

Faculty of Medicine Statement on Research Sponsored by Industry

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.

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Amendments Adopted January 1996