

Human Subjects Research – Host-based Sites

Scope and Definitions

This policy applies to all HHMI Investigators and Freeman Hrabowski Scholars, and all HHMI employees in HHMI Investigators' and Freeman Hrabowski Scholars' laboratories who are engaged in or are contemplating becoming engaged in human subjects research. HHMI laboratories at Janelia Research Campus are not within the scope of this policy; Janelia scientists who are considering engaging in human subjects research should refer to the [Human Subjects Research and Human Biospecimens Research - Janelia](#) policy before engaging in or contemplating becoming engaged in human subjects research or human biospecimens research.

As used in this policy, the following terms shall have the stated meanings and, unless otherwise specifically noted, shall be understood and interpreted in a manner that is consistent with the Department of Health and Human Services' interpretation under 45 C.F.R. Part 46 (the "Common Rule") and any associated department or agency guidance:

"Human subject" means a living individual about whom an investigator (whether professional or student) conducting research: (1) obtains information or biospecimens through intervention or interaction with the individual, and uses, studies, or analyzes the information or biospecimens; or (2) obtains, uses, studies, analyzes, or generates identifiable private information or identifiable biospecimens.

"Identifiable private information" is private information for which the identity of the subject is or may readily be ascertained by the investigator or associated with the information.

"Identifiable biospecimens" are biospecimens for which the identity of the subject is or may readily be ascertained by the investigator or associated with the biospecimen.

"Research" means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

"Human subjects research" refers to any research involving human subjects. This could include research involving identifiable private information, research involving identifiable biospecimens, or research that involves intervening or interacting with human subjects who have consented to participate.

A **"clinical trial"** is a research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on health-related biomedical or behavioral outcomes. Generally, the purpose of a clinical trial where an interventional product is studied (i.e., an investigational drug, device or biologic) is to gather data from humans with the intention of submitting those data to a regulatory agency, such as the United States Food and Drug Administration ("FDA"), in support of some form of regulatory approval or clearance. Not all clinical trials involve investigational products

subject to FDA jurisdiction. In order to constitute a clinical trial, a study must: (i) include human participants, (ii) include prospective assignment of participants to an intervention, (iii) be designed to evaluate the effect of the intervention on the participants, and (iv) evaluate a health-related biomedical or behavioral outcome. Studies that are ancillary to a clinical trial may or may not themselves constitute clinical trials, depending on the circumstances.

An “**observational study**” is a research study involving human subjects that does not constitute a clinical trial. Observational studies may include the study of clinical data from target human subject populations (including but not limited to patients enrolled in a clinical trial) 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, phenotype studies, studies focused on elucidation of pathogenetic mechanisms, studies aimed at identifying novel biomarkers, comparison studies that do not evaluate the effect of the interventions on the participants, and epidemiological studies (prospective or retrospective). Observational studies may or may not have a connection to a clinical trial. For example, an observational study may use data, tissue samples, or blood obtained from patients enrolled in a clinical trial.

Questions about whether a proposed study constitutes an observational study or a clinical trial for purposes of this policy should be directed in the first instance to the [HHMI attorney](#) responsible for your site and your [HHMI Scientific Officer](#).

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 (<https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>), applicable federal regulations related to the protection of human research participants, 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 conducted by HHMI’s host-based laboratories, Investigators and Freeman Hrabowski Scholars. 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 providing or securing any Institutional Review Board (“IRB”) review and other institutional oversight (including compliance with the requirements of any collaborating institutions) that is required by applicable laws or institutional policy 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 an Observational Study

An Investigator or Freeman Hrabowski Scholar is free to use their HHMI budget to cover the costs of observational studies conducted by the Investigator's or Freeman Hrabowski Scholar's laboratory, without any prior discussion with or approval from HHMI. This includes costs associated with an observational study that is ancillary to a clinical trial, as well as payments to collaborators in connection with collecting data or samples from human subjects 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 or Freeman Hrabowski Scholar may use funding from commercial sources in support of an observational study provided that the company funding has been approved by HHMI under its policy on [Company Funding Arrangements-Host-based Sites](#) and provided that the use of such funds for that purpose is consistent with any terms or restrictions imposed by the commercial funding source.

In addition, if an Investigator or Freeman Hrabowski Scholar is collaborating with colleagues at other non-profit or academic institutions or for-profit companies on an observational study, the arrangement must also meet the requirements of HHMI's policy on [Research Collaborations](#).

Human Subjects Research that is a Clinical Trial

Sponsorship in General: Investigators and Freeman Hrabowski Scholars may serve as principal investigators and co-investigators on clinical trials sponsored by government agencies or other organizations, including companies, provided the requirements of this policy are satisfied. 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, Freeman Hrabowski Scholars, and other HHMI employees working in the Investigators' or Freeman Hrabowski Scholars' laboratories 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.

Disclosure to HHMI: Investigators, Freeman Hrabowski Scholars or other HHMI employees who propose to serve as a principal investigator or co-investigator on a clinical trial should inform their HHMI [Scientific Officer](#) of their interest in participating in the clinical trial at the time the clinical trial is submitted for IRB review. This communication can occur by email and should include a brief description of the proposed clinical trial and the proposed role of any HHMI employees, including the Investigator or Freeman Hrabowski Scholar. The Investigator or Freeman Hrabowski Scholar also should inform the appropriate [Scientific Officer](#) at the time the IRB approves or declines to approve the clinical trial or if the request for IRB approval is withdrawn. As a reminder, the Investigator or Freeman Hrabowski Scholar must comply with all host institution policies with

respect to any notifications to the host institution regarding the Investigator's or Freeman Hrabowski Scholar's proposal to serve as a principal investigator or co-investigator on a clinical trial.

Use of HHMI Budget for Clinical Trial Costs Not Permitted: An Investigator or Freeman Hrabowski Scholar may not use the laboratory's HHMI budget to directly or indirectly cover the costs associated with a clinical trial. An Investigator or Freeman Hrabowski Scholar must use funds other than HHMI budget funds for these costs. The following is a list of examples of costs that cannot be covered by an Investigator's or Freeman Hrabowski Scholar's HHMI budget either directly or as a reimbursement to the Investigator's or Freeman Hrabowski Scholar's host institution:

- 1) Administrative costs of a clinical trial;
- 2) Costs associated with monitoring the conduct of a clinical trial;
- 3) Patient care costs in connection with a clinical trial (for example, the cost of medications);
- 4) Salary and benefits of personnel whose responsibilities include administering medication or medical treatments to patients enrolled in a clinical trial or other patient-related activities, such as obtaining data and blood or other tissue samples from patients, or counseling patients, in furtherance of the clinical trial; and
- 5) Salary and benefits of personnel whose main duties are to ensure compliance with FDA or other regulatory requirements associated with a clinical trial.

In addition, HHMI-owned equipment cannot be used for human subjects research in clinical facilities or otherwise to provide or generate information or results that are communicated to patients or to physicians for clinical decision-making or care.

Other Funding: An Investigator or Freeman Hrabowski Scholar may be involved in clinical trials that are funded by another organization or a company, provided that all of the following conditions are met:

- 6) Third party funds will not be used to pay any part of the salary or professional time of the Investigator, Freeman Hrabowski Scholar or any other HHMI employee.
- 7) The agreement covering the clinical trial allows publication of the results of the trial on terms that are consistent with customary academic standards.
- 8) The agreement covering the clinical trial will not interfere with the Investigator's or Freeman Hrabowski Scholar's ability to pursue their 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 entities. HHMI also is not a party to, and does not review, clinical trial agreements between the host institution and company sponsors. The host institution is responsible for ensuring that the clinical trial agreement is consistent with the above requirements. A host institution should contact the responsible HHMI site attorney if the host institution has any concerns about whether a clinical trial agreement is consistent with the requirements of this policy.

Service as Physician of Record for Patients Enrolled in a Trial: In some cases, an Investigator or Freeman Hrabowski Scholar may serve as physician of record for patients, for example to fulfill their host institution departmental requirements for patient service, and some of the patients may be eligible to participate or already participating in a clinical trial. An Investigator's or Freeman

Hrabowski Scholar's service as physician of record for patients under these circumstances will not in itself be regarded as involvement with the clinical trial for purposes of this policy.

Special Conflict of Interest Rules for Human Subjects Research

The following conflict of interest rules apply whenever an Investigator or Freeman Hrabowski Scholar serves as a principal investigator or co-investigator on a clinical trial or engages in an observational study that evaluates or uses a company's technology including but not limited to technology that is in development and not yet available to the scientific community on standard commercial terms. **Please note that if a company is funding an observational study subject to both this policy and [HHMI's Company Funding Arrangements – Host-based Sites policy](#), the conflict of interest rules in this policy apply in lieu of any less restrictive requirements in the [Company Funding Arrangements – Host-based Sites policy's](#) conflict of interest provisions. Please also note that the responsibility to adhere to these rules falls on the Investigator or Freeman Hrabowski Scholar; Investigators and Freeman Hrabowski Scholars must comply with these rules regardless of whether the underlying circumstances would be permissible under a host institution's policies and procedures.**

Financial Relationship with Companies – In General: If an Investigator or Freeman Hrabowski Scholar is a principal investigator or a co-investigator on a clinical trial or engages in an observational study that evaluates or uses a company's technology, neither the Investigator, Freeman Hrabowski Scholar, nor their immediate family members may:

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

Financial Relationship with Companies – Honoraria and Travel: If an Investigator or Freeman Hrabowski Scholar is involved in a clinical trial or engages in an observational study that evaluates or uses a company's technology, the Investigator or Freeman Hrabowski Scholar 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 or Freeman Hrabowski Scholar 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 or observational study.

If an Investigator or Freeman Hrabowski Scholar is invited to speak at a non-profit organization, the Investigator or Freeman Hrabowski Scholar is not required to ask whether the honorarium or other fee would be paid by a company that is sponsoring a clinical trial or whose technology is being evaluated or used in an observational study in which the Investigator or Freeman Hrabowski Scholar is currently involved. However, if it is clear to the Investigator or Freeman Hrabowski Scholar that a company that is sponsoring a clinical trial or otherwise participating in an observational study in which the Investigator or Freeman Hrabowski Scholar is involved is paying the honorarium or other fee (for example, because the talk is named for the sponsoring company), the Investigator or Freeman Hrabowski Scholar may not accept the honorarium or other fee. In this case the Investigator or Freeman Hrabowski Scholar 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 or Freeman Hrabowski Scholar may accept reimbursements for reasonable out-of-pocket travel expenses of giving the talk, even if these are paid by the sponsoring company.

Financial Relationship with Companies – Consulting on Design of Trial: If an Investigator or Freeman Hrabowski Scholar is not currently involved in a clinical trial or observational study in which a company's technology is being evaluated or used, the Investigator or Freeman Hrabowski Scholar may, subject to the policies of the host institution, consult for the company on the design of a trial or study and be paid for the work, even if (1) the Investigator's or Freeman Hrabowski Scholar's laboratory is currently working on the technology that would be the subject of the trial (e.g., a compound) or study, (2) there is a possibility that the Investigator or Freeman Hrabowski Scholar may later be asked to be a principal investigator or co-investigator on the trial or study if it goes forward, and/or (3) the Investigator or Freeman Hrabowski Scholar may receive royalties with respect to the technology that would be included in the trial or study. If the Investigator or Freeman Hrabowski Scholar becomes a principal investigator or co-investigator on the trial or becomes engaged in an observational study that evaluates or uses a company's technology, however, the Investigator or Freeman Hrabowski Scholar 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 or study (i.e., the royalty interest must be permanently waived).

Financial Relationship with Companies – Other Consulting: An Investigator or Freeman Hrabowski Scholar who is participating in a clinical trial or is engaged in an observational study that evaluates or uses a company's technology may be asked by the company to serve on a panel or otherwise advise the company. Depending on the circumstances, this may be permissible provided that the Investigator or Freeman Hrabowski Scholar 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 or Freeman Hrabowski Scholar 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 and consistent with the host institution's policies. Similarly, subject to the policies of the host institution, an Investigator or Freeman Hrabowski Scholar may serve on a trial or study management committee on an uncompensated basis.

Financial Relationship with Sponsoring Company – Gift in Support of Laboratory: An Investigator or Freeman Hrabowski Scholar may not accept a gift from a company in support of the

Investigator's or Freeman Hrabowski Scholar's research if the Investigator or Freeman Hrabowski Scholar is participating in a clinical trial or is engaged in an observational study that evaluates or uses a company's technology including but not limited to technology that is in development and not yet available to the scientific community on standard commercial terms, either during the trial or study or for six months after the issuance of the final report for the trial or publication or presentation of the study.

Other Legal Requirements

Please note that research involving human subjects 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 regulations). Please confer closely with the appropriate host institution personnel, and contact the [HHMI attorney responsible for your site](#) with any questions.

Related Procedures, Forms and Policies

- [Human Subjects Research Policy - Janelia](#)
- [Company Funding Arrangements - Host-based Sites](#)
- [Research Collaborations Policy](#)

Contact

Contact the [Scientific Officer](#) or [HHMI attorney responsible for your site](#).

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