INNOVATION FELLOW PROGRAM: ELIGIBILITY REQUIREMENTS AND OTHER GUIDELINES Outbound Fellows		
Eligibility Criteria	**Detailed Information**	**Point of Contact**
GENERAL PROGRAM ELIGIBILITY REQUIREMENTS		
"Active" employee at MGB	Fellows must be "active status" employees in the Mass General Brigham (MGB) system, meaning they are employed, part time or full time, and receive salary and benefit options from MGB. Fellows must remain "active" employees while performing the Fellow's Project at Host Industry site.	Dept Administrator
PhD: Post Docs candidates	Post Docs are eligible to participate in the program after 2 years in a post doc program. Some exceptions do apply.	MGB Innovation
MD candidates: Residents or Clinical Fellows in active ACGME or GME accredited training programs/Fellowships	As per MGB GME Policy, an Innovation Fellow may *not* be a Resident or a Clinical Fellow *and* an Innovation Fellow concurrently. 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
MD candidates: Early to mid-career	Early to mid-career MDs (or MD, PhDs) are eligible to participate in the program as long as they completed residency training.	MGB Innovation
MD and PhDs with **HMS Faculty appointments**	Because Innovation Fellows remain employed by an MGB entity, the time an Innovation Fellow spends at a company is not considered to be "outside work" subject to the normal HMS policy limitation of a maximum of twenty percent (20%) time spent on "outside work." The Innovation Fellows Program has requested and received approval from HMS Faculty Affairs for Innovation Fellows who are full-time HMS Faculty to be allowed to participate in the Fellows Program as part of their HMS appointment up to the following limits: --For a 1 year (12 months) Fellows Project: 40-50% or up to 2.5 days a week offsite at Industry --For a 6 months Fellow Project: 60% or up to 3 full days a week offsite at Industry Requests for additional time to be spent on a Fellow's project will be handled on a case by case basis with HMS Faculty Affairs.	HMS Faculty Office

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Non-permament US Residents/Visa Holders	Due to laws requiring J and most H visa holders to work solely at the site of their visa sponsor, J and H visa holders at MGB entities are not permitted to participate in this program. 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
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.
FAQ'S FOR GENERAL ELIGIBILITY AND EMPLOYEE STATUS		
What are my MGB employee entitlements while at Industry?	As an Active Status employee at MGB--Fellow receives full employee benefits as per usual including salary, benefits, insurances and the like.	Dept Administrator
What are my MGB employee requirements while at Industry	All requirements of an Active Status employee remain in effect for Fellow: Health Stream trainings, flu shot reporting, Annual Career Conference or review and the like.	Fellow
Am I eligible for a salary increase while I'm a Fellow at Industry site?	Yes. As an active employee, Fellow remains eligible for the annual increase. Date of increase would follow the standard set by your department, possibly in accordance with your annual career conference or review.	Dept Administrator
Will I have a mentor while at Industry?	Fellow will have 2 mentors: 1 from the company, and one from MGB. Fellow will meet regularly with assigned MGB Mentor throughout the term of your Fellow Project.	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 and may be refined during the Fellow recruiting and selection process to more closely align with the Fellow's skill sets.	Host Industry with Fellow

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Is there an onboarding process at Industry and what does that 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 framework agreement or for any additional terms not addressed in the framework agreement.**	Host Industry with Fellow
GUIDELINES RE: CONDUCTING RESEARCH AT INDUSTRY SITE; DEALING WITH CONFIDENTIALITY AND IP		
Performing Research at Host Industry Site as part of the Fellow's Project	The Industry project scope may allow Fellows to be involved in company clinical research and Human Subject Research (HSR)/clinical trials ***as long as*** involvement does not create "institutional engagement" as determined by the MGB IRB. THAT SAID, and minimally, a Fellows' clinical research activities/responsibilities listed in a Industry host partner's scope of work should not be performed at any clinical trial sites that are enrolling /treating patients. The Innovation team will review all scopes of work involving clinical research with OII and IRB prior to execution of any agreements to confirm if research activities are allowable. As Fellows "assign" to host company any and all inventions and IP, all work performed during the course of the Fellow's Project at the company must be clearly separate and distinct from the Fellow's hospital research and other work, and must remain confidential and not be shared with anyone at MGB. Same for hospital site research-- it must be clearly separate and distinct from work at the company, and Fellows may not share any hospital IP with your Industry host/team. To discuss further, please contact your Innovation Fellows Program contact.	MGB Innovation/OII/ IRB
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 must not discuss Industry Confidential Information outside of their company responsibilities.	Fellow/ Industry

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How do I treat Background IP?	Any IP created prior to the start of the Fellow Project is and shall remain solely owned by Hospital. In order to ensure that such Background IP does not become entangled with new IP created during the performance of a Fellow's Project at a company, it is imperative that all work at the company be separate and distinct from any hospital-based activities.	Fellow
How do I treat new IP?	In general, any new IP created by a Fellow in hospital-based activities shall be owned by the hospital and governed by the MGB Intellectual Property Policy, and must be kept confidential and not shared with the company; and any new IP developed during the performance of a Fellow's Project at a company belongs to the company. Fellows must keep this IP confidential and not share with anyone from the hospital.	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; however, it is possible and will depend upon discussion with the Company and be subject to the terms of the agreement.	Fellow
GUIDELINES RE: IDENTIFYING AND MANAGING CONFLICTS OF INTEREST		
All Fellow candidates will be required to complete the COI Checklist 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 conflict can be managed effectively in order for the applicant to participate.		
Reponsiblities at hospital: eg. Clinical Trials/research, pre-clinical research, teaching, patient care, administration, clinical care providers *(see below for more detail)*	A Fellow candidate needs to discuss with a supervisor what activities they will continue to engage in at the hospital while participating in a Fellow's Project at a company, and Fellow candidate, prior to signing any agreement to participate, will be reviewed for conflicts of interest. Generally speaking, certain research activities cannot be performed concurrently with a Fellow's participation in a Fellow's Project.	COI Checklist to be completed and reviewed by OII and IRB as necessary
Clinical care providers | clinical researchers	Clinicians and/or clinical researchers who use or prescribe any technology or products of sponsoring company in patient care practice or during clinical research studies need to disclose this information up front on the COI checklist for review by OII to make sure that conflicts of interest can be adequately managed.	COI Checklist review by OII
Fellow candidate who currently participates in a Clinical Trial/s at MGB **sponsored** by Fellow's Project Host Industry	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 candidate is considering becoming a Fellow**.	IRB/OII

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Institutional Rules on conducting Clinical Research: Regarding conducting Clinical Research on the technology of Company sponsoring the Fellow's Project	Fellow candidate must disclose and confirm on the COI checklist if participating in any clinical research currently (or anticipates future participation) either *on* any technology, or *using* any technology of the company that will be funding your Fellow's Project – this relates to the MGB and Harvard 1(a) rule on clinical research. **Review and attestation by signature of understanding of the application of Harvard's Clinical Research Rule ("Harvard 1(a)") to involvement in Innovation Fellows Program required.**	IRB/OII
HMS Conflict of Interest Policy	https://ari.hms.harvard.edu/outside-activities/faculty-medicine-coi-policy	IRB/OII
Disclosure of Research activity at MGH	Fellow candidate 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 candidate 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
Financial Interest in Fellow's Project Host Company	If a Fellow candidate or a family member has any financial interest in the Host Company, there may be a conflict of interest that triggers MGB and HMS conflict of interest rules regarding participation in clinical or non-clinical research at that company. Fellow candidate must disclose if receives compensation from Host company: 1. If Cash, how much per calendar year 2. If Equity (includes stock options and any other form of ownership interest) 3. Any Other financial interest in the company	OII
Funding Sources	Fellow candidate 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 determine whether management is needed under the federal COI regulations).	OII

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MD Fellow candidates must 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