

**2007 HHMI Investigator Competition in Patient-Oriented Research**  
**Questions and Answers**

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## **A. Eligibility**

### ***A1. What are the eligibility requirements?***

To be eligible for this competition you must:

- Have an M.D. or M.D./Ph.D. degree or the equivalent;
- Be licensed to practice medicine in the United States;
- Hold a tenured or tenure-track (or equivalent) position at one of the listed institutions;
- Be a Principal Investigator on an active NIH RO1 grant or a project leader on an active NIH PO1 grant;
- Have between four and 16 years of experience as an assistant professor; to meet this requirement, we expect that you would have first assumed an independent faculty position no earlier than January 1991 and no later than January 2003; and
- Have an outstanding patient-oriented research program.

In addition, you cannot be an HHMI investigator if you have significant administrative responsibilities or other duties that would preclude devoting a minimum of 75% of your total effort to the direct conduct of research.

### ***A2. I'm not sure whether my research program qualifies as "patient-oriented". How is HHMI defining "patient-oriented" research in this competition?***

We seek investigators whose research shows the impact of direct contact with patients. We define "patient-oriented" research as research that includes the direct study of human subjects and/or data derived from human subjects, with the goal of understanding diseases or disorders that affect humans and making it possible to better diagnose and treat such diseases or disorders.

In considering whether to apply for this competition, it may be useful to consider the distinction between the targeted area of *patient-oriented* research and the related area of *disease-oriented* research. Many current HHMI investigators focus on research that is directed towards understanding the genetic, molecular, and cellular basis of human disease. By and large, this *disease-oriented* research does not necessarily directly involve human subjects or data derived from them, but rather utilizes materials derived from patients and/or animal models that are surrogates for patients. An example of such disease-oriented research is the cloning of a disease gene, like that causing cystic fibrosis. This research was successfully accomplished not by studying patients directly, but through the analysis of DNA samples from unaffected and affected individuals. In contrast, *patient-oriented* research utilizes a thoughtful combination of laboratory studies and human subject studies to address the mechanism by which the abnormal cystic fibrosis gene produces its damage in the lung and pancreas of living patients and to determine how these abnormalities can be treated effectively. This competition focuses on *patient-oriented* research, with a key attribute of successful candidates being the

potential of their research programs to reveal important new insights into pathogenesis, treatment, or prevention of *human* disease.

***A3. My institution is not on the list of 121 eligible institutions. How may I request changes to the list?***

Please do not contact us to request changes to the list. This is the same list of institutions we used in the 2002 HHMI competition for patient-oriented investigators; after extensive consideration we have decided that no changes are warranted at this time.

***A4. I'm an adjunct professor at one of the listed institutions and a tenured or tenure-track faculty member at another institution that is not on the list. Am I eligible?***

No.

***A5. My primary appointment and research space are at a Veterans Administration Hospital, although I am on the faculty at an eligible institution. Am I eligible?***

No. If your primary appointment and/or principal research location is at a federal institution such as a VA Hospital, you are not eligible.

***A6. I'm not sure if I am eligible, since my primary institution does not have a tenure track. What should I do?***

If your primary institution offers a tenure track, then tenure or tenure-track is a requirement. For institutions that have no tenure track, we require that applicants have a position that is the most similar to tenure-track available at that institution (i.e., equivalent in terms of institutional commitment to the employee, etc.). If you are uncertain about whether or not the terms of your appointment meet this eligibility requirement, you should email the inquiry desk at [POR2007@hhmi.org](mailto:POR2007@hhmi.org) and provide information about the terms of your position prior to submitting an application. We will then consider your situation and respond as soon as possible.

***A7. I am a PI on a RO1 now, but I've been told my RO1 will not be renewed. Am I still eligible?***

Yes, if you have an active RO1 grant at the time your application is submitted.

***A8. I am a co-PI on my RO1. Am I eligible?***

Yes.

***A9. My only NIH funding is as a co-investigator rather than a PI on an RO1 grant. Am I eligible?***

No.

***A10. I am just a few months short of having four years of experience as an independent investigator. Am I eligible?***

Eligibility is to be determined by the date when you first assumed an independent faculty position; to meet this requirement we expect that you would have first assumed an independent faculty position no later than January 2003.

***A11. I have been an independent investigator for more than 16 years but my career was interrupted for several years. If you take the interruption into account, I would be within the 16-year limit. Could I be eligible?***

In general, we will determine your eligibility by the date when you first assumed an independent faculty position; to meet the 16-year rule you should have first assumed an independent faculty position no earlier than January 1991. If you believe that your circumstances warrant an exception, please describe them to us in an email to our inquiry desk at [POR2007@hhmi.org](mailto:POR2007@hhmi.org) , and we will respond as soon as possible.

***A12. What is HHMI policy with regard to eligibility of faculty members with administrative responsibilities?***

Duties must be compatible with HHMI's requirement that investigators devote at least 75% of their total professional effort to the direct conduct of research. HHMI has under some circumstances permitted its investigators to serve as department chair, director of a departmental division, head of a research center, head of a graduate program or the like, when it could be determined that those duties would not, in fact, interfere with this requirement. The permitted 25% of non-research activity includes all administrative duties, teaching, committee service, grant and journal reviewing, participation in the activities of scholarly societies, and consulting (subject to HHMI's rules on consulting). HHMI investigators may not hold the positions of dean, provost, vice president, or president of an institution as we do not believe it is possible for individuals in these positions to meet the 75% requirement. Also note our salary policy, Question E5.

## **B. Components of Application**

### ***B1. What must my application include?***

Your application must include the following documents, all submitted electronically to the HHMI website at [www.hhmi.org/research/application/por2007](http://www.hhmi.org/research/application/por2007):

- Your curriculum vitae, bibliography, and a list of your current research support (for these three items you should use the NIH PHS 398 biographical sketch format; however, in order to provide your complete bibliography you can exceed the NIH's 3-page limit);
- A 250-word summary of your major achievements as an independent investigator;
- A summary of your ongoing and planned research program. The text of this is limited to 3,000 words, and you may also include up to one page of figures. Figures and references are not counted towards the 3,000-word limit; and
- Five selected publications that document the applicant's most important scientific contributions should be provided. For each publication provide a statement that begins with the journal reference and summarizes, in 300 words or less, the importance of the selected publication. Only published papers or papers that have been officially accepted are to be included.

### ***B2. What about reference letters?***

You should not include reference letters in your application. If you are a semi-finalist, you will be notified in late June and asked to solicit three reference letters.

### ***B3. In the summary of my ongoing and planned research program, can I include work that is already supported by my grants?***

Yes. HHMI supports people, not projects, so we are interested in the full range of the work you are doing and planning to do, regardless of current sources of funding. Your summary should give some idea of how HHMI support might influence your research plans.

### ***B4. Should I include specific program aims in the summary of my ongoing and planned research program?***

You may; but please keep in mind that because we support people, not projects, we do not believe an investigator should necessarily be tied to specific goals. We hope and expect that investigators will use HHMI's support as an opportunity to take on new projects with a high degree of scientific risk that would be unlikely to be funded by other organizations.

### ***B5. How much background should I provide?***

Some description of background information is appropriate to set the stage for the description of your research program; please note that HHMI's reviewers will also receive your selected publications and the 250-word summary of your major achievements as an independent investigator.

## **C. Review Process**

### ***C1. How does HHMI's review process work?***

HHMI will use a two-stage initial review process, leading to selection of semi-finalists by June 2007. A third review will result in the final selection by the fall of 2007.

### ***C2. Who are the reviewers?***

Reviewers include current and past members of HHMI's Medical Advisory Board and Scientific Review Boards, HHMI investigators, and HHMI's scientific staff. If necessary, based on volume and breadth of applications, HHMI may select additional distinguished scientists to serve as reviewers.

### ***C3. Can I get a list of potential reviewers who might be assigned to my application?***

No. HHMI does not make public the roster of reviewers for its competitions.

### ***C4. Does HHMI give a preference to applicants who are already at institutions where there are other HHMI investigators?***

No. HHMI's goal is to identify and appoint the best candidates, regardless of whether they are located at institutions where there are currently investigators. Only 45 of the 121 eligible institutions already have one or more HHMI investigator.

#### **D. Employment; Time Commitment to Research**

***D1. I understand that as an investigator I would become an HHMI employee. Would this affect my faculty status at my institution?***

Maintaining faculty status at the host institution is a condition of an investigator's HHMI appointment.

***D2. I am a tenured faculty member at my institution and I also have a faculty appointment at another institution. Will I have to give up that other faculty appointment if I become an investigator?***

No. However, if you have a second laboratory at the other institution, we would need to discuss that situation with you before your appointment, and we might need to put in place an agreement between HHMI, your host institution, and the institution at which your second laboratory is located. Please note that HHMI is unlikely to pay for space, equipment, or personnel for a second laboratory.

***D3. If I am selected to be an investigator, how long would my HHMI appointment continue?***

Investigator appointments are for an initial term of five years, and may be renewed for additional five-year terms contingent on successful scientific reviews. If an HHMI scientific review is unsuccessful, the investigator is provided with phase-out support for an appropriate period, typically two additional years.

***D4. My institution allows me to consult or engage in other outside activities for up to one day per week. Does HHMI have a limit on outside activities?***

Yes. Investigators are required to devote at least 75% of their total professional effort to the direct conduct of research. This includes all research, regardless of how funded. Investigators may spend up to 25% of their effort on other activities, such as teaching, administrative duties, service as a journal editor or reviewer, and consulting for companies (subject to HHMI's policies on consulting, described below).

***D5. I am considering moving to a new institution after January 2007. If selected by HHMI in this competition, could I be appointed at the new institution?***

No. The application must be submitted from the same institution that will be the site of your appointment. Also, an HHMI investigator who changes institutions prior to completion of his or her first five-year term of appointment must resign from HHMI. After successful scientific review, an investigator may transfer to another HHMI host institution as detailed in HHMI's transfer policy. Only one transfer is permitted over the course of an HHMI investigatorship.

## **E. Compensation and Benefits**

***E1. I understand that as an investigator I would receive my full salary from HHMI. How will my initial HHMI salary be determined?***

Investigator salaries are set by HHMI by comparison to the salaries of colleagues at the same institution who are at the same career stage and have similar scientific stature.

***E2. Is it possible that HHMI might offer me an initial salary that is lower than my current compensation?***

Yes. Institute policies do not allow salaries of current patient-oriented (and other) investigators to contain increments that reflect past or present practice plan earnings and past or present administrative duties. For that reason, it is possible that some applicants in this competition may have current salaries that will not be matched by the Institute. Salaries for the new patient-oriented investigators appointed through this competition will be limited to the range of salaries of recently appointed patient-oriented investigators.

***E3. Does HHMI review compensation annually?***

HHMI reviews compensation annually; merit increases are typically established for each year. When an investigator is promoted to a new academic rank within his or her institution (e.g., Associate to full Professor), the Vice President and Chief Scientific Officer discusses an appropriate salary adjustment with the host institution. If an investigator assumes an administrative position, the Institute does not provide a salary supplement and does not permit a salary supplement from any other source.

***E4. Does this mean I cannot receive compensation from my institution for the patient care I do? What about compensation from the faculty practice plan of which I am a member?***

As an HHMI investigator you could not receive compensation from your institution or its affiliates, including a faculty practice plan; this includes compensation for patient care. However, your institution or its affiliates, including a faculty practice plan, may bill patients for professional services that you render, and may use the revenues at their discretion for purposes other than providing direct compensation to you or other HHMI employees.

***E5. Does this mean I cannot receive salary supplementation from my institution for administrative duties?***

Yes. HHMI investigators cannot receive compensation for administrative activities.

***E6. I receive subsidized housing from my host institution. Would that be a problem for HHMI?***

Not as long as the housing subsidy is comparable to what your host institution would provide to other similarly-situated faculty. If you are successful in this competition, we would want to review this issue with you prior to your appointment.

***E7. I expect to receive tuition remission for my children from my host institution. Would that be a problem for HHMI?***

No, this is not a concern for HHMI, but eligibility is determined by host institution policies.

***E8. I don't receive either subsidized housing or tuition remission from my host institution. Would HHMI provide these benefits?***

No, HHMI does not provide these benefits. HHMI does offer many other benefits to its employees, including health, dental, and vision coverage, life insurance, and retirement benefits.

## **F. NIH and Other Grant Funding**

***F1. Can I continue to get grant funding from other sources if I become an HHMI investigator?***

As an investigator you could continue to get grant funding from government agencies and non-profit organizations. All such funding would be through your host institution, not HHMI, and your host institution would retain all indirect costs associated with the grants. Although no-strings-attached gifts from companies may also be accepted, company-sponsored research is not permitted in HHMI laboratories.

***F2. Right now I get my salary from my NIH grant funds. Do I have to turn those funds back if I am appointed as an investigator?***

You must either turn those funds back or ask for those funds to be reallocated to other categories supported by the grant. Your institution could not continue to accept funds for your salary after your HHMI appointment is effective.

***F3. I am currently reporting very close to 100% effort on my government grants. Would that be an issue for HHMI?***

Yes. Although HHMI does not use effort reporting, we do not believe it is consistent with a researcher's role as an HHMI investigator to spend almost 100% of his or her time on grant-funded projects. Accordingly, if you are successful in this HHMI competition, we would ask you and your institution to reexamine your effort commitments.

## **G. Budgets, Indirect Costs and Laboratory Staff**

### ***G1. What does an investigator's HHMI budget include?***

Investigator budgets include a component for personnel (laboratory staff) and a component for operations (e.g., supplies and minor equipment). Requests for major equipment are not part of an investigator's budget. Instead, HHMI groups these requests and considers them three times a year.

### ***G2. How does HHMI set an investigator's budget?***

Investigator budgets are determined by HHMI's Vice President and Chief Scientific Officer and are subject to the approval of HHMI's President and Trustees. Initial budgets for a cohort of investigators tend to be similar. Over time, budgets become more individualized as the specifics of each investigator's research program develop.

### ***G3. Does HHMI pay indirect costs?***

HHMI does not pay indirect costs. HHMI does make payments to the host institution for occupancy of an investigator's research and office space and for certain other expenses. HHMI negotiates these directly with the host institution and they are not a part of investigator budgets.

### ***G4. If I am appointed as an investigator, can some of my laboratory staff become HHMI employees? Would they get health insurance from HHMI? Who sets their salaries?***

Yes. Any of your postdoctoral associates, technicians, and other research staff could become HHMI employees (subject to the limitations of your budget). All full-time HHMI employees, and all part-time HHMI employees scheduled to work at least 20 hours per week, are eligible for benefits that include retirement, health, dental, and vision coverage. You would set their salaries, within HHMI salary guidelines.

***G5. What about graduate students?*** Your graduate students cannot become HHMI employees. Investigators typically support graduate students from institutional or grant funds.

***G6. What if someone on my staff wants to remain an employee of my host institution? Do I have to make that person an HHMI employee?*** You are expected to have some HHMI employees in your lab other than yourself, but we do not require anyone other than investigators to change employment status.

## **H. Research Collaborations and Consultancies**

***H1. I understand that HHMI policy does not allow company-sponsored research in HHMI laboratories. As an HHMI investigator, could I still work with a company on a research project?***

HHMI investigators can and do collaborate with companies on an unfunded basis. We strongly encourage such collaborations as long as they are driven by scientific considerations and the company is making a direct and substantial scientific contribution to the joint project. Collaborations with companies must be documented by an agreement that has been reviewed by HHMI's Office of the General Counsel and approved by the Science Department.

Please note that an investigator may not consult for and collaborate with a company at the same time. Involvement with a clinical study or trial sponsored by a company is considered to be a special form of collaboration; see the section on Clinical Research, below.

***H2. Can I be appointed as an HHMI investigator if I have company-sponsored research in my laboratory?***

No. Your company-sponsored research would have to be terminated before you could be appointed as an investigator.

***H3. What about collaborations with my academic colleagues? Do I have to make any changes in these in order to be appointed as an HHMI investigator?***

It is very likely no changes would need to be made unless you have a significant scientific collaboration with an academic colleague who is funded for that research by a company. If you are successful in this competition, we would need to discuss any such situation with you.

***H4. As an HHMI investigator, can I consult for a company?***

Yes, provided that:

- You meet the requirement that 75% of your total professional effort be spent on research.
- You do not consult for companies for more than a total of 36 days per year.
- Your compensation for the consulting is not based on incentives such as the company's meeting specified sales or revenue targets.
- Your consulting is covered by an agreement that has been reviewed by HHMI's Office of the General Counsel and formally approved by HHMI's Science Department.
- You provide advice only and do not conduct or oversee research.
- You do not own a significant equity interest in the company. An interest of more than 5% is always considered significant.
- You do not collaborate with the company.

Please also note that service as a member of a company's board of directors is permitted only in limited circumstances, and service as an officer of a company is never permitted.

***H5. What about consulting for a non-profit organization?***

Consulting arrangements with non-profit entities do not need to be reviewed by HHMI headquarters if (1) they are not in writing or (2) they are in writing but cover only basic terms such as the scope of duties, time commitment, and amount of compensation, if any. If a non-profit organization asks you to sign an agreement that asserts rights or imposes limitations that may affect your laboratory operations, research results, or ability to publish, HHMI headquarters needs to review and approve the agreement before you sign. This consulting does not count against the 36-day limit, but would have to be taken into account as part of the 25% of time permitted by HHMI policies for non-research activities.

## **I. Clinical Research**

### ***11. Can I perform clinical trials or studies as an HHMI investigator?***

Yes, HHMI investigators can and do serve as principal investigators and co-investigators on trials and studies. HHMI's policies relating to clinical studies or trials apply equally whether the investigator is involved as a PI or as a co-investigator.

### ***12. Will HHMI pay for the costs of a clinical study or trial on which an investigator is a PI or co-investigator?***

HHMI does not in general sponsor interventional clinical trials or pay for patient care costs. Investigators may, however, allocate part of their budget to research activities that are a part of clinical trials and studies.

### ***13. Does HHMI have an IRB that will review my human subject protocols?***

No, HHMI does not have an IRB. As an investigator, you would continue to submit your human subjects protocols to your host institution's IRB.

### ***14. Does HHMI provide professional liability (medical malpractice) insurance for the investigator?***

No. We require that the host institution provide the investigator with professional liability (medical malpractice) coverage.

### ***15. I've been asked to be a PI on a clinical trial that would be funded by a company. Is this a problem for HHMI?***

A number of investigators have been PIs on company-sponsored trials, which we consider to be a type of research collaboration with a company. HHMI has a number of requirements relating to company-sponsored trials. These include the following:

- As to the investigator and his or her laboratory, the company funding may be used only for patient care costs, not to support research in the laboratory;
- There can be no salary support for the investigator or any staff in the laboratory, whether or not employed by HHMI;
- Publication must be allowed on terms HHMI considers acceptable; and
- The agreement with the corporate sponsor cannot interfere with the investigator's ability to pursue his or her own research program effectively.

### ***16. I'm already a PI on a company-funded clinical trial that is expected to run for the next couple of years. If I become an investigator, will HHMI still apply its requirements to this trial or could it just go on until it is completed as scheduled?***

If the arrangements for the trial are not consistent with our requirements, the arrangements would need to be modified or your involvement with it would need to end before we could proceed with your appointment.

### ***17. Can I own stock in a company that I'm collaborating with?***

This depends upon the nature of the collaboration. Consistent with HHMI's approach to conflict of interest issues, we do not permit an investigator to collaborate with a company

on a clinical trial or study of a pharmaceutical product or medical device that is proposed or under development by the company, if the investigator or a member of his or her immediate family owns stock or other equity in a company. A similar approach applies to those under the investigator's supervision: if they or members of their immediate family own stock or other equity in a company, they should not be involved in this type of collaboration with the company.

If you are collaborating or propose to collaborate with a company on a project other than one described above, we will ask you whether you or your immediate family have an equity interest in the company, and will consider whether it is appropriate for you to proceed with the collaboration while holding the equity.

***18. Can I receive royalties from a company with which I'm collaborating?***

This depends on the nature of the collaboration and the royalty interest. Consistent with HHMI's approach to conflict of interest issues, we do not permit an investigator to collaborate with a company on a clinical trial or study of a pharmaceutical product or medical device proposed or under development by the company, if the investigator or a member of his or her immediate family is entitled to receive royalties from the company with respect to any technology relating to the trial or study. Receipt of royalties in cash form from the company under a prior license of technology that does not relate to the trial or study would not be precluded. A similar approach applies to those under the investigator's supervision: if they or members of their immediate family are entitled to receive royalties from a company with respect to technology relating to a company-sponsored trial or study, they should not be involved in work on the trial or study.

So, for example, as an HHMI investigator you could not be a PI on a company-sponsored clinical study or trial of a compound or device that you developed and that is licensed to the sponsoring company, if you receive or will receive a share of royalties under the license (whether in the form of equity or cash). You could receive royalties, in cash form only, under a prior license to the company of technology that is unrelated to the compound or device.

If you are collaborating or propose to collaborate with a company on a project other than one described above, we will ask you if any technology you developed has been licensed to the company, and discuss with you any issues that this may present.

***19. I do a lot of very short-term consulting for pharmaceutical companies; for example I might meet with company representatives for just part of a day. Could I still do this if I am a PI on a trial that the company is sponsoring?***

You could still meet with the company, and you could accept reimbursement of reasonable out-of-pocket travel expenses, but you could not accept an honorarium or other fee. Any agreement covering your meeting with the company must be reviewed and approved by HHMI in advance.

## **J. Intellectual Property – Patenting and Licensing**

### ***J1. How does HHMI handle intellectual property?***

As the employer, HHMI owns any intellectual property developed by its investigators and other employees. HHMI assigns intellectual property rights back to the host institution, and shares with the host institution in patenting and licensing expenses and in any royalty income. Distributions of royalty income to inventors are generally not affected by HHMI's involvement, since HHMI defers to the relevant host institution's policy on the amount and timing of such distributions, and it is the host institution that makes any such distributions.

### ***J2. Some technology I developed in the past has been licensed to companies. Does HHMI care about those arrangements?***

Yes, if they affect your ongoing research. If you are successful in this competition, we will ask your host institution for copies of all licenses to for-profit companies of technology developed in your laboratory. If any such licenses cover future improvements that might result from your research as an HHMI investigator, we are likely to ask that modifications in those licenses be made before your appointment can proceed.

### ***J3. If I get royalties from a company that licensed technology I developed in the past, could I still collaborate with or consult for that company?***

Yes, assuming that the license and collaboration or consulting arrangements are consistent with HHMI policies. Also, although our policies would not allow you to have any financial interest in a company with which you are collaborating on a clinical study or trial, we do make an exception for cash royalties from a past license of unrelated technology. For example, if you are a PI on a clinical study that is sponsored by a company, our policies would allow you to receive cash royalties under a prior license of technology unrelated to the current study.