



AIM-HI Accelerator Session #4

Working with Academic Institutions: SRAs, Options, and Licenses

Stephanie Palmer

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Roadmap



Sponsored Research Agreements

- Pros and cons vs. CROs
- Payment obligations

Options

- Scope
- Timing and mechanics

License Agreements

- Scope
- Economics

Sponsored Research Agreements

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FAQ:

We know someone in Shiz University's lab.
Shouldn't we use them instead of a CRO?

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SRAs: What are they?

- Agreement between academic institution (“University”) and another entity (“Company”)
- Company pays for research at University in an area of interest to Company
- Limited scope
 - Research and budget agreed before execution
- Mimics a services agreement, with key differences
 - Company will not own arising IP
 - Company will not control publication



SRAs: Research

Principal Investigator

- Company should have approval over substitutes

Conduct of research

- Industry standard; compliance with laws
- Record keeping and sharing

Research Plan

- Needs clear objectives and deliverables
- Needs clear timeline

SRAs: Payments

Set the budget

Payment schedule

- Reimbursements or installments?
- In advance or in arrears?
- Method – probably wire
- *Watch out for overhead*

Changes, overruns

Obligation on termination

- There may be a tail period for wind down

SRAs: Results and Inventions

University owns results and inventions

University discloses results and inventions to Company

Company has the right to use results

Company has preferential rights to inventions

SRAs: Confidentiality, Publications

Confidentiality

- Should always be two-way
- Company should have rights to use results
- Be sure to include carveouts for sharing with investors, subs, etc.

Publication

- Universities must have the right to publish
- Company has right of review and comment
- Company has right to delay (for IP protection) and remove Confidential Information

SRAs: Term and Termination



Term

Usually pre-defined period
Often no automatic extension right



Termination

Company should have the right to terminate at will
University may also request unilateral rights
For breach
For insolvency



Effect of Termination

Wind-down activities
Return any materials and confidential information
Non-cancellable costs: obligation to cover; salaries

Quiz Review: SRAs

True or False: Companies decide what data gets published from the work they pay for.

True or False: Companies own all arising inventions from the SRA work they pay for.

Options

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FAQ:

I need to raise money based on these Shiz University rights. What's the fastest way to do that?

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Options: What Are They?



Company pays University to lock up specific rights for a defined period



Gives Company time to evaluate the technology, conduct due diligence, and raise funding before making a final licensing decision

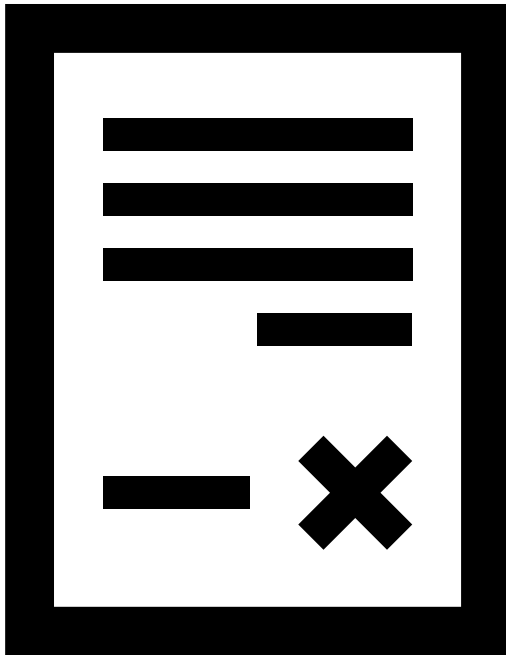


Gives University and Company time to negotiate a full license



Built for speed—secures rights faster, even if it will ultimately probably take longer to get to the full license

Options: Kinds of Options



Can be part of SRA or standalone document

Terms can be:

- Negotiated later
- Included in a term sheet attached to the agreement
- Fully pre-negotiated

Options: Patent Prosecution

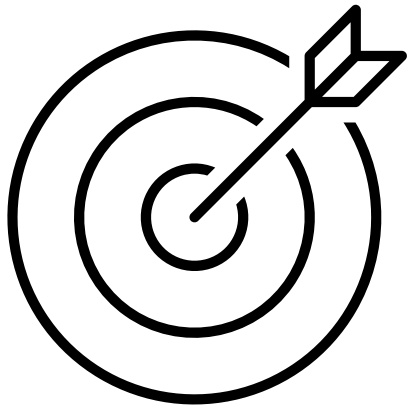


University will
likely control

Company
should have
rights of review
and comment

Company
reimburses
University's
costs

Options: Scope



Exclusive or non-exclusive license

Patents and know-how

- If know-how is in, make sure that it adds value

Field

- Field splits are hard, but sometimes no way around them with a University

Options: Exercise

Option period

- Make sure clearly defined
- Length depends on the work being done during the option period

Negotiation period

- Make sure clearly defined
- Exclusive or non-exclusive

Aggregate multiple inventions if possible

Interplay with an existing license

- University will rarely allow options on inventions to be folded into existing license agreements

Options: Negotiation



Negotiation

What can the parties do during the negotiation (exclusive, non-exclusive?)
Level of efforts (negotiate in good faith)



What happens if no agreement is reached?

Right of first refusal?
Right of first negotiation?
Notice right?
Most Favored Nation clause?

Quiz Review: Options

True or False: Company often pays for patent filings during the option period.

License Agreements

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FAQ:

We need to sign this in a month. Is that possible?

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University License: What is it?



License agreement between University and Company



University grants a license to the Company with respect to patents, know-how, or materials generated by the University



License versus assignment

Assignment is a one-shot only grant

Licenses can be granted multiple times in separate or (for non-exclusive) overlapping scope.



University licenses are a different beast—key differences from commercial license agreements.

University License: How To



Each University has its own template agreement and pre-authorized fallback positions.



University Startup Basic Outlicensing Template (US-BOLT)



Keep your pharma sublicense in mind.

Assignment vs License

- Assignment: Can only assign the entire patent and cannot assign it more than once
- Exclusive License: Can grant multiple exclusive licenses of non-overlapping scope:
 - A particular field (research, veterinary)
 - A particular indication (diabetes)
 - A particular type of product (small molecule therapeutics)
- Non-Exclusive License: Can grant multiple non-exclusive licenses of same or overlapping scope
- Termination: A license is easier to “undo” than an assignment—termination causes automatic reversion to the pre-grant status quo

University License: Licensed IP

Licensed Patents

- Often limited to a single patent application and its family

Licensed Know-How

- Make sure know-how and data add value; don't just automatically include them

University License: Licensed Product

Licensed Compound

- Often limited to a specific compound defined in an exhibit

Licensed Product – balance your rights with what you will pay on

- Specific: Any therapeutic product that contains the Licensed Compound, a derivative thereof, or *another compound that binds to and inhibits Target X*, in each case, whether alone or together with one or more other active ingredients.
- Broad: Any product (a) the manufacture, use or sale of which would, but for the license granted herein, infringe a claim of a Licensed Patent or (b) that *incorporates, uses or was made or developed using the Licensed Know-How*.

University License: Scope

Exclusive vs. non-exclusive

- Even with exclusive, University retains certain rights and can grant those rights to others

Field – limits how you can practice the license

- Territory, indication, mechanism of action

Sublicensing

- Multiple tiers
- Survival if main agreement terminates

Diligence: Obligations



Key difference between Universities and Pharma deals



In a typical partnering deal, a pharmaceutical licensee will only agree to use commercially reasonable efforts to develop and commercialize a single Licensed Product in the Major Markets



University want absolute diligence with firm dates

If Licensee fails to achieve a milestone by the date, Licensor can terminate unless Licensee timely cures
New Trend: diligence events have been extending much further out



Clarify that affiliate and sublicensee activities count toward achievement

Diligence: Mitigation

First: Try to change to an obligation to use commercially reasonable efforts to achieve the milestones.

Second: Mitigate as much as possible

- Exclude delays outside of Licensee's control
- Extend event dates for a certain period for *free* with an updated plan, with limits on the University's ability to withhold approval for the extension
- Buy extensions
- Each extension should push back all future dates, not just the next one
- Licensee can *cure* breach by pre-payment of the next milestone

Goal is to keep University from being able to terminate despite good faith efforts

University License: Financial Terms

Upfront

Equity

Milestones

Royalties

Annual
Maintenance
Fee

Minimum
Royalties

Sublicensing
Revenue

Patent Cost
Reimbursement

Change of
Control Fee



University License: Upfront and Equity

Upfront

- Usually modest, five to low six figures

Equity

- A requirement if the Licensed IP is foundational
- University will push hard for equity from early-stage company, even if not foundational
- Initial equity usually a set percentage (3–8%) of the anticipated first/next financing
- University will insist on antidilution up to a certain threshold (\approx \$20)

University License: Milestones



Cash payments due upon achievement of certain defined pre-clinical, development, regulatory and (rarely) sales milestones



Milestone events may be the same as diligence milestones



Payable once only, or once per product



Due regardless of whether milestone is achieved by Licensee, its affiliates or sublicensees—watch for double-dip with sublicensing revenue

University License: Royalties

Minimum Royalties

- Starts on first commercial sale

Royalties

- Paid on Net Sales of Licensed Products by Licensee, its affiliates and its sublicensees
- Rates:
 - Low single digits (2–5%) for exclusive licenses to composition of matter patents
 - Lower for method patents, know-how only licenses and non-exclusive licenses
- If tiered, higher rates are paid on incremental sales
- Royalty term can be patent life; no reductions for patent expiration or generic entry
- Combination products adjustment
- Royalty stacking

University License: Sublicensing Revenue

Rates:

- Percentage usually decreases over time as the value of Licensee's contributions increase
- Highest percentage can be up to 25–35%; lowest is often 5–10%

What consideration is included is negotiated:

- Cash upfronts and milestone payments should be included
- Royalties are always excluded but profit-share payments may not be

Exclude payments that are really consideration for something else:

- Purchase of Licensee's equity (to extent payment does not exceed FMV)
- Research, development and manufacturing work performed by Licensee
- Loan or convertible debt (except to extent forgiven or not at market terms)
- Patent prosecution or other expenses

Allocation for consideration for the sublicense

University License: Other Financial Terms

Annual Maintenance Fee

- Usually modest, but can increase over time

Patent Cost Reimbursement

- University's existing patent costs are reimbursed on the effective date
- Future patent costs are reimbursed as incurred

Change of Control Fee

- Addresses the hole that sublicensing revenue is paid if a sublicense is granted but not if the Company is acquired
- Universities will often ask for a % of the purchase price, sometimes agree to a flat payment
- If you agree to a percentage, make sure to cap it

Quiz Review: Licenses

True or False: Always make sure to get a license to know-how.

True or False: Change of Control fees should be capped.

Questions?

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