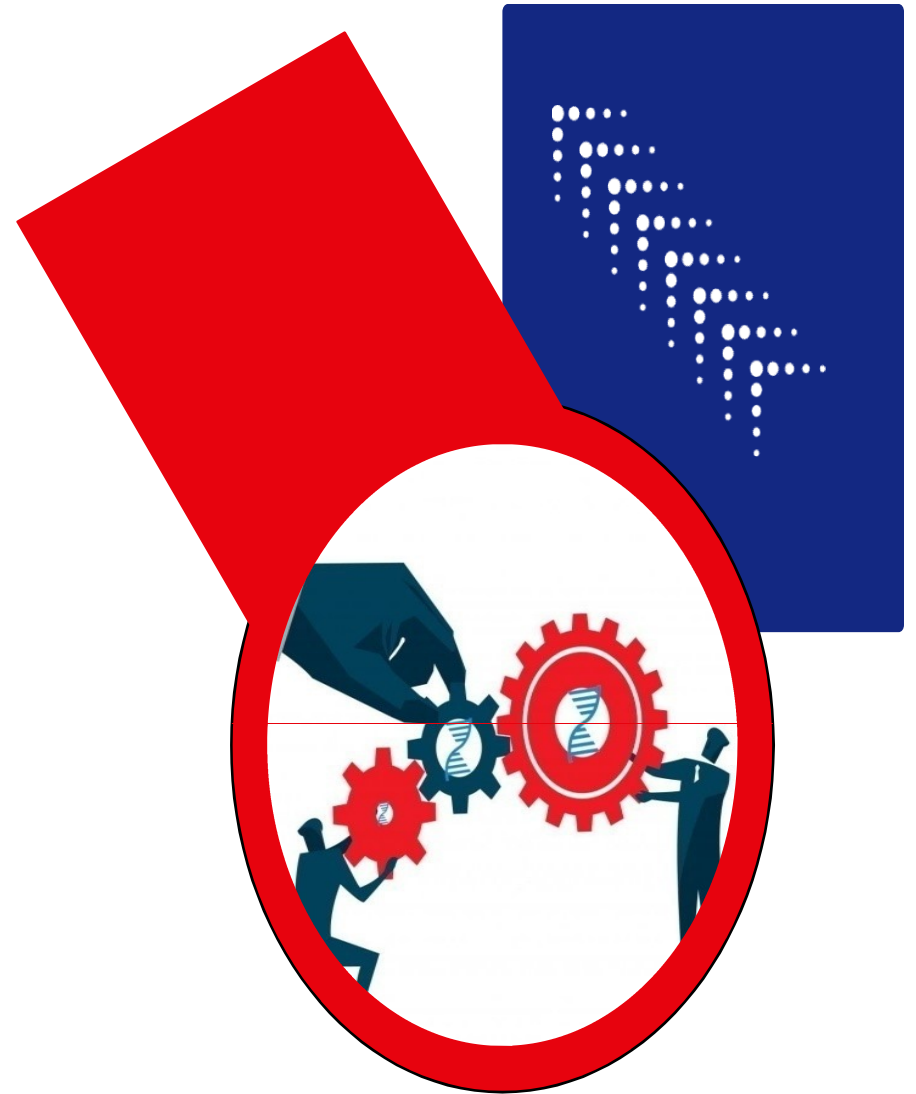




TechEx.in
Tech Transfer Hub at Venture Center
Supported by NBM - BIRAC



Topic: Only NDA and MTA
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OVERVIEW

- What is NDA
- When it is needed
- Elements of NDA
- What is MTA
- When it is needed
- Elements of MTA
- Best Practices

WHAT IS NDA?

Non Disclosure Agreement (NDA)

- ❖ Legal Contract between two or more parties
- ❖ Parties agree to share **Confidential Information** specified in the agreement
- ❖ To restrict the use of Confidential Information from generalized use or disclosure
- ❖ Should be signed **prior to exchanging the information**
- ❖ Sometimes called as Proprietary Information Agreement (PIA) or Confidentiality Disclosure Agreement (CDA) or secrecy agreement
- ❖ Can be one way or two way

WHEN DO YOU NEED NDA?

- ❖ When a Startup wishes to disclose the confidential subject matter with investors
- ❖ When an inventor wishes to get sponsor for developing research work through industrial partner
- ❖ Between the two parties in order to evaluate potential business relationship
- ❖ To participate in preliminary discussions with potential Licensee
- ❖ Need to ensure your employees cannot share your organization's sensitive data while on the job or once they leave
- ❖ Mergers and Acquisitions: When selling your business, sensitive financial and operations information must be shared not just with the entity that's buying your business, but with intermediaries and brokers as well. An NDA ensures that data is protected
- ❖ Contracting with vendors

WHAT IS CONFIDENTIAL INFORMATION

- The information that is not publically available
- Valuable for enterprises/inventor
- Kept as secret by owner

Examples of Confidential Information

- Data, chemical structures, formulae, drawings, manufacturing process, idea/invention yet to be disclosed to public
- Unpublished patent application
- Software code, algorithms
- Financial information, business plans, client lists

ADVANTAGES OF NDA

- ❖ A Confidential Clause in the Non-Disclosure Agreement defines the '**Confidential Matter**' for which the Non-Disclosure Agreement is entered into
- ❖ It assists in maintaining the utmost confidentiality between the parties by legally binding them through various clauses constituted under the Non-Disclosure Agreement. The receiving party is then prohibited from disclosing confidential information.
- ❖ Various clauses of the Non-Disclosure Agreement also specify the time frame within which the party is required to keep the information secret. This period could extend beyond the NDA's effective period.
- ❖ By protecting their confidential information, businesses can maintain a competitive edge, build trust with partners and customers, and attract investors to help them grow and expand.

TYPES OF NDA

1. One Way NDA

A party agrees to accept or disclose confidential information with another party

e.g. If any professor wishes to share novel process for preparing a new chemical molecule with a pharmaceutical company in order to check possibility of research collaboration

Employment contract

2. Two way NDA

When two or more parties mutually agree to share their respective confidential info with each other

e.g. one company is merging or acquiring another company, a mutual NDA ensures none of the parties participating in the process divulge confidential information.

ELEMENTS OF NDA (Sample Agreement)

- ❖ Identification of Parties (ABC Pvt. Ltd AND XYZ Institute)
- ❖ Purpose (*why the parties want to enter into NDA & Conf. Info can only be used for the Stated Purpose*)
- ❖ Unilateral/Mutual
- ❖ Definitions (**Confidential Information**)
- ❖ Obligations (to keep information secret)
- ❖ **Permitted Exceptions**
- ❖ Return of Information
- ❖ Ownership (No assignment, license, no IP rights)
- ❖ Term (Perpetuity should be avoided)
- ❖ Miscellaneous/Legal provisions (governing law, jurisdiction, disputes , breach etc.)

CONFIDENTIAL INFORMATION

The term “**Confidential Information**” shall, without limitation, mean and include all technical and non-technical information relating to the Product, technology, processes, trade secrets, all intellectual property related information, inventions, improvements, modifications or discoveries, whether patentable or not, patent and patent applications, copyrights, trade secrets technical/process/scientific information, study, drug, research, experimental work, clinical development plans, protocols, data, know-how, techniques, formulae, drug delivery regimens, materials, processes, apparatus, equipment, engineering details, sketches, drawings, models, algorithms, software programs and source documents, design details, procurement, manufacturing, commercial and financial information, customer lists, business plans, forecasts, sales and marketing plans, current, future, and proposed products and services, vendors, investors, employees, business and contractual relationships and any other information including above mentioned information relating to the Disclosing Party’s and its Affiliates;

PERMITTED EXCEPTIONS

These are the types of information which do not need to be kept confidential.

All rights have certain exceptions. Similarly, the right to confidentiality also comes bearing certain limitations.

- When the information is public knowledge
- When the recipient receives information from a third party
- When is required by law, regulation, rule, act, or order of any governmental authority or agency to be disclosed
- The information is known to the recipient before signing the NDA (non-disclosure agreement)

ELEMENTS OF NDA

Disclaimer of Warranty Clause

The NDA should explicitly state that the parties are not making any representations or warranties with respect to the accuracy or usefulness of any disclosed Confidential Information.

Remedy for Breach Clause

The NDA should allow, in the event of breach, the affected party to be able to seek equitable relief by way of injunction.

BEST PRACTICES

- ❖ When the number of NDAs starts reaching into the hundreds, reviewing, negotiating, and concluding unique contracts manually is extremely demanding and time-consuming. A standard, adaptable confidentiality agreement can be created with the help of expert
- ❖ Use clear and concise language that focuses only on disclosure.
- ❖ One must ensure that all confidential information shared or will be shared with the other party is clearly and unambiguously mentioned in the Non-Disclosure Agreement.
- ❖ None of the clauses in the same Non-Disclosure Agreement shall be confusing or in conflict with each other.
- ❖ The following definition can be used:

“Data and information that a party wishes to have deemed **“Confidential Information”** shall be treated as such provided (i) if in a tangible format, it is labeled or marked as “confidential” or “proprietary”, and (ii) if not in tangible format, such as oral or visual disclosures, it is identified as Confidential Information at the time of the disclosure and that identification is confirmed in a writing within twenty (20) days after the disclosure.

MATERIAL TRANSFER AGREEMENT (MTA)

- A Material Transfer Agreement (MTA) is a contract governing the transfer of materials between two parties. It defines the rights of the provider and the recipient with respect to the materials and any derivatives.
- what is being shared, for what purpose, and how it can be used.
- MTAs ensure that the transfer of biological samples and associated data is conducted transparently and efficiently, while protecting the interests of the sample owners.
- Materials may include cell lines, plasmids, nucleotides, proteins, transgenic animals, plant varieties, bacteria, pharmaceuticals and other chemicals.
- address issues such as ownership of the transferred material and modifications and derivatives made by the recipient.

MATERIAL TRANSFER AGREEMENT

(MTA)

Avoid Duplication - Sharing resources prevents wasted time and money by avoiding **redundant research**.

Nature of Entities - Public research entities, focused on advancing knowledge, are more open to sharing materials than commercial entities driven by profit.

Nature of Materials - Research tools and bio-samples are shared more freely, while final products are less likely to be exchanged due to market risks.

Market Dynamics - Competitive industries (e.g., pharmaceuticals) are more focused on the market potential of innovations, while academic institutions prioritize gaining funding and prestige.

WHY DO YOU NEED MTA

- To prevent misuse of “Material” transferred to other party
- To get proper compensation for your intellectual efforts
- To protect interests of Provider
- A public health emergency can depend upon the ability to move relevant samples and associated data from one place to another
- Enabling transfers and subsequent use by the recipient, whilst protecting the interests of the transferee
- Intellectual property (who owns improvements and new inventions relating to materials)
- MTAs reduce legal risks and disputes by ensuring that materials are used as agreed

WHEN TO USE MTA

There are a number of scenarios where an MTA might help clarify conditions associated with the movement or use of samples and associated data. These might include:

1. Export or international movement of samples and associated data;
2. Domestic movement of samples and associated data to a separate legal entity (or in some cases perhaps even for different parts of the same legal entity);
3. Determining the eventual use or further distribution of samples and associated data shared for one purpose but with the potential for additional uses;
4. Uses or purposes where there are specific rules or regulations, or when a third party, such as a government agency such as a Ministry of Health, is (or needs to be) involved;
5. Where the material being moved has a potentially important intrinsic value (either the material itself or the possibility of using it in other processes or for product development);
and
6. As part of larger overarching agreements, such as research protocols or bilateral agreements.

TYPES OF MTA

- Incoming MTA
- Outgoing MTA
- Transfer between academic or research institutions
- Transfer from academia to industry
- Transfer from industry to academia

ELEMENTS OF MTA

❖ Definitions

“Material”, Provider, Recipient

❖ Restrictions of Recipient’s use of materials

Not for use on humans, Recipient's responsibility of safety and handling precautions, any activity will be conducted as per applicable laws and regulations else will obtain permits and approvals

❖ Provider’s rights

Publication, IP?

❖ No commercial rights

Only research rights and not for sale, offer for sale, distribute, use for commercial purpose

❖ No further transfer of rights without explicit permission of Provider

ELEMENTS OF MTA

❖ **Modifications of Material**

Recipient intend to modify the Material? What are other applications? details

❖ **Publication rights**

Recipient can publish data for the experiments which he carried out while duly acknowledging the Provider & source of material

❖ **Informing about toxicity, health risks etc. to be informed by Provider**

❖ **Term**

Specific term of the agreement (the project duration) or termination by any either party

Confidentiality

Both parties need to maintain the confidentiality of oral, written disclosure of info shared w.r.t. materials

ELEMENTS OF MTA

❖ **Termination**, use of Material shall be discontinued by Recipient and Material shall be returned/destroyed

❖ **Ownership of IP rights**

❖ **Warranties**

Material is provided on “as is” basis, no warranties , no warranties of merchantability or fitness for a particular purpose, or that the use of the human material will not infringe any IPR

❖ **Liabilities , Assignment, Amendments, Notices, Dispute resolution**

❖ **No Reverse Engineering**

Recipient agrees that it will not attempt to analyze or otherwise reverse engineer the Materials.

INTRINSIC LIMITS OF MTA'S

- Dependence on Agreement - MTAs rely on mutual agreement, which can be hindered by conflicting priorities between researchers (focused on scientific progress) and legal teams (focused on asset protection).
- Implementation Challenges - Delays in the negotiation and transfer of materials can disrupt research and render projects obsolete.
- Transaction Costs - The lengthy negotiation process, costs associated with legal team involvement, and misunderstandings between departments can slow down research progress.
- Inconsistent Terms - Lack of standardization in key terms (e.g., intellectual property, modifications, and derivatives) leads to confusion and increased legal disputes.

STANDARDIZATION AS A SOLUTION

- Need for Standardization: The lack of commercial customs and standardized practices in biotechnology complicates MTA negotiations.
- UBMTA as a Model: Standardized agreements, such as the Uniform Biological Material Transfer Agreement (UBMTA), can help reduce transaction costs, streamline negotiations, and improve collaboration across institutions.

QUESTIONS TO BE ASKED

- Is the recipient a for-profit entity?
- Is the material human-derived, genetically modified, or hazardous?
- Does the material require special protocols or handling?
- Do I want anything in exchange for the materials (other than shipping costs)?
- Is any component of the material proprietary and do I want it kept confidential?
- Am I preparing my own publication relating to the material?
- Could the results of recipient's research be commercialized?
- Is any component of the material potentially patentable?
- Is any component of the material owned by a third party?
- Is the material currently licensed?

BEST PRACTICES

- An MTA or similar agreement should be executed to document the obligations and responsibilities of parties involved in the transfer of materials from a repository prior to shipment. The agreement should be in place before the transfer occurs.
- Repositories that receive or send material should have an MTA and maintain documentation for such transactions. Repositories should have templates of this document that can be used or modified as needed.
- The “Project Plan” and transferred Material can be separately mentioned in Annexure approved with signatures by Parties.
- Explain the Material clearly. The title, description, list of materials, protocol of handling if any, toxicity details, amount etc.

TEMPLATES OF MTA

1.

<https://www.osp.pitt.edu/osp-teams/clinical-corporate-contract-services/negotiations/material-transfer-agreements-mtas>

2.

https://www.sec.gov/Archives/edgar/data/1788028/000121390021037334/fs42021a1ex10-21_amplitude.htm

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FOR MORE INFO



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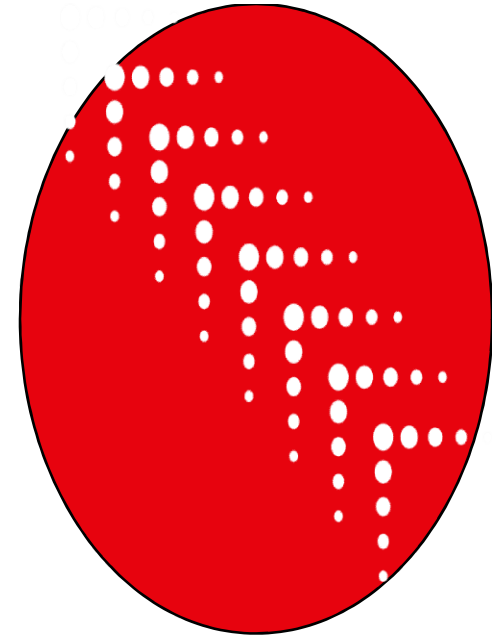
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