



Uniform Biological Material Transfer Agreement (UBMTA)

- Dr. Mamatha Rangaswamy



The UBMTA: Origin and Evolution

What is UBMTA?

- Is a standardized legal framework.
- Created to **simplify** and **expedite** the transfer of biological materials between academic, nonprofit, and other research institutions.
- eliminates the need for repeatedly drafting and negotiating individual Material Transfer Agreements (MTAs), which were known to delay collaborative research projects.

Why it is needed?

Traditional Challenges:

- Complex and restrictive MTAs imposed **significant delays** in sharing critical research materials.
- Researchers often encountered **administrative hurdles** when obtaining materials from other institutions.

Research Collaboration:

- Need for a framework that encouraged **open and timely exchanges** to enhance research productivity and innovation.

Administrative Simplification:

- Reduce the burden on Technology Transfer Offices (TTOs) and allow researchers to **focus** on their work.

Historical Background:

1980s Research Landscape:

- The rapid growth of biotechnology and academic research partnerships in the 1980s revealed **inefficiencies in sharing biological materials**.
- Material Transfer Agreements (MTAs), which defined the terms of material exchanges, were **overly specific and time-consuming**, often **delaying** important research.

Administrative Burden:

- Faculty, researchers, and TTOs spent **considerable time negotiating terms and resolving disputes** over material usage, ownership, and intellectual property rights.

NIH's Role:

Initiating Change:

- Recognizing the challenges, the National Institutes of Health (**NIH**) initiated a dialogue with the Association of University Technology Managers (**AUTM**) and other stakeholders in 1990.
- NIH emphasized the **need for a universal agreement to expedite** research collaborations and **eliminate** bottlenecks caused by traditional MTAs.

Outcome:

NIH and AUTM's collaboration led to the **creation of the UBMTA**, with a focus on fostering open, nonprofit research collaboration.

Goals of the Collaboration:

- To **simplify the transfer process**, especially between nonprofit institutions.
- To **address concerns about proprietary rights** to facilitate smoother transfers between for-profit and nonprofit organizations.
- To **create a legal framework** that balances accessibility with the protection of intellectual property.

Key Milestone:

- Published in the **Federal Register on March 8, 1995**, as a standard framework.
- Established as the preferred method for nonprofit institutions to exchange research materials.

Key Issues in Biological Material Transfers

Definitional Challenges:

- Precise definitions were critical to avoid misunderstandings and disputes
- The key terms addressed included:
 - **Original Material:** Provided by the donor.
 - **Progeny:** Material grown from the original.
 - **Unmodified Derivatives:** Components derived without alteration.
 - **Modifications:** Altered or combined substances.

Ownership and Control:

The UBMTA clarified ownership rights to foster mutual trust:

Provider Rights:

- Retains ownership of the original material, any progeny, and unmodified derivatives.

Recipient Rights:

- Owns substances they create, but only if these do not include or depend on the provider's original material or derivatives.

Patent Considerations:

- Recipients may file patent on inventions resulting from the use of the materials.
- must notify the provider if their claims relate to modifications or methods involving the original material.
- ensures that providers remain informed about potential commercial applications stemming from their materials.

Key Considerations UBMTA:

Material Scope:

- Includes a range of items such as **biological materials** (e.g., cell lines, DNA), **molecular components** (e.g., proteins, pharmaceuticals), and antibodies.

Legal Protections:

- Materials may be protected by **patents, trade secrets, privacy laws, or copyright.**
- These protections affect how UBMTAs are structured and enforced.

Implementation of UBMTA:

Adoption of UBMTA:

- Published alongside a detailed implementing letter to **guide institutions in adopting the framework.**
- By the mid-1990s, over **300 institutions** had signed agreements to follow UBMTA principles.

Challenges in Adoption:

Despite its advantages, the UBM TA faced **resistance** in some areas.

Nonprofit Institutions:

- Often preferred negotiating individual agreements to address specific concerns, bypassing the standardized framework.

Case-by-Case Reviews:

- Many transfers required tailored terms, particularly for sensitive or high-value materials.

For-Profit Hesitations:

- Commercial entities were reluctant to use the UBM TA due to fears of intellectual property loss and concerns over material misuse.

Ongoing Challenges:

The adoption of the UBMTA has not entirely eliminated the issues associated with MTAs:

Complexity:

- Even with a standard framework, material transfers often involve detailed negotiations to address specific scenarios.

Commercial Interests:

- For-profit institutions impose additional restrictions to safeguard their investments and proprietary technologies.

Inconsistent Adoption:

- Nonprofit institutions frequently modify the terms of UBMTA agreements, undermining its uniformity.

Proposed Solutions:

Promote Broader Use:

- **Encourage** institutions to adopt UBMTA for common material transfers, reserving custom agreements for exceptional cases.

Simplify Processes:

- **Develop** shorter, less restrictive agreements for routine transfers.

Embrace Technology:

- **Implement digital tools** to automate the preparation, signing, and tracking of MTAs, reducing delays and administrative workload.

Recent Initiatives for Improvement

➤ **Science Commons:**

- ❖ Aims to **create modular, standardized contracts** to address diverse material transfer needs and includes:
 - The UBMTA as a foundational agreement.
 - Simple letter agreements for straightforward transfers.
 - Alternative clauses for specialized requirements.

➤ **Addgene:**

- A **nonprofit plasmid repository** using UBMTA for most transactions.
- Operates a web-based system that simplifies the request and agreement process, ensuring faster transfers and better record-keeping.

➤ **eMTA Commons:**

- ❖ A **digital platform** developed, involving multiple research institutions with key features such as:
 - Custom workflows to accommodate institutional policies.
 - Searchable databases for biological materials.
 - Standardized agreements for efficient processing.

Conclusion and Future Directions

Significance of UBMTA:

- Simplifies material transfers, reducing delays and enabling collaborations.
- Promotes trust and standardization among participating institutions.
- streamlined the process of sharing biological materials, enabling faster research collaborations
- fosters trust and transparency by providing clear guidelines on ownership, usage, and intellectual property rights.

Vision for the Future:

Universal Standardization:

- **Widespread adoption of standardized agreements** like the UBMTA can eliminate many of the current inefficiencies.

Digital Integration:

- **Advanced web-based platforms** can automate MTA processes, improving speed and accuracy.

Collaborative Research Culture:

- By reducing administrative barriers, the research community can focus on innovation, leading to faster scientific breakthroughs and transformative discoveries.

Definitions

Term	Definitions
Provider	Organization providing the Original Material. Name and address specified in the implementing letter.
Provider scientist	Individual providing the material; details included in the implementing letter.
Recipient	Organization receiving the Original Material. Name and address specified in the implementing letter
Recipient scientist	Individual receiving the material; details included in the implementing letter.
Original material	The material being transferred; described in the implementing letter.
Material	Includes Original Material, Progeny, and Unmodified Derivatives. Excludes Modifications and other substances created by the recipient.

Term	Definitions
Progeny	Unmodified descendants of the material (e.g., cell from cell, virus from virus).
Unmodified derivatives	Functional subunits or products expressed by the Original Material (e.g., proteins, antibodies).
Modifications	Substances created by the recipient incorporating the Material.
Commercial purposes	Use of the material/modifications for profit (e.g., sales, licensing, contract research). Excludes industrially sponsored academic research unless it meets commercial conditions.
Nonprofit organization(s)	Universities, 501(c)(3) organizations, government agencies, or state-recognized nonprofits.

Case study 1:

Addgene and CRISPR Research: Revolutionizing Genome Editing

CRISPR (clustered regularly interspaced short palindromic repeats)

Technology:

- Groundbreaking tool for precise and safe genome editing in living organisms.
- Significant potential to transform genetic research and applications.

Role of Addgene:

- A nonprofit organization established to accelerate science.
- Facilitates open distribution of CRISPR reagents, RNA, and plasmids for academic use.
- Promotes access to materials and information for researchers globally.

Distribution Process of CRISPR Constructs:

Step 1: Deposit Agreement

- Initiated by the depositing scientist's Technology Transfer Office (TTO).
- Deposit agreement signed, granting Addgene authority to distribute materials under the **UBMTA**.

Step 2: Material Transfer Agreement (MTA)

- Requesting scientists and/or TTO completes the MTA.
- Process streamlined using Addgene's custom **electronic MTA (eMTA)** system.

Efficiency of eMTA:

- Average turnaround time: **2 days**.
- One signature enables execution of thousands of MTAs quickly and efficiently.

Documentation and Record-Keeping:

- Addgene maintains detailed transaction records.
- Online access provided for both depositors and TTOs.
- Enables precise tracking of distributed materials, enhancing accountability.

Key Achievements of Addgene

Impact at Scale:

- Over **200,000 MTAs** facilitated to date.
- Current distribution rate: **600 items per day**.
- Researchers in **95+ countries** benefit from Addgene's resources.

Exponential Growth in CRISPR Demand:

- As shown in usage trends demand for CRISPR materials has surged dramatically, reflecting the importance of the platform.

Benefits of Addgene's Approach

Facilitating Collaboration:

- Provides a seamless exchange process for CRISPR materials among researchers.
- Encourages global scientific cooperation.

Streamlined Workflow:

- Rapid processing of agreements ensures timely access to critical research tools.
- Accurate record-keeping enhances transparency and trust.

Challenges and Limitations:

Availability of CRISPR Constructs:

- Not all CRISPR constructs are accessible through Addgene.

Navigating Commercial Interests:

- Academic and commercial interests sometimes clash, particularly for transformative technologies.
- Commercial potential can hinder the open sharing of materials for academic research.

Conclusion

- Addgene has revolutionized the distribution of CRISPR materials, supporting researchers worldwide.
- Its success highlights the importance of efficient processes and transparency in advancing science.
- Moving forward, balancing academic collaboration with commercial incentives will be crucial to sustaining innovation.

Case study 2

BioBricks Foundation (BBF)

Purpose:

- Develops legal tools and frameworks for open, collaborative, and distributive synthetic biology research.

BioBrick Public Agreement v1.0 (BPAv1.0):

- Framework for sharing engineered biological sequences.
- Allows access to sequences as information via the BBF website.
- Enables creation of physical biomaterials through DNA synthesis.
- Some sequences incorporated into plasmids accessible through Addgene.

Open Material Transfer Agreement (OpenMTA)

Objective:

- Simplify and standardize the sharing of biological materials.
- Promote broad sharing without restrictions while ensuring safety and responsible research.

Development:

- Collaborative effort led by BBF and OpenPlant Synthetic Biology Research Centre.
- Involved input from diverse stakeholders, including researchers, legal experts, and funding agencies.

Key Features:

- Standard template for easier integration into automated systems (e.g., Addgene's eMTA).
- Accelerates MTA processing and reduces restrictions when appropriate.
- Information and resources available at **OpenMTA.org**.
- Formal review period for the OpenMTA Master Agreement is ongoing.

iGEM Foundation

Registry of Standardized Biological Parts:

- A primary resource with over 20,000 biological parts, growing annually.
- DNA sequences and related information available online.
- Accessible at http://parts.igem.org/Main_Page.

Distribution Practices:

- Shares biological parts with academic laboratories upon request.
- No MTA required for sharing parts, including those used in student competitions.

Technical Standards:

- Biological parts must be compatible with the BioBrick RFC10 assembly standard.
- Ensures easy combination of parts for research and applications.

Collaborative Impact:

Partnerships:

- BBF and iGEM work together to support:
 - Open and collaborative innovation.
 - Responsible research practices in synthetic biology.

Shared Goals:

- Enhance accessibility to biomaterials and legal frameworks.
- Drive progress in synthetic biology through community-driven initiatives.

UBMTA and Implementing Letter

Upon execution of an Implementing Letter in the form attached which specifies the materials to be transferred, this organization agrees to be bound by the terms of the attached Uniform Biological Material Transfer Agreement ("UBMTA") published in the Federal Register on March 8, 1995.

Attachments:

UBMTA

Implementing Letter

Organization:

Address:

Authorized Official:

Title:

Signature:

Date:

Please return an executed copy of this Master Agreement to: The UBMTA Project, Association of University Technology Managers (AUTM), 111 Deer Lake Road, Suite 100, Deerfield, IL 60015. AUTM will be maintaining signed originals and the official list of signatory organizations.

Format of UBMTA Implementing Letter

The purpose of this letter is to provide a record of the biological material transfer, to memorialize the agreement between the PROVIDER SCIENTIST (identified below) and the RECIPIENT SCIENTIST (identified below) to abide by all terms and conditions of the Uniform Biological Material Transfer Agreement (“UBMTA”) March 8, 1995, and to certify that the RECIPIENT (identified below) organization has accepted and signed an unmodified copy of the UBMTA. The RECIPIENT organization’s Authorized Official also will sign this letter if the RECIPIENT SCIENTIST is not authorized to certify on behalf of the RECIPIENT organization. The RECIPIENT SCIENTIST (and the Authorized Official of RECIPIENT, if necessary) should sign both copies of this letter and return one signed copy to the PROVIDER. The PROVIDER SCIENTIST will forward the material to the RECIPIENT SCIENTIST upon receipt of the signed copy from the RECIPIENT organization.

Please fill in all of the blank lines below:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL: _____ Organization:
_____ Address:

2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL: _____ Organization:
_____ Address:

3. ORIGINAL MATERIAL (Enter description):

4. Termination date for this letter (optional):

5. Transmittal Fee to reimburse the PROVIDER for preparation and distribution costs (optional). Amount:

This Implementing Letter is effective when signed by all parties. The parties executing this Implementing Letter certify that their respective organizations have accepted and signed an unmodified copy of the UBMTA, and further agree to be bound by its terms, for the transfer specified above.

PROVIDER SCIENTIST

Name: _____
Title: _____
Address: _____
Signature: _____
Date: _____

RECIPIENT SCIENTIST

Name: _____
Title: _____
Address: _____
Signature: _____
Date: _____

RECIPIENT ORGANIZATION CERTIFICATION :

I hereby certify that the RECIPIENT organization has accepted and signed an unmodified copy of the UBMTA (May be the RECIPIENT SCIENTIST if authorized by the RECIPIENT organization):

Authorized Official: _____

Title: _____

Address:

Signature:

Date:

Thank you