The DFCI IRB is committed to ensuring the safety of research participants at DF/HCC and the integrity of the research. To this end, the DFCI IRB requires that protocols be reviewed for Institutional Conflicts of Interest (Institutional COIs) in addition to individual study team member COIs. Institutional COIs may arise, for instance, when an institution participating in the research owns equity in the research sponsor. If an Institutional COI is identified, the DFCI IRB requires that steps be taken to effectively manage the COI.

Overview of the DFCI IRB's Institutional COI requirements:

- Institutional COI review is required for all new protocols, amendments that add a new site under the DFCI IRB, amendments that add an industry study sponsor, and amendments that add a new study intervention. The review is performed by the DFCI Office of Research Integrity (ORI), which works closely with all DF/HCC institutions.
- While OHRS facilitates the DFCI ORI's reviews, the study team is responsible for obtaining all ICOI-related documents (described below) directly from ORI and submitting them to OHRS for IRB review. The study team is also responsible for maintaining these documents.
- Institutional COI review is generally required prior to IRB review. Please note that this may result in delays of the IRB review.
- If an Institutional COI is identified, the study team must provide the Institutional COI Management Plan for review by the DFCI IRB. The IRB may determine that the Institutional COI Management Plan is sufficient, or may require that additional steps be taken.
- The Management Plan typically requires disclosure of the Institutional COI in the consent form. The DFCI IRB typically requires that the disclosure be included in all consent forms (e.g., Screening Consent, Pregnant Partner Consent).
- The Management Plan typically requires that a Participant Information Sheet be provided. The DFCI IRB typically requires that the Information Sheet be provided to the participants at the site that has the Institutional COI, but requires that it be made available to all participants at the other DF/HCC sites (because the Information Sheet is referenced in the consent form used by all DF/HCC sites).
- Some Management Plans require independent data and safety monitoring for the study. When required by the Management Plan, details must be included in the protocol (or protocol addendum). Specifically, the protocol must state who will perform the monitoring, the frequency of the monitoring, and the focus of the monitoring. Additionally, if applicable, the protocol must describe how the independent monitoring intersects with other monitoring planned for the study.
- Eligibility Exception requests will be reviewed by the Full IRB, rather than via expedited procedures, if the potential participant is either at a DF/HCC site subject to an Institutional COI Management Plan or enrolling on a protocol for which the lead DF/HCC site is subject to an Institutional COI Management Plan.
- During the course of the study, if the DFCI ORI notifies the study team that there is an Institutional COI and implements a management plan, the Overall PI is responsible for submitting an Amendment to OHRS for IRB review. The Amendment should include the

Management Plan, Participant Information Sheet, and revised consent form(s) with disclosure language.

- It is the responsibility of the Overall PI to comply with all institutional and IRB Institutional COI policies. Violation of these policies, or of an Institutional COI Management Plan, must be reported immediately to the DFCI IRB via submission of a Major Violation to OHRS.

For questions about Institutional COIs, please contact the DFCI Office of Research Integrity at DFCIORIICOI@dfci.harvard.edu.

For questions about the DFCI IRB's Institutional COI requirements, please contact OHRS at (617) 632-3029 or ohrs@dfci.harvard.edu.