

Study Team Member Outside Interest Disclosures

The DFCI IRB requires that study team members disclose any outside interests that could be perceived as having an impact on the conduct of the research. An outside interest may be considered by the IRB to be a Conflict of Interest (COI) requiring a plan for ensuring objectivity in the selection of subjects, informed consent, and gathering, analyzing and reporting of data. For example, a COI may arise when an investigator participating in the research owns equity in the sponsor of the research study. If a COI is identified, the Office of Research Integrity and Compliance (ORIC) will provide a management plan which may include disclosure in the informed consent form which is then reviewed by the DFCI IRB to ensure the integrity of the research is maintained and subjects are protected.

Please note: Study team member COI reviews are separate from reviews for Institutional COIs which may arise, for instance, when the institution itself owns equity in the study sponsor. Please refer to the DFCI Information Sheet entitled “DFCI IRB Institutional Conflicts of Interest Policy” for more information.

➤ **Who needs to report outside interests?**

- All members of the study team (e.g., MDs, NPs, Research Nurses, CRCs, etc.) unless the study is determined by the IRB to be Exempt or Not Human Subject Research.
- ORIC and the DFCI IRB will only review outside interests held by an investigator for DF/HCC sites. When a DF/HCC institution serves as the lead site for a multi-center study, each participating site is responsible for reviewing and managing outside interests.

➤ **What interests do study team members need to disclose?**

- *Study team members must report any outside interests that they have in an entity that sponsors, provides support for, owns or produces technology being investigated, or otherwise has an interest in the research.*
 - Interests over \$0 must be reported.
 - Study team members must report not only interests they hold directly, but also those held by their spouse and dependent children.
 - Interests must be reported for the current calendar year (beginning January 1).
 - 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

➤ **When do study team members report outside interests?**

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- With the New Protocol Application: When a study team member on a new protocol has an outside interest to be disclosed to the IRB, an Outside Interest Form must be included with the new protocol submission.
 - Prior to adding a new study team member: When a new study team member wants to be added to an IRB-approved study but has an outside interest to be disclosed, an Outside Interest Form must be submitted as an amendment prior to the study team member being added to the study.
 - When a study team member has a change in outside interests: If an existing study team member's interests change during the course of the study, the interest must be reported within **30 days** of the change using the Outside Interest Form. The Outside Interest Form is submitted to OHRS as an administrative amendment. Failure to report a change in interest within 30 days of the change should be logged on the minor deviation/violation log.

➤ **Why are outside interests reported to ORIC and OHRS?**

- Any non-zero interest is reported via the Outside Interest Form, and any amount over the *de minimis* is reviewed by ORIC to determine if it rises to the level of a conflict of interest that may impact the risks and benefits of the research and the subject's willingness to participate in the research. Emphasis is placed on the potential risk to the safety and welfare of subjects, and on the potential for bias. This review takes into account, for example, the value of the interest, and the relationship, if any, between the outside interest and the research.

➤ **How are outside interests reviewed by the DFCI IRB?**

- ORIC reviews outside interest disclosures at the time of new protocol review.
- When a new study team member wants to be added to an IRB-approved study but has an outside interest to be disclosed, or when a study team member reports a change in outside interests, ORIC reviews any disclosure over the *de minimis*. The IRB will review any management plans developed by ORIC.

➤ **How are conflicts of interests managed by the ORIC?**

- ORIC may forward significant interests to the appropriate FCOI committee for review, which may impose a management plan or not allow the investigator to conduct the research. Steps to manage the conflict may include, for example:
 - Requiring the study team member to divest
 - Not permitting the study team member to participate in the research
 - Requiring independent data and safety monitoring
 - Disclosure of the interest in the consent form:
 - The following language should be included in the consent form if there is any study team member disclosure to OHRS that is greater than \$0. Study teams can also include this language in the consent form if they anticipate any future study team member disclosure of over \$0:

"It is possible that certain researchers on this study may have earned money from, or own some publicly-traded stock in, the company that makes or is developing

the study [drug/device/intervention/other: please specify]. The amount of money that a researcher may earn and still take part in research is limited by the Harvard Medical School Faculty of Medicine Policy on Conflicts of Interest and Commitment. For more information, please speak with a member of the study team or contact the Dana-Farber Cancer Institute Office of Research Integrity at 617-432-4557 or researchintegrity@dfci.harvard.edu.”

For questions about your disclosure of outside interests to the ORIC, please contact the Office of Research Integrity and Compliance, ResearchIntegrity@dfci.harvard.edu.

For all other questions, please contact OHRS at ohrs@dfci.harvard.edu.

References:

Harvard Faculty of Medicine Policy on Conflicts of Interest and Commitment - <https://ari.hms.harvard.edu/outside-activities/faculty-medicine/faculty-medicine-policy-conflicts-interest-commitment>

DFCI Policy on Conflict of Interest and Commitment - <https://dfci.widen.net/s/w79fkdfdj7/policy-on-conflict-of-interest-and-commitment-15.13-rev-0224.pdf>

Financial Conflict of Interest: HHS Guidance - <http://www.hhs.gov/ohrp/regulations-and-policy/guidance/financial-conflict-of-interest/>

NIH: Financial Conflicts of Interest and Research Objectivity - Issues for Investigators and Institutional Review Boards: <https://grants.nih.gov/grants/guide/notice-files/NOT-OD-00-040.html>

Disclosing Conflicts of Interest in Clinical Research: Views of Institutional Review Boards, Conflict of Interest Committees and Investigators - <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1850937/>

Responsible Conduct of Research (RCR) Conflicts of Interest: http://ori.hhs.gov/education/products/columbia_wbt/rcr_conflicts/foundation/#4