

Material Transfer Agreement Process

Background

There is continuing frustration with the time it takes to complete a material transfer agreement (MTA) at UW-Madison. Delays stem from several points, including the many questions asked before processing, the extensive research done on everything surrounding the material transfer, and the actual negotiations. These delays, in turn, end up delaying the initiation of research. While there are situations where a delay is unavoidable, such as when a provider uses their own template agreement, the majority of MTAs at UW-Madison are template agreements: UBMTA, NIH Simple Letter Agreement, or repository agreements.

Calendar Year 2017 data show there were 785 MTAs completed. These MTAs break down as follows:

Incoming MTAs: 547 total*

Academic/Non-Profit	# Processed	Likely Agreement Used	% of total agreements
Addgene	267	Standard - UBMTA w/add'l terms	48.8
ATCC	16	Standard - Common terms	3.0
DHHS	21	Standard - NIH SLA	4.0
MMRRC	5	Standard - Common terms	0.2
WiCell	12	Standard - Common terms	2.0
UBMTA signatories	98	Standard - UBMTA or Toolkit MTA	18.0
Other	32	Variable	6.0
Industry	96	Variable	18.0

* Approximately 76% of incoming MTAs utilize standard terms. When materials are being provided by collaborating institutions for use in research, the choice of agreement is often left up to the provider. However, RSP suggests use of the UBMTA Implementing Letter, Toolkit MTA, or NIH Simple Letter Agreement whenever we believe it to be appropriate.

Outgoing MTAs: 238 total**

Academic/Non-Profit	# Processed	Likely Agreement Used	% of total agreements
Addgene	11	Standard - Master Deposit Agreement	5.0
ATCC	3	Standard - Master Deposit Terms	1.0
DHHS	10	Standard - NIH SLA	4.0
WiCell	5	Master Deposit Agreement with materials specific terms	2.0
UBMTA signatories	131	Standard - UBMTA or Toolkit MTA	55.0
Other	45	Variable	19.0
Industry	33	Variable	14.0

**Approximately 65% of outgoing MTAs utilize standard terms. When an outgoing MTA incorporates third-party materials or otherwise implicates third-party rights, RSP has less control over the type of agreement and terms it will include, as the governing agreements often dictate to whom, how, and for what purposes we can further distribute materials.

With the above numbers in mind, the goal here is to define a new process to expedite the processing of these template MTAs which, if successful, will provide more time available to devote to non-template agreements and other research agreements.

Expedited Process

Underlying Principles

Moving forward, the University will expedite the signature of MTAs that use a template agreement. Since these agreements generally have approved language accepted by many institutions, including UW-Madison, quick signatures should be the norm. To enable this expediency, the following principles will be utilized:

- The MTA process will reflect an emphasis on research and a recognition of the lower risk associated with common MTA agreements.
- The University will rely on the PI's understanding of their current agreements and the implications of adding a new agreement.

Incoming Material Transfer Agreements

As the data from CY 17 indicates, a higher percentage of incoming MTAs use a standard template than our outgoing MTAs. The process outlined below takes advantage of that fact to simplify the negotiation activities.

1. MTAs that need signature must be placed into a WISPER record.
2. WISPER will generate an email at the creation of the record notifying the PI to review the agreement and ensure that the agreement does not conflict with other obligations the PI may have (funding, other MTAs, etc.). If the PI has any uncertainty, the PI should reach out to the RSP staff to alert them to concerns.
3. Once the WISPER record has been signed and routed to RSP, then RSP staff will review the agreement to determine whether it is a template agreement.
 - a) If it is a template agreement then, during review, RSP staff will make sure there have not been any alterations. Short of identifying a material alteration to the template agreement, and unless the PI has raised concerns about the language in relation to other agreements, the RSP staff will sign the agreement quickly after this review.
 - b) If it is determined that the template agreement has had a material alteration, RSP staff will attempt to negotiate the revision as necessary.
 - c) If it is determined to be a template agreement and the PI has concerns related to the language or other projects, RSP staff will address those concerns, potentially through negotiations with the provider of the material.

- d) If it is identified as a non-template agreement, RSP staff will address the language as necessary through negotiations with the provider of the material. As part of these negotiations, RSP staff will keep the PI updated on the status of the negotiation through updates in WISPER as well as through email as necessary.
4. Upon execution of the agreement, a notice will be sent to the PI advising them that the agreement was signed and that they should review the terms so that the PI and lab staff know the obligations associated with the agreement.

Outgoing Material Transfer Agreements

Similar to incoming MTAs, the University will expedite the signature of outgoing MTAs that use University templates as much as possible. This is contingent on the University having the authority to share the materials, as well as sponsors agreeing to use our template agreements. The outline of this process follows:

- 1) Prior to submitting a WISPER record, the department should ask the PI the following questions:
 - A) Is the material the subject of an invention disclosure to WARF?
 - B) Was the material derived from human subjects under an approved IRB protocol or from patients for clinical purposes?
 - C) Was the material that is the subject of this MTA derived from or created using other materials that are also subject to MTAs or other contractual agreements?
 - D) Is the recipient a commercial entity?

If the answer to each of these question is “no,” the University will use either the UBMTA or Simple Letter Agreement to expedite the MTA. If the answer to question A is “yes”, the request for a MTA should be sent to WARF, and the PI should reach out to their IP Manager at WARF for assistance with the transfer. If the answers to questions B, C, or D are “yes,” the Dean’s Office will work with RSP to seek additional information to insure the materials can be sent and to determine the type of agreement to be used.

- 2) If the material is owned by the University, a WISPER record should be created and routed through for approvals. The department should provide the answers to the above questions within the WISPER record in the “Comments” tab of WISPER.
- 3) RSP will generate an MTA agreement based on the answer to the above questions using UW-Madison’s template agreements. This template will be sent to the sponsor.
- 4) If the sponsor is willing to use the template agreement from the University, the agreement will be signed shortly after receiving it and returned to the sponsor unless the PI alerts RSP staff about concerns. If concerns are raised by the PI, RSP staff will work to negotiate the agreement language to alleviate concerns.
- 5) If the sponsor insists on using its own template, RSP staff will address the language as necessary through negotiations with the recipient of the material. As part of these negotiations, RSP staff will keep the PI updated on the status of the negotiation through updates in WISPER as well as through email as necessary.

Impact

Adopting these new processes for MTAs should positively affect the processing times of MTAs. By signing the template agreements quickly, the material should arrive to the lab sooner. Additionally, efforts will be redirected away from reviewing template agreements and devoted toward reviewing more complicated agreements.

There will also be the effect of shifting responsibility to PIs to know the obligations of the MTA, as well as other agreements that may exist that impact the MTA. As a result of expediting the agreements, it is imperative that PIs are aware of obligations they may have. We believe that is generally the case, but RSP is available if there are any questions.

1. Before sending out materials, PIs should be sure that they have the ability to share the materials. Often, there may be restrictions on rights given to other parties that may limit the sharing of the materials. If a PI is concerned about whether they have the ability to share, the PI should reach out to the RSP staff.
2. Before receiving materials, the PI should review the terms of the agreement to be sure that the obligations fit with what the PI wants to do, as well as to be sure that the obligations do not conflict with other obligations. It is possible that other obligations may exist that give rights to third parties that would conflict with the agreement to receive materials. It is also possible that there are restrictions on the use of materials that would impact the intended direction of the research. If a PI is concerned about how the language impacts the research, or is concerned about other obligations that might conflict, the PI should reach out to the RSP staff.