

iRIS PRMS

1. NPA FEASIBILITY ROUTING
2. IRIS NAVIGATOR

Tuesday, January 19, 2021

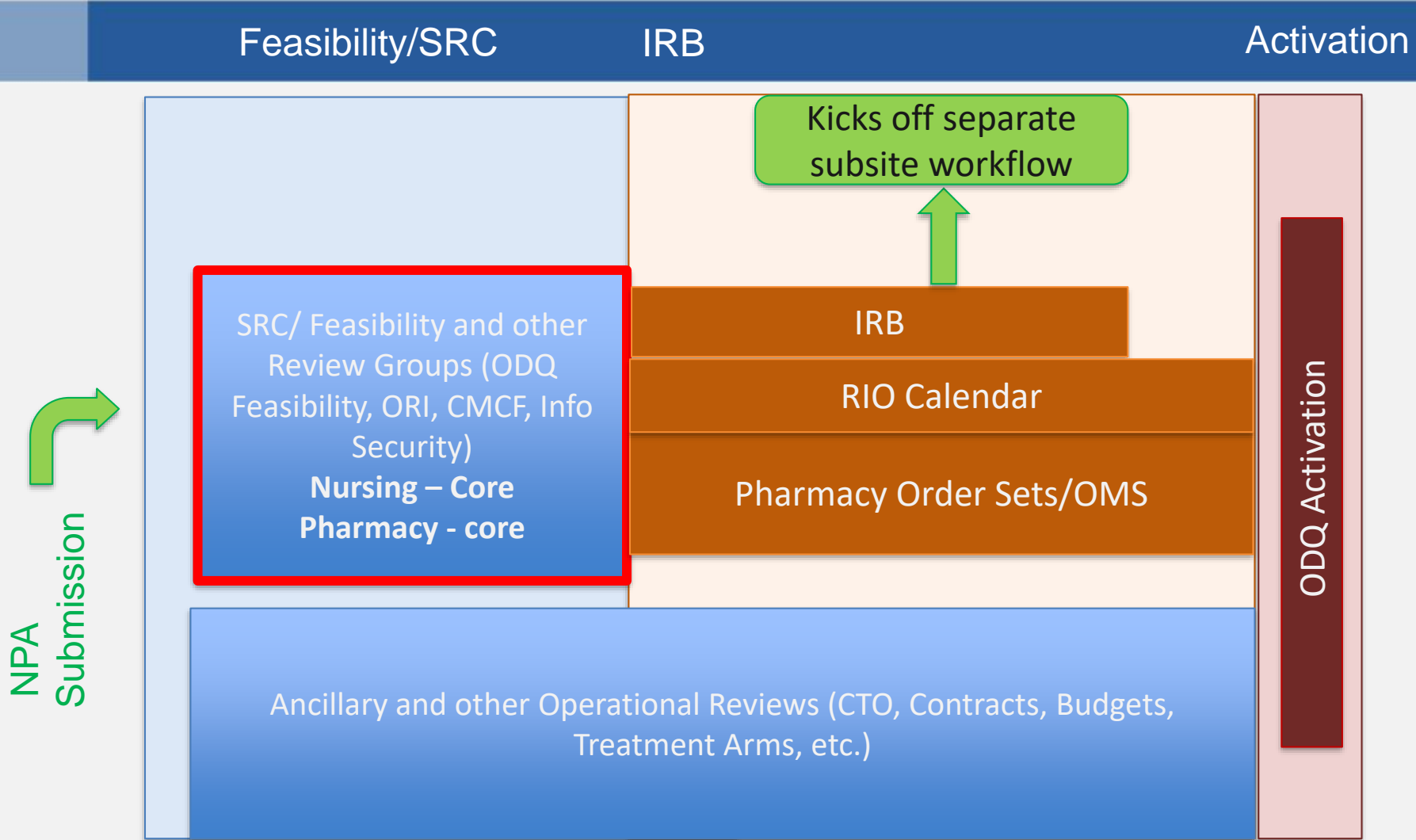
Topic #1: NPA Feasibility Routing

New protocols **submitted after the iRIS update** can proceed to IRB review even if Nursing and Pharmacy feasibility have not yet approved

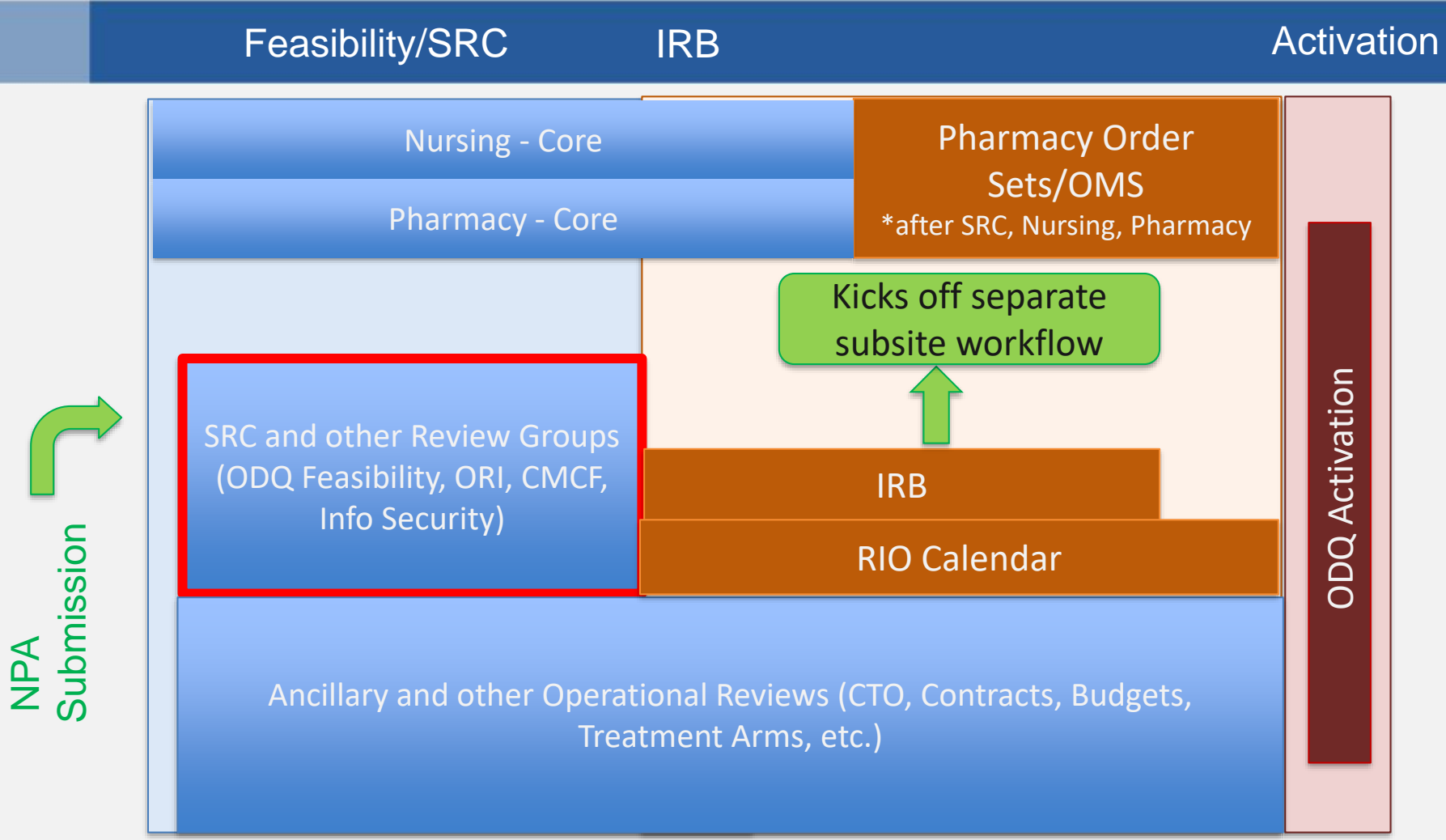
Order Sets/ OMS will only be routed after SRC, Nursing and Pharmacy approval.

This change is for the initial submission only. Nursing and Pharmacy feasibility approvals are still required prior to IRB review of Amendments with this release.

Prior to the Update – NPA Old Routing



After the Update – NEW Routing



What remains the same?

- SRC and other feasibility committees (ODQ Feasibility, ORI, CMCF etc.) must give approval prior to the submission routing to the IRB.
- All documents must be ready and in iRIS (including the consent) before IRB review can be scheduled.
- Nursing + Pharmacy are still routed upon initial submission and the expected timelines for reviews to be completed are unchanged.
- No changes to subsite process for new protocols.
- ODQ Activation will not be routed until all committees complete their signoffs .

Visuals

- The Wiki will have updated Visio workflows and the Submission Routing Paths for a visual of the new workflow

Submission Routing Paths UPDATED!

Work Instructions:

- Navigating iRIS - Study Assistant **UPDATED!**
 - iRIS Quick Reference Guide **UPDATED!**
 - Defining Submission History and Protocol Status
 - Guide on Who to Contact
 - Document Management **UPDATED!**
 - How to Delete, Retract and Withdraw Submission
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- New Protocol Application (NPA) - Core Site **UPDATED!**
 - New Protocol Application (NPA) - Sub Site **UPDATED!**
 - Responding to Conditions - Core and Sub-Site
 - New Project Application Operational Readiness – Core and Sub-Site

PRMS User Documentation / ... / Training Materials

Workflows

New Protocol Application (NPA) DFCI IRB – Complete Workflow

New Protocol Application (NPA) External IRB – Complete Workflow

New Protocol Application (NPA) - Sub Site Process Only

Amendments (AM) Submission that Requires Feasibility Review

Amendments (AM) - Operational Readiness NOT Required

Operational Readiness for Amendments/sIRB Amendments – Study Team Process Complete Workflow

Dose/Cohort Open/Closure Submission Workflow

Nursing and Pharmacy Review New Protocol

Nursing and Pharmacy Review Amendments with Feasibility

New Protocol Submission (NPA) – Complete High Level Overview

Document Changes During IRB Review

There may be circumstances where Nursing/Pharmacy request a document change after a submission has routed to IRB. **This should be uncommon.**

If this occurs, the study team must email the **OHRS Mailbox** to notify OHRS if any document, such as an alert page, is *added or revised* after:

- Submission has routed to the IRB
- IRB review has been scheduled
- Submission is already IRB approved

OHRS will make every effort to ensure the documents are approved with the initial submission. However, if OHRS is not notified, the documents may not be IRB approved with the initial submission and may need to be submitted with the next amendment.

What's not changing? - Documents

- Any changes made in response to conditions **before** the submission has routed to the IRB do not require an email to OHRS.
- Research teams can continue to email OHRS to request adding documents to the initial submission outside of a response to conditions.
- There are no changes to the current consent process. OHRS will continue to request the consent form prior to IRB review if one is not available.

Topic #2: iRIS Navigation Multiple Submissions

NEW as of 12/16/2020

ODQ is offering enhanced navigation assistance to investigators and research staff to aid in the triage and coordination of time sensitive Phase I and Phase I/II amendments received when an AM or NPA is already in process within iRIS.

Please do not submit another amendment if there's a pending AM or NPA in iRIS without contacting the Navigators first.

Reminder: Multiple Submissions

- The following submissions can be submitted in parallel with an NPA or AM **with no navigation** support needed.
 - Continuing Review/ Progress Report
 - Administrative Modification
 - Dose/Cohort Open/ Closure
 - Events
 - Sponsor-Investigator Add/Open/Complete External Site

Process – Received New AM

- If there is an initial submission or amendment pending in iRIS, please evaluate whether the new amendment can wait for the prior submission to be activated.
- If the new amendment is time sensitive and cannot wait for the prior submission, please email DFHCCiRISNavigator@dfci.harvard.edu and provide the protocol number and a summary of the **not-yet-submitted** documents and changes.
- Copies of the clean and tracked documents are appreciated, if available.

What can the Navigator do?

- Help you determine the quickest path to approval and activation depending on individual circumstances.
- Help maintain version control of documents across multiple submissions.
- In some cases, they may be able to help you merge submissions or avoid the need for an additional amendment altogether.

What can the Navigator **not** do?

- Navigators are not able to expedite SRC/IRB review dates.
- Navigators are not able to push reviewers to approve urgent submissions more quickly.

Study teams remain responsible for tracking the status of their submissions within iRIS and following up with reviewers based on expected turnaround times or OHRS for SRC/IRB scheduling questions.

Reminder: Wiki Updates

- As with all iRIS updates, all applicable Wiki documents will be revised and posted with the update.
- For comprehensive documentation on the iRIS releases please see the iRIS Releases section on the iRIS Wiki home page:

Welcome to the DF/HCC iRIS Wiki Page

[CLICK HERE](#) TO LOGIN TO iRIS

