

Science Policies

Human Subjects Research (SC-800)

Scope

This policy applies to all HHMI Investigators and Early Career Scientists (collectively “Investigators”), and all HHMI employees in HHMI Investigators’ laboratories, who are engaged in or are contemplating becoming engaged in human subjects research. Human subjects research refers to any research involving human subjects, including research using human tissues or materials derived from human tissues, as well as research involving individuals who have consented to participate in an observational study or clinical trial.

The term “human subject” means a living individual about whom an investigator (whether professional or student) in the course of conducting research obtains: (1) data through intervention or interaction with the individual, or (2) identifiable private information.

The term “host-based laboratory” is used in this policy to refer to HHMI laboratories at host institutions. HHMI laboratories at Janelia Research Campus (“Janelia”) are not within the scope of this policy, as no human subjects research is conducted or contemplated at Janelia. Any proposal by a Janelia laboratory head to engage in human subjects research at Janelia must be reviewed and approved in advance by the President of HHMI, the Vice President and Executive Director of Janelia, and HHMI’s Vice President and General Counsel. Approval will be given only if arrangements are made to ensure application of the same high ethical standards and review and oversight mechanisms as this policy requires of similar host-based human subjects research.

The term “clinical trial” is used in this policy to refer to research that tests on humans a new drug, biologic, or medical device, or tests on humans an existing drug, biologic, or medical device for a new indication (e.g., to treat an additional disease), new mode of delivery (e.g., nasal inhalant versus oral tablet), a new patient population (e.g., pediatric versus adults), or a new dosing regimen (including a new combination of drugs). Generally, the purpose of a clinical trial is to gather data from humans with the intention of submitting those data to a regulatory agency, such as the Food and Drug Administration, in support of some form of regulatory approval or clearance.

The term “observational study” is used in this policy to refer to research involving humans that does not aim to test a drug, biologic, medical device, or other intervention. Observational studies may include the collection of clinical data from target patient populations in order to better define the natural history of a disease process, including its modification in response to routine clinical care. Other examples may include genetic studies, studies focused on elucidation of pathogenetic mechanisms, and epidemiological studies (prospective or retrospective). Observational studies may or may not be associated with a clinical trial.

Policy

In General

HHMI recognizes the importance of protecting the rights, well-being, and personal privacy of individuals participating in human subjects research. HHMI expects all employees who are engaged in human subjects research to adhere to the highest ethical standards in conducting the research. These standards include, for example, the principles described in the Belmont Report and, where applicable, the privacy and data security provisions of the Health Insurance Portability and Accountability Act (“HIPAA”) and its implementing regulations, as well as all other applicable laws, regulations, and institutional policies.

HHMI’s host institutions are responsible for review, oversight and implementation of human subjects research of HHMI’s host-based laboratories. Accordingly, any HHMI employee in a host-based laboratory who is engaged in or is contemplating becoming engaged in human subjects research must comply with all requirements and guidance of the relevant host institution relating to human subjects research. This is the case regardless of how the research in question is or will be funded.

Specific responsibilities of the host institution include provision of any Institutional Review Board (IRB) review and other institutional oversight that is required by applicable laws in connection with the research of HHMI laboratories at that host institution, and treatment of HHMI employees at that host institution as part of the host institution’s workforce for purposes of HIPAA and other federal and state medical privacy laws.

Human Subjects Research that is not a Clinical Trial

An Investigator is free to use his or her HHMI budget or funding from other nonprofit sources to cover the costs of human subjects research that is not a clinical trial, without any prior discussion with or approval from HHMI, provided that any required host institution IRB approval for the study has been obtained. This includes making payments to collaborators in connection with collecting patient data or samples in connection with an observational study. Payment requests submitted to HHMI or entered into HHMI’s financial systems must not include information about medical conditions or treatment of specific individuals.

An Investigator may use funding from commercial sources in support of human subjects research that is not a clinical trial provided that the proposal meets all of the requirements of HHMI’s policy on [Company Funding Arrangements-Host-based Sites \(SC-350\)](#).

In addition, if an Investigator is collaborating with colleagues at other non-profit or academic institutions or for-profit companies on human subjects research that is not a clinical trial, the arrangement must also meet the requirements of HHMI’s policy on [Research Collaborations \(SC-340\)](#).

Human Subjects Research that is a Clinical Trial

Sponsorship in General: Investigators may serve as principal investigators and co-investigators on clinical trials sponsored by government agencies or other organizations, including companies. Other HHMI employees may serve as principal investigators and co-investigators on clinical trials only with the advance written consent of HHMI. Because of the extensive compliance responsibilities that must be assumed by the sponsor of a clinical trial, Investigators and other HHMI employees are strongly discouraged from serving as a sponsor of a clinical trial, and may only do this with the advance written consent of HHMI and their host institution. HHMI itself does not sponsor clinical trials.

Use of HHMI Budget for Clinical Trial Costs: An Investigator may use his or her HHMI budget to cover the costs of laboratory research activities in connection with a clinical trial, provided that any required host institution IRB approval for the trial has been obtained. An Investigator may also use his or her HHMI budget to reimburse the host institution for administrative costs in connection with a clinical trial, such as the costs of engaging an outside firm to monitor the conduct of a trial sponsored by the host institution. However, an Investigator may not use his or her HHMI budget to pay for patient care costs in connection with a clinical trial (for example, the cost of medications) without prior approval from HHMI. HHMI approval will depend on the specific circumstances, and will be contingent in all cases on host institution IRB approval. If HHMI funds are used to pay for administrative or patient care costs in connection with a clinical trial, the Investigator is responsible for making it clear to the host institution and other organizations involved with the trial that HHMI is not taking on the role of sponsor of the trial. Payment requests submitted to HHMI or entered into HHMI's financial systems must not include information about medical conditions or treatment of specific individuals.

HHMI Employment of Clinical Personnel: HHMI does not employ personnel (other than Investigators) whose duties involve the administration of medication or medical treatments to patients. These individuals should be employed by the host institution, as host institution employment will generally facilitate obtaining hospital and clinic access and medical professional liability insurance. However, an Investigator may use funds from his or her HHMI budget to make payments to the host institution to cover all or a part of the salary and benefits of laboratory personnel whose responsibilities include administering medication or medical treatments to patients. Investigators who wish to do this should discuss their situation with their local Manager of Administrative Services, who will work with HHMI headquarters staff and the host institution to set up a formal agreement under which funding can be provided. With advance approval from the Science Department, an Investigator may hire, as HHMI employees, laboratory personnel whose duties do not involve the administration of medication or medical treatments but do involve other patient-related activities, such as obtaining data and blood or other tissue samples from patients, or counseling patients.

HHMI also does not employ personnel whose main duties are to ensure compliance with FDA or other regulatory requirements (e.g., clinical coordinators). These personnel may also be funded through payments to the host institution from the Investigator's budget; Investigators wishing to set up these arrangements should discuss the situation with their local Manager of Administrative Services.

Company Funding: An Investigator may be involved in clinical trials that are funded by a company, provided that all of the following conditions are met:

- Company funds will not be used to pay any part of the salary or professional time of the Investigator or any other research personnel in the laboratory (whether or not employed by HHMI). However, company funds may be used to pay for the costs of non-HHMI personnel whose main duties are to ensure compliance with FDA and other regulatory requirements (e.g., a clinical coordinator), and non-HHMI personnel responsible for administering the test article (drug, biologic, or device) and monitoring the subjects (e.g., a hospital physician or clinical nurse).
- The agreement covering the clinical trial will allow publication of the results of the trial on terms that HHMI considers acceptable in accordance with customary academic standards.
- The agreement covering the clinical trial will not interfere with the Investigator's ability to pursue his or her own research program effectively.

Review of Agreements with Trial Sponsor: HHMI is not a party to and does not typically review clinical trial agreements between the host institution and sponsoring government agencies or non-profits. HHMI is also not a party to clinical trial agreements between the host institution and company sponsors, but does review these agreements when they are in close-to-final form to determine whether they are consistent with the above requirements. The host institution is responsible for sending to HHMI for review any proposed agreement under which a company will sponsor a clinical trial with which an Investigator at that host is involved.

Service as Physician of Record for Patients Enrolled in a Trial: In some cases, an Investigator may serve as physician of record for patients, for example to fulfill his or her host institution departmental requirements for patient service, and some of the patients may be eligible to participate or already participating in a company-sponsored clinical trial. An Investigator's service as physician of record for patients under these circumstances will not in itself be regarded as involvement with the company-sponsored clinical trial for purposes of this policy.

Financial Relationship with Companies – In General: If an Investigator is a principal investigator or a co-investigator on a company-sponsored clinical trial or study of a pharmaceutical product or medical device, neither the Investigator nor his or her immediate family members may:

- Have any equity interest in the company (e.g., own any stock or options in the company), or hold debt issued by the company;
- Receive compensation or other remuneration from the company, including compensation as a consultant (except as expressly set forth below); or
- Receive royalties from the company with respect to any technology relating to the trial (i.e., the drug(s), biologic(s), or medical device(s) that are under study in the trial). In addition, anyone under an Investigator's supervision who receives royalties from the company on technology relating to the trial may not be involved in working on the trial. However, the Investigator and those under his or her supervision may receive cash royalties under a prior license to the company of technology that is not related to the current trial.

Financial Relationship with Companies – Honoraria and Travel: If an Investigator is involved in a company-sponsored clinical trial, the Investigator may not accept an honorarium or other fee from the company for giving a talk or participating in a meeting or seminar. However, subject to the policies of the host institution, the Investigator may accept reimbursements for reasonable out-of-pocket travel expenses. This includes reasonable out-of-pocket expenses of traveling to meetings to review data regarding the trial, as well as reasonable out-of-pocket expenses of traveling to give talks or participate in meetings or seminars that are not related to the trial.

If an Investigator is invited to speak at a non-profit organization, he or she is not required to ask whether the honorarium or other fee would be paid by a company that is sponsoring a clinical trial with which he or she is currently involved. However, if it is clear to the Investigator that a current company trial sponsor is paying the honorarium or other fee (for example, because the talk is named for the sponsoring company), the Investigator may not accept the honorarium or other fee. In this case the Investigator may decline the invitation, ask that the inviting non-profit look for alternative sources of funding for the honorarium that would be permissible, or give the talk without accepting the honorarium or other fee. Subject to the policies of the host institution, the Investigator may accept reimbursements for reasonable out-of-pocket travel expenses of giving the talk, even if these are paid by the sponsoring company.

Regardless of the source of funding for an honorarium or other fee, Investigators should avoid speaking at any program where the program content is controlled by for-profit companies.

Financial Relationship with Companies – Consulting on Design of Trial: If an Investigator is not currently involved in a clinical trial sponsored by a company, the Investigator may consult for the company on the design of a trial and be paid for his or her work, even if (1) the Investigator is currently working in his or her laboratory on the technology that would be the subject of the trial (e.g., a compound), (2) there is a possibility that the Investigator may later be asked to be a principal investigator or co-investigator on the trial if it goes forward, and/or (3) the Investigator may receive royalties with respect to the technology that would be the subject of the trial. If the Investigator becomes a principal investigator or co-investigator on the trial, however, he or she may no longer receive consulting or other compensation or retain the right to receive royalties with respect to the technology that is the subject of the trial (i.e., the royalty interest must be permanently waived).

Financial Relationship with Companies – Other Consulting: An Investigator who is participating in a company-sponsored clinical trial may be asked by the sponsoring company to serve on a panel or otherwise advise the company. Depending on the circumstances, this may be permissible provided that the Investigator does not accept compensation from the company. For example, if the company is convening a panel of experts to review certain classes of company drugs, it may be in the public interest for the Investigator to be able to participate on an uncompensated basis. A confidential disclosure agreement may be signed to cover this type of service, provided that the terms are acceptable to HHMI. Similarly, an Investigator may serve on a trial management committee on an uncompensated basis.

Financial Relationship with Sponsoring Company – Gift in Support of Laboratory: An Investigator may not accept a gift from a company in support of the Investigator's research if the Investigator is participating in a clinical trial sponsored by the company, either during the trial or for six months after the issuance of the final report for the trial.

HHMI 75% Research Requirement – Patient Care

Under HHMI policy, an Investigator's research activities must constitute, in the aggregate, at least 75 percent of his or her overall professional activities. HHMI recognizes that from time to time certain Investigators may be involved in medical tests, diagnoses, procedures, and other activities and services that are rendered in connection with the care of a patient. These activities and services are considered "patient care" under this policy and are not counted as a research activity.

Other Legal Requirements

Please be advised that research involving human subjects research may be subject to additional legal requirements, particularly if it involves collaborating with scientists in foreign countries (for example, requirements under U.S. Office of Foreign Assets Control ["OFAC"] regulations). Please confer closely with the appropriate host institution personnel, and contact the [HHMI attorney](#) responsible for your site with any questions.

Issued by: Science

Issue Date: June, 2012