

Outside Interests Form

Instructions

All investigators, sub-investigators, and study personnel who are responsible for the design, conduct, or reporting of the research and will make a direct and significant contribution to the research (e.g., recruiting subjects, administering the informed consent document, determining subject eligibility, generating study data, assessing primary endpoints, evaluating efficacy data, etc.) must complete this form at the time of initial new protocol submission or when added to a protocol later, even if they have no financial interests to report. A separate form is completed for each protocol and Part B of the form must be specific to a single study. If you have no outside interests to report, please leave Part B blank and sign the attestation in Part C.

While research is ongoing, changes in outside interests must be submitted on this form within 30 days of acquiring the interest. A failure to report an outside interest within 30 days is considered a protocol violation.

The form must be submitted to OHRS as part of any one of the following submission types, regardless of the IRB of record:

- **Initial Submission of a New Research Protocol** – Submit a separate administrative modification in iRIS in parallel with the initial submission. The Core Site is responsible for submitting this information for applicable individuals listed on the initial submission.
- **Updates/Additions** – Submit an administrative modification in iRIS when an applicable individual joins an existing protocol, or whenever an applicable individual has a change in outside interests to be disclosed to the IRB.

Reporting outside interests on this form does not automatically satisfy additional reporting requirements as mandated by DFCI policy administered by the DFCI Office of Research Integrity (ORI) or any other institutional requirements. For questions about your disclosure of outside interests to the ORI, please contact the Office of Research Integrity at ResearchIntegrity@dfci.harvard.edu or (617) 632-3490.

For questions about submitting this form, please contact the OHRS at ohrs@dfci.harvard.edu.

Part A – Study Information

DFCI Protocol No.

Protocol Sponsors

Protocol Title

Name of Person Completing this Form

Home Institution

Phone

Email

Part B - Outside Interests Information

Report any outside interests (over \$0) in an entity that sponsors, provides support for, owns or produces technology being investigated, or otherwise has an interest in the research.

- Report not only interests you hold directly, but also those held by a spouse and/or dependent children.
- Interests must be reported for the current calendar year (beginning January 1). Please do not include any outside interests from the prior calendar year.
- Reportable outside interests include:
 - Cash compensation from the entity (in exchange for consulting, serving on an advisory board, etc.)
 - Ownership (such as stock) in the entity
 - Intellectual Property (IP) rights
 - Holding an Executive Position or serving on the Board of Directors for the entity

Please provide complete and detailed information about each interest. Failure to complete all fields will result in the submission being returned. Be sure to list all interests for the current calendar year, including those previously reported to and approved by the IRB. Be sure to describe the relationship between the interest and the research. If there is no relationship, then the interest does not need to be reported.

I have **do not have** outside interests to disclose.

Is this interest New/Changed/Previously Reported?	Company	Private or public?	Describe the outside interest (e.g. cash compensation for consulting, stock ownership, Intellectual Property, Board of Director service, Executive Position)	Interest holder (Me, spouse, dependent child)	Date outside interest acquired (payment date or date began service in Executive Position) (XX/XX/XX)	\$ Value	Describe the relationship between the interest and this research
<i>Example: New interest</i>	<i>Diagnostics Incorporated</i>	<i>Public</i>	<i>Cash for SAB</i>	<i>Me</i>	<i>05/27/16</i>	<i>\$3500</i>	<i>Company sponsors the research</i>
<i>Example: Previously reported</i>	<i>OncoCure</i>	<i>Public</i>	<i>Purchased stocks</i>	<i>Spouse</i>	<i>03/15/16</i>	<i>\$22K</i>	<i>Company produces the drug</i>

Is this interest New/Changed/Previously Reported?	Company	Private or public?	Describe the outside interest (e.g. cash compensation for consulting, stock ownership, Intellectual Property, Board of Director service, Executive Position)	Interest holder (Me, spouse, dependent child)	Date outside interest acquired (payment date or date began service in Executive Position) (XX/XX/XX)	\$ Value	Describe the relationship between the interest and this research

If more lines are needed, please complete another copy of this form. Please specify Log of .

Additional Comments:

Part C – Attestation and Signature

By signing below, I hereby attest that:

- I understand that this disclosure is mandated by the conflict of interest policies of the DFCI IRB.
- The information disclosed herein accurately represents all reportable outside interests held by me, my spouse, and my dependent children.
- I will update this disclosure by submitting an amendment to OHRS within 30 days of the receipt of any reportable outside interest.
- I am aware of my obligation to disclose financial interests and outside activities to my primary institution in accordance with its conflict of interest policies, and I am currently in compliance with this obligation.

Signature

Date