iRIS PRMS

SUBMISSION ROUTING

Originally presented on March 9th, 2020

Automatic Routing

- Most of the submission routing in iRIS is performed by the system based on information entered by the study team.
- Much of the routing occurs upon submission. Changes made to the submission later will not restart or alter the routing.
- Examples of automatic routing: Nursing, Pharmacy (incl. Order Sets), ODQ, SRC, IRB, RIO, DFCI CRL, CMCF, Contracts, Budgets, Grants, Research Integrity.
- OHRS/ODQ cannot stop or change automatic routing.

Key Questions that Control Routing

New Protocols	Amendments
• Classification • Sponsor Type (IST or not) • Lead Site • Does it involve a Drug, Biologic or Device? • DF/HCC Services section • Ancillary Review section	• **Proposed Changes section** • DF/HCC Services section • Ancillary Review section Note: Protocol characterics on the NPA (research type, lead site) also influence AM routing.

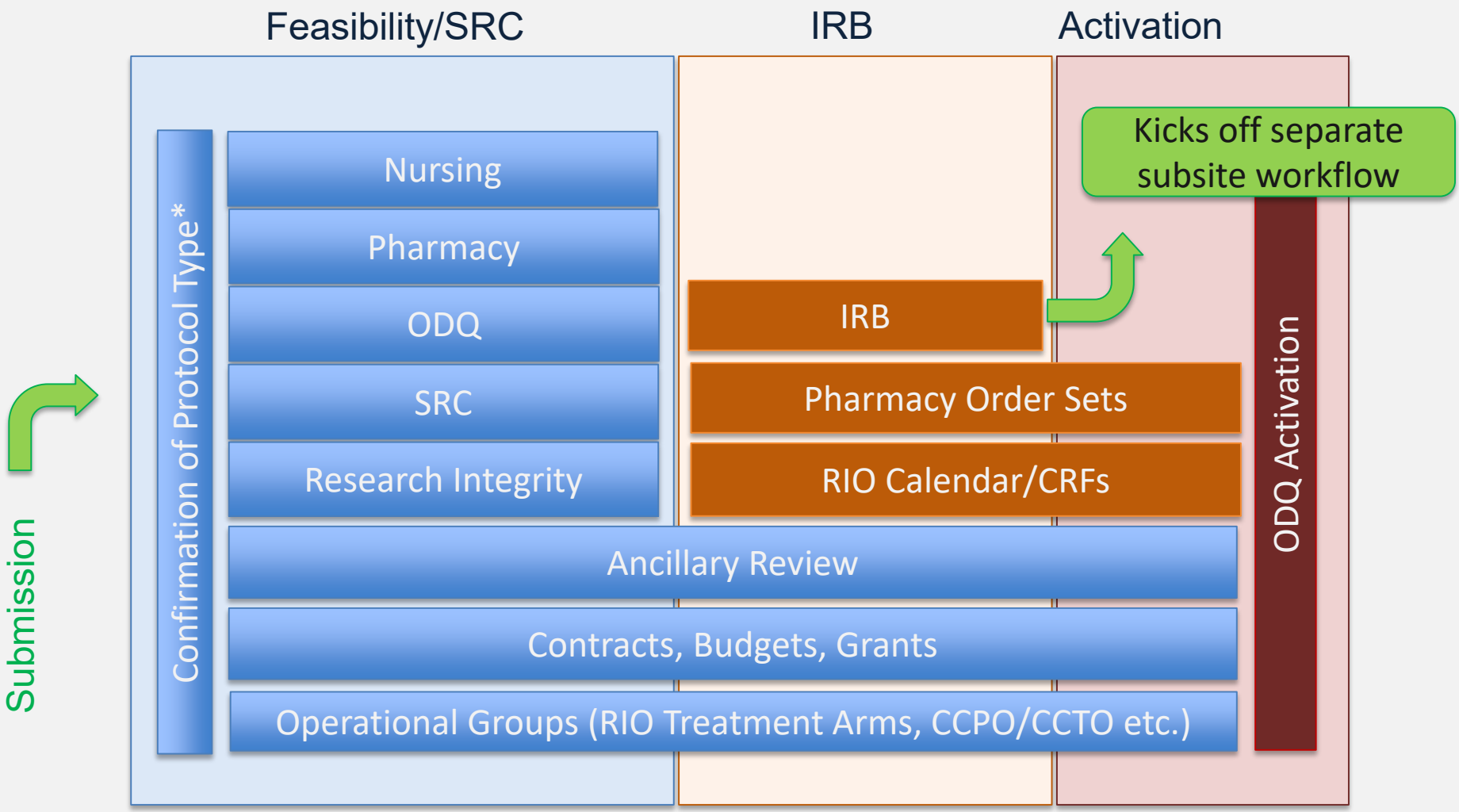
AM Routing – General

- All AMs will route to the IRB queue and then ODQ Activation, at minimum
  - sIRB Amendments will route to the sIRB Triage queue (and feasibility, when required) prior to the IRB queue
- Routing to ODQ feasibility depends on the protocol type
- Note: Although the Proposed Changes section does not control routing to IRB, ODQ Feasibility, or ODQ Activation, all reviewers look at this section to identify what is changing.

AM Routing: Proposed Changes

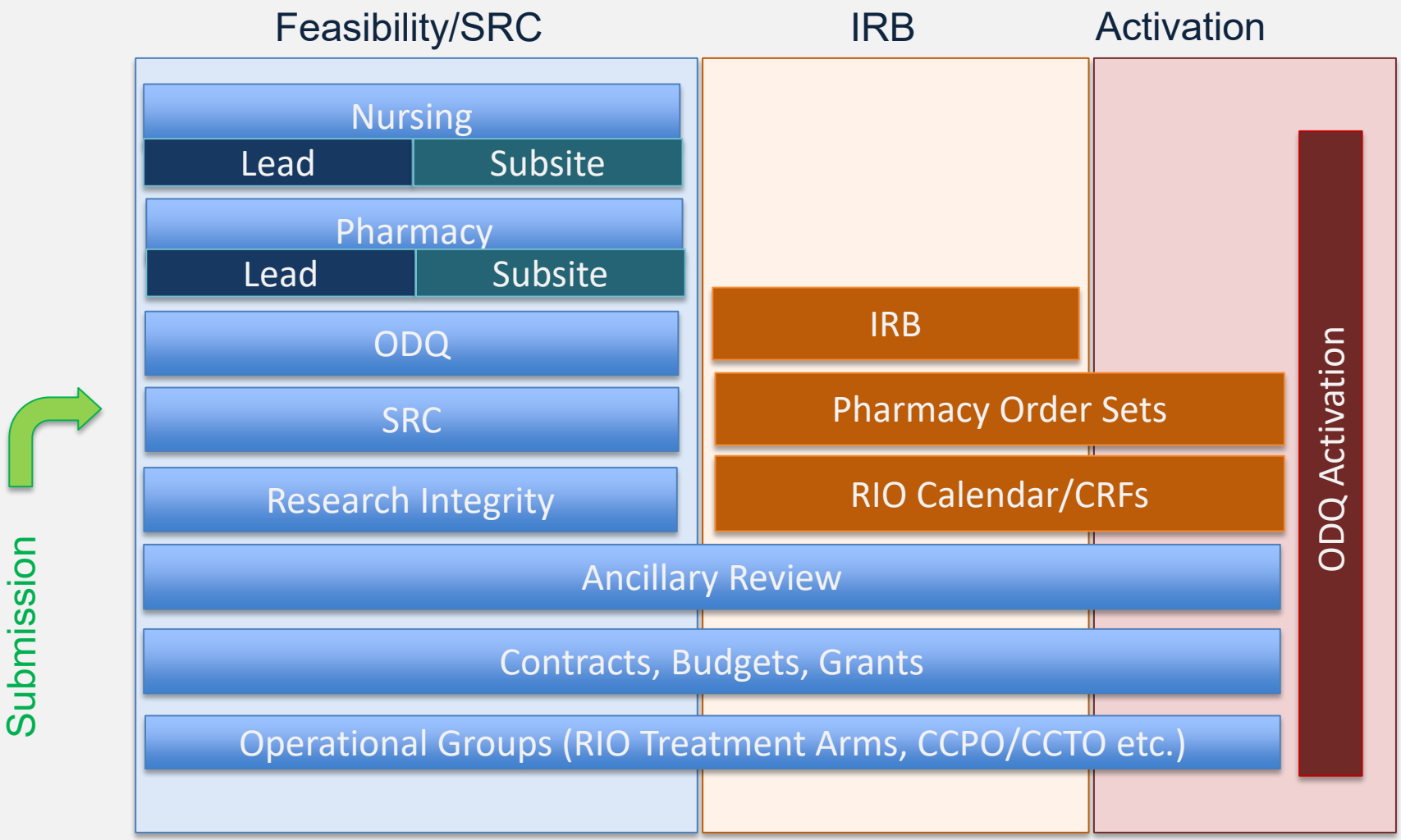
Proposed Changes	Includes changes to…
Therapy Reviewed by SRC, Nursing, Pharmacy, and Pharmacy Order Sets *Requires Operational Readiness*	Preparation, administration, schedule, route, dose Pre-medications and/or dose modification plan Add an Arm or Cohort that is NOT in previous version of the protocol
Scientific Changes Reviewed by SRC (except protocols that do not require scientific review)	Objectives, Statistical Analysis, or Overall Accrual Goals Add Correlative Studies Add an Arm or Cohort that is NOT in previous version of the protocol
Data Collection Materials Reviewed by Nursing (except non-clinical protocols)	Study diaries, questionnaires, or surveys given to participants.
Protocol Procedure Changes Reviewed by Nursing (except non-clinical protocols)	Study procedures, parameters, and tests. Windows, timing, or frequency of assessments.

General Routing Path (NPAs – DFCI IRB)

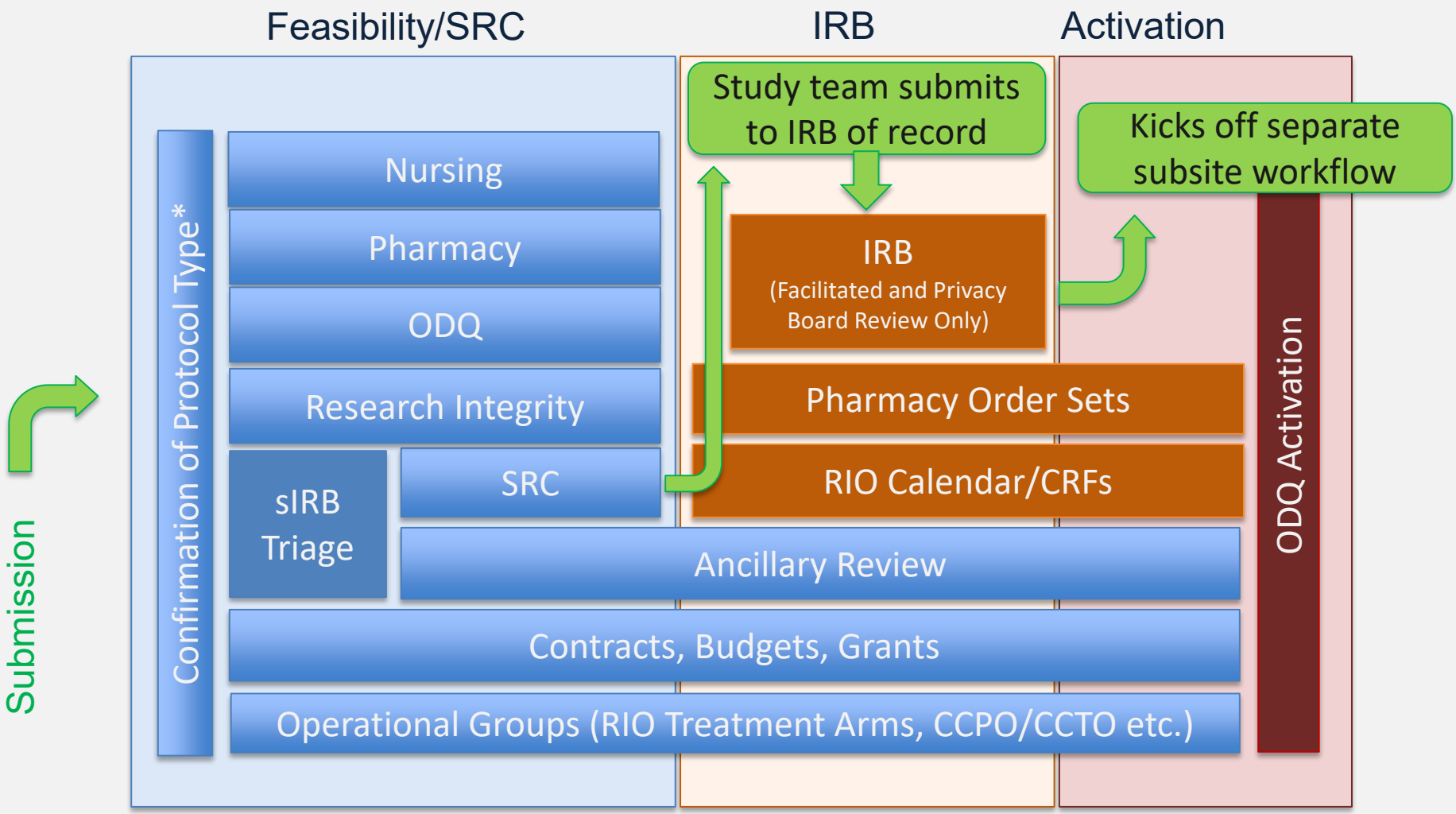


* Non-treatment protocols only.

General Routing Path (AMs – DFCI IRB)



General Routing Path (NPAs – sIRB)



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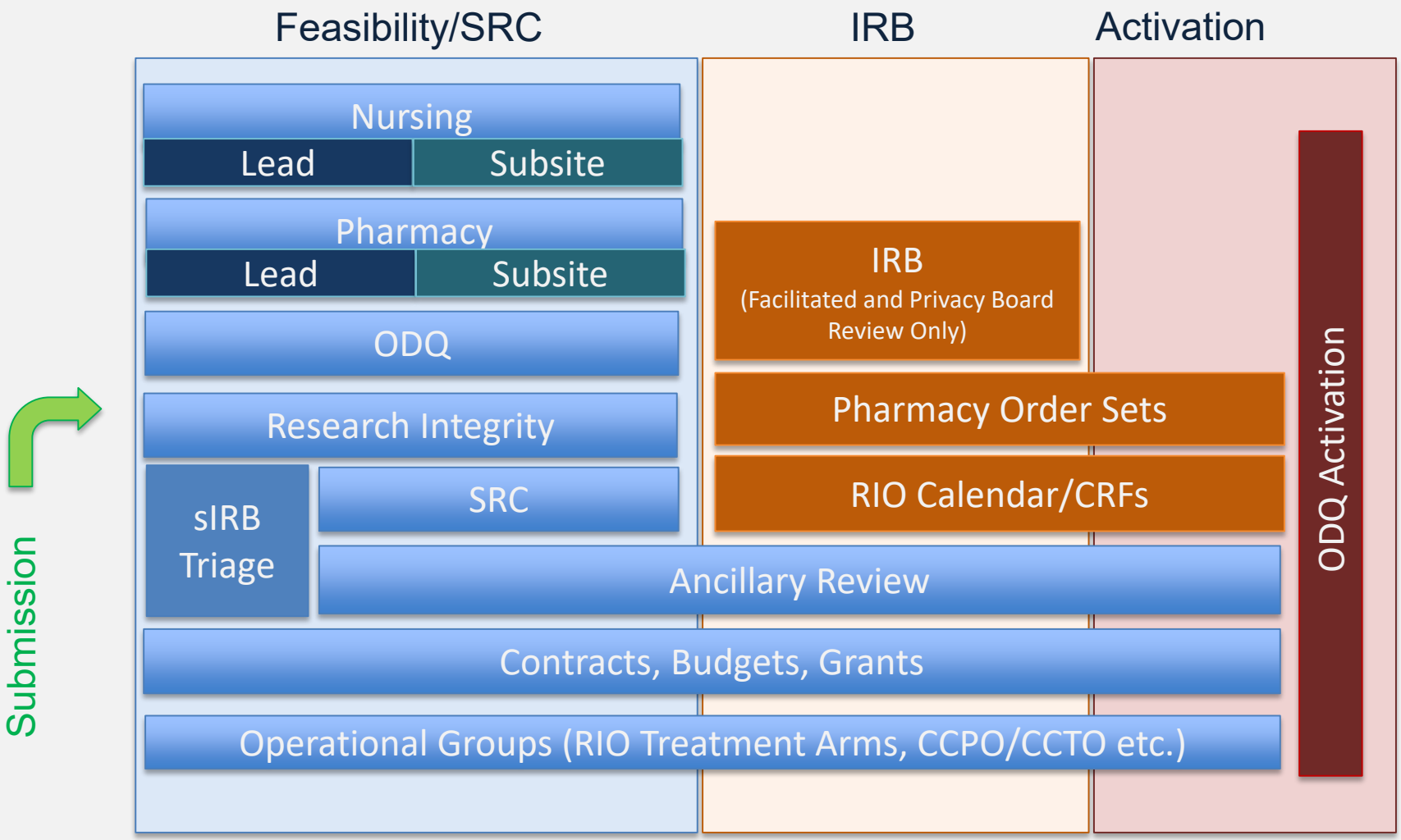
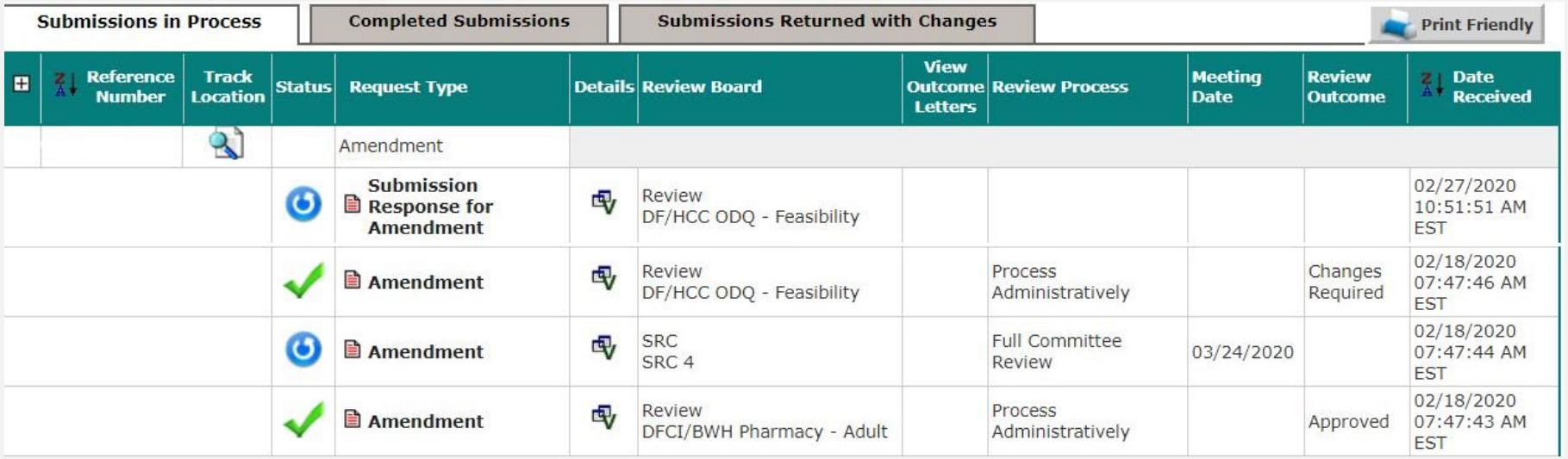
General Routing Path (AMs – sIRB)



Where is my submission?

- Use the **Submission History** and **Track Location** functions in iRIS.



Submissions in Process | Completed Submissions | Submissions Returned with Changes | Print Friendly

Reference Number	Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
			Amendment							
			Submission Response for Amendment		Review DF/HCC ODQ - Feasibility					02/27/2020 10:51:51 AM EST
			Amendment		Review DF/HCC ODQ - Feasibility		Process Administratively		Changes Required	02/18/2020 07:47:46 AM EST
			Amendment		SRC SRC 4		Full Committee Review	03/24/2020		02/18/2020 07:47:44 AM EST
			Amendment		Review DFCI/BWH Pharmacy - Adult		Process Administratively		Approved	02/18/2020 07:47:43 AM EST

  - Definitions of all icons and columns can be found in the WIKI instructions at Training > Training Materials > Study Team

Questions?

Questions? Email OHRS@dfci.Harvard.edu

Note: For troubleshooting of specific submissions, please email OHRS or submit a helpdesk ticket.