iRIS Office Hours

Submit questions using the Zoom Q&A function

Thursday, April 29, 2021

Topics

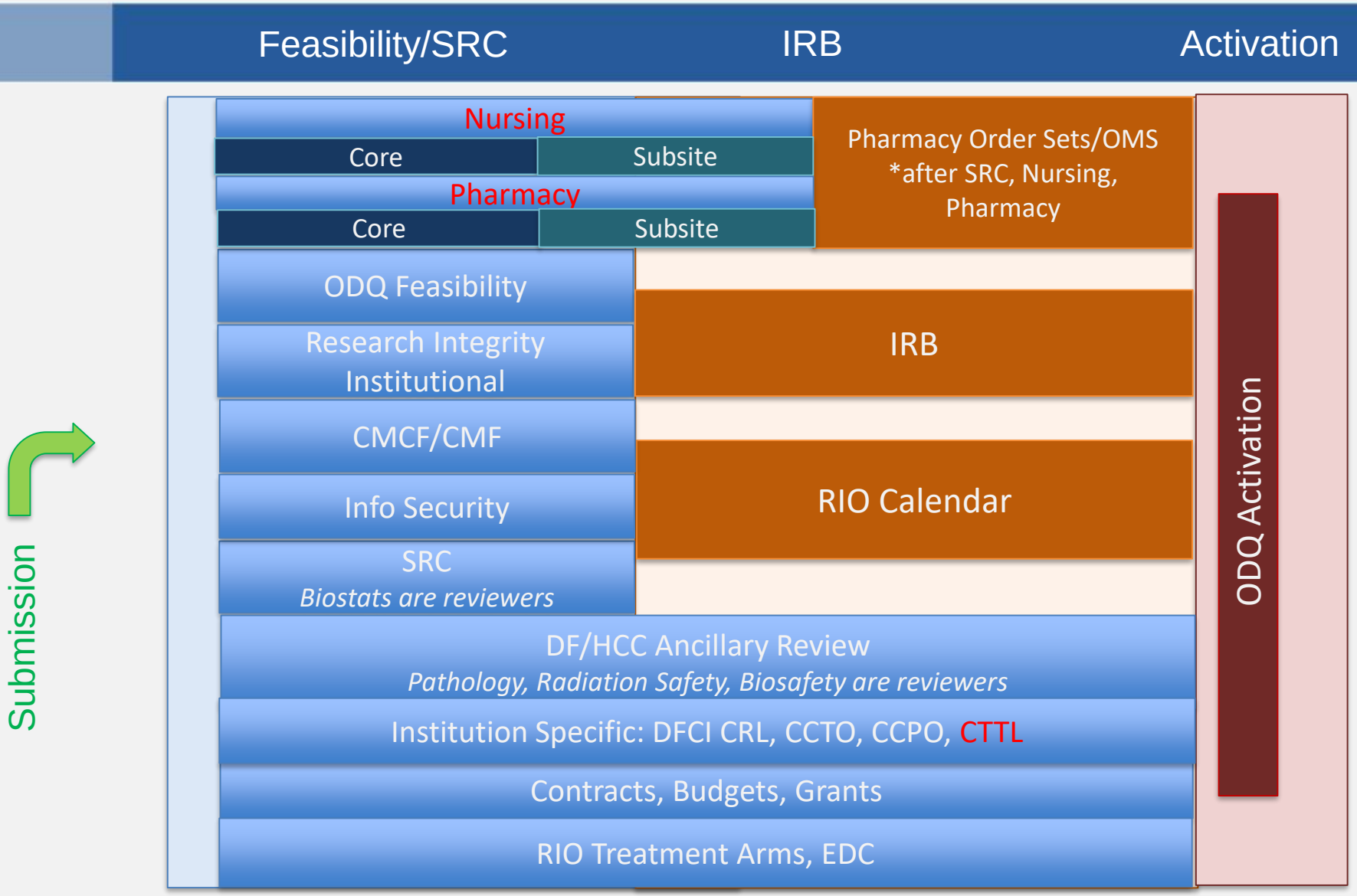
- **iRIS Updates – Release on 4/30**
- **Submission of Consent Forms with New Submission**
- **Obtaining Scheduled IRB Dates**
- **Updates to the Pregnant Partner Consent Form Process**
- **Managing Multiple Amendment Submissions**
- **General Q&A**
  - Submit questions to Q&A at any time

iRIS Updates

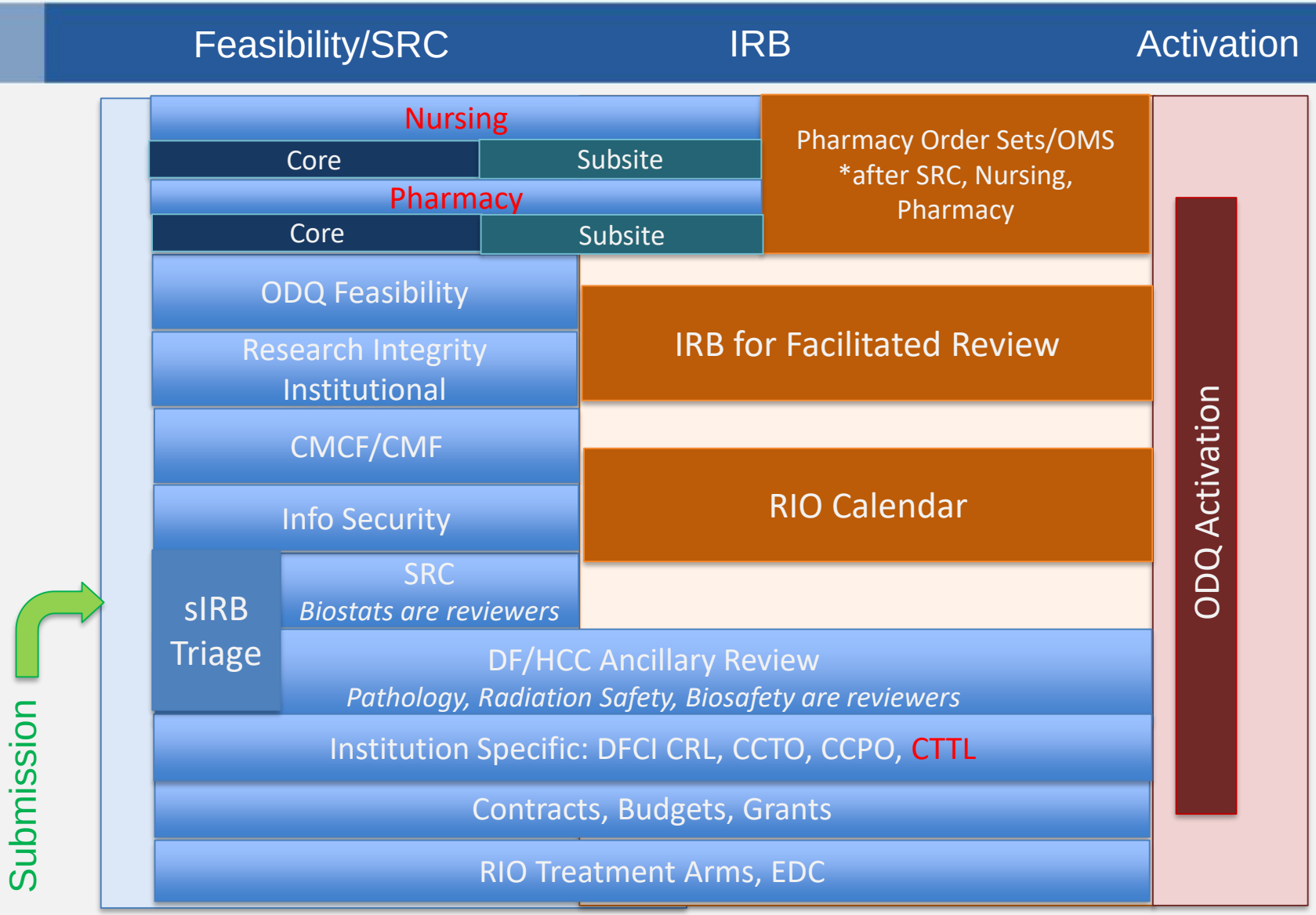
Workflow Changes

Change	Affected Workflow
1. Nursing and Pharmacy NOT required for IRB	DFCI IRB & SIRB Amendment
2. MGH CTTL NOT required for IRB and now *Signoff Only*	All Workflows

General Routing Path (AM– DFCI IRB)



General Routing Path (AM– sIRB)



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 amendment. However, if OHRS is not notified, the documents may not be IRB approved and may need to be submitted with the next amendment.

Workflow Changes

Workflow:

Change	Affected Workflow
3. TIMC email upon IRB approval	NPA & Amendment
4. Email when IBs as Admin Modifications are submitted	Administrative Modification

Form Logic Changes

Change	Affected Form
1. Consortium Participation + Priority Section	NPA
2. Provide sponsor correspondence confirming current active dose levels/cohorts	Operational Readiness Checklist-NPA (Treatment Protocols)
3. Removal of COI question	Attestation Form

Instructional Text Changes

Form:

Change	Affected Form
4. Clarify consents must be in Word format	DFCI IRB Amendment CTEP Amendment
5. Clarify Protocol Control vs. Funding Designations for Sponsors	NPA

Communication

Release Date	Change Summary

2/19/2021	• New CTEP Amendment Form for NCI CIRB Studies
	  • All applicable committees will be routed upon submission with the exception of Order Sets/ OM
	  • Order Sets/OMS will only be routed if Pharmacy Feasibility deems it necessary
	  • SRC, CTBO, CTAO and SIRB Triage Committees will not be routed
	  • This amendment form should be used for all NCI CIRB amendment submissions going forwar
	• Updated Dose/Cohort Open/ Closure Form
	  • Form will allow study teams to submit a dose escalation to expansion or moving to the next ph
	  initial submission and there are no other changes to study documents
	  • The SRC and IRB explicit approval is now being noted on the respective approval memos for
	  • Study teams will be required to attach the SRC and IRB approval memo
	  • Updated instructional text in the Therapy section of the amendment forms for clarity on what c
	  • Nursing Committees will be sent an email notification when these forms are submitted. They w
	• Instructional updates to forms
	  • NPA Form, Participant Payment Section to clarify compensation vs. reimbursements
	  • Continuing Review and Progress Report forms have additional examples clarifying what resea

1/22/2021	• Updated NPA Routing (impacts new NPAs submitted after the release on January 22nd)
	  • New protocols can proceed to IRB review even if Nursing and Pharmacy feasibility have not ye
	  • Order Sets/ OMS will be routed after Nursing, Pharmacy, and SRC approval
	  • Nursing and Pharmacy Reviewer Checklists updated
	• New question added to the DFCI IRB Amendment form in the Notification of Subject section.
	  • If an amendment updates the consent form in a way that would otherwise require a re-consent
	  • This is the case even if there are 0 participants enrolled at the time of submission
	• Instructional updates to forms
	  • NPA Form, Priority List Section to remind users to complete the field "placed before protocol #
	  • Dose/Cohort Open/ Closure Form to clarify that moving from Phase I to Phase II or escalation
	  • Amendment Form(s) Phase Change clarifying that the amendment requesting to open a new p
	  • Amendment Form(s) EDC section adding in additional examples of when to select "yes" that th

11/20/2020	• Update to the NPA form, Institutional Participation section to accommodate increasing list of DF/H • Rename *Sponsor-Investigator Add/Complete External Site* to *Sponsor-Investigator Add/Open/Cor* • Single Patient IND Applications no longer require Operational Readiness Checklists on Initial Sub • Continuing Review Form was updated to pull all DF/HCC sites
08/07/2020	• New application created for Social, Behavioral and Education Research studies • Protocol and Amendment routing was adjusted accordingly • Updates to forms adding in eConsent questions

Submission of Consent Form with New Project Submission

Submitting the ICF with the NPA

- To prevent delays in IRB or other feasibility reviews, we strongly encourage submitting the ICF document **within 2 weeks of the original NPA submission**

- This is particularly important with the recent implementation of a simultaneous review process for IRB and Pharmacy/Nursing feasibility.

- Submissions will not be scheduled for IRB review until the ICF has been submitted

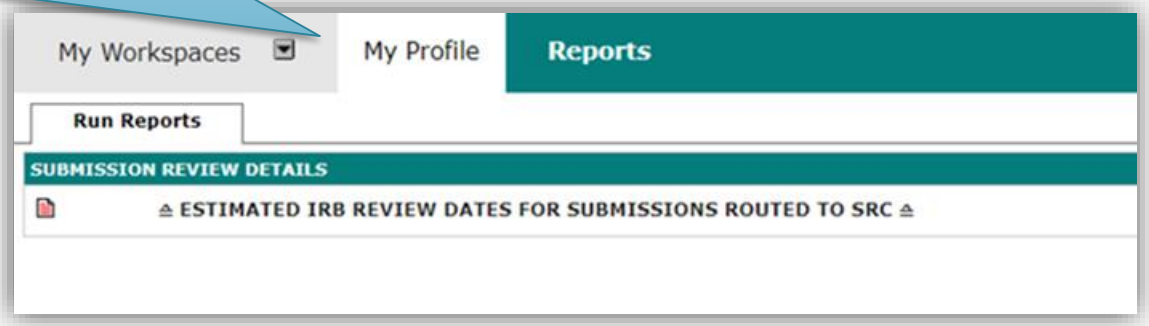
Obtaining Projected IRB Dates

Obtaining Projected IRB Dates

- Sponsors often request the projected IRB date of review from the study team
- Study teams can now generate a letter for sponsors stating the projected IRB review date using iRIS reports

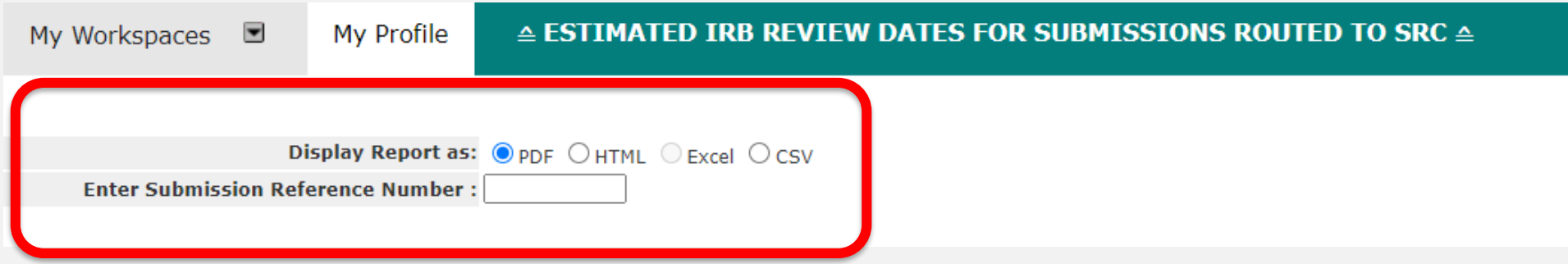
To access:

1. Navigate to "My Profile"
2. Choose "Reports"
3. Access report titled "Estimated IRB Review Dates for Submission Routed to SRC"



Obtaining Projected IRB Dates

- The projected dates will only be available once the SRC review is scheduled.
  - If SRC is not yet scheduled, this will be clear in the report
- To create the report, enter the ***reference*** number



Pregnant Partner Consent Forms

Updates to Pregnant Partner Consent Form Submissions

Updated policy

- Pregnant Partner Consent Forms will be reviewed and approved only when they are needed during the trial, rather than at initial review

Rationale

- Data indicates that the need rarely arises for these to be approved at initial review
- To meet the regulatory requirements for these forms, there is often extended communication needed between the study team and IRB, which can cause unnecessary delays in activating the study

Impact for Study Teams

- Do not submit Pregnant Partner Consent Form as part of the NPA
- Instead, submit the form via an amendment when a known pregnant partner will be enrolled
- During the transition period, OHRS will void any forms that are submitted with the NPA

Multiple Amendment Submissions

Multiple Amendment Submissions

When to bundle, when to submit separately, etc.

- **If you are adding or revising a document that is part of the same submission** (e.g., you need to add the consent form or another pending document prior to IRB review), email OHRS to add it to the submission. This cannot be done if the addition/changes would need to be seen by other reviewers or would have changed the routing. Therefore, this is limited to administrative changes or documents that are allowed to be pending at initial submission.

- **If you receive a condition asking to revise a document or add a document**, make the changes when you submit the response.

- **If you receive new changes and want to include them in a submission already in process**, check with the iRIS Navigator in ODQ.

- If the submission already has IRB Conditional Approval, **new changes should be avoided**. Please **only make the necessary changes to resolve IRB conditions**.

Q&A

Please submit questions using the Q&A feature.

Panelists:

Lydia Buchert (RIO)
Nick Farley (ODQ)
Sarah Florio (DFCI CTO)
Sarah Kiskaddon (OHRS)
Caroline Kokulis (OHRS)
Jon Matichak (RIO)
Lara Sloboda (OHRS)
Ryan Williams (RIO)

Please do not submit questions in Chat.