Transferring Materials and Information with Material Transfer Agreements (MTAs)



What is a Material Transfer Agreement (MTA)?



What is an MTA?

An MTA is a written agreement that governs the terms and conditions in which one party provides (or transfers) physical materials, information or data to another party for evaluation, experimentation, or research.

What are the Materials?

The Materials may include:

- biological materials (DNA, cultures, cell lines, plasmids, nucleotides, proteins, transgenic animals, cDNA libraries, seeds, live plants/rootstocks)
- chemical compounds (drugs, chemicals or nanoparticles)
- devices (medical devices or apparatuses)

What are Information and/or Data?

The Information and/or Data may include confidential or proprietary:

- information or documents related to the Materials, such as DNA sequences or performance characteristics
- Data or data files about people, such as income, health, education or other data



- MTAs may sometimes be called:
 - ✓ Bailment Agreements
 - ✓ Collaboration Agreements
 - ✓ Confidentiality Agreements such as
 - ✓ Confidential Disclosure Agreements (CDAs)
 - ✓ Non Disclosure Agreements (NDAs)
 - ✓ Data Transfer Agreements
 - ✓ License Agreements





- MTAs may sometimes be associated with other agreements:
 - ✓ Confidentiality Agreements
 - ✓ Sponsored Research Agreements
 - ✓ Clinical Trial Agreements
- MTAs are generally categorized as:
 - ✓ Incoming MTAs
 - ✓ Outgoing MTAs

Characteristics of an Incoming MTA:

- ➤ Your Principal Investigator (P.I.) requests to RECEIVE materials from an outside organization (Example a local seed company)
 - ➤ The outside organization will almost always require your organization to use their MTA
 - Your organization will probably have to negotiate changes to the terms and conditions of the outside organization's MTA

Complexity of MTAs:

- Many are very easy, but many are very difficult
- 1 to 25 pages or more
- A few 100 to several 1,000 words
- Sometimes "signed" on line; PDF of signed MTA; or originals signed in duplicate or triplicate
- May take 1 day to 1 year or more to draft, negotiate and sign

Example of envelope "sticker" agreement

Removing this sticker constitutes your acceptance of this product's End User's License Agreement.

L'enlèvement de cet autocollant constitue votre acceptation du Contrat de Licence Utilisateur Final de ce produit.

Retirar este autoadhesivo constituye su aceptación del Contrato de Licencia para Usuarios Finales.

Die Entfernung dieses Aufklebers impliziert, dass Sie sich mit dem Endbenutzer-Lizenzvertrag einverstanden erklären.

Example of online "click" agreements

- · Please read the below MTA.
- . Acknowledge by checking the "I Agree" below the MT
- After acknowledging, you will be taken to the Seed Request webpage.

A hard copy of this 'shrink wrap' MTA will be sent with your seeds. Thank you for your cooperation.

UC DAVIS C.M. Rick Tomato Genetics Resource Center **Material Transfer Agreement**

TThese plant materials ("MATERIALS") requested from the C.M. Rick Tomato Genetics Resource Center ("TGRC") are the property of The Regents of the University of California as represented by its Davis campus ("THE REGENTS") for distribution to companies, institutions, universities and other entities ("USERS"). Use of the MATERIALS is subject to the USAGE RESTRICTIONS below. For other use and commercial use, please contact THE REGENTS for appropriate licenses.

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USERS will cite the UC Davis/C.M. Rick Tomato Genetics Resource Center in any publication(s) describing the research utilizing the MATERIALS. The suggested acknowledgment statement is as follows: The MATERIAL was developed by and/or obtained from the UC Davis/C.M. Rick Tomato Genetics Resource Center and maintained by the Department of Plant Sciences, University of California, Davis, CA 95616.

The MATERIALS have not been thoroughly evaluated by the TGRC. THE REGENTS MAKES NO WARRANTIES OF ANY KIND, EXPRESSED OR IMPLIED, REGARDING THE ACCURACY OF THE INFORMATION PROVIDED BY THE TGRC: THE QUALITY, HEALTH, OR PHYTOSANITARY CONDITION OF THE MATERIALS; OR THE GENETIC IDENTITY OF THE MATERIALS. INCLUDING ITS ORIGIN, PURITY, TRUENESS TO TYPE, GENETIC BACKGROUND, AND THE PRESENCE OR ABSENCE OF ANY TRANSGENES. The USER is responsible for verifying that genetic identity is correct in its own plantings, and the USER will notify the TGRC of any potential problems it observes with the MATERIALS, such as aberrant segregation, incorrect phenotypes, unexpected traits, or other problems.

Any MATERIALS provided pursuant to this Agreement are understood to be experimental in nature and may have hazardous properties. THE REGENTS MAKES NO REPRESENTATIONS AND EXTEND NO WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIALS WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS. Nothing in this Agreement grants by implication, estoppel, or otherwise any rights in the intellectual property of THE REGENTS except as explicitly set forth herein.

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Unless prohibited by law, USERS assume all liability for claims for damages against it by third parties which may arise from the USERS' use, storage or disposal of the MATERIALS. In addition, when USERS are for-profit entities, USERS, to the extent permitted by law, will hold harmless, defend, and indemnify THE REGENTS against any claims, costs or other liabilities which may arise as a result of the USERS' use, storage or disposal of the MATERIALS.

I have read and agree with the terms of the MTA.	Agree	
- Thave read and agree with the terms of the min.	Agree	

Important Terms in an MTA

- 1. Definitions of Material, Modifications, Research, Confidential, Information, etc.
- 2. Use of the Material
- 3. Confidentiality Obligations
- 4. Inventions and Intellectual Property Rights
- 5. Warranties
- 6. Liability and Indemnification
- 7. Publications and Reports
- 8. Governing Law and Jurisdiction
- 9. Termination
- 10. Legal Parties



Definitions (1.):

1. Definitions

- A. ORIGINAL TRANSFERRED MATERIAL
- **B. MATERIAL**
- C. PROGENY
- D. UNMODIFIED DERIVATIVES
- E. MODIFICATIONS
- F. RESEARCH USE
- G. RECIPIENT INVESTIGATOR
- H. CONFIDENTIAL INFORMATION



Definition of "Material"

- Most MTAs use a carefully defined term (e.g., "Material") to describe the material being transferred.
- Elsewhere in the MTA, the provider will:
 - 1. assert ownership of the Material,
 - 2. restrict use of the Material,
 - 3. restrict the transfer of the Material, and
 - 4. ask that the Material be returned or destroyed upon completion of the research.
- These provisions are generally acceptable when the definition of Material is limited to a precise description of the Material that is actually being transferred.

Acceptable Definitions of Material:

- Original Transferred Material The physical material actually transferred to the Recipient by the Provider.
- Progeny -unmodified descendants of the Material.
- Unmodified Derivatives unmodified sub-unit or product expressed by Original Material - e.g. protein expressed by DNA/RNA.

Unacceptable Definitions of Material:

- Derivatives very broad, can mean anything derived from use of the Original Transferred Material
- Modifications substances created by modifying the Original Transferred Material -e.g. plasmid inserted in cell
- Improvements
- Information
- Data

Acceptable Uses of the Material (2.A):

- Research Use defined or described in the MTA
- In compliance with applicable rules and regulations
- In noncommercial research, even if sponsored by companies

Unacceptable Uses of the Material (2.A):

- Commercial purposes
- In humans
- Outside the defined research use
- > Transfers to third parties

Confidentiality Obligations (2.C):

- If Confidential Information (C.I.) will also be transferred, C.I. should be defined
- C.I. may be reduced to writing and marked "confidential" when disclosed orally or visually
- C.I. should not include non-confidential information such as UC's 5 exclusions
- > C.I. should not include research results
- Confidentiality obligations should be limited at most to 5 years

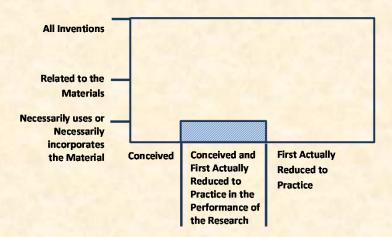


Rights to Inventions, Intellectual Property (IP) and Research Results (2.E):

- Recipient owns its inventions, IP and research results
- Recipient should not assign title to the inventions, IP or research results to the Provider
- Recipient can grant to the Provider a Non Exclusive Royalty-Free (NERF) License to inventions:
 - √ for research purposes only
 - ✓ for commercial purposes in rare circumstances devalues the invention
- Recipient may grant an option to a Commercial License to inventions, but:
 - ✓ It must be Time Limited 6 months or less unless the Provider pays patent prosecution costs
 - ✓ It must not have a Most Favorite Nations or Right of First Refusal Clauses No other party will want to negotiate a license
 - ✓ Must not use the MTA to "hereby" grant a license to future inventions that have not been invented yet

Rights to Inventions, IP and Research Results:

 Limit the scope of the inventions that the Provider will get free rights to: "patentable inventions that necessarily use or necessarily incorporate the Materials and are conceived and first actually reduced to practice in the performance of the research under the agreement."





Warranties (2.F):

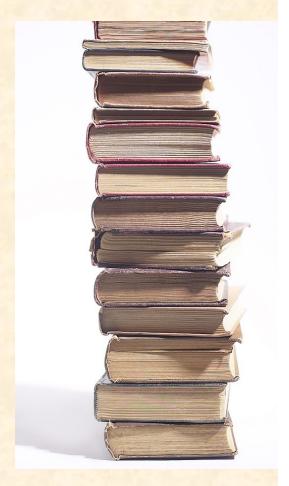
- A warranty is a promise by one party that a particular fact is true (i.e., "UC ANR can warrant that its legal name is 'The Regents of the University of California'")
- As a practice, because of the consequences attached to warranties, Providers do not agree to make any warranties in MTAs
- Warranties can amount to a promise to indemnify the other party for any damages if the underlying fact(s) prove to be untrue
- If the underlying facts prove to be untrue or misleading, the Recipient may be able to sue the Provider for the breach of the warranty

Liability and/or Indemnification (2.G):

- The Recipient can assume liability and indemnify the Provider for the Recipient's use, storage or disposal of the Material
- The Recipient should not assume liability or indemnify the Provider for the actions of other parties with regards to the Material
- Beware of indemnification arising out of Provider's actions (i.e., related to, or in connection with, our use of the material)

Publications (2.H.):

- Delays
 - √ None, if preferable
 - √ 30 days for review by Provider
 - √ 30 more days for patent issues
- Restrictions on Contents
 - ✓ None, other than not publishing Provider's Confidential Information



Reports to Providers:

- The Recipient can submit reports to the Provider such as a:
 - ✓ Summary Annual Report
 - ✓ Summary Final Report at the end of the study
- Reports should be for the Provider's internal research purposes until the P.I. publishes

Termination (2.1):



- ✓ Include termination terms unless you want the MTA to last forever
- ✓ Agree to a specific number of years after the effective date of the MTA or when the research is completed
- ✓ Can agree that either party can terminate the MTA with advanced written notice for example 30 to 60 days

Governing Law and Jurisdiction (2.J):

- ✓ Ideally, the MTA should be governed by the law where the research is being done where the Recipient is located - for example, UC ANR prefers California law when UC ANR receives materials
- ✓ The Recipient generally should not accept governing law and/or, jurisdiction outside of its state or country
- ✓ Many MTAs are silent on governing law



Legal Parties (3)

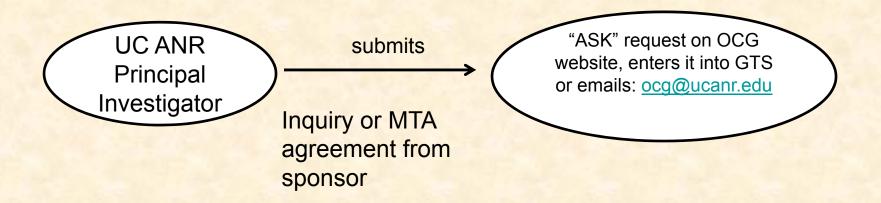


- ✓ MTAs should only be signed by officials who can legally bind the Recipient and the Provider
- ✓ The P.I. or other researchers should not sign as legal parties to the MTA they put themselves at risk of being sued
- ✓ The P.I. can sign as having acknowledged, read and/or understood the MTA

Other Terms in MTAs:

(Other laws, regulations, requirements, policies, etc.)

- Assignability of the MTA to Third Parties
- Export Controls when U.S. Institutions send materials outside of the U.S.
- Fees and Reimbursements
- Human Subjects (IRB)
- Health Insurance Portability and Accountability Act (HIPAA)
- Institutional Animal Care and Use Committee (IACUC)



- ✓ PI enters it into GTS and uploads the MTA agreement and submits it to OCG who:
 - ✓ Reviews the Material Transfer Agreement
 - √ Or contacts Provider and sends a copy of our own MTA

OCG Conducts Review:

- 1. Reviews GTS file entry
- 2. Reviews material transfer documents for applicability
- 3. Works with PI to confirm intent/resources
- 4. If there is a component of funding, then analyst determines whether it should be a standalone MTA or combined with a research agreement/service agreement

OCG Officer or Analyst Negotiates the terms of the MTA

Challenging MTAs:

- Consult with Director and or/Office of General Counsel (OGC) at UCOP
- ➤ Ask Innovationaccess for Expections to Policy
- ➤ Have Principal Investigator and/or County Director sign Informed Participation letter

- 1. The "Bayh-Dole Act of 1980"
 - http://www.ucop.edu/ott/faculty/bayh.html
- ➤ The Bayh-Dole Act (and subsequent amendments) are the basis for technology transfer practices in U.S. universities
- ➤ The Bayh-Dole Act created incentives for universities, industry and the federal government to work together to commercialize new technologies for the public benefit.

- 3. The "Tax Reform Act of 1986" http://patron.ucop.edu/ottmemos/docs/ott00-01.html
- 4. INCOMING MATERIAL TRANSFER AGREEMENTS:
 Guideline for University of California MTA Negotiators
 http://www.ucop.edu/research-policy-analysis-coordination/resources-tools/contracts-and-grants-manual/chap11.html
- 5. Other laws, regulations, policies and guidelines -
- ✓ Health Insurance Portability and Accountability Act (HIPAA)
- ✓ Institutional Animal Care and Use Committee (IACUC)
- ✓ USDA
- ✓ CA Department of Food and Agricultural permits

UC ANR and the other Party agree on every term in the MTA

Who signs the MTA?

- OCG Director/Officer are officials who have the authority to sign the MTA for UC ANR
- > The Providing Party's authorized official signs the MTA
- Principal Investigator(s) not as legal parties, but as having read and understood the agreement
- ➤ The Providing Party sends the material, information and/or data to the Receiving Party

Office of Contracts and Grants Contact Information

Kathleen Nolan

Director 530-750-1306

Wendy Ernst

Officer 530-750-1305

ocg@ucanr.edu