Guidance Tool: iRIS Pre-submission review for ICOI

New Application Management when ICOI is Identified

DFCI Office of Research Integrity and Compliance performs reviews for oncology trial applications to identify instances of Institutional Conflict of Interest (ICOI) for all DF/HCC sites and the Broad Institute (*when Broad is a participating site*) regardless of governing IRB.

ORIC identifies instances of ICOI, regardless of the lead/participating sites, by following the steps outlined below:

BCH (Boston Children's Hospital)

Trials in which BCH is a lead or participating site are referred by email by DFCI ORIC to BCH Compliance Office for ICOI review on a trial-by-trial basis. If BCH identifies ICOI, BCH will review and provide ORIC with their decision regarding participation on the clinical trial. ORIC will communicate BCH's decision with the study team and will document the record as necessary in iRIS, in some cases the trial may be placed on hold pending BCH's decision or implementation of BCH's management plan.

BIDMC (Beth Israel Deaconess Medical Center)

Trials in which BIDMC is a lead or participating site are referred for identification on a trial-by-trial basis by email between ORIC and BIDMC's Office of Integrity and Compliance (OIC). If BIDMC identifies ICOI, BIDMC will reach out to the investigator for next steps. BIDMC will communicate the status and outcome with the Investigator and to DFCI ORIC. If approved for manageability, BIDMC OIC will provide DFCI ORIC with their approved management plan. ORIC will upload the management plan in iRIS and/or will document the record as necessary in iRIS. The trial application will be on hold pending BIDMC's decision.

Broad Institute

In cases where Broad is participating as a research site on a clinical trial, ICOI are identified by DFCI ORIC and referred to Broad's Office of Strategic Operation (OSO) for review. Broad's OSO will confirm ICOI and coordinate management steps with the lead institution, often in coordination with DFCI ORIC. If it is determined that ICOI is manageable, ORIC will upload the management plan in iRIS and/or will document the record as necessary in iRIS. The trial application will be on hold pending Broad's decision.

MGB (Mass General Brigham)

Trials in which MGB is a lead or participating site, ICOI is identified by DFCI ORIC and referred to MGB Office of Interactions with Industry (OII) by email for review. MGB's OII reviews the trial information and notifies DFCI ORIC of its determination. If MGB confirms ICOI, MGB's OII will reach out to the Investigator of the trial for next steps. MGB applies a rebuttable presumption policy for matters related to ICOI and may require a referral to MGB's quarterly ICOI Committee meeting for determination of manageability.

The OII will communicate the status and outcome of MGB's ICOI Committee with Investigator and DFCI's ORIC, ORIC will process the trial outcome in accordance with MGB's ICOI Committee decision. If a management plan is issued, ORIC will upload the ICOI Management Plan in iRIS. The trial application will be on hold pending MGB's decision.

DFCI (Dana-Farber Cancer Institute)

In cases where ORIC determines there is a DFCI ICOI the following applies:

1) for ICOI with existing determination of manageability previously approved by the ICOI Committee:

   A. the completed pre-submission form will be returned by email noting ORIC's identification of the ICOI, along with the ICOI disclosure language required in the ICF

   B. the study team must include the disclosure language in all ICFs when submitting the new application in iRIS.

2) for ICOI without existing determination of manageability approved by the ICOI Committee (ICOIC):

   A. ORIC will identify the ICOI and notify the study team by email that the ICOI requires a review for manageability by ICOI Committee.

      i.) in instances of royalty revenue: the ICOI Committee will review ORIC's proposed management plan and ICOI disclosure. If approved:

         a. the completed pre-submission form will be returned by email noting ORIC's identification of the ICOI, along with the ICOI disclosure language required in the ICF.

         b. the study team must include the disclosure language in all ICFs when submitting the new application in iRIS

      ii). in instances when DFCI has an equity interest in a Sponsor of a trial:

         a. ORIC will identify the ICOI and notify the study team by email that the ICOI requires a review for manageability by the ICOI Committee.

         b. ORIC will provide the Investigator and study team with the "Application of Rebuttal Presumption of Compelling Circumstances]" form.

         c. If the Investigator wishes to pursue conducting the trial at DFCI, the Investigator should complete and submit the "Application of Rebuttal Presumption of Compelling Circumstances" form to ORIC by email DFCIORIICOI@dfci.harvard.edu and request a review of the circumstances by the ICOI Committee.

         d. ORIC will coordinate the review of the "Application of Rebuttal Presumption of Compelling Circumstances" form at DFCI's next ICOI Committee meeting.

         e. the ICOI Committee will review the "Application of Rebuttal Presumption of Compelling Circumstances" for determination of manageability. If the ICOI

Committee agrees with the Investigator that there are compelling circumstances for the trial to be conducted at, the ICOIC will approve a management plan and DFCI ORIC will notify the study team of the outcome and:

- the completed pre-submission form will be returned to you by email noting ORIC's identification of the ICOI, along with the ICOI disclosure language required in the ICF.

- the study team should include the disclosure language in all ICFs when submitting the new application in iRIS.

The ICF disclosure language is approved by DFCI's ICOI Committee in collaboration with Office of General Counsel and may not be modified without written approval from DFCI's ICOI Committee.

All DF/HCC affiliates

Submitting a new application in iRIS following a pre-review submission when ICOI has been identified:

1) Study teams should submit their new applications in iRIS normally.

2) When the trial is routed to DFCI ORIC in iRIS, ORIC will:

- Upload the completed pre-submission review form in iRIS, noting the ORIC review outcome
- Review the NPA against the pre-submission form for any changes
- In cases of identified ICOI during the pre-review request, ORIC will:
  - Upload all ICOI documents (i.e., management plans) provided by their respective institutions in iRIS
  - When required: ORIC will verify that all ICFs include the ICOI disclosure language and that the disclosure language is correct
  - Issue comments in iRIS that ICOI documents have been uploaded
  - Notate the iRIS record outcome that a management plan is required
  - Clear the trial at time of review of new application*

**Please note: incomplete, incorrect, or missing ICOI disclosure language in any ICFs will result in ORIC issuing conditions in iRIS requiring ICFs be corrected and resent to ORIC for re-review.*

For questions related to this form or ICOI review processes, please contact:
Program Manager, Institutional Conflict of Interest
Office of Research Integrity and Compliance
Dana-Farber Cancer Institute
By email: DFCIORIICOI@dfci.harvard.edu
Visit our website: DF/HCC Institutional Conflict of Interest