

Intellectual Property Protection and Licensing at Host Institutions

Scope

This policy applies to intellectual property developed in HHMI laboratories at host institutions.

This policy does not apply to intellectual property developed in HHMI laboratories at the Janelia Research Campus.

HHMI's Arrangements with Host Institutions

HHMI selects faculty and staff members at academic and research institutions across the United States ("host institutions") who become employees of HHMI (each, an "HHMI Laboratory Head") and participate in HHMI's Investigator Program or Freeman Hrabowski Scholars Program. Other personnel who conduct research in HHMI Laboratory Head laboratories at host institutions may also become HHMI employees. HHMI laboratory employees at host institutions, including HHMI Laboratory Heads, are subject to HHMI's Intellectual Property policy, which requires them to assign to HHMI their rights in inventions. This assignment obligation applies regardless of whether the host institution or third parties also provided funding in support of the project giving rise to the HHMI invention.

HHMI has a collaboration agreement with each of its host institutions that governs the relationship between HHMI and the host institution. Under the collaboration agreement in place for each HHMI host institution, HHMI agrees to assign to the host institution HHMI's rights in any intellectual property, whether or not patentable or copyrightable, resulting from the research of HHMI employees, including HHMI Laboratory Heads, who are covered by the collaboration agreement ("HHMI Inventions"). HHMI's assignment of rights in HHMI Inventions to the host institution is subject to a retained paid-up, non-exclusive, irrevocable, worldwide license to exercise any intellectual property rights with respect to the HHMI Invention for research purposes (the "HHMI Research Use License"). Unless HHMI agrees otherwise, the HHMI Research Use License is sublicensable to nonprofit and governmental entities. HHMI also retains the sublicensable right to use HHMI Inventions that are images for any purpose consistent with HHMI's mission ("Image Use License"). HHMI's procedures for assigning HHMI Inventions to its host institutions are explained in the HHMI Intellectual Property Guide for Host Institutions. A host institution may not assign or grant ownership rights in an HHMI Invention to any third party without HHMI's prior written approval. HHMI will not grant approval except in exceptional circumstances, and any such approval will not relieve the host institution of its obligations to HHMI under the HHMI – host institution collaboration agreement.

Patenting and Other Intellectual Property Protection

Under the HHMI – host institution collaboration agreement, the host institution is responsible for patenting or copyrighting HHMI Inventions, subject to certain HHMI requirements, including requirements designed to ensure that HHMI Inventions are made available for the benefit of the public, consistent with HHMI's mission of conducting scientific research in the public interest. This means that, generally, the host institution will make decisions about pursuing, maintaining, and enforcing patent, copyright, or other intellectual property rights in HHMI Inventions arising at its site.

The collaboration agreement specifies whether, and if so, the extent to which reasonable costs associated with obtaining, maintaining, and enforcing intellectual property protection, and commercializing HHMI Inventions, are borne solely by the host institution or shared with HHMI. The collaboration agreement also specifies arrangements for sharing income generated by HHMI Inventions among HHMI inventors, HHMI, and the host institution.

Licensing

In General. Under the HHMI – host collaboration agreement, the host institution also is responsible for licensing or distributing HHMI Inventions, subject to various other provisions of the agreement. This means that, generally, the host institution will handle selecting one or more appropriate licensees and negotiating licenses to HHMI Inventions consistent with HHMI policies, and also must ensure that certain provisions for HHMI's benefit are included in any license of an HHMI Invention. A brief discussion of the relevant policies and the required license provisions for any license of an HHMI Invention is provided below; additional information is available in the HHMI Intellectual Property Guide for Host Institutions. Host institutions should contact the HHMI MTA/License Review Attorney responsible for the site with any questions about what provisions for the benefit of HHMI should be included in any license of an HHMI Invention to a nonprofit organization.

HHMI generally will defer to the host institution on license provisions, other than HHMI's required provisions, as long as the license terms are otherwise consistent with HHMI policies. For example, HHMI will defer to the host institution on the appropriate amount and timing of payment of consideration for a license, but will object to provisions obligating HHMI laboratories to disclose or discuss future research results with a licensee before they are published or otherwise become generally available.

Consistent with HHMI's commitment to making the results of its research available for public benefit, HHMI expects that in most cases an HHMI Invention will be licensed to a company only in expectation of, or following, public disclosure of the HHMI Invention, for example, in a scientific talk or presentation, in a scholarly publication, or in a filed patent application.

HHMI Review. Unless HHMI has specifically agreed to other arrangements in writing, consistent with the HHMI – host collaboration agreement, host institutions must provide a close-to-final draft license of any HHMI Invention prior to execution for HHMI's review to confirm that the required provisions have been included and to ensure that the license otherwise complies with HHMI policies; the draft license should be sent to <u>ip@hhmi.org</u>. HHMI is not a party to, and does not sign,

licenses of HHMI Inventions. However, following its review, HHMI will confirm to the host institution that the license complies with HHMI's policies and contains the required provisions. If any substantive changes are made to the license after the host institution has received HHMI's confirmation, the host institution should send the revised license to HHMI before it is executed so that HHMI can confirm that the revised license continues to comply with HHMI's policies. Host institutions also are expected to email a copy of the final license after it has been signed by all parties to ip@hhmi.org.

Inter-Institutional Agreements. HHMI requires that its host institutions take the lead on commercialization of HHMI Inventions. However, in some circumstances, for example when another institution has made an inventive contribution toward an HHMI Invention a host institution may enter into an inter-institutional agreement ("IIA") with other nonprofit organizations or government agencies that have an interest in such an HHMI Invention, and the IIA may provide that an organization or agency other than the host will take the lead on commercialization. The IIA must provide that the lead organization or agency will include HHMI's required license provisions in any license of the HHMI Invention and permit the host institution to submit a close-to-final draft of any such license to HHMI for review prior to execution to confirm HHMI's required provisions are in the license and to otherwise ensure that such license is consistent with HHMI policies. HHMI has developed Uniform Provisions for Inter-Institutional Agreements that include HHMI's required terms for IIAs. The host institution is required to provide a close-to-final draft of the IIA to HHMI for review to allow HHMI to confirm that HHMI's Uniform Provisions for Inter-Institutional Agreements are incorporated into the IIA and that the IIA otherwise complies with HHMI's policies.

Confidentiality. Unless otherwise required by law, it is HHMI's practice to maintain in confidence the information included in disclosures of and patent applications for HHMI Inventions, and any confidential information provided to HHMI by the host institution about the patenting or licensing of such inventions, until the information becomes public or the host institution informs HHMI that the information need not be treated as confidential. If HHMI receives a subpoena or other legal request to provide such information to a third party, to the extent possible, HHMI will consult with the host institution before responding.

HHMI Policies Affecting Licenses

Research Tools and Software. Consistent with the NIH guidelines on obtaining and disseminating research resources, HHMI expects its host institutions to ensure that unique research resources arising in HHMI laboratories are made available to the scientific research community on reasonable terms and in a manner that enhances their widespread availability. HHMI research tools must be made available to scientists at academic and nonprofit organizations either for free or at a low cost, and with no reach-through rights or claims of ownership extending beyond the original materials, progeny, and unmodified derivatives. HHMI recognizes that in some cases, broad distribution of an HHMI research tool may require obtaining rights from third parties who have rights in components of the research tool or techniques used to make the research tool, or combining the HHMI research tool with other resources in which third parties have proprietary rights. HHMI expects that the host institution will work with the third parties in an effort to allow availability of the tool in a manner consistent with this policy. When a host institution licenses on an exclusive basis a research tool

developed in an HHMI laboratory, the host must retain rights to make the research tool available to the academic and nonprofit research community on terms that are consistent with HHMI policy and expressly reference HHMI's retained research use rights in the license agreement.

HHMI presumes that most software developed in its laboratories ("HHMI software") will be useful as a research tool. As a consequence, HHMI strongly encourages its host institutions and HHMI Laboratory Heads to provide HHMI software to academic and nonprofit laboratories for free or at minimal cost, preferably by making the source code available in a manner that permits the recipient to modify it for non-commercial purposes. Because the need for substantial investment in development costs, which often justifies the grant of exclusive licenses in the biotech and pharmaceutical industries, is much reduced in the software area, HHMI expects that exclusive licenses of HHMI software to a company will be rare. If there is such a license, HHMI expects that the software will be made available to scientists at academic and nonprofit organizations at no or low cost and without reach-through rights or other restrictive terms. In addition, if a host institution proposes licensing HHMI software exclusively to a company, HHMI expects host institutions to consider whether improvements made in the software by the licensee company should also be made available for research purposes to scientists at academic and nonprofit organizations at a reasonable cost and without reach-through rights or other restrictive terms.

Sharing Published Materials/Responsibilities of HHMI Authors. Under HHMI's sharing policy, HHMI Laboratory Heads are expected to make data, software, and tangible research materials that are integral to their publications available for use by other academic and nonprofit scientists. When a host institution proposes to license on an exclusive basis data, software, or tangible research materials that have been published by an HHMI Laboratory Head, HHMI generally will require the host institution to show in advance how the HHMI Laboratory Head will be able to fulfill their obligations under HHMI's sharing policy. If a host institution proposes to enter into a license that includes a form of material transfer agreement (MTA) that is required to be used in transferring materials covered by the license, the form MTA also must be provided to HHMI for review to ensure that the terms are consistent with HHMI's policies, including HHMI's Materials Transfer policy.

Research Funding in Connection with Licenses. HHMI recognizes that a commercial licensee may provide research funding to an academic laboratory in connection with a license of intellectual property developed in that laboratory. Any such funding in connection with a license of intellectual property developed in an HHMI laboratory is subject to HHMI's Company Funding Arrangements — Host-based Sites policy.

Supply Provisions. Because HHMI laboratories should not serve as production facilities for research materials needed by companies, a commercial license of research materials should not call for multiple shipments of materials from the HHMI laboratory.

HHMI Required Provisions in Licenses

Every license of an HHMI Invention must include provisions that conform to the following requirements.

<u>Scope of Rights</u>. The scope of rights granted under a license must be limited to technology that is already in being.

Retained Research License. Exclusive licenses must reflect the HHMI Research Use License. HHMI considers its retained research license to cover use of licensed technology in HHMI laboratories in any research, including research sponsored by commercial entities and research collaborations with commercial entities.

Indemnification and Insurance. HHMI requires that it, and its trustees, officers, employees, and agents, be indemnified and held harmless by licensees and sublicensees against any claims, liabilities, and other costs (including reasonable attorneys' fees) based on or arising out of the license agreement or, if the host institution is transferring tangible research materials to the licensee, the use of such material by any recipient in the licensee's chain of possession. If a licensee asks for notice and settlement rights, HHMI may ask for certain limitations on those rights. HHMI also asks for the same insurance protection as the host institution receives under the license, but does not need to receive certificates of insurance from the licensee.

<u>Third-party Beneficiary Status</u>. The license must describe HHMI's status and rights as a third-party beneficiary.

<u>Survival Terms</u>. The HHMI indemnification and third-party beneficiary provisions must survive termination or expiration of the license.

<u>Sublicenses.</u> A license agreement may allow the licensee to sublicense, but only if the sublicense is subject to a written agreement that contains obligations, terms and conditions in favor of HHMI and its indemnitees that are substantially similar to those in the license agreement, including those regarding indemnification, insurance and HHMI's third party beneficiary status.

<u>Arbitration</u>. A license to HHMI intellectual property may provide that disputes unrelated to HHMI's rights are subject to binding arbitration, however the provisions of a license governing HHMI's rights must not be subject to binding arbitration.

Royalty and Expense Sharing

Royalty Sharing with HHMI Inventors. The HHMI – host collaboration agreement provides that the share of royalty income from licensing (which includes royalties, up-front payments, maintenance, milestone, and other fees) to which an HHMI inventor is entitled is determined under their host institution's royalty-sharing policies, and those policies are to be applied to inventors who are employees of HHMI in the same manner and to the same extent as if the inventors were employees of the host institution. In general, HHMI expects the host to recoup its and HHMI's out-of-pocket costs, if applicable, and reimburse HHMI, before it makes any distributions of income to inventors, whether or not they are HHMI employees.

Royalty and Expense Sharing with HHMI. HHMI and its host institutions share royalty income from licensing HHMI Inventions (including royalties, up-front payments, maintenance, milestone, and other fees) and the costs of commercializing HHMI Inventions as provided in the applicable HHMI – host collaboration agreement.

HHMI's share of the costs of protecting intellectual property rights in HHMI Inventions should be invoiced to HHMI no less frequently than twice per calendar year. If bills are presented more than one (1) year after the expenses were incurred, HHMI generally will not pay them.

HHMI expects that the host institution will distribute to HHMI its share of royalty income from a license (as determined under the HHMI – host collaboration agreement) as promptly as possible after the host institution receives payment from the licensee, consistent with the host institution's standard schedule for making royalty distributions (e.g., quarterly).

HHMI's share of royalty income is payable to HHMI as an institution and is not to be returned either in whole or in part to the HHMI employee/inventor's laboratory without HHMI's express approval. If a host institution's policy provides for a portion of royalties to be directed to the inventor's laboratory, this amount may be paid to the laboratory from the host institution's institutional share; HHMI's institutional share is not reduced.

HHMI generally treats any consideration paid by a licensee to a host institution in connection with the licensing of an HHMI Invention, regardless of what the payment is called, as royalty income subject to institutional sharing. However, some payments may not be consideration for the license, such as funds paid to support additional research, as noted above under Research Funding in Connection with Licenses. In addition, as noted below, HHMI may not claim a share of certain license fees that total \$5,000 or less.

Host institutions may be asked by other research funders, such as nonprofit foundations, to share with them a portion of net royalties from commercialization of the results of the funded research. For HHMI Inventions, host institutions may fund this type of royalty-sharing from their own institutional share of IP revenue; HHMI's institutional share is not reduced, unless HHMI specifically agrees otherwise.

Unpatented Inventions. A host institution may wish to license HHMI Inventions that have been publicly disclosed but that have not been and will not be patented. In general, if the license fee for such an HHMI Invention is \$5,000 or less, and the host institution intends to direct the full amount to the laboratory in which the HHMI Invention was developed, HHMI will not object and will not claim a share of the fee. As a general rule, however, a fee in excess of \$5,000 for an HHMI Invention will be subject to the income-sharing policies described above, regardless of whether the transaction is cast as a license, material transfer, gift, bailment, or otherwise. In addition, HHMI reserves the right to have the income-sharing policies described above apply in cases where a host institution establishes a program of licensing HHMI Inventions at a fee of \$5,000 or less per license, and proposes to direct the full amount of each license to the laboratory in which the HHMI Invention was developed.

Transfer Processing Fees. A host institution may impose a modest processing fee on transfers of materials from the laboratories of HHMI Laboratory Heads. Provided that the fee is retained by the laboratory or a host facility that paid costs that the fees are intended to cover, these processing fees are considered to be in the nature of an administrative charge rather than royalty income. Generally, host institution processing fees of more than \$5,000 per transfer are not considered modest.

Management Fees. The HHMI – host collaboration agreement limits the amount of management fees (i.e., fees for licensing and management of patents, patent applications, and other intellectual property rights in HHMI Inventions) that host institutions or their affiliates may deduct from the total royalty income relating to an HHMI Invention. Host institutions may deduct from the total royalty income received in connection with commercialization of an HHMI Invention a reasonable management fee as provided in the applicable HHMI – host institution collaboration agreement. The deduction for a reasonable management fee applies on an invention-by-invention basis, and not on a license-by-license basis, which means that the limitation in the HHMI – host collaboration agreement applies to an HHMI Invention once regardless of how many times it is licensed. If the HHMI Invention is subject to an IIA that provides for an organization or agency other than the host to take the lead on commercialization, HHMI will permit the lead organization or agency to take a reasonable management fee. Any such management fee must be specified in an IIA approved by HHMI.

Royalties in the Form of Securities. Although HHMI recognizes that a host institution may accept securities as consideration for a license, to avoid the possible conflict of interest (actual or apparent) that can arise from holding stock in a licensee company, HHMI does not accept its share of licensing consideration in the form of securities. Instead, if a host institution accepts securities as consideration for a license, it should notify HHMI of the fact, retain all of the securities, and distribute to HHMI its share of any cash proceeds after receipt of those proceeds (for example, cash dividends and sale proceeds). Specifically, HHMI's procedures regarding the securities held by the host institution and attributable to HHMI under the royalty sharing arrangements noted above ("HHMI Securities") are as follows:

- The HHMI Securities are issued to and held by the host institution, which notifies HHMI of its acceptance of the HHMI Securities. At no time does HHMI have custody or voting rights of the HHMI Securities, and HHMI has no role, formal or informal, in deciding whether or when to dispose of the HHMI Securities.
- The host institution decides whether and when to dispose of the HHMI Securities according to its own internal rules and in the context of its own investment strategy.
- HHMI has an income interest in any cash arising from the HHMI Securities, whether in the
 form of dividends, distributions or sale proceeds. The host institution notifies HHMI of any
 dividend, distribution, or sale and promptly distributes the cash to HHMI.

Abandonment of Inventions/Ceasing Commercialization Efforts

If a host institution decides to abandon all efforts to protect, maintain, or commercialize intellectual property rights in an HHMI Invention, the host institution should notify HHMI by emailing ip@hhmi.org to provide an opportunity for HHMI to assert rights in the HHMI Invention. HHMI ordinarily will decline to assert rights, and in those instances will provide written confirmation to that effect on request.

If a host institution proposes to release an HHMI Invention to the inventor(s), the host institution should also notify HHMI by emailing ip@hhmi.org to provide an opportunity for HHMI to assert rights in the HHMI Invention. HHMI will ordinarily decline to assert rights beyond the HHMI Research Use License and Image Use License, which HHMI retains with respect to all HHMI

Inventions. HHMI also asks that HHMI's indemnification language be included in any licenses of the HHMI Invention by the inventor(s). In addition, if the host institution is receiving reimbursement and a share of any future income, HHMI also will expect to receive reimbursement and a share of future income in accordance with the terms of the HHMI – host collaboration agreement. If a host institution proposes to release an HHMI Invention to any third party other than the inventor(s), the host institution should contact the HHMI MTA/License Review Attorney. Please note that a host institution may not release an HHMI Invention to a third party without HHMI's prior written approval.

Related Procedures, Forms, and Policies

- Intellectual Property Policy
- Intellectual Property Guide for Host Institutions
- Sharing Published Materials/Responsibilities of HHMI Authors Policy
- Materials Transfer Policy
- Company Funding Arrangements Host-based Sites Policy

Contact

Questions about intellectual property developed in HHMI laboratories at host institutions may be raised with the HHMI MTA/License Review Attorney responsible for the site.

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