Intellectual Property and Licensing Policies

Licensing by Host Institutions to Companies (SC-610)

Scope

This policy applies to the licensing to companies of intellectual property developed in HHMI laboratories at host institutions. Under HHMI's collaborative arrangements with its host institutions, the host institution is responsible for efforts to commercialize intellectual property developed in HHMI laboratories at the site.

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

Policy

Ownership and Assignment

HHMI has an interest in any invention or discovery as to which at least one inventor is an HHMI employee ("HHMI Invention"). Under <u>HHMI's Intellectual Property policy</u>, HHMI laboratory employees are required to assign rights in any HHMI Invention to HHMI. HHMI in turn assigns rights in the HHMI Invention to the host institution, subject to an HHMI-wide research-use license. The procedures for these assignments are explained in the <u>HHMI Intellectual Property</u> <u>Guide for Host Institutions</u>.

Patenting and Other Intellectual Property Protection

In General. Under HHMI's collaborative arrangements with its host institutions, the host institution generally has responsibility for making decisions about pursuing, maintaining, and enforcing patent, copyright or other intellectual property rights in HHMI Inventions arising at the site.

Expense Sharing. HHMI shares the reasonable out-of-pocket costs of protecting intellectual property rights in HHMI Inventions, such as patent attorneys' fees and filing fees. These costs should be invoiced to HHMI no less frequently than twice per calendar year. If bills are presented more than one year after the expenses were incurred, HHMI will generally not pay them.

Indirect Costs. HHMI does not pay indirect costs with respect to its research activities at host institutions. Consistent with that operating principle, HHMI generally does not pay management fees to a host institution or its affiliates in connection with the commercialization of intellectual property developed at that host institution. Affiliates include, for example, foundations set up to manage commercialization of technology developed at the host institution.

Licensing

In General. HHMI is not a party to, and does not sign, licenses of HHMI Inventions. Under HHMI's collaborative arrangements with its host institutions, the host institution generally has responsibility for negotiating, implementing, and overseeing such licenses in a manner consistent with HHMI policies. For example, each host institution is under an obligation to include certain provisions for HHMI's benefit in any license of an HHMI Invention to a company. An explanation of the required license provisions is below. More information about these provisions is available in the HHMI Intellectual Property Guide for Host Institutions, which is posted on HHMI's research policies page. Host institutions may also contact the MTA/License Review Attorney for assistance.

HHMI generally will defer to the host institution on license provisions other than HHMI's required provisions as long as they 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 may object to provisions obligating HHMI laboratories to disclose to or discuss with a licensee future research results before they are published or otherwise become generally available.

Expense Sharing. HHMI shares the reasonable out-of-pocket costs of commercializing HHMI Inventions, such as outside counsel fees for negotiating licenses. These costs should be invoiced to HHMI no less frequently than twice per calendar year. If bills are presented more than one year after the expenses were incurred, HHMI will generally not pay them.

HHMI Review. Unless other arrangements have been specifically agreed to with HHMI, HHMI expects host institutions to provide to the <u>MTA/License Review Attorney assigned to their site</u> a close-to-final draft license of any HHMI Invention to a company prior to execution, so that it can be reviewed to ensure that the required provisions have been included and that it otherwise complies with HHMI policies. Host institutions are also expected to provide to the <u>HHMI Host</u> <u>Liaison</u> a copy of the final license after it has been signed by all parties.

Inter-Institutional Agreements. A host institution may enter into an inter-institutional agreement ("IIA") with other non-profit organizations or government agencies that have an interest in an HHMI Invention, and the IIA may provide that an organization or agency other than the host will take the lead on commercialization. In this situation, the IIA must provide that the lead organization or agency will include HHMI's required license provisions in any commercial license of the HHMI Invention and otherwise ensure that such licenses are consistent with HHMI policies. HHMI will review a close-to-final draft of the IIA to confirm that this is the case.

Although HHMI does not pay management fees to its host institutions or their affiliates, HHMI recognizes that host institutions may not be able to prevent other organizations from assessing a management fee in situations where the other organizations are taking the lead on commercializing technology. Accordingly, HHMI will not object to an IIA providing for a

reasonable management fee for a lead organization or agency other than the host institution at which the technology was developed or an affiliate of that host institution.

HHMI Research Tools Policy. Under <u>HHMI's policy on research tools</u>, which is 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. When a host institution proposes to license on an exclusive basis a research tool developed in an HHMI laboratory, HHMI generally will require the host institution to show how the research tool will be made available to the scientific research community on terms that are consistent with HHMI policy.

HHMI Policy on Sharing Publication-Related Materials, Data, and Software. Under HHMI's sharing policy, HHMI Investigators are expected to make materials, data and databases, and software that are integral to their publications available for use by other scientists. When a host institution proposes to license on an exclusive basis materials, data or databases, or software that have been published by an HHMI Investigator, HHMI generally will require the host institution to show how the Investigator will be able to fulfill his or her obligations under HHMI's sharing policy.

Required Provisions. Every license of an HHMI Invention must include provisions that conform with the following requirements.

<u>Scope of Rights</u>. In general, HHMI does not review the financial terms of the license, but HHMI does require that the scope of rights in future technology granted under the license not go beyond that needed to ensure that the licensee will be in a position to commercialize an HHMI Invention that already is in being.

<u>Retained Research License</u>. Licenses must reflect the fact that HHMI retains an institution-wide, paid-up, non-exclusive irrevocable license to such intellectual property for research purposes. Please note that HHMI considers this retained research license to cover use of licensed technology in HHMI laboratories in collaboration with commercial entities.

<u>Indemnification and Insurance</u>. 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. 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 of the license.

<u>Arbitration</u>. Any dispute over the HHMI provisions of a license must not be subject to binding arbitration.

Royalty Sharing with HHMI Inventors. The share of license income (including royalties, maintenance, milestone, and other fees) to which an HHMI inventor is entitled is determined under his or her host institution's royalty-sharing policies. In general, HHMI expects the host to recoup its and HHMI's out-of-pocket costs, and reimburse HHMI, before it makes any distributions of income to inventors.

Royalty Sharing with HHMI. HHMI shares in the net income from licensing of an HHMI Invention in the same proportion as it shares in expenses related to the invention. HHMI's share of license income is calculated after the distribution of the inventors' shares, and unless expressly otherwise agreed, is not reduced by any management fee charged by the institution. HHMI expects that the host institution will distribute to HHMI its share of net income from a license as promptly as possible after the host institution receives payment from the licensee, given the host institution's standard schedule for making royalty distributions (e.g., quarterly).

HHMI's share of license income is payable to HHMI as an institution and generally should not be returned either in whole or in part to the inventor's laboratory. HHMI's policy does not affect the implementation of the host institution's policy, which may provide for a portion of royalties from the host's share of license income to be directed to the inventor's laboratory.

HHMI generally regards any consideration paid by a licensee to a host institution in connection with the licensing of an HHMI Invention as license income subject to institutional sharing. This generally does not apply to payments that are not consideration for the license, however, such as support for additional research that is provided by a licensee. In addition, as noted below, there is an exception where a laboratory charges a fee of \$5,000 or less in connection with a license of unpatented materials.

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 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. Accordingly, HHMI at no time has custody or voting rights of the securities, and HHMI has no role, formal or informal, in deciding whether or when to dispose of the 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.

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 policy on <u>Company</u> <u>Funding Arrangements – Host-based Sites (SC-350)</u>. In addition, a license to existing technology cannot grant a company rights in the results of research to be conducted under a sponsored research or other agreement. Rather, any rights granted to a company in connection with future research in an HHMI laboratory must be set forth in the research agreement and must be consistent with HHMI's policy on <u>Company Funding Arrangements – Host-based Sites (SC-350</u>).

Licensing of Unpatented Inventions. A host institution may wish to commercialize HHMI Inventions that have not been and will not be patented. In general, if the fee imposed for the transfer of 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 claim no 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 assignment and income-sharing policies described here, 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 assignment and income-sharing policies described here apply in cases where a host institution establishes a program of licensing HHMI Inventions at a fee of \$5,000 or less per license, even if the full amount is directed to the laboratory in which the HHMI Invention was developed.

As provided in HHMI's policy on <u>Sharing of Publication-Related Materials</u>, <u>Data and Software</u>, HHMI investigators may at their discretion request or require that scientists requesting materials reimburse the providing HHMI investigator's laboratory for costs directly associated with filling the request, such as postage, packaging, and cost of reproducing the materials (but not overhead, profit, or a pro rata share of the costs of research). Similarly, a host institution may impose a modest processing fee on transfers of materials from the laboratories of HHMI investigators. 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 licensing revenue. Host institution processing fees of more than \$5,000 per transfer are not considered modest.

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

March-in Rights. Under its collaborative arrangements with host institutions, HHMI retains march-in rights with respect to HHMI Inventions. In general, this retained right permits HHMI to require licensing or distribution of an HHMI Invention where necessary to meet the needs of public health or safety if, in HHMI's judgment, the host institution has not taken effective steps within a reasonable time to achieve practical application of an HHMI Invention. HHMI will not exercise its march-in rights unless it is clear that the host institution has not made a good-faith effort to license an HHMI Invention to an appropriate licensee.

Confidentiality. Unless otherwise required by law, HHMI will 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 the information to a third party, HHMI will consult with the host institution before responding.

Licensing to Start-up Companies. An HHMI Investigator who is considering participating in the formation of a start-up company should review <u>HHMI's Start-Up Handbook</u> and contact the HHMI attorney or scientific officer responsible for his or her site at the earliest possible opportunity to discuss the proposed arrangements. Investigators and host institutions should be aware that HHMI consulting policies place restrictions on the nature and scope of services that an HHMI investigator can perform for a company as well as the total equity an Investigator can own in the company. These policies should be taken into account in structuring any transactions relating to a start-up company that involves an HHMI Investigator or an HHMI Invention. HHMI's consulting policies and Start-Up Handbook are posted on the research policies webpage (http://www.hhmi.org/about/policies).

Abandonment of Inventions

If a host institution decides to abandon all efforts to commercialize an HHMI Invention, the host institution should notify the <u>HHMI Host Liaison</u> to provide an opportunity for HHMI to assert rights in the HHMI Invention. HHMI will ordinarily decline to assert rights, and 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 the HHMI attorney assigned to their site to provide an opportunity for HHMI to assert rights in the HHMI Invention. HHMI will ordinarily decline to assert rights beyond the non-exclusive, royalty-free, perpetual license to use the Invention in its own research, which HHMI retains with respect to all Inventions. HHMI also asks that HHMI's indemnification language be included in any licenses of the Invention by the inventor(s). In addition, if the host institution is receiving reimbursement and a share of any future income, HHMI will also expect to receive reimbursement and a share of future income.

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