

Division of Medical Sciences | Harvard Medical School
Mentor/Trainee Potential Conflict of Interest Disclosure Form

Note to the Dissertation Advisor: After reviewing the attached DMS and HMS policies on Conflicts of Interest and Commitment, please complete all fields, sign, and date. Provide a copy of the form to the student's Dissertation Advisory Committee. Submit updates as needed.

Student's name: _____ Year of entry: _____

DMS Academic Program: _____

Dissertation Advisor: _____

List all (names but not dollar values):

(a) Sources of support for research in the Dissertation Advisor's laboratory:

(b) Names of significant holdings by the Advisor of stock or income in a sponsoring Business, as reported to Harvard Medical School:

(c) Names of companies or entities for which the Advisor consults:

(d) Any other constraints, such as sharing agreements, which could affect the Student's research progress and completion of the dissertation:

Student and Dissertation Advisor have discussed the above.

Signature of Student: _____ Date: _____

Signature of Dissertation Advisor: _____ Date: _____

Guidelines on Conflicts of Interest Division of Medical Sciences, Harvard Medical School

I. Mentor's Obligations to Students and Trainees in Industrial Sponsored Research

(a) Trainees (medical students, graduate students and postdoctoral fellows) must always be encouraged to conduct research in areas that optimize their training. Special care must be taken to assure that a trainee's research is not designed to (and does not appear to) enhance their mentor's Financial Interest, and is not adversely affected by that interest or by contractual aspects of the Sponsored Research agreement that inhibit scientific communication or that commit intellectual property rights to the industrial sponsor.

(b) **Before embarking on a research project**, a trainee must be provided by the mentor with a clear description of 1) any corporate support of the research to be undertaken, 2) any personal Financial Interest the mentor has in a sponsoring Business, and 3) any restrictions that might be imposed on the scientific communication of the data.

(c) **Written approval** must be obtained before a trainee can be assigned to conduct research which is sponsored by a Business or which involves a Technology to which the Business has license rights, and in which the mentor has any Financial Interest.

In the case of graduate students (Ph.D., M.D./Ph.D., M.P.H., and D.M.Sc. candidates), permission must be given by the chairperson (or designated faculty member or committee) for the graduate program and by the mentor's department chairperson.

In the case of medical and dental students (M.D., and D.M.D. degree candidates), permission must be given by the mentor's Medical School department chairperson. Additionally, for research in the Quadrangle departments, permission must be given by the Executive Dean for Academic Programs. For research in the Hospital, permission must be given by the appropriate Faculty Dean.

In the case of postdoctoral fellows, permission must be given by the mentor's Medical School department chairperson.

(d) A trainee may appeal his/her involvement in any industrially Sponsored Research or research which involves Technology to which a Business has license rights when the trainee believes that he or she is being adversely affected by any conflict of interest (real or apparent) resulting from the mentor's relations with the sponsoring Business or with any Business that may benefit from the trainee's research or from the Sponsored Research agreement. The appeal should be made as appropriate to the Executive Dean for Academic Programs, the Hospital's Faculty Dean, and or the School's or Hospital's Ombudsperson.

Faculty in the Division of Medical Sciences should provide the information requested on the Conflict of Interest form to all students doing dissertation research in their laboratories. The completed form should be discussed by the student's Dissertation Advisory Committee (DAC) to ensure that students work on research which can contribute unimpeded to their dissertation. The DAC will require that any updates are disclosed to the student and to the committee. The DAC will also be responsible for item (c) above.

DMS students can contact David Cardozo in the Division of Medical Sciences, or Gretchen Brodnicki, J.D, Dean for Faculty and Research Integrity, Harvard Medical School.

Mentors' Obligations to Students and Trainees in Industrial Sponsored Research, from: Harvard Medical School Conflict of Interest Policy c. 2004, 2008

II. Excerpt from: Academic Rules and Guidelines, Division of Medical Sciences (2013-14)

Conflict of Interest Disclosure: Harvard Medical School's rules on avoiding conflicts of interest require that each dissertation advisor and advisee share a list of potential conflicts of interest and discuss them. Students should make sure that they understand these and how they may or may not have any impact on them and their work. The advisor will prepare a list which is signed by both the advisor and the student. Students should also disclose any potential conflicts of interest that they may have. The dissertation advisory committee (see below) must ensure that this information has been discussed. The intent is to make sure that extraneous activities and financial arrangements do not interfere with the timely progress to degree of each student. See your program administrator or go to the Division or Medical Sciences website [for a form].

Harvard University Faculty of Medicine Policy on Conflicts of Interest and Commitment Harvard Medical School

Excerpts from Harvard Medical School [Faculty Policies on Integrity in Science](#) of special relevance to Mentors and Trainees in the Division of Medical Sciences:

I. Policy on Conflicts of Interest and Commitment ([full text](#)) ([pdf version](#)) (accessed May 2016)

Section IV: Mentors' Obligations to Trainees

The relationship between trainees (medical students, graduate students, residents, and post-doctoral fellows) and those Faculty assigned to mentor them is one that Harvard views as central to the success of medical and scientific training and must be fostered in a way that benefits both the mentor and those mentored. It is recognized that Faculty mentors and their trainees may not have equivalent information, given their relative positions. Furthermore, trainees' Research projects may be dictated, in part, by their mentors' interests and areas of focus, and they may not be privy to their mentors' various relationships with industry. As a result, a risk exists that trainees may not have the information or leverage to recognize projects designed to enhance their mentors' Financial Interests, or object to their own involvement in projects in which a potential financial conflict of interest exists. Because Harvard aspires for a culture where open conversation and communication is paramount and without retribution, trainees should never be forced to choose between challenging a mentor and resigning themselves to involvement in Research about which the trainee has concerns. For these reasons, this policy seeks to ensure that trainees are provided with complete information about any Financial Interests their mentor may have in Research projects, and a neutral process through which trainee's interests may be protected.

Instruction and Advising of Trainees:

A Faculty member's outside activities should not adversely influence the instruction, guidance, or supervision of trainees. Academic assignments should principally serve the interests of the trainees in their academic advancement. To that end, Faculty should not assign trainees to Participate in projects that could constrain their ability to freely discuss, defend, and publish their Research. Additionally, no Faculty member may assign any trainee to any project in which the Faculty member has a Financial Interest has a Financial Interest above the *de minimis* thresholds without prior approval of the Dean or the Dean's designee.⁹

⁹ Faculty who are directly supervising Research are considered to be Participating in the Research.

Disclosure by Mentor of Relevant Financial Interests:

A Faculty Mentor is responsible for ensuring that those who conduct Research with him or her do so with full information about the nature of any relationships with industry that may be impacted positively or negatively by the work.

- **General Disclosure to all Trainees:** Faculty must disclose to all individuals whose job description includes assisting with the Faculty's Research work any Financial Interests (whether Income or Equity) held by the Faculty member in any Business related to the Faculty member's Research, teaching, or clinical care. The individuals to whom such disclosure must be made may include, but are not limited to, students, trainees, and other Faculty. **Such disclosure must be made prior to or at the time an individual is offered a position or collaboration** with the Faculty member's Research team or Research laboratory or any other job that may encompass assisting with the Faculty member's work.
- **Project-Specific Disclosure:** Before a trainee may be involved in any specific Research project, the trainee's Faculty mentor must provide a clear description of the following to the trainee:
 - the source of funding of the specific Research project (industry or otherwise);
 - any Financial Interest (whether Income or Equity) held by the Faculty mentor in a Business that provides Sponsored Research support to the project;
 - any Financial Interest (whether Income or Equity) held by the Faculty member in a Business whose Technology is being investigated in the project;
 - any restrictions that may be imposed on the timing of the scientific communication of data.
- **Trainee Right to Raise Concerns Confidentially:** A trainee shall have the right to raise concerns regarding his/her participation in Research that is sponsored by a Business or Research investigating a Technology of a Business in which a co-investigator or mentor holds a Financial Interest (whether Income or Equity). Concerns should be raised to and addressed by:

1) In the case of undergraduate or graduate students (A.B., Ph.D., M.D./Ph.D., M.P.H., and D.M.Sc. candidates), concerns may be brought to the Dean for Faculty and Research Integrity, the chairperson (or designated Faculty member or committee) for the undergraduate concentration or graduate program, or to the mentor's department chairperson.

2) In the case of postdoctoral fellows, residents, and medical and dental students (M.D. and D.M.D. degree candidates), concerns may be brought to the Dean for Faculty and Research Integrity or to the mentor's department chairperson.

II. Faculty of Medicine Statement on Research Sponsored by Industry ([full text](#)) (accessed 10/2015)

The Harvard University Faculty of Medicine welcomes industrially supported research agreements which stimulate its investigators, promote technological transfer, and provide valuable support. At the same time, it recognizes the need to avoid arrangements that might compromise, or seem to compromise, its intellectual principles and purposes and the freedom of inquiry that members of the Faculty enjoy. As an institution, the University benefits from public research funds and the public's trust, and it has an obligation to develop its research discoveries with concern for the public's interest.

This statement outlines some general principles - concerning how and why research is conducted within the Faculty of Medicine—with which all research agreements concluded with for-profit external sponsors (referred to, hereafter, as industrially-sponsored research agreements) should conform.

I. Conduct of Research

The exchange of information and the discussion and interchange of ideas are basic elements of all University research. Agreements to perform secret research in Harvard laboratories are unacceptable.

A. The proscriptions on secrecy in industrially-sponsored research agreements must conform with those that apply to federally-sponsored research. If involvement in a research project would inhibit free and open interactions among scholars, the University should not accept it. However, it is recognized that it may be appropriate to accept confidential background information from industrial sponsors. Such disclosures should be minimized and should be made available only to those members of the research team who require access to them. Harvard and the principal investigator should assure that the confidential nature of the information is understood by those who receive it and should exert reasonable efforts (no less than the protection given Harvard's own confidential information) to maintain such information in confidence. Acceptance of confidential background information must not be permitted to affect the ability of investigators to openly publish all the results of sponsored research. Investigators may agree not to include confidential background information in publications so long as such omissions do not affect the reporting of research results and the ability of other scholars to replicate the published results.

B. It is essential that the research of students and postdoctoral-fellows-in-training contribute, and be perceived to contribute, to their scholarly development. They should not ordinarily participate in industrially-sponsored research that involves confidential information or otherwise constrains the right to publish or communicate freely. Exceptions consistent with the principles of Faculty of Medicine should be approved in advance by the student's Department or at a higher level. In addition, Departments, degree-granting committees and/or the Division of Medical Sciences should periodically review the work of students engaged in industrially-sponsored research to see that the educational commitment of the University to its students is maintained.

C. Agreements may permit industrial sponsors to examine manuscripts for potential inventions or discoveries on which patent applications should be filed. With Principal Investigator approval, sponsors may be given an advance period of thirty (30) days to review such manuscripts before they are submitted for publication so that optimal protection of intellectual property can be achieved. If necessary to permit the preparation and filing of patent applications before publication, the Principal Investigator may agree to delay submission for an additional period of up to thirty (30) days. Agreements with industry may not otherwise restrict the rights of investigators to publish their findings nor to communicate their research results freely in other ways consistent with ethical and professional standards. Agreements to treat University-based research as confidential, to withhold publication, or to permit sponsors to modify materials submitted for publication, are unacceptable.

D. The responsibility for the design and conduct of industrially-sponsored research programs and flexibility in directing them must remain with principal investigators. Sponsors may consult on matters of mutual concern but they may not dictate how research shall proceed.

E. Protocols for research to be funded by industry must be approved by the Department head.

F. Faculty members should be informed of the existence of industrially-sponsored agreements in their Department, and any special provisions in these agreements should be explained to them.

G. General information on the subject, duration, funding sources, and budget of each industrially-sponsored research agreement should be openly available, along with information on whether there are any associated exclusive or nonexclusive patent agreements or any restrictions on open communication.

H. The support of a major portion of a faculty member's research by a single corporate sponsor is generally undesirable; whenever such support is permitted, the research should be periodically reviewed and approved by the Dean.

I. It is expected that these guidelines on free and open exchange of information will be followed in all instances that involve concepts, processes, products, and other information about natural phenomena. There may, however, be situations (for example, studies involving

records of individuals or identifiable industrial organizations, or university-coordinated educational programs of an apprenticeship character) where exceptions to these guidelines are consistent with the University's educational, professional and scholarly principles. Such exceptions should be granted only after detailed review by the appropriate Dean with advice from appropriate Faculty Committees, and the reasons should be publicly explained.

II. Motivation for Research (Conflicts of Interest)

Section II. Motivation for Research (Conflicts of Interest) has been superseded by the Policy on Conflicts of Interest and Commitment.

III. Quality of Research (Project Review)

The distinction between fundamental intellectual inquiry and commercially targeted development is not always clear and no faculty committee should attempt to define a line of demarcation. Many investigators in the faculty of Medicine are committed to studying tools and processes whose primary purpose is to benefit the health or welfare of society in areas that might have commercial value. Nevertheless, the following University principles and policies apply:

A. The primary assurance of the quality of research carried out under University auspices stems from the scholarly qualifications required of individual principal investigators.

B. Since most federally or foundation sponsored research proposals are subject to peer review, prior approval by the Dean of the scientific content of proposals to conduct such research is often perfunctory. In the absence of other review processes, the Department head should examine the suitability of an industrially-sponsored research proposal before granting Departmental approval. When proposals are large, extend over a long period, and/or entail a substantial commitment of a Department's resources, the Department head and/or Dean may arrange for an additional and more extensive review. Continuing projects should be subject to periodic review.

C. The responsibility faculty members bear for the intellectual development of their research students and the responsibility of the Department, degree-granting committee and/or the Division of Medical Sciences to oversee graduate student research are especially important when industrially-sponsored research is involved, and when conflicts of interest may appear to exist for faculty members or for the University.

IV. Commercial Applications of Research (Patent Licensing)

A. License negotiations should be governed by the University's policy on patents and copyrights, and especially the principle that any invention deriving from University-based research should be developed fully and rapidly in the public interest. In some instances, this goal may be achieved by granting non-exclusive licenses to every company that wishes to develop the research commercially. In others, exclusive licenses may be more appropriate. When they are, for example to justify the investment a pharmaceutical company must make in testing before commercial introduction of a new product, the potential exclusive licensee should satisfy Harvard that:

1. commercial products for public use will be developed as or more effectively through exclusive licenses than through non-exclusive licenses; and that 2. adequate resources can and will be committed to bringing these commercial products promptly into use.

B. The University should retain the right to "march-in" if, after a suitable period, a licensee has not developed and/or commercialized the discovery satisfactorily.

C. The prospective granting of exclusive licenses in industrially-sponsored research agreements raises a number of questions. When one does not know what the invention will be, one cannot demonstrate in advance that an exclusive license will be needed nor that the sponsor will be able to develop it effectively. Accordingly, prospective exclusive licensees should be required to give evidence of their willingness and ability to develop and commercialize the kinds of products or processes likely to result from the research.

In cases in which the investigator or the University has a significant private financial relationship with a potential industrial sponsor of research, it should ordinarily be presumed that a prospective exclusive license would create at least the perception of a conflict-of-interest. Prospective exclusive licensing in such situations should only be contemplated after the Dean or his designee (or, for agreements not emanating from a single Faculty, a committee of Deans or their designees) has examined the private financial relationships, the suitability of the research, and the licensing terms. The Harvard Corporation should be advised of the background and conditions of any such proposed arrangement.

October 1983

Amendments Adopted January 1996