



LEHIGH
UNIVERSITY

Legal Updates:
Research Contracts
Workshop

April 18, 2011



Research Contracts Workshop



- The Context for Research Contracts
- The Big Issues in Research Contracts
 - Intellectual Property & Licensing IP
 - Representations & Warranties
 - Confidentiality, Proprietary Info. & Publication
 - Indemnity, Liability & Insurance
- Negotiating with Commercial Sponsors & Prospective Liaison Program Members

The Parties: Important Distinctions



Universities	For-Profit Corps.	Government
Non-profit : Revenues to mission	For-profit : Revenues to private shareholders	The Public
Tax-exempt : Public benefit	Taxed : Private benefit	Taxing authority enforcing distinction between 2 others
Mission: <u>general</u> knowledge generation; Internal competition OK	Make profit by <u>specific</u> lines of business; Internal competition controlled	Govern 2 other spheres via taxing, spending, regulation, etc.
Creation / <u>dissemination</u> of knowledge for <u>public</u> benefit	Creation / <u>restriction</u> of access to knowledge (<u>secrecy</u>) for <u>competitive</u> advantage	Creation / dissemination of knowledge for public benefit



University Tax-Exempt Status

Federal income tax exemption

Internal Revenue Code Section 501(c) (3) :

- Exempts any “corporations...

(i) organized and

(ii) operated

(iii) exclusively for religious, charitable, (etc.)... or
educational purposes,

(iv) no part of the net earning of which inures to the benefit
of any private shareholder or individual

What does this have to do with research contracts?



Tax Exempt	Taxable (or not permitted)
<p>Research:</p> <ul style="list-style-type: none"> ✓ Pursuit of educational mission ✓ University involvement in design of protocol ✓ Furthers faculty / student pursuit of knowledge 	<p>Testing:</p> <ul style="list-style-type: none"> ✓ Commercial objectives ✓ Corporate sponsor design of protocol ✓ Merely sampling / certifying to known standards
<p>Publication of results</p>	<p>Delay (unreasonable) or prohibition on publication of results</p>
<p>University ownership of IP and results</p>	<p>Transferring IP or assets for less than fair market value (incl. \$0)</p>
<p>Public benefit:</p> <ul style="list-style-type: none"> - Publishing results + commercializing IP to benefit the public 	<p>Private gain:</p> <ul style="list-style-type: none"> - Keeping results proprietary + secret and/or delaying commercialization for private competitive gain

Negotiating Research Contracts: Getting off to a good start



Use University form contracts:

- Reflect our requirements as a tax exempt institution
(... and reflect standard higher education terms)
- Can help us conclude a contract in a timely, efficient way

What is the Project or Relationship?

We have form contracts for:

- Sponsored Research
- Testing
- Research & Testing
- Liaison Program Membership
- ... and more

The Big Issues in Research Contracts



- Intellectual Property (IP) & Licensing IP
- Representations & Warranties
- Confidentiality, Proprietary Info. & Publication
- Indemnity, Liability & Insurance

Intellectual Property – General Principles



- Types of IP:
 - Inventions – patentable ... device or method
 - Works of authorship – copyrightable
 - Know-how – non-patentable
 - Trade secrets – universities unable to maintain
- Inventorship is determined by patent law
- Ownership is determined by answering the question:
 - “To whom (if anyone) is the Inventor legally obligated to assign / transfer his ownership of what he/she invented?”
- Inventorship and/or ownership can be sole or joint

Licensing Intellectual Property: General Principles



- License = owner granting permission to another to use owner's property
- Types of licenses:
 - Exclusive or non-exclusive
 - Revocable or irrevocable
 - Worldwide or in territory(ies)
 - Limited to field(s)
 - With or without right to sublicense
 - ... and more

Intellectual Property

Frequently Negotiated Terms in Research Contracts



Who will own the IP that might result from the research?

✓ Company position (often, not always) – the Company must own resulting IP

Why this is incorrect and not acceptable –

- Research sponsorship does not buy IP resulting from research :
 - consulting / commissioning model is incorrect one
 - tax exempt resources / assets issue – for-profit co. cannot acquire assets from tax exempt entity for free, or below FMV
- Cannot place market value on IP that has not been created yet

Intellectual Property Terms in Research Contracts



Key Terms for University:

- University should own IP it creates
- University should be paid fair market value for its IP
 - License terms should be negotiated only after IP is created (... if any is created)
 - Company can be granted 1st option to negotiate (... but not exclusive right to negotiate)

Note: Research contracts can be silent on IP;
Law determines inventors & ownership

Company / Industrial Sponsor Positions → Intellectual Property



- *“We’re paying for the research/testing so we must own the results, including resulting IP.”*
- *“If IP results from the research/testing, we need to know now what it will cost us for rights (... we need to own IP or lock in licensing terms).”*
- *“We need rights to any necessary background IP...we can’t have Lehigh block us with other patents after we’ve acquired the research IP.”*

An occasional Lehigh faculty PI position: *“I’m not going to invent anything, so IP ownership does not concern me.”*

Intellectual Property Terms in Research Contracts



Responses:

- University owns IP it creates:
 - Research sponsorship or testing fees pays for research / testing, not IP
- University must be paid fair market value for its IP
 - Value of IP won't be known until it's created ... Company can get 1st option to negotiate then
 - Background IP must be licensed separately
 - FMV issue
 - Can't license other faculty IP without agreement of other faculty

Intellectual Property Terms in Research Contracts



Key Intellectual Property Terms for University ...

(continued)

- Include disclaimer of warranties by University regarding its IP:
 - disclaimer of merchantability, fitness, and non-infringement
- Include indemnification / insurance by user of University IP
- Cannot be silent on these terms

Disclaimer of Warranties - Sample



LEHIGH MAKES NO WARRANTIES, EXPRESS OR IMPLIED, AS TO ANY MATTER WHATSOEVER, INCLUDING, WITHOUT LIMITATION, WARRANTIES WITH RESPECT TO THE CONDUCT, COMPLETION, SUCCESS OR PARTICULAR RESULTS OF THE SPONSORED RESEARCH, OR THE CONDITION, OWNERSHIP, MERCHANTABILITY, OR FITNESS FOR A PARTICULAR PURPOSE OF THE SPONSORED RESEARCH OR ANY LEHIGH INTELLECTUAL PROPERTY. UNIVERSITY SHALL NOT BE LIABLE FOR ANY INDIRECT, CONSEQUENTIAL ...

- Entire provision must be “clear & conspicuous” (ALL CAPS)

Disclaimer of Warranties & Limitation of Liability



Why we must include disclaimer of warranties & limitations on liabilities:

- primary mission of education; not to commercialize IP and move products to market
- institutional decision not to assume these risks -- products liability + infringement litigation are extremely costly \$\$
- unlike for-profit companies, we do not meet commercial standards of IP ownership control or commercial quality control

Company / Industrial Sponsor Positions → Warranties / Liability



“If Lehigh performs the work (research), it should stand behind it.”

(representations & warranties, non-infringement of IP)

Responses:

See above – Research is a University mission;
not a business assuming commercial risks

Publication Rights - Sample



“Sponsor recognizes that under University policy, the results of University projects must be publishable and agrees that researchers engaged in the Project shall be permitted to present at symposia, national or regional professional meetings, and to publish in journals, theses or dissertations, or otherwise of their own choosing, the results of the Project, provided however that Sponsor shall have been furnished copies of any proposed publication in advance of the submission.”

Publication Rights



- Another mission-critical contract term
- University missions: creation and dissemination of knowledge
- Another component of satisfying the requirements of tax-exempt status
- The challenge: for-profit corporations seek to keep information secret for competitive advantage



Confidentiality vs. Publication

- Delays for patenting vs. sponsor deciding (and reserving right to deny publication)
- Who is bound? – Faculty PI and research group vs. entire university (infringes academic freedom)
- Defining and marking confidential information



Confidentiality vs. Publication

- Disparity in university vs. industry security practices & infrastructure
- An occasional Lehigh faculty PI position:
“I’m not going to publish anything, so publication or confidentiality terms do not concern me.”
 - Right to publish still matters :
 - Student dissertations, presentations
 - Tax exempt compliance

Confidentiality Clauses



- Requires one or both parties to keep the other's proprietary information confidential for a defined period of time (typically 5 years, although we prefer 2 years or less)
- The challenge: Universities do not meet commercial standards of confidentiality

Confidentiality Clause Pitfalls



- If dispute, Confidentiality clause often used as basis for breach of contract lawsuit because:
 - Easy to claim breach
 - Difficult to defend (to disprove disclosure)
 - Definition of confidential information often open-ended as to form (written, tangible or oral), subject matter and/or time
 - Alleged damages due to disclosure are often very significant (\$\$)

Indemnification - Sample



Except to the extent caused by the sole negligence of any of the Indemnified Persons (as hereinafter defined), Sponsor shall defend, indemnify and hold harmless University, its trustees, officers, faculty, students, employees, subsidiaries, affiliates and agents (hereinafter referred to collectively as the "Indemnified Persons") from and against any and all liability, claims, lawsuits, losses, damages, costs or expenses (including without limitation attorneys' fees), which the Indemnified Persons may hereafter incur or be required to pay as a result of: (a) Sponsor's use of the results of Project or any University Intellectual Property, Joint Intellectual Property, or Sponsor Intellectual Property; or (b) any breach of this Agreement; or (c) any act or omission of Sponsor, its employees, subsidiaries, affiliates, contractors, licensees or agents.

Indemnification / Indemnify:



- To restore the victim of a loss, in whole or in part, by payment, repair, or replacement
- Theory : tool to allocate risks between contracting parties based upon economic considerations and without regard to either party's relative degree of fault

Indemnity Provision - Analysis



- **Except to the extent** caused by the sole negligence of any of the Indemnified Persons (as hereinafter defined),
- **Sponsor shall defend, indemnify and hold harmless**
- **University**, its trustees, officers, faculty, students, employees, subsidiaries, affiliates and agents (hereinafter referred to collectively as the "Indemnified Persons")
- **from and against any and all** liability, claims, lawsuits, losses, damages, costs or expenses (including attorneys' fees),
- **which the Indemnified Persons may hereafter incur** or be required to pay **as a result of:** (a) Sponsor's use of the results of Project or any University Intellectual Property, Joint Intellectual Property, or Sponsor Intellectual Property; or (b) any breach of this Agreement; or (c) any act or omission of Sponsor, its employees, subsidiaries, affiliates, contractors, licensees or agents.

Why Insurance? – Financial Assurance



- To ensure the other party can fulfill financially its promise to indemnify Lehigh.
- To ensure the other party has the financial ability to pay Lehigh for damages regardless of a contract or an enforceable indemnity provision.

Types of Insurance



- Commercial General Liability (CGL)
- Automobile Liability Insurance
- Workers' Compensation
- Umbrella Liability Insurance
- Professional Liability

Insurance Specifications



- “Company shall carry the following insurance coverage with companies licensed to do insurance business in the Commonwealth of Pennsylvania and acceptable to the University”
 - “Commercial General Liability Insurance at the minimum limit of \$1,000,000 per occurrence and \$2,000,000 aggregate”.



Insurance Specifications

Commercial General Liability (CGL)

Commercial General Liability (CGL) Insurance covers the insured's liability for:

- Bodily Injury
- Personal Injury (e.g., slander, defamation of character, false arrest)
- Property Damage
- Contractual Liability (contractually assumed liability)
- Products and Completed Operations
- Independent Contractors

“Additional Insured” Status



- Provides University with insurance protection under the other party’s insurance policies
- Allows Lehigh to present a claim directly to the other party’s insurer
- Protects Lehigh from adverse loss experience
- May cover defense and damages if indemnity doesn’t apply or is ruled invalid

Contract Review Process



- Current review process for research contracts:
 - Office of Research and Sponsored Programs
 - incontrx@lehigh.edu
- New (future) process: Lehigh University Contract Administration (LUCA) website



Challenges in Industry Sponsored Research

Building sponsorship relations with industry:

-- Key elements:

1. Sponsor's prior experience sponsoring university research
2. Appreciation of what value each party brings to the relationship
3. Resources and process to form the relationship

Sponsor's Prior Experience Sponsoring University Research



A. Most experience with, and knowledge of, universities:

Pharmaceutical companies, industry-sponsored research institutes (e.g. EPRI), federal govt.

B. Least experience:

Small companies, non-pharmaceutical manufacturing companies, transportation, energy industries, county govts.

C. In the middle:

Large chemical companies (e.g. DuPont), large computer hardware/software companies, state govt.

At Lehigh, we see mostly B. and C., plus the federal govt. in A.

Effects of lack of Sponsor prior experience with University research:



1. Sponsor demands starting with its form agreement which deviates significantly from University's needs, requirements, and reality of research.
2. Sponsor does not appreciate University's interests, and Sponsor questions University's motives from a for-profit perspective.

Effects of lack of Sponsor prior experience with University research:



3. Sponsor uncertain of with whom it is contracting:
Sponsor wants the faculty PI's expertise but wants to bind the entire University.
4. Sponsor believes its sponsorship funding pays for the full costs of the research and all results and intellectual property.
5. Sponsor can find "outliers" among universities and cites these as evidence that University's position is unreasonable and outside norms.

Process and Speed to Complete Agreements



- A.** Sponsor's prior experience / knowledge of University sponsored research is crucial.
 - How far apart are we starting?
- B.** University resources to negotiate and construct agreements are limited.
- C.** University's decentralized structure and at times lack of consistent negotiating positions reduces Sponsor's confidence in sincerity of University's positions.

Process and Speed to Complete Agreements



- D. Company negotiator lament: “If I don’t use our Company form agreement (or if you want changes to it),... then I have to run it by our legal department.”
- E. Why lawyers should negotiate only with lawyers ...
 - the Rules of Professional Responsibility
- F. Keeping contracts short ...
 - it can be done
 - parties and counsel should agree upfront on rationale and it should be rational (form following function)

Best Practices: Examples to Emulate



- ✓ Professional organizations have many form agreements:
AUTM, NCURA, NACUA, LES
Lehigh's form agreements and policies are consistent with these organizations' suggested forms.
- ✓ Universities: Many examples; institutions with medical schools are often leaders.

Negotiation: Tips & Strategies



- Preparation:
Know our target (goal agreement terms) + other party
- Bargaining:
Values and interests vs. positions
- BATNA:
Best Alternative To a Negotiated Agreement
- Irritators and ultimatums

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QUESTIONS?