

## Science

# Materials Transfers

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### Scope

This policy applies to transfers of biological and other research materials to or from HHMI laboratories, including laboratories and shared resource facilities at HHMI’s Janelia Research Campus (“Janelia”). HHMI laboratory heads referred to in this policy include host institution-based laboratory heads (“Investigators”) and laboratory heads at Janelia.

### Background

The sharing of biological and other research materials among laboratories is an essential aspect of scientific citizenship. In that spirit, HHMI expects its laboratory heads, and all members of the academic research community, to make their published materials available for research use by other scientists and to handle requests for such materials expeditiously. Please see [HHMI's policy on Sharing Published Materials/Responsibilities of HHMI Authors](#) and [HHMI's policy on Research Tools](#).

## Policy

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### Overview

***Inbound MTAs.*** HHMI reviews in advance, and is a party to, materials transfer agreements for proposed transfers of research materials into HHMI laboratories (“Inbound MTAs”). The primary purpose of HHMI’s review of Inbound MTAs is to ensure that HHMI’s core scientific interests—the freedom of HHMI laboratory heads to publish their research and build upon and disseminate the results of their work—are respected.

***Outbound MTAs from Host-Based Laboratories.*** If a transfer of research materials from an HHMI laboratory is to a scientist at a nonprofit institution and HHMI has approved the form of the agreement that is used for the transfer, then HHMI does not need to review or be a party to the individual materials transfer agreement (“Outbound MTAs”). This policy identifies [several form agreements that are automatically approved by HHMI for transfers to nonprofit institutions](#). This policy also identifies types of changes that may be made in these form agreements by host institutions without approval by HHMI. Other changes in a form agreement require review and approval by HHMI. All Outbound MTAs for transfers of research materials from HHMI’s host-based laboratories to companies require review by HHMI.

***Outbound MTAs from Janelia.*** As a general rule, laboratories at HHMI’s Janelia Research Campus may transfer published research materials to laboratories at nonprofit institutions for research use

without an Outbound MTA, provided that internal records of transfers are kept. This policy explains when an Outbound MTA is to be used for transfers from Janelia. Janelia laboratories may wish to include with the materials, or in an email to the recipient U.S. laboratory head, a brief explanation of HHMI's [expectations for use of materials](#), even if no Outbound MTA is signed.

***Deposits in Nonprofit Repositories.*** HHMI encourages its laboratory heads to deposit research materials developed in their laboratories with nonprofit repositories for distribution to the scientific community. Absent unusual circumstances, HHMI does not require the use of any MTA or other agreement for such deposits. However, because host institutions require MTAs or other agreements in almost all cases, HHMI laboratory heads at host institutions should consult with their host institution technology transfer office before depositing materials in a repository for distribution. A Janelia laboratory head who has questions about depositing research materials in a nonprofit repository should consult with the Head of Innovation Management or the [HHMI attorney](#) responsible for the site.

***Sharing Software.*** HHMI encourages its laboratory heads to share on an open-source basis any software programs and tools they develop, while respecting and accommodating the rights of other institutions that may hold copyrights in, for example, subroutines or other components of the code to be distributed. Questions about sharing software that come up in host institution-based HHMI laboratories should be directed to the host institution technology transfer office; at Janelia, questions about sharing software should be directed to the Head of Innovation Management.

## **Policy Details**

### **Inbound MTAs: Transfers to HHMI Laboratories**

***No Inbound MTAs Required by HHMI.*** HHMI does not require transfers of biological or other research materials to HHMI laboratories to be documented by a written agreement. However, if the host institution requires that transfers of research materials to laboratories on its campus be documented, HHMI laboratories at that host institution are expected to comply with the host institution's policies.

***Expectations When No Inbound MTA Is Used.*** When HHMI laboratories receive materials without a written agreement, they are ordinarily expected to (1) use the materials only for research purposes, obtain permission from the original provider of the materials before passing the materials on to others, and (3) acknowledge the source of the materials in resulting publications and presentations.

In addition to obtaining permission from the original provider before distributing third-party research materials to other laboratories, HHMI laboratory heads may also need to obtain permission from the original provider before distributing modifications of third-party research materials that have been made by the HHMI laboratory. HHMI laboratory heads should consult with their host institution technology transfer office or, if at Janelia, the Head of Innovation Management, before distributing any such modifications. Laboratory heads must also be sure to obtain any necessary permission before using third-party materials or modifications of third-party materials in research

funded by a company or in which a company otherwise has rights.

***If Inbound MTA Is Required - Concerns.*** HHMI's primary concerns about Inbound MTAs for HHMI laboratories reflect its core scientific interests: ensuring that the provider of the materials (1) cannot control the content of or unduly restrict or delay publication of the research results and (2) does not obtain inappropriate access to or control over HHMI research or intellectual property in return for the materials.

***If Inbound MTA Is Required - Procedures.*** HHMI's Office of the General Counsel negotiates terms of Inbound MTAs for HHMI laboratories to receive materials from companies or nonprofit institutions. For an HHMI laboratory at a host institution, these negotiations are conducted jointly with the host institution's technology transfer office. All Inbound MTAs must be sent to the [HHMI MTA/License Review Attorney](#) responsible for the site for HHMI's review. HHMI laboratory heads at host institutions may also wish to send these agreements to their host institution technology transfer office for concurrent review, but HHMI will, in any event, coordinate its review with the host technology transfer office. Host-based laboratory heads may need to complete an intake form for their host institution; HHMI also has an optional [MTA questionnaire](#) that HHMI laboratory heads may complete using the [HHMI Investigator Portal](#), or, if at Janelia, may download from the Janelia intranet and forward upon completion to the Office of Innovation Management. HHMI laboratories may check on the status of their pending Inbound MTAs through the MTA Status Viewer portlet on HHMI's employee portal. HHMI laboratory heads should be aware that the terms of materials transfer agreements, and of other agreements covering their laboratory's research, may restrict their laboratory's ability to obtain materials from other sources for use in the same research.

### **Outbound MTAs: Transfers by HHMI Laboratories at Host Institutions**

***General Rule—Follow Host Institution Policies and Procedures.*** HHMI's host institutions in almost all cases require the use of an Outbound MTA where an HHMI laboratory is transferring research materials. To streamline the process of sharing materials, if HHMI has approved the form of agreement that will be used to transfer research materials from its laboratories at a host institution to other nonprofit institutions, then the host institution handles these transfers and HHMI does not need to (1) review, (2) be a party to, or (3) receive copies of the individual Outbound MTAs. Host institutions may also agree to certain changes in form agreements used for Outbound MTAs of HHMI laboratories at their site, without HHMI approval, as detailed below. HHMI's host-based laboratories must follow their host institution's policies and procedures when transferring materials.

***Acceptable Forms of Outbound MTA.*** For transfers to scientists at nonprofit institutions, the host institution may use the following form agreements without any further review, approval, or signature by HHMI:

- The Uniform Biological Materials Transfer Agreement (UBMTA) developed by the NIH in 1995. In addition, if all institutions that are parties to a transfer of materials have signed the UBMTA, the materials can be transferred under the terms of the UBMTA upon execution of an Implementing Letter for the particular transfer.

- The one-page Simple Letter Agreement developed by the NIH in 1999.
- The Materials Transfer Agreement for the Transfer of Organisms (MTA-TO) developed by the NIH in 2008.
- Any other form of Outbound MTA agreed upon by the host institution and HHMI.

***Acceptable Changes in Forms of Outbound MTA.*** For transfers to scientists at nonprofit institutions, the host institution may agree to the following types of changes in an Outbound MTA without any further approval by HHMI:

- Changes in or deletion of choice of law and forum provisions.
- Clarification of whether the use of materials in research sponsored by a company at the recipient institution is permitted research use.
- Clarification or additional provisions regarding the recipient institution's obligation to comply with applicable laws and regulations, including those relating to export controls.
- Deletion of an indemnification provision, or changes to reduce the scope or otherwise limit the application of an indemnification provision.
- Removal of the recipient scientist as a party to the agreement.

***If Host Institution Does Not Require Outbound MTA.*** In those rare instances where the host institution does not require HHMI laboratories at that site to use an Outbound MTA for particular transfers, the host-based laboratory head must follow any other host institution procedures for materials transfers. If the laboratory head has questions for HHMI about particular transfers, he or she should consult with the [HHMI MTA/License Review Attorney](#) responsible for the site.

***Outbound MTAs to Companies.*** Outbound MTAs to companies are reviewed by HHMI in the same way as proposed licenses to companies. Under HHMI's arrangements with its host institutions, HHMI reviews and comments on close-to-final drafts of licenses of reagents or other technology developed by its laboratories at the host institution to ensure that the licenses are consistent with [HHMI's policy on Host Institution Responsibilities for Intellectual Property Protection and Licensing](#), but HHMI is not a party to these agreements. The same procedure applies to Outbound MTAs to companies. However, if a host institution and HHMI agree on a form of Outbound MTA for the host to use for transfers to companies, the host may use that form without any need for HHMI review of each individual Outbound MTA.

## **Outbound MTAs: Transfers from HHMI's Janelia Research Campus**

### **Transfers to Scientists at Nonprofit Institutions**

***General Rule—No MTA Required for Transfers.*** HHMI does not require the use of a written materials transfer agreement when a Janelia laboratory or shared resources facility is transferring materials to a laboratory at a nonprofit institution for research use unless:

- The materials are hazardous;
- The materials are of human origin;
- The materials will be used by the recipient laboratory in humans;
- There are third-party restrictions on transfer of the materials; or
- There are other reasons to use a written agreement (for example, the materials are unpublished or the materials are being commercialized or there are plans to commercialize the materials in the future).

If any one of the above conditions is satisfied, a written materials transfer agreement may be required and the Janelia laboratory or shared resources facility must coordinate with the Head of Innovation Management prior to transferring the materials out of a Janelia laboratory. In addition, Office of Environmental Health and Safety/Compliance (“EH&S/C”) review is required prior to any transfer of materials to an institution outside of the United States.

***Expectations When No MTA Is Used.*** Even if no written agreement is signed for a transfer of materials from Janelia, the recipient laboratory head is expected to ensure that his or her group (1) uses the materials only for research purposes, (2) does not use the materials in humans, (3) obtains consent from the original provider of the materials before passing the materials on to others, and (4) acknowledges the source of the materials in resulting publications and presentations. Janelia laboratories may wish to include with the materials, or in an email to the recipient laboratory head, a brief explanation of these expectations. In addition, each Janelia laboratory is expected to keep records of all transfers of materials by the laboratory, regardless of whether a written agreement is signed.

***Hazardous Materials.*** When transferring hazardous materials, a Janelia laboratory or shared resources facility must use an Outbound MTA specifically approved by EH&S/C for the particular materials. Generally, hazardous materials include:

- Any chemical that is on the CDC list of hazardous chemical agents (<http://www.bt.cdc.gov/agent/agentlistchem.asp>).
- Any material that is on the CDC list of select agents and toxins (<http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20List.html>).
- Any other potential pathogens, including viral vectors such as vesicular stomatitis virus and vaccinia virus.

Janelia researchers should consult with EH&S/C if they have questions about whether specific materials should be considered hazardous.

***Materials of Human Origin or To Be Used in Humans.*** When transferring materials that are of human origin or that will be used by the requesting laboratory in humans, the transferring Janelia laboratory or shared resources facility must use an Outbound MTA specifically approved for the particular materials, and the transfer must be approved by both the Janelia Vice President &

Executive Director and the Chief Administrative Officer. For purposes of this policy, materials of human origin would not generally include fragments or sequences of human DNA not traceable to any particular individual; rather, "materials of human origin" means tissue, blood products, serum, DNA, and other biological materials or specimens that were obtained from (1) patients as part of their regular clinical care, but that were excess and would otherwise be discarded or archived, or (2) individuals participating in clinical research who have agreed to donate their specimens for research or for deposit in tissue repositories.

***Third-Party Restrictions or Other Reasons to Document Transfer.*** If the transfer of specific materials is subject to restrictions imposed by a third party, a special agreement to transfer those materials to others may be needed. Similarly, there may be other reasons to document transfers of specific materials, for example, if the materials have not yet been published, the materials are covered by a patent or patent application, or the materials are being commercialized or there is a plan to commercialize them in the future. Janelia researchers should consult with the Head of Innovation Management if they have any questions about third-party restrictions on transfer of materials or other circumstances that might warrant using a written agreement for a materials transfer.

#### **Transfers by Janelia Laboratories to Scientists at For-Profit Institutions**

A Janelia laboratory head who receives a request from a company for materials should forward the request to Head of Innovation Management before making any commitment to send the requested materials. If materials are provided to a company, the transfer must be done either under an Outbound MTA or a license agreement; either type of agreement must be approved by the Head of Innovation Management and the Chief Administrative Officer. The materials may not be transferred until the company has signed a written agreement approved by the Head of Innovation Management and the Chief Administrative Officer.

## **Contact**

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Questions about HHMI's policy on transfers of biological and other research materials to or from HHMI laboratories, including laboratories and shared resource facilities at HHMI's Janelia Research Campus, may be raised with the [HHMI MTA/License Review Attorney](#) responsible for the site, or at Janelia with the Head of Innovation Management or the [HHMI attorney](#) responsible for the site.

Managed by: Science and Janelia, jointly  
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