownership of such an outcome. Our policy requires that we retain ownership to such IP, but, we are willing to grant you an option to negotiate for a royalty bearing license in the future once the market value of any IP developed under this agreement becomes known. We can not agree to pre-license terms due to our IRS non-profit status in order to avoid “private use” and unrelated business income tax issues. (if this were federal pass-through, you would argue Bayh-Dole applicability as well).

TOP TEN TOPIC #7 Disputes: Choice of Law, Jurisdiction, Venue

- Choice of Law
- Jurisdiction
- Venue
- Dispute Resolution
- State Laws
- Federal Laws
- International Law and Treaties

SCENARIO

- You are negotiating for a state public University for flow-through funding (you are the subcontractor) with a University in the European Union who has received EU funding and is flowing terms to you. Jurisdiction, Choice of Law and Venue is in the United Kingdom.

Top Ten Tactic to Try #7 – Jurisdiction and Venue

Dear Negotiator,

As a sovereign entity of the state of X, we are unable to agree to the jurisdiction of a different governmental entity (cite statute or legal precedent here). Therefore, we request that the state of x replace your original jurisdiction/choice of law/venue language. Alternatively, we could agree to leave this provision silent, or (if allowed by your counsel), we could agree to Arbitration for dispute resolution so long as such arbitration recognized our public status and indemnification/liability limits specified under governmental immunity laws of our state. (Also must specify arbitration association to be used, language of such arbitration, and venue)

TOP TEN TOPIC # 8 Termination and Damages

- COMPENSATORY-
- NOMINAL-
- PUNITIVE-
- CONSEQUENTIAL-
- SPECIAL -
- LIQUIDATED-
- INJUNCTIVE (SPECIFIC PERFORMANCE)-

SCENARIO

- You are negotiating with a company who wants to be able to unilaterally terminate your agreement upon verbal or written notice and, if for cause, they state that in addition to other claims, they can hire someone else to do the work and you must pay for any negative difference in what the company would have paid you versus what someone else will charge them for the same work.

Top Ten Tactic to Try #8

Termination and Damages

Dear Negotiator,

Our institution requires 30 days prior written notice in order to mitigate costs relative to a termination. We also require such termination right to be mutual. As a non-profit research institution, we are charging you only our actual costs of doing the work, there is no profit included in the budget, thus, we charge far less for our unique type of work than you might be able to obtain from other sources. Thus, please remove the remedies specified in the termination clause. We only ask that you provide payment for work performed up to the point of termination. Any unexpended funds will be returned to you if our work has been unsatisfactory, so, you will not face any financial harm for work left unperformed₃₆

TOP TEN TOPIC # 9 Adverse Events

- Report Adverse Events within a particular time
- Multi-Site – Report back to sites?
- Coverage for participant medical costs associated with adverse events
- In accordance with protocol – variations = different liability?

SCENARIO

- A large pharmaceutical company is negotiating with you on a multi-site clinical trial agreement and disavows liability for adverse events, is providing the drug “as is” and requires you to report any adverse events to them.

TOP TEN TOPIC #10

REPORTING AND AUDIT

- Reporting
 - Technical
 - Financial
 - IP
 - Other
- Audit Rights
- Record Retention

SCENARIO

- You are negotiating with a local government entity who has given you a fixed price agreement. They have also required you to provide monthly financial reports and the right to audit your financial records relating to the project for up to seven years after the project ends.

Top Ten Tactic #10 – reporting and Audit

Dear Negotiator,

Because this agreement is fixed price, you agree to provide payment based on delivery of the work, rather than payment related to how the institution actually expended the funds. Therefore, the audit and record retention requirements are not necessary and, in fact, violate our record retention policy where we keep records for only three years after the project ends. Additionally, the invoice requirements you propose create undue administrative burdens for both our faculty and staff that serve to distract, rather than support our efforts toward providing high quality research services to you as a sponsor.

Contract Negotiations

Verbal Judo

- Disarm the opponent by agreeing with him on something
- Soften up the opponent by complimenting or commiserating
- Move in for the attack by providing a resolution to the other person's concerns

CONTRACT NEGOTIATIONS

- **NEGOTIATION MISTAKES**

- NEVER make an enemy of your inside champion
- It is always risky to start with your bottom line – this undermines the goal of the negotiation process
- NEVER start a negotiation without adequate preparation or knowledge of your own needs and limitations
- Abrasive, arrogant, and aggressive styles rarely work in situations where ongoing relationships are anticipated – also gives other side incentive to fight harder
- Trying to be someone you are not

The background of the slide is a blue-tinted photograph of a vast, calm ocean stretching to a distant horizon. The sky is filled with soft, wispy white clouds. The overall mood is serene and contemplative.

QUESTIONS?