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# THE LIFE SCIENCES GROWTH SERIES

## Early Stage Commercial Agreements

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# Early Stage Commercial Agreements

**Topics Covered:**

1. Confidential Disclosure Agreements
2. Material Transfer Agreements
3. Consulting Agreements
4. Evaluation/Feasibility Agreements
5. Master Services Agreement

# 1. Confidential Disclosure Agreements

## Why Have a Written Confidentiality Agreement?

- Confidentiality agreements are standard and an expected part of most negotiated deals
- Protection of trade secrets under state law can be lost (deemed waived) if they are disclosed without a written agreement
- Written contracts are typically easier to enforce
- They avoid confusion over what the parties consider to be confidential
- The parties can specify what they expect from each other

# 1. Confidential Disclosure Agreements

## When to Enter into a Confidentiality Agreement

- As soon as possible
- Prior to disclosure of any confidential information

**PRO TIP: If disclosures of confidential information have been made prior to entering into a confidentiality agreement, make sure that the confidentiality agreement specifically covers all prior disclosures**

# 1. Confidential Disclosure Agreements

## Are You More Likely to Receive or Disclose Information?

- Whether you are primarily disclosing confidential information or receiving confidential information will drive some of your strategy for the structure of the confidentiality agreement
- A Licensor's interest is different from a Licensee's interest
- Licensee's Interest:
  - A Licensee typically wants the exclusions from confidential information to be as broad as possible and permission to disclose all confidential information to Licensee's advisors and representatives
- Licensor's Interest:
  - A Licensor typically wants the Licensee's exclusions to be as narrow as possible
  - Contain other restrictions such as non-solicit or non-compete

# 1. Confidential Disclosure Agreements

## Unilateral

Positive:

- Restricts the disclosing party only

Challenges:

- Does not protect confidential information of the other party that may be disclosed later
- Does not protect nonbusiness information (such as deal terms or deal process) that both parties will likely want to keep confidential

**vs.**

## Mutual

Positives:

- Protects confidential information of both parties
- Protects nonbusiness information about the actual deal
- Provides a more balanced form that typically results in a faster review and signing process

Challenge:

- Imposes restrictions on both parties to the transaction, regardless of which party has more leverage in the deal

# 1. Confidential Disclosure Agreements

## Contents of a Confidentiality Agreement

- Parties to the confidentiality agreement
- Definition of confidential information
- Exceptions to confidentiality
- Permitted use and restrictions on disclosure
- Term
- Return of confidential information
- Remedies
- Other covenants/provisions

**PRO TIP: To protect confidential information, the disclosing party should carefully manage the disclosure process and consider additional confidentiality procedures for extremely secretive information**

# 1. Confidential Disclosure Agreements

## Parties to the Confidentiality Agreement

- The principal parties to the transaction are the Licensor and Licensee.
- Most confidentiality agreements limit disclosures to third parties but permit disclosures on some basis to "Affiliates" and "Representatives" (both of which are negotiated terms).
- The disclosing party typically asks that the recipient be responsible for unauthorized disclosures by its Representatives.

# 1. Confidential Disclosure Agreements

## Definition of "Confidential Information"

- Defining what is confidential is central to any confidentiality agreement
- The types of matters that are typically categorized as confidential include:
  - Scientific, technical or business information
  - Derivatives of scientific, technical or business information
  - The contemplated transaction itself, including any terms
- Exceptions to Confidentiality
  - Is or becomes public other than through a breach of the confidentiality agreement by the recipient
  - Was available to the recipient on a nonconfidential basis before disclosure
  - Was already in the recipient's possession
  - Becomes available through a third party not bound by a confidentiality agreement or obligation
  - Is independently developed by the recipient without using the confidential information

# 1. Confidential Disclosure Agreements

## Other Common Exceptions to Confidentiality

- Disclosures required by law
  - Confidentiality agreements usually allow the recipient to disclose confidential information if required to do so by court order or other legal process
  - The recipient usually has to notify the disclosing party of any such order and cooperate with the disclosing party to obtain a protective order

**PRO TIP: In negotiating a confidentiality agreement, always keep in mind the distinction between restrictions on disclosure and restrictions on use.**

# 1. Confidential Disclosure Agreements

**Term**

- Indefinite or termination upon a certain date or event
- Depends on the type of information involved and how fast such information changes
- Disclosing parties typically prefer an indefinite period
- Recipients typically prefer a set term

# 1. Confidential Disclosure Agreements

## Return of Confidential Information

- Confidentiality agreements typically provide for the return of confidential information in the following circumstances:
  - On the termination of negotiations between the parties
  - At the end of the term of the agreement
  - At any time upon the disclosing party's request
- Recipients often want:
  - The option to destroy the confidential information instead of returning it to the disclosing party
  - To include language that allows them to keep copies of the confidential information for archival or evidentiary purposes or if required to do so under law or professional standards

**PRO TIP:** Disclosing parties should make sure they have rights to the return of their confidential information or an adequate process to confirm destruction or archival under satisfactory procedures.

# 1. Confidential Disclosure Agreements

## Other Covenants/Provisions

- Injunctive relief in addition to monetary damages
- No Representations or Warranties
  - The disclosing party may clarify that it makes no representations or warranties with respect to any of the disclosed information. If the recipient claims that the information is incomplete or inaccurate in any way, the disclosing party points to this clause to avoid liability.
- No license granted
- Obligation to inform of unauthorized disclosure
- No further obligations
- Keeping quiet about the deal
- Residual rights

# 1. Confidential Disclosure Agreements

## Miscellaneous Provisions

- Often viewed as “standard” or “boilerplate” but may have unintended consequences, restricting the Buyer’s activities in the industry and the Buyer’s options as the negotiations progress, even if a transaction never materializes
- Terms may prove very consequential in the event of a subsequent dispute between the parties
- Common topics include: (a) Entire agreement; (b) Assignment, especially the ability of Seller to assign agreement to another acquiror of business; (c) Choice of law and jurisdiction; (d) Waiver of jury trials; (e) Availability of equitable relief; (f) Notice provisions; (g) Amendments and waivers; (h) Override of other confidentiality agreements

# 2. Material Transfer Agreements

## What is an MTA?

- Agreement for purposes of documenting the transfer of materials (e.g., biological or chemical) from one party to another
- Often arises in context of university researchers receiving materials to seek to replicate results achieved another lab
- Life sciences start-ups receive needed materials from university labs
- Addresses rights and obligations with respect to the use of the transferred materials
- Includes provisions addressing ownership of the materials and sometimes also IP arising from the use of the transferred materials

# 2. Material Transfer Agreements

## Different Varieties of MTAs

- Uniform Biological Material Transfer Agreement (UBMTA) – NIH endorsed
- Institutional Forms (drafted by the providing institution)
- Company Forms
- Repository Forms (e.g., ATCC – American Type Culture Collection)
- Electronic MTAs – on-line click-through acceptance of terms

# 2. Material Transfer Agreements

## Reasons for an MTA

- The provider wants to restrict how the material is to be used
- The material is infectious, hazardous or subject to special regulations
- The provider wishes to protect against any potential liability
- The provider wishes to ensure that correct and appropriate acknowledgement is included in any publication regarding the use of the material
- The material is ***proprietary****
- The provider wishes to obtain ***rights to the results**** of the research for which the material is to be used

# 2. Material Transfer Agreements

**Important Considerations in an MTA**

- Definitions of ***"Material"***
  - Usually includes original material, progeny and unmodified derivatives
  - Usually excludes modifications and modified derivatives but not always

- Restrictions on recipient's use of the Material
  - for ***research use only***
  - ***not for use in humans***

# 2. Material Transfer Agreements

## Important Considerations in an MTA (continued)

- Ownership of Material – provider retains ownership; recipient only has right to possess and use for research
  - Consider impact of provider owning the Material
  - Critical to review how ***Material*** is defined

# 2. Material Transfer Agreements

**Important Considerations in an MTA (continued)**

- Confidentiality – need clarity on scope of confidentiality obligations
  - continued development permitted
  - publication not restricted
- Warranty disclaimer
- Indemnification
- Restriction on reverse engineering
- **Scope Creep – MTA's can but probably should not be used as a substitute for an evaluation agreement or research collaboration**

# 3. Consulting Agreements

**Why Have a Consulting Agreement:**

- Govern contributions by non-employees
  - Similar to a Proprietary Information and Invention Agreement (PIAA)
- Coverage for gaps in CDA
  - IP provisions
  - Diligence obligations
  - Regulatory and Compliance terms

# 3. Consulting Agreements

**Who Enters into a Consulting Agreement:**

- Individuals
  - Consultants
  - Advisors
  - Occasionally Founders
- Organizations
  - Vendors
- Avoid misclassifying an employee as a Consultant

# 3. Consulting Agreements

**When to Enter into a Consulting Agreement:**

- As soon as possible – similar to CDA
- Prior to commencement of any work by the Consultant

**PRO TIP: If consultant or advisor has provided services to the Company prior to entering into a consulting agreement, make sure that the consulting agreement specifically covers any prior work and all resulting IP**

# 3. Consulting Agreements

**Scope of Services:**

- What are the Services to be performed?
  - Specificity vs. Flexibility
- How often will the Services be provided?
- Where will the Services be performed?
  - Company Facility vs. Offsite
- How will compensation be structured?
  - Hourly (FTE) Rates
  - Flat Fee

# 3. Consulting Agreements

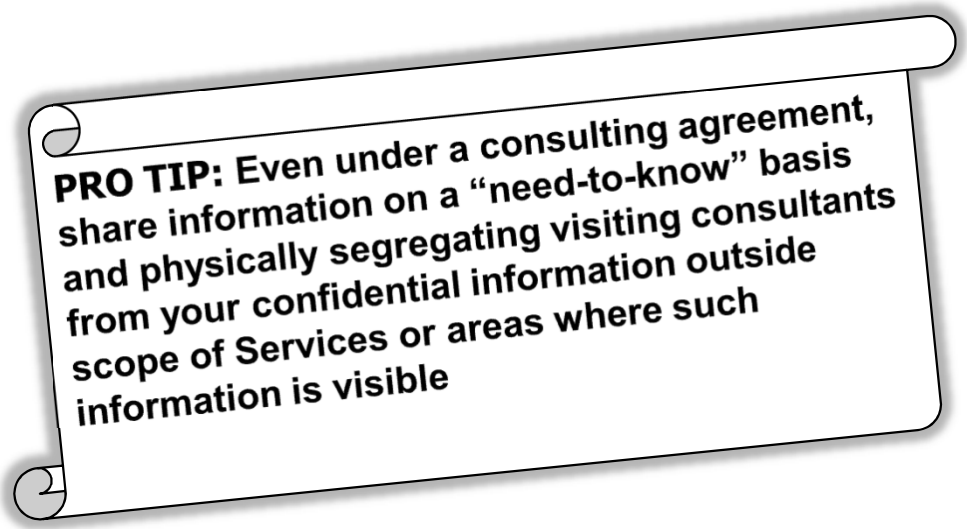
**IP Provisions:**

- Contribution of IP by Consultant
- Work Product / Deliverables
- Arising IP
  - Inventorship
  - Obligation to Disclose
- Assignment and Assumption
  - Obligation to assign
  - Present grant ("hereby grants")
- Further Assurances

# 3. Consulting Agreements

**Confidentiality:**

- Similar concerns to CDA
- Special concerns:
  - Part-time Consultants
  - On-site Consultants



# 3. Consulting Agreements

**Term and Termination:**

- Term
  - Fixed Term vs Open-Ended / Auto-Renewal
- Termination for convenience
- Termination for cause
  - Breach
  - Bankruptcy
- Incapacity of Consultant
- Effects of Termination

# 3. Consulting Agreements

**Additional Key Provisions:**

- Compliance
  - Applicable laws
  - Data protection/security
  - Company policies
- Insurance
- Indemnification
- Limitation of liability
- Independent contractor

# 4. Evaluation/Feasibility Agreements

**What is an Evaluation/Feasibility Agreement?**

- Agreements to test out technologies for compatibility in potential collaborations
- Often involve the transfer of materials, sometimes from both parties
- Usually limited to running the experiments, generating and sharing data and results for the evaluation
- Typically, no compensation – these are not generally considered to be arrangements to receive services

# 4. Evaluation/Feasibility Agreements

**Why enter into a Evaluation/Feasibility Agreement?**

- This can be the "toe in the door" that can validate the technology and remove the barriers to a broader research collaboration
- From the perspective of the party conducting the evaluation, it can be a way to "lock up" a particular technology or opportunity
  - achieved through exclusive option or exclusive negotiation rights

# 4. Evaluation/Feasibility Agreements

**Important practical considerations and common pitfalls**

- Access to data and results – mutual is fairest but may not always be appropriate
- Publication rights – mutual or not; consider delay for patent filings
  - Can the data generated be used to support patent claims?
- Allocate ownership and/or license rights in data and results of evaluation
- If any exclusivity will be granted, ensure scope is appropriately tailored and appropriately compensated

# 5. Master Services Agreements

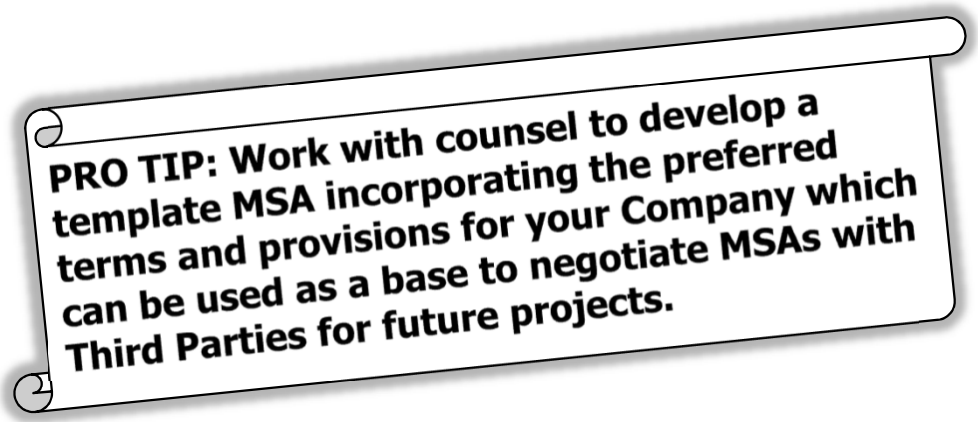
## What is a Master Services Agreement (MSA)?

- Omnibus Agreement
  - Framework of terms and conditions for current and future projects
  - Conduct multiple projects under an MSA
- Broad range of Services
  - Research
  - Clinical and Pre-Clinical Development
  - Distribution
  - Supply
  - Additional Services

# 5. Master Services Agreements

**Why Have a MSA:**

- Long-Term Arrangements
- Convenience
- Efficiency
- Cost-Saving
- Standardization and Quality Control



# 5. Master Services Agreements

**What Should a MSA Cover:**

- General Responsibilities of the Parties
- Governance and Project Management
- Intellectual Property
- Payment Terms
- Dispute Resolution

# 5. Master Services Agreements

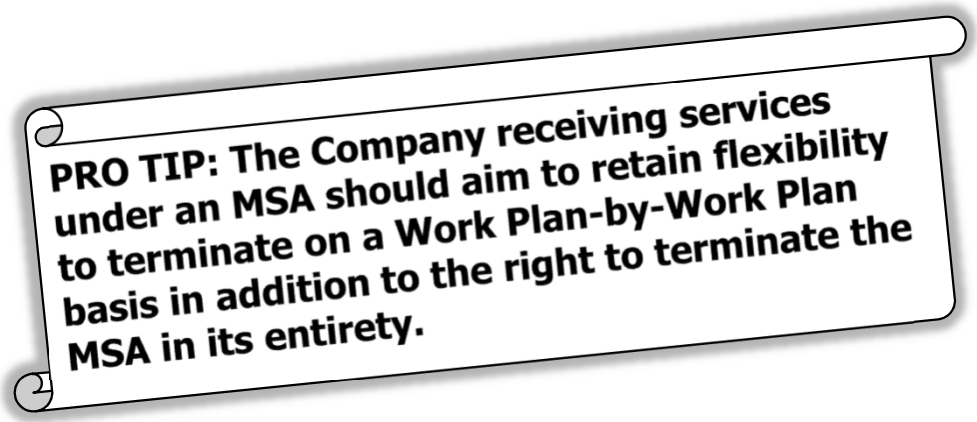
## What Should a Work Plan Cover:

- Specificity vs. Flexibility
- Services / Activities
  - Responsible Party
  - Timelines
- Background IP
- Deliverables / Work Products
- Financial Terms

# 5. Master Services Agreements

## Term and Termination:

- Fixed Term vs Open-Ended
- Termination
  - Breach
  - Bankruptcy
  - Convenience



# 5. Master Services Agreements

**Additional Key Provisions in an MSA:**

- Reporting and Record Keeping
- Audit Rights
- Confidentiality
- Compliance
- Representations and Warranties
- Liability and Indemnification

# Biography

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David G. Glazer advises and represents life sciences, healthcare, and technology companies in matters throughout the United States, Europe, and Asia. Working closely with clients to understand their businesses, David structures and negotiates deals to meet their objectives and find practical solutions to complex problems. He is the co-editor of the Morgan Lewis Emerging Life Sciences Companies Deskbook. David's clients range from biotechnology startups to global Fortune 100 pharmaceutical companies.

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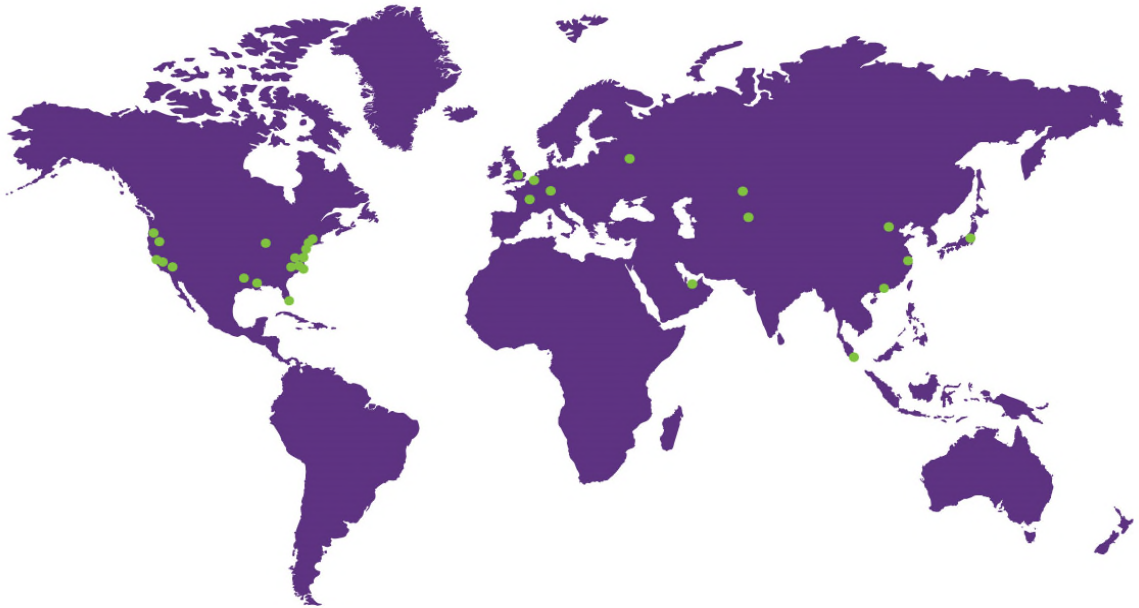

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