

## Guidance Tool: iRIS Pre-submission Review for Institutional Conflict of Interest

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.

To request an early review for potential ICOI and to receive ICF disclosures prior to submitting NPA's in iRIS, please complete the "iRIS Pre-submission ICOI Review Request Form" and submit it via email to Office of Research Integrity and Compliance at: [DFCIORICOI@dfci.harvard.edu](mailto:DFCIORICOI@dfci.harvard.edu).

*Pre-submission review does not replace the routing and review in iRIS but does streamline the process at time of new application.*

The **benefits** of utilizing this process are:

- expediting ICOI disclosures for ICFs,
- reducing conditions pertaining to ICOI disclosure and decreasing processing time when applicable
- providing insight on potential ICOI to assist study teams with their decisions to proceed with the trial or not
- in cases where ICOI are identified, this process may allow time for Investigators to work with their respective institutions for review of the trial and determination of manageability.

### Timing

Investigators or study teams may request a pre-submission review for ICOI determination *up to four weeks* prior to submitting a new application in iRIS.

### Procedure

Study teams – may submit a fully completed form by email for ICOI review *up to four weeks* prior to submission of a new application in iRIS.

ORIC - will conduct the review and provide study teams with its determination by notating the outcome on the form and returning it to study teams.

### Outcomes

Determination of "**No ICOI**":

In cases where ORIC determines there is no ICOI identified on the trial: the completed form will be returned to the study team by email noting ORIC's ICOI determination for your records.

Determination of "**ICOI**":

Please visit: "[Guidance Tool: iRIS Pre-submission Review for ICOI -New Application Management When ICOI is Identified Guide](#)" when an instance of ICOI is Identified this document provides detailed information for Investigators and study teams related to their respective institution's ICOI review and process for management of their ICOI in cases where

ICOI was identified during the review process.

Submitting a new application in iRIS following a pre-review

- 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 with the ORIC review outcome
  - Review the NPA against the pre-submission form for any changes
  - **In cases of identified ICOI**, 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 the 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: [DFCIORICOI@dfci.harvard.edu](mailto:DFCIORICOI@dfci.harvard.edu)

Visit our website: [DF/HCC Institutional Conflict of Interest](#)