

iRIS PRMS

OPERATIONAL READINESS AT ACTIVATION

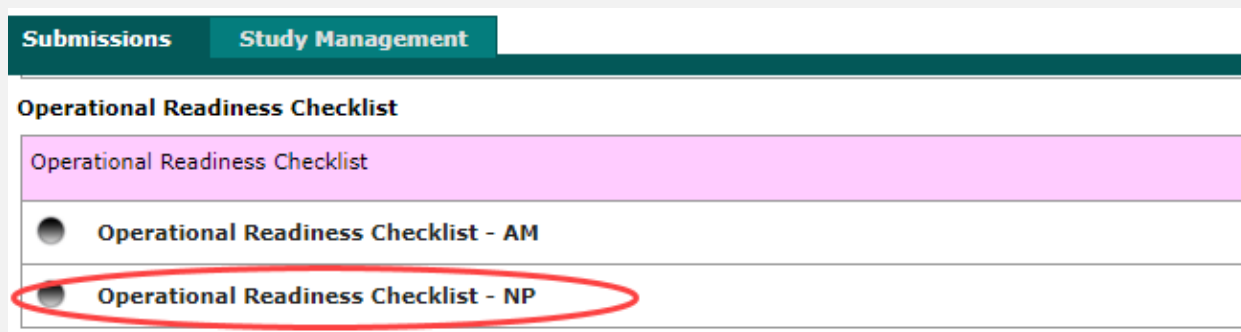
Originally presented on February 28th, 2020

Operational Readiness

- Purpose: Allows study teams to verify that local operational tasks are completed prior to activation.
- Operational Readiness is only required for New Protocols and Amendments that include Therapy changes.
- The Operational Readiness process does not replace communication between DF/HCC study teams.

When to start the ORC?

- The lead site can begin completing the Operational Readiness Checklist (ORC) as soon as the submission is routed for feasibility/SRC.
- Subsites can begin completing the ORC after IRB approval.
- To begin your checklist, go to Study Assistant > Submissions page and select the appropriate Operational Readiness Checklist (NP or AM).



The screenshot shows a web interface with two tabs: "Submissions" and "Study Management". Under "Study Management", there is a section titled "Operational Readiness Checklist". Below this title, there is a list of options. The first option is "Operational Readiness Checklist" with a pink background. The second option is "Operational Readiness Checklist - AM" with a radio button. The third option is "Operational Readiness Checklist - NP" with a radio button, which is circled in red.

| Submissions | Study Management |
|--|--------------------------------------|
| Operational Readiness Checklist | |
| Operational Readiness Checklist | |
| <input type="radio"/> | Operational Readiness Checklist - AM |
| <input type="radio"/> | Operational Readiness Checklist - NP |

- Then select add a New Form to create the checklist.

Completing the ORC

1.5 Sites


Which sites are you completing the checklist for?

- BIDMC
- BCH
- BWH
- DFCI
- MGH
- None of the above


- Core site: Only select the core site institution.
- Subsite: Only select your institution.

Completing the ORC

3.1 Kits and reagents for the CRL on site

| Date Complete | Not Applicable | Comments |
|--|--------------------------|----------------------|
| <input type="text"/>  | <input type="checkbox"/> | <input type="text"/> |

3.4 IVRS Setup

| Date Complete | Not Applicable | Comments |
|--|--------------------------|----------------------|
| <input type="text"/>  | <input type="checkbox"/> | <input type="text"/> |

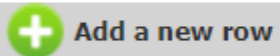
- All sites: Depending on the submission and your institution, operational questions will appear.
- These questions were requested by your institutional clinical trials office.
- If something does not apply to your submission, check the Not Applicable box and enter a comment to explain.

Completing the ORC

4.0 Treatment Arms

4.1 Treatment Arms

Please copy and paste the description of the treatment arms from OnCore that will open to accrual.

 Add a new row

| Treatment Arm Name |
|----------------------------|
| No records have been added |

- Core Site Only: Enter the treatment arms that will open at activation. Names must match OnCore.
- This allows the Core Site to indicate what arms are opening when the new protocol activates. This may not have been known at initial submission or may have changed.

NPs Only – Ready to Activate?

5.0 Activation Status

5.1 Status

When operationally ready:

- This trial should be opened to accrual
- This trial should be posted to OncPro, but NOT opened to accrual. It will be opened to accrual with an amendment.

- Core site only: Indicate whether the study is opening to accrual at activation.
- If not ready to Open to Accrual, the submission will be activated and documents will be posted. The protocol status will remain On Hold.

AMs Only – Ready to Activate?

Entire view of the Form

Print Friendly Refresh Constant Fields Save Section

4.0 Operational Readiness of Sub-Site(s)

4.1 Are there any sub-sites that needed to prepare for operational readiness?

Select Sites for Information Request Send Notification to Sites Retract the Site Request(s) Delete Site Request(s)

| Select | Request Status | AM Form Version | Institution/Site Information | Check when Ready to Activate |
|--------------------------|----------------|-----------------|---|------------------------------|
| <input type="checkbox"/> | 2 | 1 | Dana-Farber Cancer Institute Brigham and Women's Hospital - DFCL/BWH Kidney Choueiri, Toni K, MD | <input type="checkbox"/> |
| <input type="checkbox"/> | | 1 | Massachusetts General Hospital - MGH Genitourinary Cancers Michaelson, MD, Ph.D | <input type="checkbox"/> |

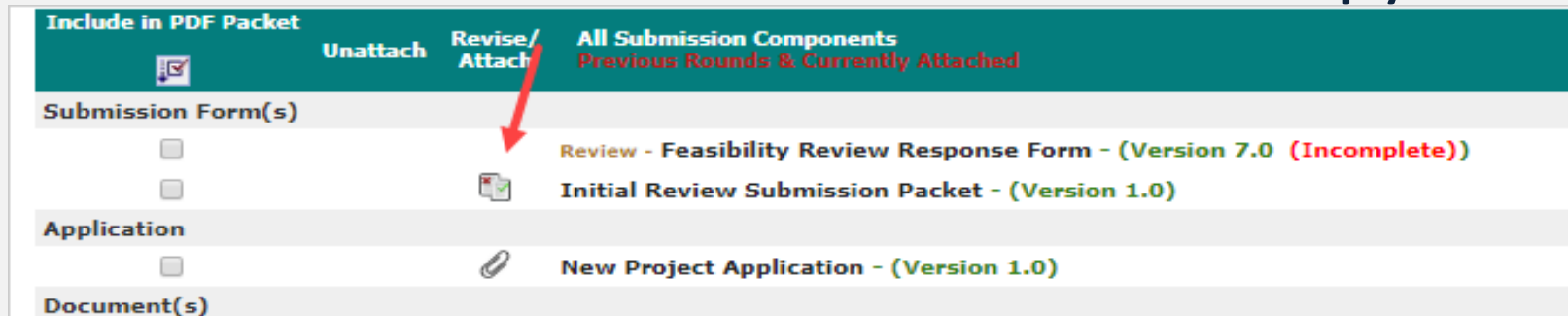
- The Core Site must 1) enter form version and save, then 2) select all active subsites and send notification.
- Subsites must complete their own ORC and indicate “Yes” for ready to activate.
- Once this is done, the Core Site ORC will show all sites as ready. The Core Site can now submit their ORC to ODQ Activation.

Attaching the ORC

- When a submission that requires Operational Readiness hits the ODQ Activation queue, ODQ will return it to the Core Site to ask for the completed ORC (if not already attached).
- **The checklist must be completely filled out before it can be attached.**

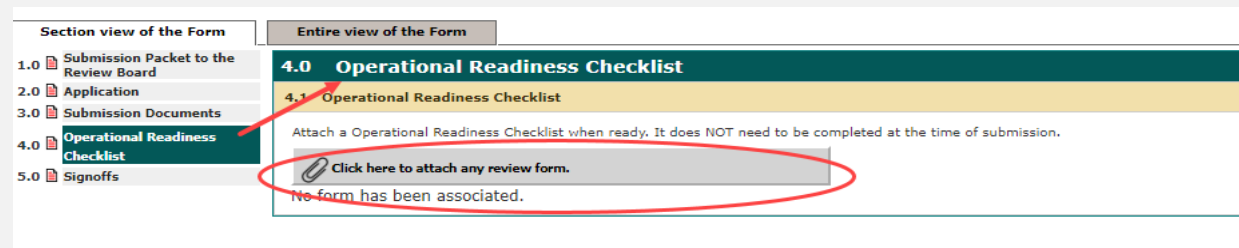
Attaching the ORC: Lead Site (NPs or AMs)

1. Revise the Submission Packet or Therapy AM



| Include in PDF Packet | Unattach | Revise/Attach | All Submission Components Previous Rounds & Currently Attached |
|-------------------------------------|----------|---|--|
| <input checked="" type="checkbox"/> | | | |
| Submission Form(s) | | | |
| <input type="checkbox"/> | | | Review - Feasibility Review Response Form - (Version 7.0 (Incomplete)) |
| <input type="checkbox"/> | |  | Initial Review Submission Packet - (Version 1.0) |
| Application | | | |
| <input type="checkbox"/> | |  | New Project Application - (Version 1.0) |
| Document(s) | | | |

2. Go to Operational Readiness section and click to attach a form.




Section view of the Form | Entire view of the Form

- 1.0 Submission Packet to the Review Board
- 2.0 Application
- 3.0 Submission Documents
- 4.0 Operational Readiness Checklist
- 5.0 Signoffs

4.0 Operational Readiness Checklist

4.1 Operational Readiness Checklist

Attach a Operational Readiness Checklist when ready. It does NOT need to be completed at the time of submission.

 [Click here to attach any review form.](#)

No form has been associated.

3. Follow the prompts to select and save the appropriate ORC.

Attaching the ORC: Sub Site (New Protocols)

1. Save the ORC as a PDF
2. Revise the Sub-Site Information Questionnaire
3. Go to Operational Readiness section and attach the ORC

Section view of the Form

Entire view of the Form

1.0 General

2.0 Study Team

3.0 Protocol Participation Components

4.0 DF/HCC Reviews and Services

5.0 Site-Specific Documents

6.0 Operational Readiness

6.0 Operational Readiness

6.1 Operational Readiness Checklist

When ready, follow the steps below to attach an Operational Readiness Checklist. It does NOT need to be completed at the time of submission.

1. Navigate to your completed "Operational Readiness Checklist - NP".
2. Click the "Print Friendly" button.
3. Save the form to your desktop as a PDF.
4. Click the button below to add the checklist. Use a category of "Other (Do NOT Post to OncPro)".
5. Remember to click "Attach" to exit the "Add a New Document" dialog box.

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. | | | | | | | |

Common Therapy AM ORC Pitfalls & Solutions

| Pitfall | Solution |
|--|--|
| Core site submits the ORC to ODQ before the subsites are ready to activate. | ODQ will return the ORC. The Core site must verify all sub-sites are ready (green check mark will appear and the "yes" radio button will be selected). |
| Core site submits the ORC without sending the notification to the sub-sites. | ODQ will return the ORC. The Core Site must initiate a new ORC and re-send the notification to each subsite. |
| Core site tries to complete the ORC for all sites (i.e., checks off all sites in section 1). | The Core Site must initiate a new ORC . If the erroneous one was never submitted, it can be deleted. |
| Core site creates a revision (minor version) of the ORC | Subsites will not populate on the revised version. You will need to submit version 1.0 to ODQ to show that all subsites are ready to activate. If a new notification is needed for the subsites, create a new ORC. |

Questions?

Questions? Email OHRS@dfci.harvard.edu



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