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Words of Wisdom for Negotiating Non-Standard MTA's

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Words of Wisdom for Negotiating Non-Standard MTA's

Speakers:

Sue Kim, University of Southern California
Janina Maniaol, Stanford University
Emily Moscati, Massachusetts Institute of Technology

May 27, 2015

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Emily Moscati,

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MTAs

- MTA stands for Material Transfer Agreement. An MTA is used to effect the transfer of research materials from one entity to another
- Importance:
  - Protecting university IP
  - Protecting research and publishing rights of the PI
  - Limiting liability of the PI and University
  - Crediting researchers who develop valuable materials, and hopefully encouraging the sharing of materials to further research
  - Allowing researchers access to materials that are otherwise not commercially available

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Today:

- Definitions – identifying materials to identify rights
- Publication
- Confidentiality
- Ownership & Intellectual Property
- Indemnification/Reps & Warranties
- PI Obligations
- Potential Deal-breakers
- Expectation Management

Standard Agreements

- University/Nonprofit transfers (both incoming and outgoing)
- Uniform Biological Material Transfer Agreement ("UBMTA")
- Simple Letter Agreement
- AUTM MTA Toolkit
- http://www.autm.net/Material_Transfer_Agreements/12632.htm

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University – Industry

- Open research
- Conservative IP Approach
- Public Use & Benefit
- Education Focus

- Confidentiality
- Expectant of IP
- Company Benefit
- Profit Focus

Definitions

- UBMTA definitions can be used for biological materials as a standard (Progeny, Unmodified Derivatives, Modifications)
- Define even commonly used and accepted terms to avoid potential dispute
- Special consideration in the transfer of compounds
- Defining "inventions" will be covered in later slides
- Be mindful of broad definitions or company template language that may not be applicable or appropriate for that particular transfer

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Definitions

- Examples of problematic language in compound MTAs:
  - "Material" as used herein refers to the Materials listed in Exhibit B and as added to Exhibit B by Company throughout the prosecution of the Research, including any derivative or modification thereof that is substantially based upon or incorporates one or more essential elements of the Material.
  - "Material" shall mean certain retinoid and rexinoid compounds and any related material or substance that is replicated or derived therefrom, and associated know-how, technology, technical and business information and data.
  - "Derivative(s)" means any derivative resulting from modification of the Research Material.

Definitions

- Suggested solutions when faced with "non-standard" terms
  - In biological MTAs, stick to UBMTA terms
  - In compound MTAs, stick to the description of the actual material being transferred when possible
  - If needed, consult with PI and technology manager to draft a narrow workable definition of "Derivatives"
    - E.g. "Derivatives" shall mean any substance created by RECIPIENT's modification of the Material and which has an equivalent function expressed by the Material including isomers, analogs, racemers, other salt or acid forms, esterified forms, purified or crystallized forms, labeled forms, solutions and fractionated subsets of the Material.

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Publication

- Publication language usually covers:
  - Freedom to publish research results
  - Provision of proposed publication to Provider 30 days prior to publication for Provider to review for its confidential information or patentable material.
  - Provider must respond within thirty days of receipt.
  - Provider can request that Recipient remove confidential information or delay for additional time to file patents (usually 30 days but no longer than 60 additional days)
  - PI will acknowledge Provider as the source of the Material
- Avoid any language that allows Provider to control, compromises the integrity of, or potentially bars publication.

Publication continued

- Negotiation Considerations
  - Protect integrity of publication
  - Foster dissemination of research results
  - Fulfill mandate of research universities
  - Avoid language that might be interpreted as a restriction on publication

- Other considerations
  - Using different time limits for written publications and oral presentations (especially important for longer than average periods of review)
  - Temporary moratorium on publication sometimes acceptable for publications of multi-site trials/studies and collaborations

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Publication continued

- Preventing joint publication from turning into a publication restriction:
  - "It is the intention of the parties to publish jointly. However, each party reserves the right to publish separately."
  - Carve out a time limit on joint publication

Publication continued

- Example #1 of problematic language:
  - Provider's contribution will be expressly noted in all written or other public disclosures concerning the Research using the Materials by acknowledgment or co-authorship, whichever is appropriate. At least two (2) months prior to making any submission for publication or other public disclosure, RESEARCHER will provide Provider with a copy thereof for review and comment, and to allow Provider to purge any disclosure of its confidential or proprietary information, prior to the submission for publication or other public disclosure.

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Publication continued

- Example #2 of problematic language:
  - Recipient shall not publish any results from the use of the materials and/or confidential information without Provider's prior written approval. Recipient may publish results obtained using the Materials, provided Recipient (a) provides Provider with copies of any such manuscript prior to publication and (b) Recipient acknowledges Provider as the source of the Materials in any such publication. Provider scientists may be co-authors on such publications, if warranted. Recipient shall provide any disclosure to Provider thirty (30) days prior to such a disclosure for review of confidentiality and patentability.
- Example #3 of problematic language:
  - Provider and Recipient will jointly publish the results accruing from the use of the material. Recipient will not present or deposit any data from use of the Material in any oral, written or electronic form, except within his own research group, without the explicit permission of Provider.

Publication Continued

Acceptable Language:

Principal Investigator shall be free to publish and otherwise publicly disclose the results of the RESEARCH PROJECT provided that Principal Investigator shall provide to PROVIDER a confidential copy of any such proposed publication or disclosure at least thirty (30) days prior to publication. Within that thirty (30) day review period, PROVIDER may require Principal Investigator to delete any PROVIDER Confidential Information from the proposed publication, and, if the proposed publication contains patentable subject matter directly relating to the MATERIALS, then at PROVIDER's written request within said thirty (30) day period, the Principal Investigator will delay publication for up to an additional thirty (30) days to allow for filing of appropriate patent application(s). Notwithstanding anything to the contrary herein, PROVIDER agrees to allow Principal Investigator to disclose sufficient information regarding the MATERIALS to enable the accurate publication of Principal Investigator's RESEARCH PROJECT results

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Confidentiality

- Confidentiality obligations (~3 years)
- Limited disclosure period
- Marking Requirement, including identifying when disclosed verbally (important for preserving publication)
- Usual exceptions:
  - Can demonstrate the info was previously known
  - Is or becomes public knowledge
  - Can demonstrate it was independently developed
  - Lawfully obtained from an independent source
- Required to disclose by law (prefer not to include as an exception since it will remain confidential information)
- Confidential Materials
  - Will add specification that PI can disclose enough information about the Material to accurately publish on his/her research.

Confidentiality continued

- Negotiation considerations:
  - PIs may not be used to keeping information confidential
  - PI will want to publish and should have a clear understanding of what the company considers confidential

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Confidentiality continued

- Example of problematic language:
  - The Recipient shall maintain the Material and any information relating thereto (the Information) in confidence and not disclose or use, at any time during or subsequent to the Agreement, any secret or confidential information of Provider, its Affiliates (as defined below) or its commercial partners created or acquired by the Recipient hereunder including without limitation information about inventions, products, processes, methods, techniques, formulas, compositions, other compounds, projects, developments, plans, research data, clinical data, financial data, investor relations, potential investors, financing arrangements, personnel data, computer programs, customer and supplier lists or such organisations or individuals, research, commercial or other activities, except as required in connection with the Recipient's performance of the agreed study with Provider's prior written approval.

Confidentiality continued

- Acceptable language:
  - The Recipient shall maintain any information disclosed by Provider to RECIPIENT and relating to the Material ("Information") in confidence and not disclose or use, at any time during or for a period of three (3) years subsequent to the Agreement, any said Information. Information that is disclosed in document form (physical or electronic) shall be marked by the disclosing party as "confidential" or with words of similar import at the time of disclosure. Information that is disclosed verbally or in other non-tangible form shall be indicated by the disclosing party as confidential at the time of disclosure and followed, within 30 days after each such disclosure, by a written summary identifying the confidential aspects of the disclosure indicating that such Information is to be treated as confidential under this Agreement.

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Confidentiality

- Alternative solutions to the marking requirement
  - Notwithstanding the foregoing, information disclosed by the disclosing party to the receiving party that is of a character and nature that is commonly and reasonably regarded as confidential or proprietary by persons knowledgeable in the applicable science shall be the disclosing party's Information hereunder even if not marked or identified as confidential by the disclosing party.
  - Discuss obligations with PI
- In one-way confidentiality clauses
  - Be sure to protect confidentiality of PI's research results or inventions if required to be disclosed to the company.

Anecdote

- A real life scenario that involved both confidentiality and publication issues…
  - Company provided compound to a PI.
  - PI used the Company's compound to co-crystalize the PI's protein in order to determine the structure.
  - PI wanted to publish the structure of his protein bound to the company's compound.
  - No marking requirement in the MTA and no language that explicitly allowed the PI to publish the structure.
  - Company claimed the structure as its confidential information during review of the PI's publication
  - In order to timely publish PI had to blur the image of the Company's compound, ultimately compromising the quality of the publication.

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Ownership

- Ownership of Materials
  - Provider may retain ownership of original Materials, progeny, & unmodified derivatives, as well as their confidential information
  - We are cautious of "reach through" rights that claim ownership to any modification derived from the Research or ownership to modifications made with related materials
- Ownership of Inventions
  - Patentable or non-patentable
  - "Inventorship and title to any patent and other intellectual property rights resulting from the research performed under this Agreement will be determined in accordance with U.S. patent law"
- Ownership of Results
  - While Provider retains ownership of the Materials and Provider C.I., we retain ownership of the Research results

Ownership

- Joint Ownership (for Stanford)
  - We will share a joint, undivided interest in joint inventions
  - Both Stanford and Provider may exercise or otherwise commercialize their respective rights in the joint invention without accounting to the other
  - If we choose not to commercialize, it's acceptable for the provider to file in both our names at their expense

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Example

- Example: Promptly after completing the Research Project, Institution shall provide Provider all results obtained from the use of the Provider Materials. If use of the Provider Materials results in an invention or discovery relating to the Provider Materials or materials that directly modulate the same biological target as the Provider Materials, including without limitation, a new use, diagnostic method or diagnostic product, (an "Invention"), Institution shall promptly disclose such Invention to Provider.

Example (Modified)

- Modified Language:
  - Promptly after completing the Research Project, Institution shall provide Provider with a detailed report of all results obtained from the use of the Provider Materials. If use of the Provider Materials results in an invention or discovery that contains or necessarily incorporates the Provider Materials (an "Invention"), Institution shall promptly disclose such Invention to Provider through its Office of Technology Licensing.

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Negotiation Considerations

- We do not have the mechanisms in place to monitor PI's collaborations with other entities in that field
- Other materials outside of this agreement may come with their own sets of obligations
- Disclosure process is handled by OTL
- We do not allow for "reach through" rights

Provider's rights in Recipient's IP

- If Recipient gives Provider rights to inventions developed in Recipient's research with the material
- Examples of definitions to use for IP
  - Inventions made in the scope of research
  - Inventions made by direct use of the material by Recipient
  - Inventions that contain or necessarily incorporate the material

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Licensing back to Provider

- Broad rights → narrow rights
  - Assignment
  - Automatic Exclusive
  - Option for Exclusive
  - Non-exclusive (commercial or internal research)
  - Notify
  - Include "subject to third party rights"

Negotiation considerations

- Bayh-Dole Act: assignment of inventions using federal funding goes back to government if university doesn't elect title
- Can't grant automatic commercial license because: liability risks, no diligence terms, no patent reimbursement
- Existing obligations through sponsored research
- Consider Recipient PI's input when deciding response

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IP Example #1

- Provider's original language in MTA for antibodies:
  - "Company and its Affiliates will have a perpetual, irrevocable, world-wide, royalty-free, fully paid-up, non-exclusive license, transferable and sub-licensable, under any patent rights and know-how, data, findings, results etc. (hereafter "Discoveries") concerning the Materials, including the molecule class or functional class to which the Materials pertains, which are generated during the course of the Studies and/or which are generated by use of the Materials."

Example #1 continued

- Negotiated language:
  - "After an invention disclosure is received by University, University shall disclose in confidence to Company any inventions which could not have been made but for the use of the Material that compromise 1. any substances created by University which contain/incorporate the Material ("Modifications"); 2. new methods of manufacture of the Material; and/or 3. new methods of use of the Materials ("University Invention")."

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Example #1 continued

- "For each University Invention on which a patent application is filed by University, Company and its Affiliates will have a perpetual, irrevocable, world-wide, royalty-free, fully paid-up, non-transferable, non-exclusive license to use the University Invention for internal research and pre-clinical development purposes."

Example #1 continued

- "Furthermore, subject to third party rights, if any, University grants Company the exclusive option to obtain an exclusive license under reasonable commercial terms with regard to such University Invention. Such option shall expire 90 days after University's written notice to Company of such University Invention. Upon Company's exercise of the option, University and Company will negotiate in good faith in an attempt to reach a license agreement satisfactory to both parties, the negotiation period not to exceed 6 months".

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Provider's rights in Recipient's Data/Results

- Deciding whether to allow Provider to use Recipient's data and results:
  - For internal research purposes or educational purposes
  - For preclinical development purposes
  - In Provider's patent applications and/or regulatory filings
  - In Provider's publications (co-authorship)

Negotiation considerations

- Recipient owns the data generated from the research with the material
- Recipient needs to protect researcher's ability to publish
- Recipient needs to protect researcher's ability to use the research results in future research
- Recipient PI's input

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Example #2

- Provider's Original Language:
  - "All data obtained in the course of the Studies with the Materials and derivatives thereof will be submitted to Company. These data may be used by Company without restriction. University grants to Company full access to any primary data relating to Materials and derivatives thereof as well as the right to include the data into any patent applications and regulatory filings."

Example #2

- Negotiated Language:
  - "A summary of all data obtained in the course of the Studies with the Materials and derivatives thereof ("Research Results") will be submitted to Company, in confidence, within sixty (60) days of the conclusion of the Studies or termination of this Agreement. Research Results are the exclusive property of University. These Research results may be used by Company for internal research and pre-clinical development purposes".

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Penalty Clauses

- RECIPIENT shall grant PROVIDER an exclusive license to patent rights to any inventions or discoveries resulting from any unauthorized use of any MATERIAL by the RECIPIENT
- Subject to third party rights

Indemnification/Reps and Warranties

- We indemnify…
  - 3rd party claims arising from our use, handling, storage, & disposal of the materials
  - except for those that arise out of the gross negligence of the provider
- We Remove…
  - Indemnification for breach of the Agreement
  - Assurances against 3rd party patent infringements
  - Warranties for anything other than the right to enter the Agreement
- Have them indemnify…
  - Use of the research results
  - Exercise of a nonexclusive license granted in the MTA

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Example #1

- University agrees to defend, hold harmless, and indemnify Provider from and against all liabilities, expenses, damages, and/or losses resulting from suits, claims, or demands arising directly or indirectly out of a breach of any of University's obligations under the terms of this Agreement.

Example #1 – Revised

- University agrees to defend, hold harmless, and indemnify Provider from and against all 3rd party liabilities, expenses, damages, and/or losses resulting University's use, storage, or disposal of the Materials, except to the extent caused by the gross negligence or willful misconduct of Provider.

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Example #2

- Recipient warrants that the rights and obligations set forth herein do not, and will not, conflict with any other right or obligation provided under any other agreement that Recipient or Investigator has with any third party, including any company or government entity.

- Replace: Recipient represents that it can and shall fully perform its obligations set forth in this Agreement

Jurisdiction

- Stanford prefers to have California jurisdiction
  - The work is taking place in CA; witnesses and evidence would likely be in CA
  - Stanford has a singular location (versus many company branches)
  - Provide Alternatives:
    - Elect a neutral state (NY or UK)
    - Jurisdiction of the Defendant
    - Silence

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P.I. Obligations

- Confidentiality obligations
- Reporting requirements
- Site audits
- Unusual IP
- Publication Issues (co-authorship, delays, etc.)
- Joint ownership arrangements
- Transfer restrictions

Dealbreakers

- Circumstances when we have to walk away:
  - Rights for use of materials w/ same biological targets
  - Publication issues that involve restrictions or control over our researchers' publications
  - Over-reaching IP rights
  - Provider insists on owning results or keeping results confidential
  - Terms conflict with Sponsored Research Agreement terms
  - Conflicts of Interest

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Example

- Within thirty (30) days following completion of the Research, Recipient agrees to furnish Provider with a written summary report setting forth all the data and results generated in performing the Research and/or relating to the Materials ("**Report**"). Such Report shall be the Confidential Information of Provider, and Provider shall have the right to use any data, results or other information arising from or related to the Research for any purpose, including without limitation, for publication, for filing and supporting of Provider's patent applications or in preparing regulatory filings. During the term of this Agreement, and for a period of three (3) years thereafter, Recipient agrees to keep and maintain complete, current, accurate, and authentic written records of the performance of the Research and all Recipient Inventions. Such records shall properly reflect all work in sufficient detail for patent and regulatory purposes.

Managing Expectations

- Routing Form with FAQs
- Department talks
- Notify labs that company and foreign tend to take longer
- Notify labs that we can't proceed if their protocols are not in place
- Add explanations to mark-ups in redlines that you know to be contentious (ie: "Cannot accept due to Stanford's "Openness in Research" policy. For more information, please see http://...")
- Offer alternative language in the redline rather than simple striking out of the agreement ("…however, we understand your concern and are able to agree to ____")
- Mention the hard no's up front

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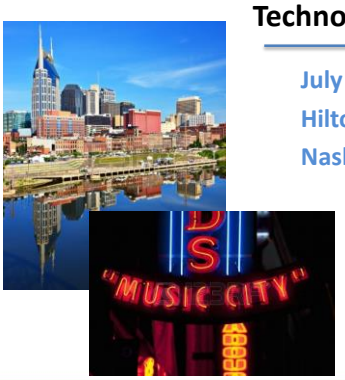

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