



Exception Request to the Research Support Rule **Faculty of Medicine**

Research must be protected from bias to ensure that the results of the Research are valid and can be relied on in the development of medical therapies and in furtherance of scientific knowledge. Concerns about the ultimate impact of financial conflicts on end-users of the Research and research integrity exist in all Research. It is presumed that Faculty who have an Equity Financial Interest above the de minimis threshold in a Business may not receive Sponsored Research support from that Business for Research. The presumption may be overcome when, in the judgment of the Standing Committee or its designee, individuals holding presumptively prohibited Equity Financial Interests present sufficient countervailing circumstances (the benefits of the proposed Research must outweigh the risks, and the Financial Interest must be able to be appropriately managed) for being permitted to simultaneously hold the Equity Financial Interest and receive Sponsored Research support.

For more information, please refer to the Faculty of Medicine Policy on Conflicts of Interest and Commitment at the following link: <http://ari.hms.harvard.edu/faculty-medicine-policy-conflicts-interest-and-commitment>.

A statement of a Faculty member's importance or expertise will not suffice. This form provides Faculty members with the opportunity to provide countervailing circumstances (detailing his/her contributions to the study as well as a reasonable plan that will protect the data and the institution).

Accordingly, when the Standing Committee considers a petition to rebut the Research Support Rule, it shall consider factors that include, but are not limited to, the following:

- Nature of the proposed Research;
- Anticipated role in the proposed Research;
- Nature of the Financial Interest and relationship with the Business;
- How closely the Financial Interest is related to the proposed Research;
- The degree to which the Financial Interest may be affected by the proposed Research;
- The degree to which the proposed Research may be affected by the Financial Interest;
- Reasons for the Faculty with the Financial Interest to be involved in the Research;
- Impact on trainees;
- If applicable, role in developing intellectual property for Technology to be studied;
- If applicable, whether the Sponsored Research is on Technology subject to an institutional license or royalty-sharing agreement, and if so, the type of license/royalty-sharing income received (i.e., one-time signing fee, success-based milestone, non-success-based milestone); and
- Likely effectiveness of potential management strategies.

Name:

Harvard Title:

Harvard Department or
Affiliated Institution:

Email:

Telephone Number:

1. Proposed amount and nature of the sponsored research support (Will the funding be all cash, materials/reagents only, or a combination of the two? Also, approximately what percentage of your lab's overall funding would this sponsored research represent? Approximately how much of this funding would go towards supporting trainees? How many trainees do you anticipate will work on this project?):

2. Anticipated research start date:

3. Anticipated length of research project:

4. Description of research aims (Please attach the research proposal):

5. Please describe your financial interest(s) in the proposed sponsor and your relationship to the business (if privately owned, please include estimate of percentage of equity owned). Please include estimate of income for service as consultant/SAB/licensing (if applicable) and spousal/partner involvement or interest (if applicable). Also please include background information about how the company was formed and your role with the company going forward:

6. Please describe the nature of the business of the proposed sponsor, including details such as: business size/number of employees, mission, diversity of product areas, corporate structure (private vs. public), market share, whether a CEO has been hired, whether there is VC funding, when incorporated:

7. If the company has licensed technology from your lab, please describe if and how it will be used in the research proposed:

8. Please describe the relationship of the proposed sponsored research to the proposed sponsor's business. Why is the sponsor interested in funding this research? Can the research be conducted elsewhere? If not, why?

9. Have you sought alternative funding for this research? If not, why?

10. Please describe how the proposed research could affect your financial interest. Please also describe how the financial interest could affect the proposed research:

11. Please identify the risks of conducting the proposed research while having a financial interest in the sponsor:

12. How can this research be structured to minimize the potential conflict of interest? Are there other management/mitigation measures that could be implemented to manage the conflict of interest? Have you already implemented these?

13. Please describe how your participation in the proposed research will contribute to scientific progress; you may also include a description of your unique qualifications to conduct the research:

14. Please describe the role your trainees will play in this research (if any). Please provide the specifics of their involvement. Even if not involved, please describe the impact (risks and benefits) that conducting this research may have on trainees in your lab:

15. Please describe how this research will be transitioned to the company at its completion:

16. Please provide any additional information you believe will assist the Committee in determining whether an exception should be granted:

Date: