

INNOVATION FELLOW ELIGIBILITY OVERVIEW AND FAQs

Outbound Fellows

Eligibility Criteria	Detailed Information	Point of Contact

HR and PROGRAM ELIGIBILITY REQUIREMENTS

What is a Fellow's employee status while performing a Fellow's Project at Host Industry?	Fellows must be "active status" employees in the Mass General Brigham system, and will remain "active" employees while performing the Fellow's Project at Host Industry.	Dept Administrator
Where does my paycheck come from--and do I get all my benefits?	Employee continues to receive full salary/benefits from your hospital department as you are accustomed to. The Industry Host reimburses hospital for salary and fringe to pay Fellow.	PHS Finance/ Cary/ Dept Admin
If I am a Resident or a Clinical Fellow funded by an NIH training grant, can I participate in this program?	<u>You may not be a Resident or a Clinical Fellow and an Innovation Fellow concurrently.</u> Eligible clinicians include those who have completed residency but have not begun a Clinical Fellowship, or those who have already completed or will complete the defined standard duration of their GME Fellowship (incl. clinical and research portions as prescribed) prior to the start of the Innovation Fellow's Project at the Industry site. If you have questions, please consult with your Fellowship Director and/or the GME Office before applying.	Fellowship Director / GME Office
I am a HMS Faculty member and we have restrictions on where we spend our time. Will this effect my ability to participate in the Program?	HMS has approved the following participation levels for Faculty wishing to participate in the program: --For a 1 year (12 months) Fellows Project: up to 2 full days offsite (40% time) at Industry --For a 6 months Fellow Project: up to 3 full days offsite (60% time) at Industry	HMS Faculty Office
What are my employee entitlements while at Industry?	As an Active Status employee--Fellow to receive full employee benefits--salary, benefits--including all insurances and the like.	Dept Administrator
What are my employee requirements while at Industry?	All requirements of Active Status employee remain in effect for Fellow: Health Stream trainings, flu shot reporting, Annual Career Conference or review.	Fellow
Am I eligible for a salary increase while I'm a Fellow at Industry site?	Yes. As an active employee, Fellows remain eligible for the annual increase. Date of increase would follow standard set by your hospital, possibly in accordance with your annual career conference or review.	Dept Administrator

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I am a visa holder. Can I apply for this program?	Possibly. J-1s and most H-1s are not permitted to participate. All other visa requests will be reviewed on a case by case basis. All visa holders should check the relevant box on the application. Requests will be screened in advance to determine any visa restrictions or issues. Unfortunately, Innovation cannot guarantee participation in this program as a result. If there are visa constraints your current department must agree to your participation.	Cary/PIPS/ Dept Admin
Will I have a mentor while at Industry?	Fellows will have 2 mentors: 1 from the company, and one from PHS. Fellows must agree to meet regularly with assigned PHS Mentor throughout the term of your position.	Fellow /Mentor
What are my general responsibilities at the host site?	Industry Hosts provide project scopes outlining general responsibilities for their Fellow Project/s. Project scopes are available through the Innovation Fellow's webpage. A link and password for this page will be sent to individuals who inquire or submit an application to the Program.	Host Industry with Fellow
What does the Industry site Onboarding Process entail?	Onboarding details differ per host site. Some will be very intensive and require drug screens and background checks, and others may just require signing paperwork. the Industry host will work with each Fellow to make sure onboarding requirements are fulfilled prior to starting at the Industry site. If you are required to sign any confidentiality terms or other documents to Onboard at Industry--Innovation should review the documents prior to your signing to assess for any terms conflicting with the master agreement or for any additional terms not addressed in the master agreement.	Host Industry with Fellow
Debarment or Disqualification to Practice	Fellow must attest to the following: As of the Effective Date of the Fellow Participation Agreement, the Fellow has not been, and is not (a) debarred from providing services pursuant to Section 306 of the United States Federal Food Drug and Cosmetic Act, 21 U.S.C. § 335a; (b) excluded, debarred or suspended from, or otherwise ineligible to participate in, any federal or state health care program or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); or (c) convicted of a criminal offense that could lead to debarment from FDA activities.	Cary/Dept Admin.

RESEARCH, CONFIDENTIALITY AND IP

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Can I conduct Research at my host site? What can and can't I do?	Research conducted at host site as part of the Fellows program is for training/educational purposes in this program, and belongs entirely to host industry. It should not leave host site. Same for hospital site research--do not share any hospital IP with your Industry host/team. If you feel like you want to discuss this--please check with Innovation contact.	Cary/Dept Admin.
How do I treat Confidentiality?	Fellow acknowledges that the Company may provide Fellow with Company's confidential and proprietary information ("Company's Information") to perform the Fellow Project and that Company may not require that Fellow sign an agreement with Company to protect Company's Information. Fellows are expected to use strong judgement and discretion not to discuss Industry CI.	Fellow/ Industry
How do I treat Background IP/ Hospital IP?	Hospital's Background IP shall be solely owned by Hospital and shall include all intellectual property generated by a Fellow in performing any Non-Fellow Project Responsibilities, and all such intellectual property shall be governed by the intellectual property policies that apply to employees of Hospital. Fellows should discuss any inventions, notebooks, etc with supervisor and validate any IP prior to starting the Fellows project.	Fellow
How do I treat new IP?	In general, IP developed while at Industry site belongs to Industry and Fellows are expected to use strong discretion to keep this IP confidential. For Fellows splitting their time between Industry and Hospital sites, Hospital IP also remains confidential.	Fellow
Can I publish work associated with my time at Industry?	Publishing is not a primary goal of this program and therefore not a guarantee. It could be possible and will depend upon discussion with the Company and subject to the terms of the agreement.	Fellow

CONFLICTS OF INTEREST

All Fellow candidates will be required to complete the Application, the COI Checklist and the Supervisor Approval form to ensure there are no Conflicts of Interest between the performance of any of their hospital activities and participation in a Fellow's Project at Industry. See below for explanations of areas that will be reviewed. If COIs do exist, the Fellow candidate and corresponding departments will determine if the applicant is a viable candidate or not at this time.

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Responsibilities at hospital: eg. Clinical Trials/research, pre-clinical research, teaching, patient care, administration, other	Fellow needs to disclose if current activities will continue during the performance of a Fellow's Project. Generally speaking, some of these activities cannot be performed concurrently with a Fellow's Project and will be reviewed for potential COI prior to consideration of a Fellow's candidacy.	IRB/OII
Relationship with Fellow's Project Host:	See details below regarding: clinical trials or research, pre-clinical trials or research, financial interests in Host Company	
Clinical Trial/s <u>sponsored by Fellow's Project Host Industry</u>	The Office of Interactions with Industry (OII) wants to be clear that Fellow candidate may NOT participate concurrently in a clinical trial or clinical research sponsored by the same Industry sponsor for which Fellow is considering becoming a Fellow.	IRB/OII
Harvard 1(a) Rule on conducting Clinical Research: Regarding conducting Clinical Research on the technology of Company sponsoring the Fellow's Project	Fellow must disclose <u>and confirm on the COI checklist</u> if participating in any clinical research currently (or anticipates future participation) either <u>on any technology, or using any technology of the company that will be funding your Fellow's Project</u> – this relates to the Harvard 1(a) rule on clinical research. <i>(Note--there is a \$25K threshold for payment by Company that might be met--but most Fellows will receive funding above that threshold for their Fellow Project--to be explored).</i> Review and attestation by signature of understanding of Harvard' Clinical Research Rule ("Harvard 1(a)") is required.	IRB/OII
Research	Fellow must disclose if conducting any research – whether clinical or non-clinical – that receives sponsored research support from the Host company. “Sponsored research support” has a broad definition and includes, e.g., materials received under an MTA in some circumstances (depending on the terms of the MTA).	IRB/OII
Research	Fellow must disclose if works in a lab that currently (or may in the future) receives funding from the Host Industry for any clinical or non-clinical research	OII
Other relationship with Fellow's Project Host	Fellow must disclose if has any relationship with the Fellow's Project Host company such as consulting, Scientific Advisory Board (SAB), Board of Directors, Executive Position, paid talks, employment etc.	OII

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Financial Interest in Fellow's Project Host Company	<p>If a Fellow or a family member has any financial interest in the Host Company that results in an individual benefit for the Fellow, there may be a conflict of interest that triggers Harvard's Research rule 1a or 1b regarding clinical or non-clinical research. Fellow must disclose if receives compensation from Host company:</p> <ol style="list-style-type: none"> 1. If Cash, how much per calendar year (more than \$25K?) 2. If Equity (includes stock options and any other form of ownership interest) 3. Any Other financial interest in the company 	OII
Funding Sources	<p>Fellow needs to disclose all funding sources for activities anticipated throughout the duration of the Fellow's Project to ensure there are no conflicts of interest or perceived bias. This includes NIH and other government grants, Industry-sponsored research {pre-clinical or clinical research/trials- including observational or sub-studies under clinical trials}, Foundation, Institutional/Dept and other funding sources (whether or not you are the PI). (OGC will most likely conduct a review of NIH-funded studies to ensure there is no financial impact on the company host).</p>	OII
Do you have a general understanding of the Sunshine Act, the Anti-Kickback Statute and The Stark Law that are mentioned in the Fellow Participation Agreement?	Innovation can provide a summary of these laws upon request.	OGC/Cary

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