

Morgan Lewis

STARTUP & ACCELERATE

**Key Commercial Agreements for Early-Stage
Life Sciences Companies**

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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

Confidential Disclosure Agreements

1. Confidential Disclosure Agreements

Why and When to Have a Written Confidentiality Agreement?

- Confidentiality agreements are standard and an expected part of most negotiated deals
- As soon as possible and prior to disclosure of any confidential information
- 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

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

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.

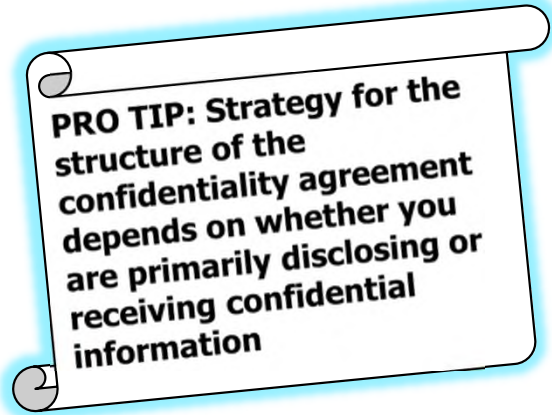
Mutual

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



PRO TIP: Strategy for the structure of the confidentiality agreement depends on whether you are primarily disclosing or receiving confidential 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 and are typically:
 - Technical or business information
 - Derivatives of technical or business information
 - The contemplated transaction itself, including any terms

Exceptions to Confidentiality

- Is or becomes public other than through a breach 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

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

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
- Remedies
- No further obligations
- Non-competes/Non-solicits
- Residual rights

Material Transfer 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. May arise in the context of Academia providing materials to Industry or vice versa
- Addresses rights and obligations with respect to the use of the transferred materials.
- Includes provisions addressing ownership of IP arising from the use of the transferred materials

2. Material Transfer Agreements

Different names of MTAs

- Electronic Material Transfer Agreement
- Simple Letter Agreement (SLA)
- Uniform Biological Material Transfer Agreement (UBMTA)
- Institutional based MTA (drafted by the providing institution)

2. Material Transfer Agreements

Reasons for an MTA

- The material and/or information is proprietary or confidential
- 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 obtain rights to the results of the research for which the material or information is to be used
- The provider wishes to ensure that correct and appropriate acknowledgement is included in any publication regarding the use of the material

2. Material Transfer Agreements

MTAs may involve the following parties

- Industry to Academic
 - E.g., Genetech to Stanford
- Industry to Industry
 - E.g., Gilead to U.C. Berkeley
- Academic to Academic
 - E.g., UCSF to USC
- Non-Profit to Academic
 - E.g., NIH to UCLA
- International
 - E.g., INSERM, University of Bonn (Germany)

2. Material Transfer Agreements

Important Considerations in an MTA

- Definitions of Material
- Restrictions on Recipient's use of the Material
- Provider's rights to inventions and research results
 - Normally, MTAs do NOT transfer ownership
 - The fact that it is in your possession doesn't mean you own it.
- Confidentiality
- Provider's access/restriction on reports and publications
- Warranty disclaimer and indemnification
- **May include a restriction on reverse engineering sample**
- **Should not be used as a substitute for a collaboration or license agreement**

Consulting Agreements

3. Consulting Agreements

What is a Consulting Agreement:

- Agreement governing relationship between the Company and a non-employee:
 - Individuals
 - Consultants
 - Advisors
 - Occasionally Founders
 - Entities
 - Vendors
 - Avoid misclassifying an employee as a Consultant
- Covers scope of services to be performed by consultant on behalf of the Company
- Includes provisions addressing ownership of IP generated by the consultant, as well as additional obligations of consultant

3. Consulting Agreements

Why and When to 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
- Enter into Consulting Agreement as soon as possible
 - Similar to CDA
 - Prior to commencement of any work

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



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

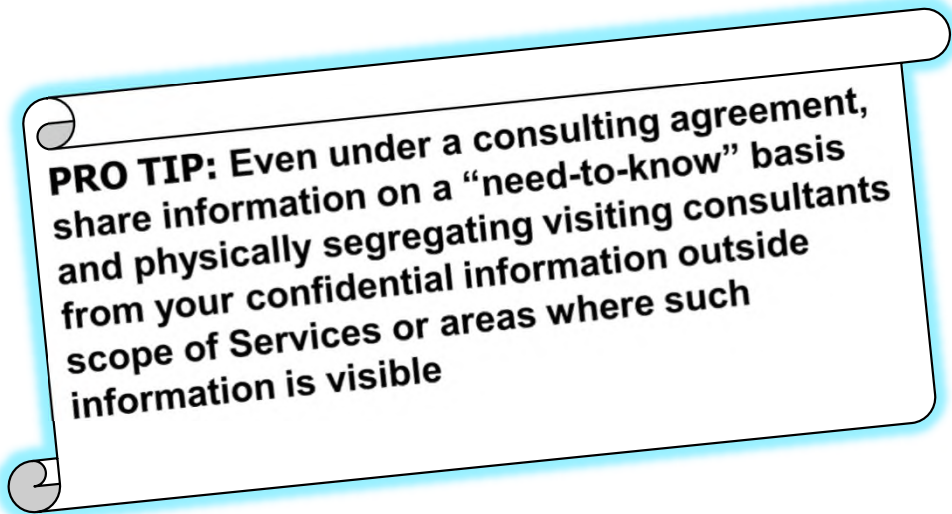
Term and Termination:

- 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:

- Confidentiality – Similar to CDA
- Compliance
 - Applicable laws
 - Data protection/security
 - Company policies
- Insurance
- Indemnification
- Limitation of liability
- Independent contractor



PRO TIP: Even under a consulting agreement, share information on a “need-to-know” basis and physically segregating visiting consultants from your confidential information outside scope of Services or areas where such information is visible

Evaluation/ Feasibility Agreements

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, apart from running the experiment or experiments to generate the data and results that will form the basis of the evaluation, no other compensation is provided – 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 and research collaboration
- From the perspective of the party conducting the evaluation, it can be a way to lock up a particular opportunity – achieved through exclusive option or 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
- 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

Master Service Agreements

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

PRO TIP: Work with counsel to develop a template MSA incorporating the preferred terms and provisions for your Company which can be used as a base to negotiate MSAs with Third Parties for future projects.

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

PRO TIP: The Company receiving services under an MSA should aim to retain flexibility to terminate on a Work Plan-by-Work Plan basis in addition to the right to terminate the MSA in its entirety.

5. Master Services Agreements

Additional Key Provisions in an MSA:

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



Questions?

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Save The Date

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Market Trends Impacting FinTech

Thursday, April 10 @ 12:30pm

THANK YOU

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