

iRIS Office Hours

MARCH 1, 2022

Submit questions using the
Zoom Q&A function

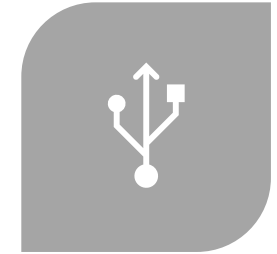
On the
agenda for
today...



**IRIS TO ONCORE
INTERFACE**



**DOSE FORM
UPDATES**



**PHASE I RESEARCH
SRC/IRB ROUTING**



**CONSENT REVIEW
COMMITTEE**



**CONTINUING
REVIEW
CLARIFICATION**



**ADDITIONAL
REMINDERS AND
UPDATES**

iRIS to OnCore Interface: 2/23/22



Welcome to the DF/HCC iRIS Wiki Page

[CLICK HERE TO LOGIN TO IRIS](#)

iRIS Releases

[iRIS Updates](#)

[iRIS to OnCore Interface NEW!](#)

[DF/HCC Broadcast](#)

[Summary of Work Instructions](#)



Welcome to the DF/HCC OnCore Wiki Page

OnCore Support

URGENT ISSUES (subject safety related or subject care critical): Call the HelpDesk at 617-632-3399 and request to have the **Patient Critical Ticket** routed to "OnCore-DFCI" to ensure the OnCall staff gets paged.

NON Urgent Issues: 'Fix an Issue' using the **IS Service Hub** and enter "OnCore - DFCI" in the Application In Use box above the description.

Additional Instructions- [CLICK HERE](#)

[OnCore to iRIS Interface](#)

iRIS to OnCore interface is live. View the [Interface Guide](#) for details on what information interfaces to OnCore.

iRIS to OnCore Interface

- Various fields are interfaced **from iRIS to OnCore. This is a one-way interface.** Information will not flow from OnCore to iRIS.
- **Not all values or submissions are interfaced.**
 - Only certain submission **types** and **fields** are sent to OnCore
 - Information in OnCore is only updated at **very specific time points..**

iRIS to OnCore Interface: Impact

- **Study Team Impact:** It is crucial to ensure the data entered in iRIS is accurate as it will flow downstream to OnCore and other systems. Corrections may require updating iRIS in addition to other systems. Otherwise, study teams should not notice a change in their day-to-day work.
- **ODQ/OHRS Impact:** A large portion of their manual OnCore updates will be eliminated. Study teams will have less need to follow up with ODQ/OHRS regarding OnCore data entry.

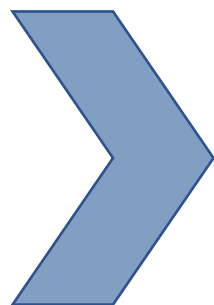
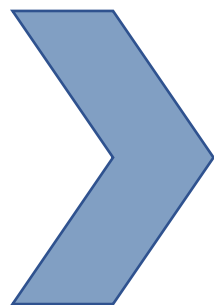
Which Submissions are Interfaced?

iRIS Submission

Initial
Submissions

Amendments
(with NPA
attached)

Events, CR,
PR, RCRI,
Study
Complete



OnCore sections

Details, Management, Staff, Sponsor,
Institution, Reviews

SRC/IRB Reviews

Which Oncore Sections are Interfaced?

Details

Staff (PIs)

Management

Sponsor

Institutions

Reviews

*Not all fields in these sections interface!

Notable Exclusions

- Staff Tab: Only the PIs (core and subsite) will interface. Study teams are still expected to maintain the staff tab in iRIS and OnCore
- Treatment Arms (and their status): ODQ controls arm status manually
- Institution Status: ODQ opens and closes protocols manually

Reading the Interface Guide

Sponsor

Interfaces at IRB Approval (for initial submissions and amendments). Study teams must search the **sponsor dictionary** in iRIS prior to adding one manually. Only sponsors not in the dictionary should be added manually.

Interfaced	Reference Code	Notes
Sponsor	SP1	Users must search from the iRIS sponsor dictionary
Sponsor Protocol Number	SP2	Not a required field
Roles	SP3	Funding or Protocol Control (i.e., Regulatory in OnCore)
Principal Sponsor	SP4	For DF/HCC Sponsored studies, DF/HCC Cancer Center is listed as Funding and Principal. For Non-DF/HCC Sponsored studies, the sponsor listed as protocol control (Regulatory) is Principal

Key

Interfaced
Not Interfaced

Sponsor Details					
Sponsor	Sponsor Protocol No.	Role(s)	Principal Sponsor	Grant No. [Fund Acct. No.]	NIH/NCI Info
SP1	SP2	Funding, Regulatory SP3	SP4	SP5	SP6

iRIS to OnCore Interface: Questions

Where do I go if I have questions?

- Start with the **Interface Guide** on the OnCore or iRIS Wiki
- If there was an error with the **information submitted in iRIS**, it will need to be corrected in the next iRIS submission.
- Error with the **information that interfaced** to OnCore (but iRIS is correct), submit a Partners Helpdesk ticket to “DFHCC-iRIS”



iRIS Release – March 4th

- ✓ Review Important Changes
- ✓ Email to DF/HCC Community will be sent on Friday
- ✓ iRIS Wiki will be updated accordingly



The screenshot shows the DF/HCC iRIS Wiki Page. At the top center is the logo for DF/HCC iRIS, which includes the text "DF/HCC" in a red box, a green circular icon, and "iRIS" in a stylized font, with "Powered by iMedRIS" below it. Below the logo is the text "Welcome to the DF/HCC iRIS Wiki Page". Underneath that is a blue link that says "CLICK HERE TO LOGIN TO IRIS". At the bottom of the page, there is a blue header bar with the text "iRIS Releases". Below this bar is a white area with a list of links: "iRIS Updates" (circled in red), "iRIS to OnCore Interface **NEW!**", "DF/HCC Broadcast", and "Summary of Work Instructions".

Updated Dose Form in iRIS

Key Policy Updates:

- Clarified the process for dose escalation/expansion on studies that were approved prior to February 2021 where the memos do not state “in its entirety”.
- Prior to February 2021, SRC and IRB usually approved all parts of phase I together (e.g., escalation and expansion). For phase I/II trials, phase II was not approved unless specifically indicated.

1.10 Type of Changes Requested

Is this submission requesting any of the following?

Opening an existing dose/cohort within the approved protocol or declaring a new dose that is included in the approved protocol design.

Transition from escalation to expansion or reopening an expansion arm that was previously closed.

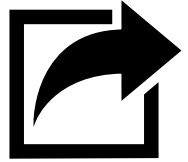
Moving from one study phase to the next (for example phase I to phase II) or reopening a phase that was previously closed.

DFCI IRB studies: Please attach [the applicable SRC and IRB approval memos for this change per the OHRS policy](#). If the SRC and IRB have not approved this portion of the study, **DO NOT USE THIS FORM** and please submit an **Amendment** form instead.

Select or Revise Existing Add a New Document Add Multiple Documents

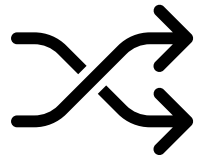
Detach	Version	Title	Category	Expiration Date	Document Outcome	Checked Out	View Document
No Document(s) have been attached to this form.							

Phase I Research – SRC/IRB Routing



Fast-track routing for Phase I industry-sponsored *new* protocols

- Initial process applies to new protocols only, with hopes to eventually expand to amendments



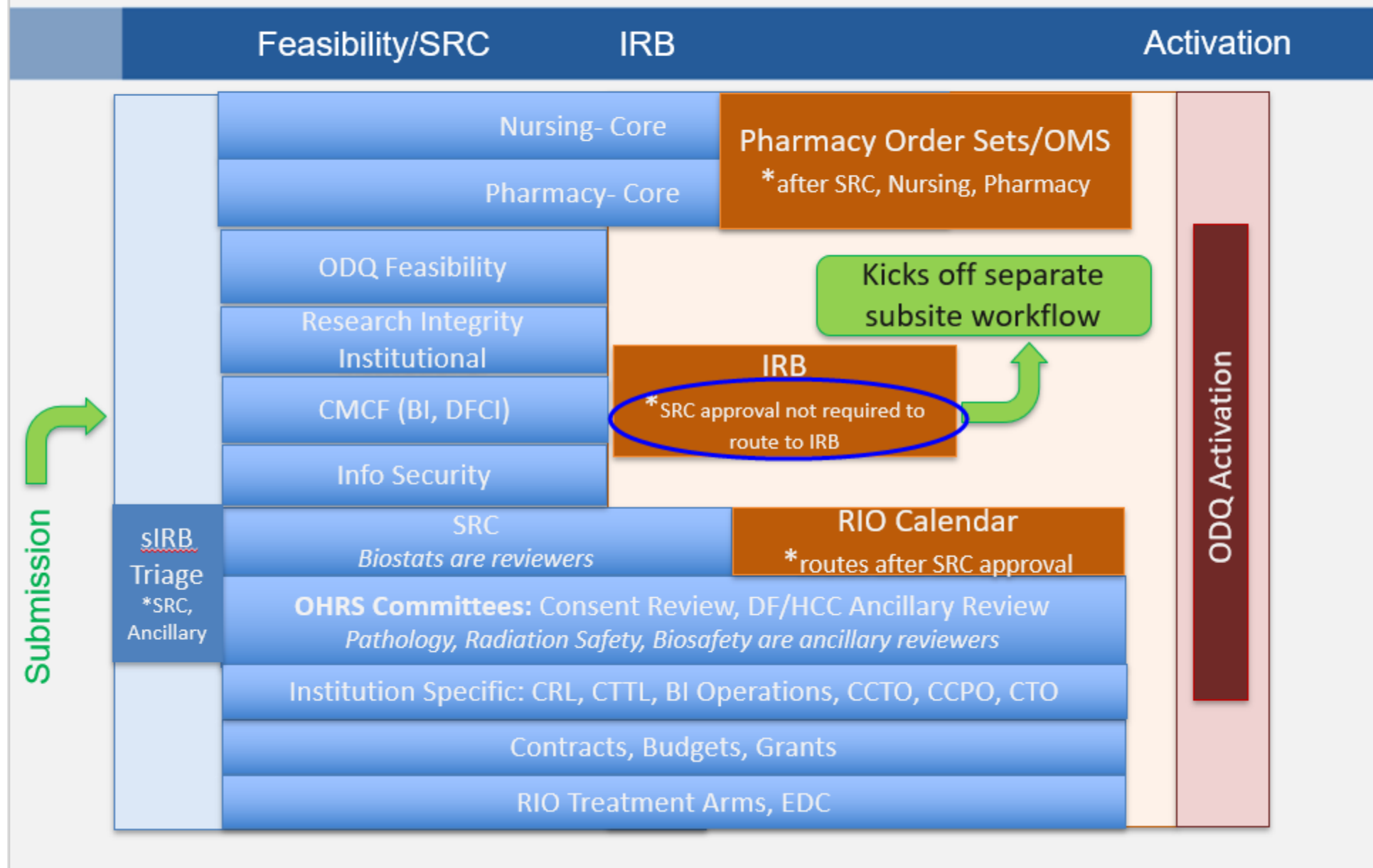
Routes study to IRB without needing to wait for SRC approval

- Final IRB approval will continue to be contingent on SRC approval
- If IRB determination comes before SRC approval, the IRB will condition final approval on SRC approval



Goal: Improve activation timeline for Phase I research

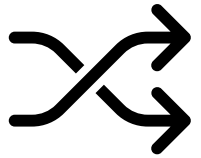
General Routing Path (Phase I Industry NPA)



Consent Review Committee – New!



New iRIS review committee for *new protocols*, managed by OHRS



Routed at initial submission, in parallel with SRC routing

- Allows early review of consent documents by OHRS, prior to assignment of IRB review date and actual IRB review



Goal: Accelerate time to IRB approval by catching and resolving common consent document issues up front

Continuing Review Clarification

3.0 Project Status

3.1 Project Status

Please select one:

- Activation Pending
- Study Activated but No Research has been conducted to date (e.g., No Enrollment)
- Enrolling Participants under DFCI IRB (Study is actively accruing locally and study intervention continues).
- Temporarily closed to enrollment with previously enrolled Subjects.
- Permanently closed to enrollment and research interventions continue (please note this is over and above standard of care follow-up).
- Permanently closed to enrollment and research activities are limited to routine clinical practice such as standard of care, observational data gathering, medical record review, etc.
- Previously reported as being in a status of data-analysis only and data analysis continues.

Additional DF/HCC Reminders

- New 15 minute micro-learning available: **Protocol Staff Changes: A Guide to Adding/Removing Staff from an Active Study**
 - Available on the DF/HCC Education and Training Page: <https://www.dfhcc.harvard.edu/research/clinical-research-support/clinical-research-support-portal/dfhcc-training-and-education/>
- **DF/HCC Policy updates recently went into effect (2/28/22)**
 - Visit the Policy Updates page to review changes: <https://www.dfhcc.harvard.edu/research/clinical-research-support/document-library/policy-updates/>
- Please complete the **DF/HCC Education and Resources Feedback Survey by Friday, March 4**, to be entered in the prize drawing!
 - Reach out to ODQEducation@dfci.harvard.edu with questions!

Q&A

Please submit questions using the **Zoom Q&A** button!



Panelists:

Lara Sloboda (OHRs)
Caroline Kokulis(OHRs)
Lydia Buchert (RIO)
Jon Matichak (RIO)
Ryan Williams (RIO)
Nick Farley (ODQ)

***Please do not submit questions in Chat.*