Material Transfer Agreements
Policies and Procedures

I. Purpose
The purpose of this Policy is to define requirements for Material Transfer Agreements (MTAs) at Albert Einstein College of Medicine (“Einstein”) and outline the procedures for executing MTAs.

II. Scope
This Policy applies to all material transfer agreements entered into on behalf of Einstein faculty or technical staff.

III. Policy
III.A. Background
A Material Transfer Agreement (MTA) is a contract governing the exchange of patented, non-patented and other proprietary biological and non-biological materials primarily for research purposes among the scientific community, including academic institutions, other not-for-profits, and industry. (Copyrighted material, such as software, is an example of a non-biological material that may be exchanged using an MTA.) An MTA is a legal contract between the owner of the material (Provider) and a party requesting permission to obtain and use the material for research purposes (Recipient). MTAs typically cover the transfer of a variety of materials, including cell lines, DNA clones, antibodies, animal models, and other reagents. Every year, Einstein engages in a significant volume of material transfer, and, in a typical year, the Office of Biotechnology and Business Development actively reviews and processes over 800 MTAs.

When transferring materials from Einstein to a third party (either another academic institution, a non-profit organization, or a for-profit company), an MTA must be executed to protect Einstein and its inventors from unauthorized use and/or distribution of the materials. Third parties transferring materials to Einstein may also require the execution of an MTA prior to sending material. A representative of the Office of Biotechnology and Business Development will draft, review, and sign MTAs on behalf of Einstein.

To learn more about MTAs, please read the information below. A general template for MTAs for academic and non-profit organizations can be found on the Office of Biotechnology and Business Development webpage.

Outgoing MTAs for industry and/or for-profit companies are negotiated on a case-by-case basis, which is further explained below.
Why is an MTA Important?

MTAs are important because they protect the rights of both parties. They address issues such as:

1. Ownership of the original materials and modifications or derivatives made by Recipients
2. Limitations of use of the material by the Recipient and the Recipient’s liability
3. Limitations of further distribution of material and derivatives or modifications by the Recipient
4. Publication rights
5. Rights to inventions arising out of the use of materials.

What is the Difference Between Incoming and Outgoing MTAs?

Incoming MTAs

Incoming MTAs involve situations in which Einstein investigators request materials from an academic, not-for-profit or commercial entity, and Einstein enters into reasonable agreements to satisfy this request. In many cases, the providing institution or commercial entity would prefer using their MTA template for such request. All incoming MTAs require signatures from the scientist requesting the material and an authorized representative of the Office of Biotechnology and Business Development. All MTAs must be forwarded to the Office of Biotechnology and Business Development for processing by emailing mta@einsteinmed.org.

Outgoing MTAs

Outgoing MTAs involve situations in which Einstein provides materials to nonprofit or commercial entities that request them. As the providing institution, Einstein requires the recipient institution or commercial entity to use Einstein’s MTA template. Any revision request to Einstein’s MTA terms must be directed to the Office of Biotechnology and Business Development by emailing mta@einsteinmed.org.

For most published research material being requested by academic and other non-profit institutions, the requestor may be directed to download Einstein's MTA template directly from the Office of Biotechnology and Business Development website. The requestor should provide the requested information and return the MTA to Einstein signed by the Recipient Scientist and by an authorized representative of the Recipient’s Scientist's institution. Detailed instructions are provided below.

For patented/patent-pending or other proprietary research material, or for any request from a for-profit or commercial entity, tailored agreements are negotiated on a case-by-case basis and are designed to reflect the nature of the relationship between the Recipient and Einstein and the nature of the intended use of the materials by the Recipient. If the Einstein PI will be involved in the Recipient’s research using the material, other than providing the material, a collaboration agreement with MTA terms would be preferred to an MTA. The intended uses may vary and may include such purposes as internal research, manufacturing, quality control, sale of the research reagent, or application in performance of a service. In some instances, an MTA is the appropriate agreement with which to transfer material, and in other instances, a license or another agreement is the appropriate method for transferring material. To determine the most appropriate agreement for a given situation, the Recipient is asked to provide the following information:
1. How will Recipient use the material (internal research, manufacturing, sale of a product/service, or other use)?
2. For what purpose does the Recipient wish to use the material?
3. If the material is being used for internal research, does Recipient anticipate needing the material for any other purpose after the research is completed? If so, for what other purpose does the Recipient wish to use the material?
4. For how long will the Recipient need the material?
5. At which site(s) will the material be used?
6. How much material will Recipient need?

MTAs and other research tool licenses involving industry are generally granted on a non-exclusive basis to the Recipient and are subject to the payment of license fees. All income generated from such licenses are distributed in accordance with the Official Policy on Intellectual Property and Licensing Agreements. All requests from industry for materials made at Einstein should be referred to the Office of Biotechnology and Business Development at biotech@einsteinmed.org or by contacting the office directly (Belfer Building, Room 908 or extension x3357).

Additionally, please note that the Office of Biotechnology and Business Development proactively markets Einstein research tools that have commercial value to industry partners. Therefore, faculty are encouraged to disclose novel research tools developed at Einstein to the Office of Biotechnology and Business Development.

**Is Processing an MTA a Complicated and Lengthy procedure?**

**MTAs with Academic Institutions**

Einstein, like many other U.S. academic institutions, is a signatory to the Uniform Biological Material Transfer Agreement (UBMTA). Use of this widely accepted agreement greatly facilitates the exchange of materials among academics, since the agreement may be executed with minimal, if any, negotiation between the parties. However, for certain proprietary material, such as patented, patent-pending, licensed, license-pending, and any unpublished material of commercial potential, Einstein, as well as many other academic institutions, may opt for a more tailored agreement depending on the nature of the material and the relationship between the institutions. Request for such materials shall be directed to the Office of Biotechnology and Business Development and will be managed on a case-by-case basis, even if the exchange is with another academic institution.

**MTAs with Industry**

Exchange of materials to and from industry is managed on a case-by-case basis. The single most significant delay in finalizing incoming MTAs from industry is negotiating acceptable terms. In many cases, industry MTAs include terms that conflict with Einstein’s policy, NIH guidelines, and/or legal obligations required of federally-funded institutions. Most negotiations center on two concerns: a company's desire to own the inventions as well as the data arising from research using company materials, and the company's desire to control or unduly delay publications. The Office of Biotechnology and Business Development’s role in the process is to ensure that MTAs are negotiated to be in compliance
with Einstein and NIH policy, as well as our legal obligations. It is our intent to protect the best interest of both Einstein and our faculty inventors in these negotiations.

All MTAs

All MTAs must be reviewed by the Office of Biotechnology and Business Development and should be directed to:

Belfer 908
Ext. 3357
Email: mta@einsteinmed.org

III.B. Process

III.B.1. Incoming Materials

For incoming materials, follow these steps:

1. Is the material in the proposed transfer hazardous?
   If yes, contact the Office of Biotechnology and Business Development for further direction. If no, proceed to #2.

2. Does the proposed transfer involve materials of human origin?
   If the answer to #2 is Yes, proceed to #3. Otherwise, skip to #4.

3. Fill out and sign the Incoming MTA Request Form and return a signed copy to the Office of Biotechnology and Business Development and proceed to #4.

4. Forward proposed MTA and company/institution contact information to the Office of Biotechnology and Business Development (Belfer Building, Room 908 or mta@einsteinmed.org). The Office of Biotechnology and Business Development will review the agreement to ensure the terms are acceptable. If they are not, the Office of Biotechnology and Business Development will contact the provider. Once the terms are agreeable, the Office of Biotechnology and Business Development will notify you and ask you to sign the agreement as "Recipient Scientist."

5. Forward a copy of the MTA signed by Recipient Scientist to the Office of Biotechnology and Business Development (Belfer Building, Room 908 or email to mta@einsteinmed.org). The Director of the Office of Biotechnology and Business Development will sign this agreement on behalf of the institution.

III.B.2. Outgoing Materials

For outgoing materials, follow these steps:

1. Is this request from a for-profit company?
   If the answer to #1 is Yes, proceed to #2. If the answer to #1 is No, proceed to #3.
2. Inform the Office of Biotechnology and Business Development of the proposed request and forward the company contact information to the Office of Biotechnology and Business Development (Belfer Building, Room 908 or mta@einsteinmed.org). Einstein provides research tools to industry and negotiates a non-exclusive license that typically includes a license fee. Income from such licenses is treated in accordance with the Official Policy on Intellectual Property and Licensing Agreements. The Office of Biotechnology and Business Development will contact the company to negotiate fair terms on such an agreement. Once the terms are agreed upon, the Office of Biotechnology and Business Development will notify you.

3. Academic and non-profit institutions that request material may be directed to download Einstein’s MTA directly from the Office of Biotechnology and Business Development website. If the terms are acceptable, the requestor should provide the requested information and return a clear copy of the MTA to Einstein signed by the Recipient Scientist and by an authorized representative of the Recipient Scientist’s institution via email to mta@einsteinmed.org. The Office of Biotechnology and Business Development will review the request, and the Director of the Office of Biotechnology and Business Development will sign and execute this agreement on behalf of the College. Once this is executed, the Office of Biotechnology and Business Development will notify you that you can transfer the materials referenced in the agreement.

III.B.3. Forms

Forms required for an MTA include:

- UBMTA, BIOT-FRM-2018-005 (form between academic/nonprofit entities)
- Incoming MTA/DUA Request Form (Internal Use), BIOT-FRM-2018-006 (form if incoming material has human origin)
- Outgoing MTA/DUA Request Form (Internal Use), BIOT-FRM-2018-007 (form if outgoing material has human origin)

IV. Definitions

None.

V. Effective Date

Effective as of: 16 July 2018

VI. Policy Management and Responsibilities

Einstein’s Office of Biotechnology and Business Development is the Responsible Office under this Policy. Einstein’s Executive Dean is the Responsible Executive for this Policy. Einstein’s Director of the Office of Biotechnology and Business Development is the Responsible Officer for the management of this Policy.

VII. Approved (or Revised)

Responsible Executive: [Signature]
Date: 7/18/2018