Exception Request to the Clinical Research Rule
Faculty of Medicine

It is presumed that Faculty who Participate in Clinical Research may not have a Financial Interest (Equity or Income) exceeding the *de minimis* thresholds in a Business whose Technology is being investigated. The presumption may be overcome when, in the judgment of the Standing Committee or its designee, individuals holding presumptively prohibited Financial Interests present demonstrable, compelling justification - consistent with the rights and welfare of Clinical Research subjects - for being permitted to simultaneously hold the Financial Interest and Participate in the Clinical Research.

For more information, please refer to the Faculty of Medicine Policy on Conflicts of 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 demonstrable compelling justification detailing his/her unique contribution to the study as well as a reasonable plan that will protect the human subjects, the data, and the institution.

Research that involves human study participants is subject to heightened scrutiny. This is because the ramifications of bias, or the appearance of bias, in Clinical Research are more immediate and can directly impact the safety and welfare of Clinical Research participants. Accordingly, when the Standing Committee considers a petition to rebut the Clinical Research Rule, it shall consider factors which may include, but are not to be 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 Clinical Research is on the Technology subject to an institutional license or royalty sharing agreement, and if so, type of license/royalty sharing income received (i.e., one time signing fee, success based milestone, non-success based milestone);
The best interests of study participants who could benefit from the Clinical Research; and
Likely effectiveness of potential management strategies.

Name:	
Harvard Title:	
Harvard Department or Affiliated Institution:	
Email:	
Telephone Number:	
Anticipated research start date:	
Anticipated length of research project:	

Description of research aims/Nature of the clinical research:

Role in the research (e.g., Principal Investigator, Co-PI, etc.). Please also describe what your contributions to the research will be:

Please describe your financial interest(s) exceeding the de minimis in a business whose technology will be being investigated as well as your relationship to the business:

Please describe the nature of the business including, but not limited to, details such as business size, mission, diversity of product areas, corporate structure (private v. public) and market share:

How will the technology be used in the proposed research?

Please describe the relationship of the financial interest to the technology being studied.

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

Please identify the risks of conducting the proposed research while having a financial interest in business whose technology is being studied?

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:

What roles will your trainees have in this research? Please provide the specifics of their involvement. Even if not involved, please describe the impact (risks and benefits) conducting this research may have on your trainees and junior colleagues:

Did you have a role in developing the Technology being studied? If so, please describe.

If applicable, please describe whether the Clinical Research is on the Technology subject to an institutional license or royalty sharing agreement, and if so, type of license/royalty sharing income received (i.e., one time signing fee, success based milestone, non-success based milestone).

What do you see as the best interests of study participants who could benefit from this clinical research?

How can this research be structured to minimize the potential conflict of interest and protect research subjects? Are there other management/mitigation measures that could be implemented to manage the conflict of interest? Have you already implemented these? (Measures may include, for example, one or more of the following: the covered party may not be allowed to (i) serve as principal investigator, (ii) analyze data, (iii) determine whether potential subjects are eligible for enrollment, iv) solicit consent, or v) determine whether an adverse event report is required.)

Please provide any additional information you believe will assist the Committee in determining whether the presumption should be overcome:

Date: