



# MATERIAL TRANSFER AGREEMENT FAQs

This document contains information related to the most frequently asked questions concerning the ATCC Material Transfer Agreement (MTA) [www.atcc.org/mta](http://www.atcc.org/mta). The MTA explains the rights and responsibilities of end users' use of ATCC materials. For your convenience, we have organized the questions into three categories: General, Content and Process. General questions cover basic information regarding the ATCC MTA. Content questions cover the material covered within the MTA and Process questions cover how an institution executes an MTA with ATCC. If you find that your question regarding the MTA is not answered by the information below, please contact ATCC at [licensing@atcc.org](mailto:licensing@atcc.org) with your specific inquiry.

## Frequently Asked Questions

### GENERAL

#### 1. What is a Material Transfer Agreement (MTA)?

An MTA is a contract that governs the transfer of tangible research materials between two organizations when the recipient intends to use it for his or her own research purposes. The MTA protects the rights of all parties involved in the exchange of biomaterials from the original depositor and distributor of the material to the end-user. The use of MTAs is widespread in today's research and development environment. They are used for transfers of materials to and from universities, government agencies, commercial firms, nonprofit organizations and others. To find the ATCC Material Transfer Agreement please visit the ATCC website [www.atcc.org/mta](http://www.atcc.org/mta).

#### 2. Why is an MTA important?

All users of ATCC products must have an active account and must agree to the terms of the ATCC MTA effective at the time of order placement, or as agreed in a previously executed blanket ATCC MTA, prior to receiving products from ATCC or its licensed distributors, because:

1. It protects the rights of ATCC from claims relating to the use, handling, storage and disposal of the materials.
2. It defines the duties of the recipients and their institutions, including the responsibility to properly handle, use and dispose of the materials according to applicable laws and regulations.
3. It protects the rights of the recipients by offering the terms of a warranty, which guarantees that if the received materials are not viable, the recipient is entitled to a refund or replacement at ATCC's sole option.
4. It prevents uncontrolled distribution of Biological Materials by requiring a specific Investigator be listed on each Sales Order and by having reporting requirements for all transfers of Modifications and Unmodified Derivatives (defined below).

#### 3. How does the ATCC MTA follow the Universal Biological Material Transfer Agreement (UBMTA)?

The UBMTA defines modifications as substances created by the recipient which contain/incorporate the biological material. The UBMTA also states that the recipient retains ownership of a modification except the material included therein. The ATCC MTA defines modifications as substances created by the purchaser which contain and/or incorporate a significant or substantial portion of ATCC Material. Like the UBMTA, the ATCC MTA states that the purchaser retains ownership of a modification but does not acquire the ownership of the ATCC Material included therein.

While the UBMTA permits third party transfers of modifications, it is also under a separate implementing letter or an agreement at least as protective of the Provider's rights. The UBMTA also states that written authorization from the Provider must be obtained for commercial use.

The ATCC MTA is similar to the UBMTA with regard to transfers. It has been recently updated so that both Modifications and Unmodified Derivatives (defined below) may be transferred from Purchaser's Investigator to a third party research collaborator or to a CRO (defined below) that is performing work on the Purchaser's Investigator's behalf. Similar to the UBMTA, it requires a separate agreement between the transferring institutions that is at least as protective as the ATCC MTA and requires ATCC's written permission before any Commercial Use can be permitted.

#### **4. Does the ATCC MTA Comply with the Bayh-Dole Act?**

The ATCC MTA does not conflict with the spirit and intent of the Bayh-Dole legislation. If a researcher at an academic institution who is doing federally funded research develops a new substance that contains ATCC material, the Government receives a non-exclusive, royalty-free license to the intellectual property developed out of that federal funding, subject however, to any third party rights that may have already existed. ATCC would not conflict with the Government's rights to newly developed intellectual property, because ATCC does not claim ownership to the newly developed intellectual property, and only claims ownership to the ATCC material that may be incorporated into the new substance.

## **CONTENT**

### **1. Can I add an addendum or rider to the ATCC MTA?**

With the exception of product-specific addendums stipulated by the contributor of ATCC materials, ATCC does not accept additional addendums and riders to the MTA.

### **2. Who should be listed as Investigator?**

In light of the new transfer freedoms afforded under the ATCC MTA and in order to maintain an accurate chain of custody, ATCC is now requiring that the individual, who is the principal investigator using the ATCC material, is listed on the applicable ATCC Sales Order as the End User. For purposes of clarity, an investigator does not include a multi-user biological material core facility nor any of the individual's working at or accessing materials from the multi-user biological material core facilities.

### **3. Can I modify the "Indemnification" provision?**

The "Indemnification" provision was written to be inclusive of all customers and be mindful of restrictions that may limit them. Specifically, federal and state governmental entities and non-profit organizations are agreeing to indemnify ATCC to the extent permitted by relevant federal or state statute. ATCC does not accept references to specific state or federal statutes as this negates our efforts to reduce administrative burden and streamline the transfer of Biological Materials worldwide.

### **4. What is a "CRO"?**

A CRO, or Contract Research Organization may also be called a clinical research organization, Such organizations provide outsourced research services on behalf of a third party customer.

### **5. What is a multi-user core biological material core facility?**

A multi-user core biological material core facility, sometimes referred to as a multi-user core biological material core repository, is a facility set up to grow up ATCC Materials for distribution to a group of users. Such facilities are not permitted under the ATCC MTA.

### **6. I'm not sure if my intended use of the material falls under "Commercial Use." What are some examples of Commercial Use?**

Commercial Use means the sale, license, lease, export, import, use or other distribution of the Biological Materials (defined below) for financial gain or other commercial purposes. In addition, if Biological Materials are being used in the development and manufacture of a product or service for sale, this would also be a commercial use.

Commercial Use does not include industry-sponsored academic research that is carried out at a non-profit organization and by the non-profit organization's employees; however, any use of the Biological Materials by such industry sponsor may require a separate license from ATCC.

Some examples of Commercial Use include:

1. Sale of a Product containing or developed with Biological Materials, such as vaccines, drugs, release assays, diagnostic kits, test kits, food products, dietary supplements, research reagents and enzymes used in manufacturing and formulation; and
2. Services provided using Biological Materials, such as testing using release assays, diagnostic kits and various toxicological or efficacy tests. For purposes of clarity, QA/QC release assays that utilize Biological Materials are considered to be a Commercial Use because such testing is necessary for the final product to be deemed ready for the marketplace.

If you are still not sure if your proposed use of ATCC materials falls under our definition, please contact us at [licensing@atcc.org](mailto:licensing@atcc.org) for additional information.

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**7. Is “Industrial Sponsored Academic Research” a “Commercial Use”?**

Industrial Sponsored Academic Research is not considered a Commercial Use unless and until one of the parties intends to use the Biological Materials being used in the research for a Commercial Use.

**8. What are some examples of each of the materials listed under “Biological Materials”?**

Biological Materials include the ATCC Material purchased by the end user, Progeny, Unmodified Derivatives and Modifications.

Materials are classified as “Progeny” if they are unmodified descendants from ATCC Materials, such as virus from virus, cell from cell, or organism from organism.

Materials are classified as “Unmodified Derivatives” if they are substances created by a Purchaser that constitute an unmodified functional sub-unit or product not changed in form or character and are expressed by the ATCC Material provided by ATCC. This includes, but is not limited to, subclones of unmodified cell lines, purified or fractionated subsets of materials provided by ATCC, proteins expressed by DNA/ RNA supplied by ATCC, and monoclonal antibodies secreted by a hybridoma cell line.

Materials are classified as “Modifications” if they are substances created by Purchaser which contain and/or incorporate a significant or substantial portion of ATCC Material, Progeny or Unmodified Derivatives. This includes, but is not limited to, cells that have been transfected with a reporter gene, induced pluripotent stem cells, and mesenchymal stem cells.

**9. What rights does ATCC have in Modifications and Unmodified Derivatives of ATCC Materials?**

ATCC’s definition of Biological Materials is set up to provide protection and define ownership for the underlying ATCC Material contained within any Modification and/or Unmodified Derivative. In no way is ATCC claiming ownership over those new substances created which do not contain ATCC Material. If an end user creates a new substance, ATCC simply claims ownership to the ATCC Material that may be incorporated into the new substance.

**10. What does “Third Party Terms” mean?**

Although ATCC identifies, to the extent that it is known to us, any third party restrictions in our product sheets and catalog, the Biological Materials distributed by ATCC are cleared for general distribution by the contributor of the material who is responsible for conveying the proprietary status of the deposit to ATCC. Because ATCC relies on its depositors to communicate any third party rights incorporated in the Biological Materials, ATCC is limited in knowing if other parties have rights to the material. For example, other parties may have filed patent applications that claim a material distributed under the ATCC MTA subsequent to its initial deposit with ATCC and, as a result, a particular use may infringe on those claims should a patent issue. A Purchaser of ATCC Materials has the responsibility for obtaining any intellectual property licenses necessitated by its possession and use of the Biological Materials.

**11. What is a CAR form/CAR restriction? How does it affect the rights conferred to me by the ATCC MTA?**

The CAR form is material specific and must be completed prior to receiving materials that may have certain permit requirements or safety regulations that require additional protections be put in place for their use. Such protections include no transfers of any Biological Materials without ATCC’s written permission.

**12. The 2012 ATCC MTA states that I shall report my transfers of Unmodified Derivatives and Modifications to ATCC within a reasonable period after the transfer. What is the process for that?**

After your organization has executed the 2012 ATCC MTA, you may take advantage of the transfer reporting process outlined below:

Within two (2) weeks of transferring an Unmodified Derivative or Modification, the Purchaser’s Investigator is required to report the transfer. Relevant information which must be included in the report includes; (1) the ATCC Catalog number of the ATCC Material the Unmodified Derivative or Modification was derived from; (2) the recipient of the materials; and (3) the purpose of such transfer. For more information or to report a transfer of Unmodified Derivatives or Modifications, please go to [www.atcc.org/transfers](http://www.atcc.org/transfers).

Please note that if your organization has not yet signed the 2012 ATCC MTA, please follow the process outlined under Question 14 of this section.

**13. How am I allowed to use the ATCC trademark when transferring Unmodified Derivatives and Modifications?**

ATCC does not allow Modifications or Unmodified Derivatives to be identified as the ATCC Material itself. The transferring party must use its own designation to identify the material. However, we do allow the transferring party to reference that the material they are sending as being tested or made using ATCC Materials.

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**14. The ATCC MTA states that I cannot transfer Progeny or ATCC Materials. Are there any circumstances where this is allowed? If so, how may I obtain permission?**

Please note that ATCC generally does not allow transfers of ATCC Materials or Progeny (“Unmodified Materials”). This is because ATCC Materials may be purchased directly from ATCC with limited disruption to research. ATCC and its distributors are committed to working with your collaborators to make sure each site is working with material from the same lot or batch number, if possible. However, we understand there are some circumstances that may necessitate the transfer of Unmodified Materials.

To that end, ATCC has a formal process to allow for the transfer of Unmodified Materials for non-commercial, research purposes only. Please note that there may be a fee for transferring Unmodified Materials to a third party as this falls outside of our general distribution practices.

An example of when such a transfer has been allowed in the past is when an Investigator is changing positions and wishes to take those Unmodified Materials that are germane their research with them to their next place of employment. A similar situation would be when a company’s subsidiary is sold to a third party. The fee is waived for both of the above listed transfers.

If you believe that you have a similar situation, or a situation that warrants ATCC’s consideration, please contact us at [licensing@atcc.org](mailto:licensing@atcc.org). In your email, please include: the materials you wish to transfer and the related sales order number; which organization they will be transferred to; if they are ATCC Materials or Progeny; and the reason for the transfer. A licensing associate will contact you concerning your request within five (5) business days.

**15. My institution is a CRO and we often have requests to use ATCC Materials or Progeny in performing contract work for our clients. Is there an agreement that we may enter into to allow these types of transfers to occur?**

ATCC is committed to providing the best service for our customers. Because of this, ATCC will review these requests on a case by case basis. Please contact [licensing@atcc.org](mailto:licensing@atcc.org) to find out more information.

## **PROCESS**

**1. How does the ATCC MTA process overlap/interact with the New Account Application? What is the process in general?**

Before materials can be purchased from ATCC, an institution needs to open an account with ATCC and have a current MTA in place. The standard MTA is available at [www.atcc.org/mta](http://www.atcc.org/mta). ATCC policy is to have organizations sign an MTA when a new account is opened. The Sales Department will guide an institution through opening a new account, including signing an MTA with ATCC. Upon review, if your institution needs no further clarification of terms, the MTA can be signed by a person with appropriate authority and sent to ATCC. However, if your institution would like to discuss the terms of the MTA in greater detail, the matter will be referred to the ATCC Licensing team by your sales representative or you may contact [licensing@atcc.org](mailto:licensing@atcc.org) directly.

The ATCC Licensing team will attempt to answer any questions or concerns an organization may have regarding the MTA and achieve a result that is agreeable to both parties. Once the terms are accepted, a copy will be returned to the organization for their signature. Upon receiving the partially executed agreement, the ATCC Licensing team will countersign the MTA and send a fully executed copy to the organization for its files.

**2. Who should sign an ATCC MTA?**

The ATCC MTA must be signed by an individual on behalf of the Purchaser’s organization capable of legally binding the organization in contract (e.g. president, vice-president, company officer, dean, or provost, but not a university department chairman or research scientist).

**3. Does an individual investigator have to execute an MTA with ATCC?**

ATCC does not require a new MTA be signed by each investigator within an institution. Instead, the MTA exists between the institution and ATCC. This enables a greater degree of freedom when placing orders and minimizes administrative delays in research.

**4. My institution does not have a current, executed institutional MTA in place, but has previously purchased ATCC materials. What/how/why are we restricted from using the material now?**

Existing ATCC account holders that do not have a current, executed MTA in place will be asked to execute a new MTA at the time of order placement. This will allow for all account holders to take advantage of the new, more flexible policies while ensuring that each account holder is aware of its rights and obligations under the MTA.

Additionally, a copy of this MTA is provided in each material shipment and by accepting and opening ATCC materials, the Purchaser is agreeing to terms and conditions of the ATCC MTA. Any materials distributed by ATCC may only be used in accordance with the MTA. If the intended use of the materials is outside of the scope of the ATCC MTA, please contact us for additional information on how to negotiate an appropriate Commercial Use license.

To see the terms and conditions of the current ATCC MTA governing all purchases from the general collection, please visit [www.atcc.org/mta](http://www.atcc.org/mta).

ATCC will be requiring all current customers to update the ATCC MTA they have on file and have a valid, executed ATCC MTA in place by the end of 2012. Please contact [licensing@atcc.org](mailto:licensing@atcc.org) if you have any questions about this new initiative.

**5. What happens if/when the ATCC MTA expires?/ Procedures for rollout of new MTA**

To remain current with standards in scientific discovery, ATCC may release new versions of the standard MTA. ATCC will notify our account holders of the new version so that all account holders may take advantage of any updated policies and execute the most current version of the MTA. ATCC's effort to require all existing ATCC account holders to have a current, signed MTA in place will allow the expedient and efficient shipment of ATCC Material. Because the MTA released in 2012 encompasses significant changes to ATCC policy, we are requesting that all current ATCC account holders update their MTA.

During this transitional period, while we update all ATCC accounts to ensure the accounts have the newly released MTA on file with us, if the previous master ATCC MTA attached to an account expires, the materials are governed by the terms and conditions of the ATCC MTA in effect at the time of order placement and available on our website. A copy of this MTA is provided in each material shipment and by accepting and opening ATCC materials, the Purchaser is agreeing to the terms and conditions of the ATCC MTA.

Please note that any materials distributed by ATCC may only be used in accordance with the MTA. If the intended use of the materials is outside of the scope of the ATCC MTA, please contact us for additional information on how to negotiate an appropriate Commercial Use license.

When a new version of the MTA is released, it will appear on the ATCC website [www.atcc.org](http://www.atcc.org). Current account holders will be contacted to discuss signing the new version of the MTA that has been released in 2012. Any requests to replace the current ATCC MTA held by your institution should be made to [licensing@atcc.org](mailto:licensing@atcc.org).

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