DF/HCC Research Support

iRIS Office Hours

February 22, 2023

Please submit questions using the Zoom Q&A function

Today's Topics:

Upcoming iRIS Release: February 24, 2023

Form Change: Administrative Modifications

- Routing to Pharmacy

Email Notifications

- Outcome Letters
- Additional email notifications

Process Change: Adding External Sites

- Selecting Sites in iRIS
- New Institution Request Form

Changing Dose/Cohort Arm to "Closed"

- Language Added to Amendment Form

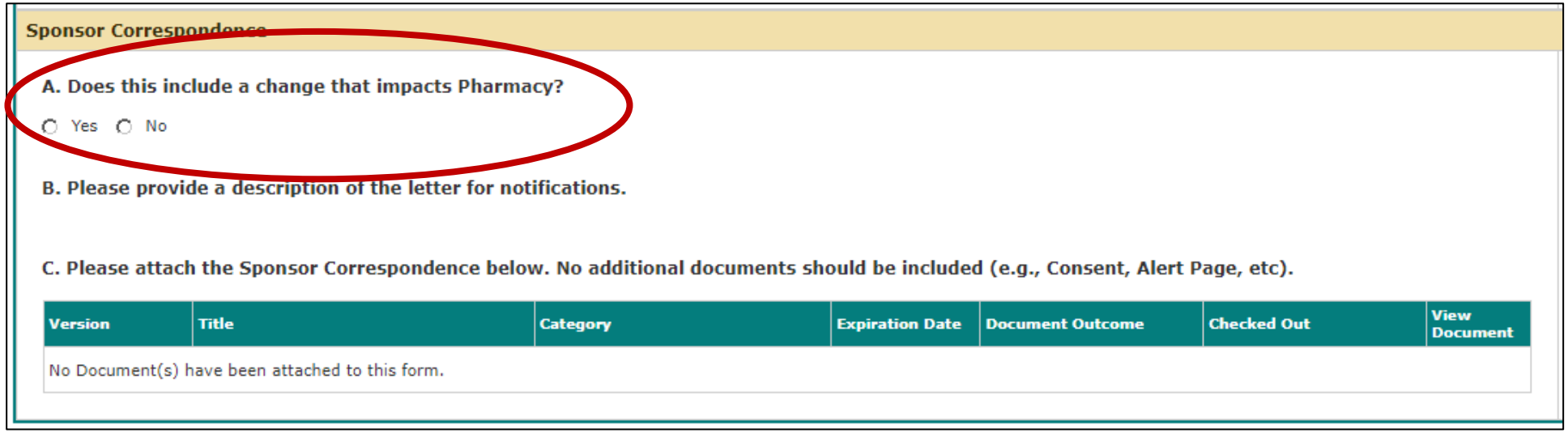
Reminders from OHRS and ODQ

- Using New Versions of CR/Progress Report
- IND Training Requirement

Form Change: Administrative Modifications

Form Change: Administrative Modifications

New question added for Sponsor Correspondence submissions to assist proper routing to Pharmacy Order Sets



Types of Changes that Impact Pharmacy

- Therapy change(s) need to be routed to Pharmacy for feasibility review
- iRIS WIKI provides guidance on which types of changes need to be routed to Pharmacy:

https://wiki.dfci.harvard.edu:8443/prms/study-team-guidance-documents/post-activation-submissions-core-and-sub/amendments/amendment-therapy-change-guidance

Therapy Change Type	Examples
Addition/Removal of a Drug	Changes for investigational, standard of care chemotherapy, premedication or support or meds, hydrations
Drug Source	Sponsor-supplied investigational drug, sponsor-supplied commercial drug, insurance-billed commercial drug
Drug Formulation	Formulation, form (capsules, tablets), route (oral, intravenous, subcutaneous injection), strength
Drug Biosimilar Updates	Adding or removing approval for use of biosimilar drugs (i.e. " or approved biosimilar")
Drug Preparation Instructions	Tubing, filter type, diluent, drug expiration times, storage, bag, light protection
Drug Administration	Outpatient/inpatient, dosing changes, frequency (i.e. once a day), schedule (i.e. on days 1,8,15); take with food or empty stomach, drug diary, in-clinic days
Dose Calculations	Fixed dose vs. weight-based changes (mg/kg, mg/m2), following institutional policy vs. protocol
Dose Modifications	Dose reductions or increases (not a new cohort), dosing after toxicities, monitoring guidelines for toxicities/adverse events
Cycle Length	Lead-in period, new cohorts with different cycle lengths (i.e. change from 14 days to 28 days)
Criteria to Treat and Lab Values	Revision to hematologic (lab values) and non-hematologic (cardiac, neuro changes, etc.) toxicities from original build; C1D1 eligibility criteria
Concomitant Medication	Drug-to-drug interactions, prohibited foods/medications, flushes (NS vs D5W), medications to use with caution

Email Notifications from iRIS

Email Notifications – Outcome Letters

- Request for Principal Investigators at subsites to systematically receive Outcome Letters (e.g., IRB Approval Letter) from iRIS. Subsite PIs cannot be added to the Core Site email notifications.

- In the previous release, we added a separate, automatic email to send Outcome Letters to the Principal Investigators at the subsites. Some Core site staff are included on these emails to ensure they have a record of the Site PI receiving the letters.

- This means that some Core Site staff may receive two emails (the original iRIS email with the outcome letter, and the separate email to the subsite PIs).

Locating Approval Memos

Reminder: Use the Submission History function to find previous requests, Outcome Letters, etc

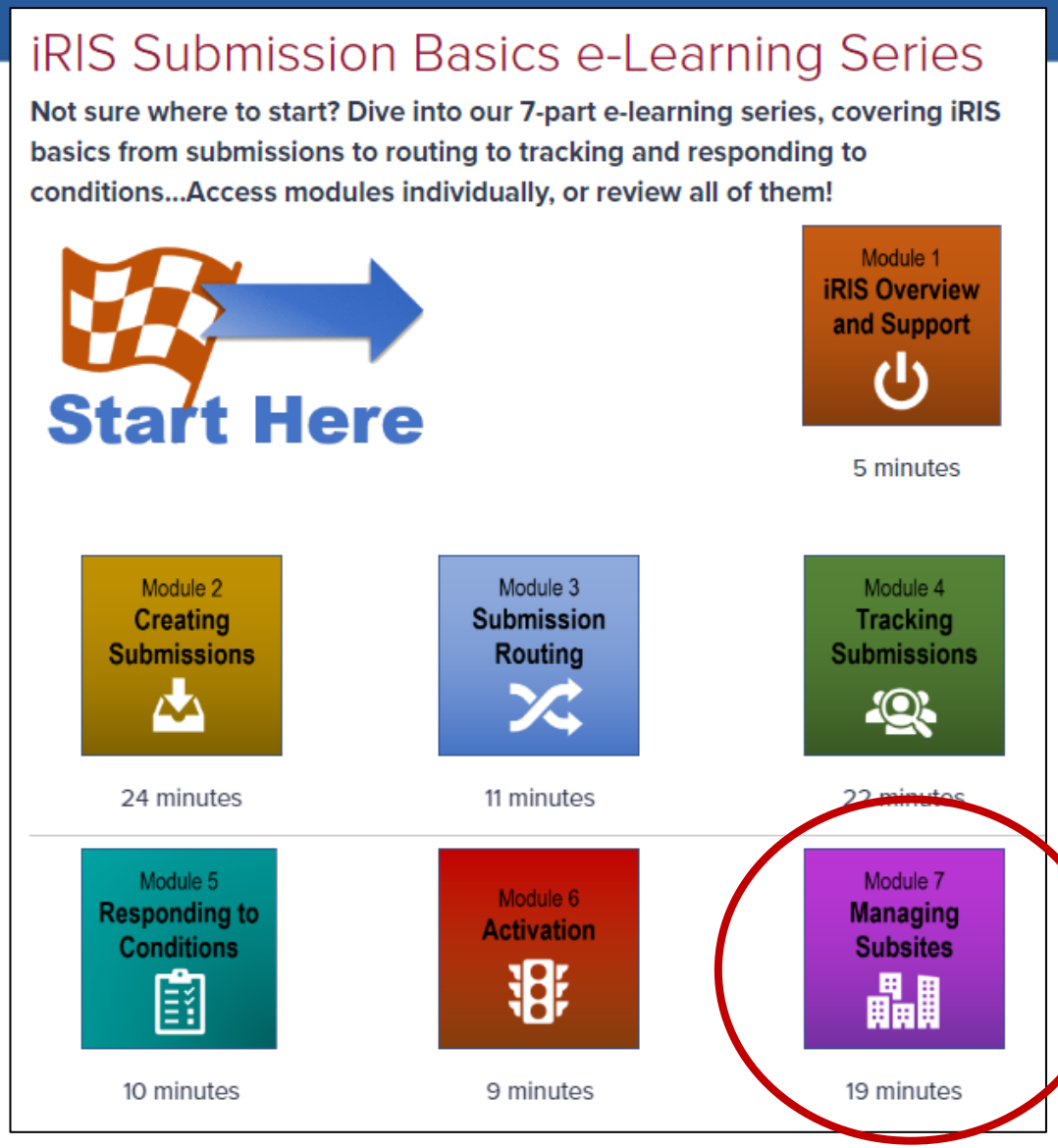
Track Location	Status	Request Type	Details	Review Board	View Outcome Letters	Review Process	Meeting Date	Review Outcome	Date Received
		Amendment							
	✓	**Amendment**		Review DF/HCC ODQ - Activation		Process Administratively		Withdrawn	05/11/2022 09:34:40 AM EDT
	✓	**Submission Response for Amendment**		IRB IRB D		Expedite	05/16/2022	Approved	04/28/2022 09:26:06 AM EDT
	✓	**Submission Response for Amendment**		IRB		Expedite		Conditional Approval	04/25/2022 05:46:34 PM EDT
	✓	**Amendment**		IRB		Expedite		Conditional Approval	04/06/2022 04:33:23 PM EDT
		Amendment							
	✓	**Amendment**		IRB		Exempt		Exempt	06/08/2021 11:07:35 AM EDT
		Initial Review Submission Packet							
	✓	**Initial Review Submission**		IRB		Exempt	06/01/2021	Exempt	05/07/2021

Additional Email Notifications

- NEW in this release, additional notifications will be sent:

  - ✓To Sub-site PIs and Study Contacts when a core site submission **activates**
  - ✓To the PI and Study Contacts when a submission is put on a **Full Board Meeting**
  - ✓To Core and Sub-site staff when Amendments, Continuing Reviews, and Progress Reports are **submitted**

iRIS Submission Basics – eLearning modules



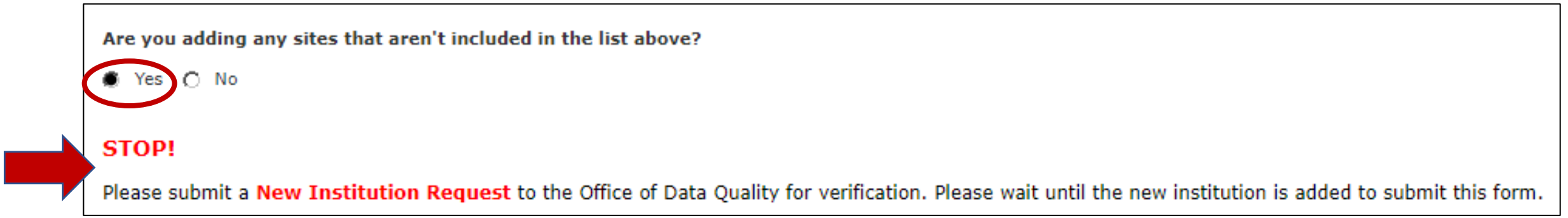
[DF/HCC website- - iRIS Training Page]

Reminder: Study teams are encouraged to review the iRIS Submission Basics e-learning for guidance

Process Change: Adding External Sites

Process Change: Adding External Sites

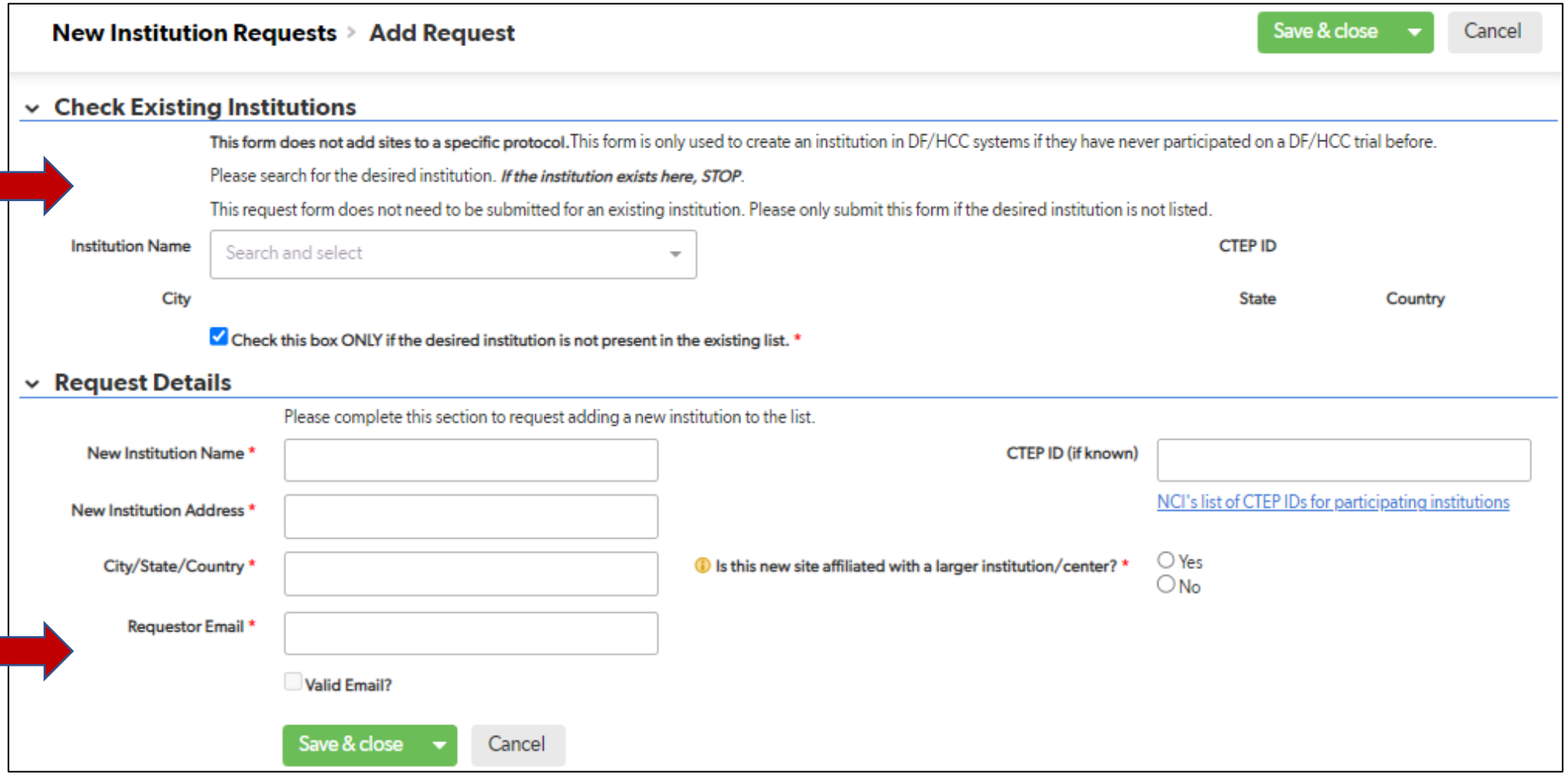
- External site names must be selected from the list in IRIS.
  - If the desired site is not in the list, a **New Institution Request** form will now be submitted outside of iRIS to request the addition of a new institution



New Institution Request Form

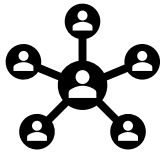
First, double check that institution doesn't already exist

If not, complete the request details and submit



New Institution Requests

Keep in mind:



This request form should only be used for **DF/HCC investigator-sponsored, multi-center trials** involving outside sites

This applies both when:

- Outside sites are relying on the DFCI IRB (added via an amendment)

and

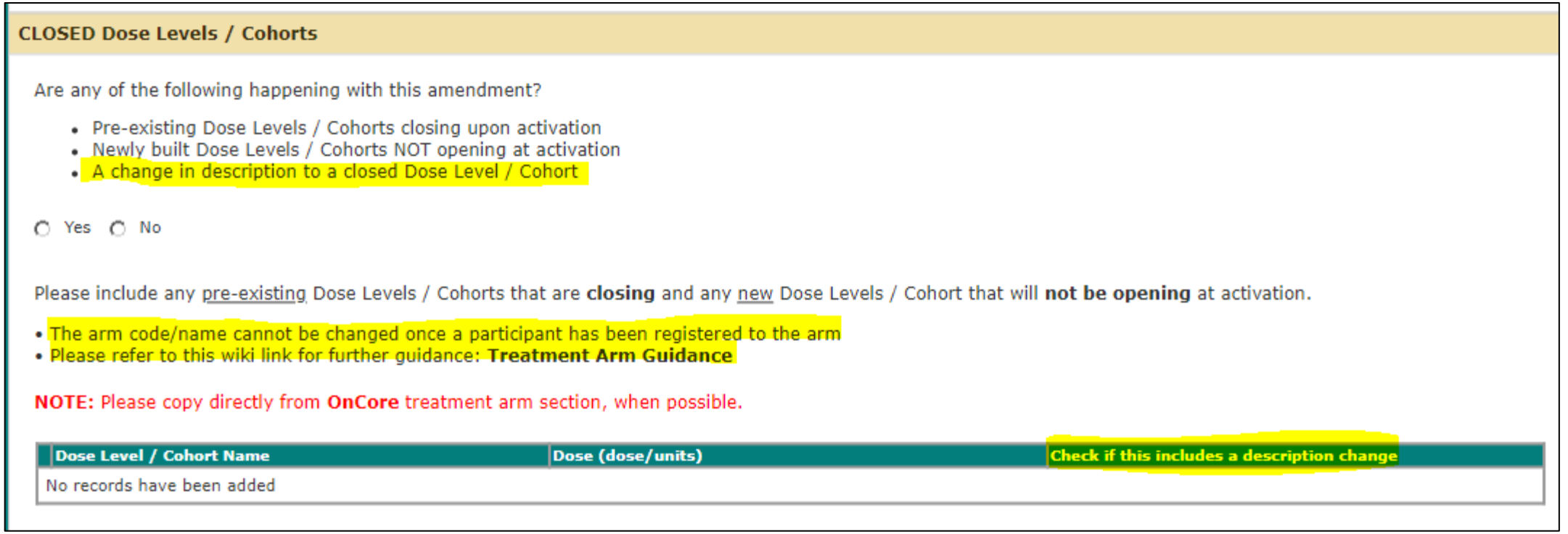
- Outside sites are relying on a central/local IRB (added via Sponsor-Investigator Add/Open/Complete External Site form)

Changing Cohort Arm to “Closed”

Amendment Form: Closed Dose Levels/Cohorts

- New language has been added to the **Closed Dose Levels/Cohorts** section of the Amendment form

- The “Description Change” column in table has been updated to be more consistent



CLOSED Dose Levels / Cohorts

Are any of the following happening with this amendment?

- Pre-existing Dose Levels / Cohorts closing upon activation
- Newly built Dose Levels / Cohorts NOT opening at activation
- A change in description to a closed Dose Level / Cohort

◯ Yes ◯ No

Please include any pre-existing Dose Levels / Cohorts that are **closing** and any new Dose Levels / Cohort that will **not be opening** at activation.

- The arm code/name cannot be changed once a participant has been registered to the arm
- Please refer to this wiki link for further guidance: **Treatment Arm Guidance**

NOTE: Please copy directly from **OnCore** treatment arm section, when possible.

Dose Level / Cohort Name	Dose (dose/units)	Check if this includes a description change
No records have been added		

Communication of iRIS Updates

Release Date	Change Summary

3/4/22	• Routing Changes for New Protocols
	  • Phase I industry-sponsored protocols will route to the IRB without needing to wait for SRC approval
	  • NEW Consent Review Committee will be routed upon submission for DFCI IRB new protocols. This committee needs to be compl
	  • RIO OnCore Calendars will be routed as soon as the SRC approves the submissions. Routing is no longer waiting for IRB approv
	• Form Changes
	  • Adverse Event Form has been updated to align with the 2/7/22 OHRS Announcement
	  • Dose/ Cohort Open/ Closure form has been updated to align with the updated OHRS policy Implementing Dose Escalations which
	  • DF/HCC OHRS Application- New Project Application has a new question to the Non-Industry Grant Support section for study team
	  • Continuing Review Form has clarified the two permanently closed to enrollment options to better distinguish that one option is whe that is limited to routine clinical practice
	  • Request to Continue Research Intervention has a a required question for study teams to confirm a continuing review has been sub
	• Updates related to the iRIS to OnCore Interface
	  • DF/HCC OHRS Application- New Project Application has new instructional text for the NCT number to clarify that only an 8 digit nu at the time of submission
	  • Operational Readiness Checklist for New Protocols was updated for clarity. The DF/HCC section clearly states that study teams m your site
	  • Sub-Site Information Questionnaire- Site Application has new instructional text to remind users that the study teams selected will i
	• The DFCI and MGH Pharmacy Order Set Committee names have been changed to "DFCI/BWH Pharmacy Order Sets" and "MGH Ph

2/23/22	• iRIS to OnCore interface is live. No changes to iRIS; however, view the **Interface Guide** for details on what information interfaces to C

11/19/21	• New Project Application(s)
	  • Reminder that the Overall PI must have an OnCore Profile
	  • Site PI field changed from a free text to a user look-up field. Reminder that you can only select one PI per site and they must have
	  • New question: Accrual Duration in months
	• Note: The above mentioned changes are necessary as we prepare for increased integration of iRIS with other DF/HCC systems

10/1/2021	• Initial Review Submission Packet
	  • "Pending" option for consents was removed
	  • Language clarifications for Consent- related documents and "Pending" diaries
	• DFHCC OHRS Application - New Project Application
	  • Accrual goal header language clarified
	  • eConsent language clarified
	• Amendment
	  • Reminder added to revise the last approved consent document in iRIS to make any changes. Do not edit the documents posted in
	  • New guidance document is linked to clarify what are considered to be Therapy changes
	• Operational Readiness Checklist for DFCI had two new items added regarding flowsheets and Chestnut Hill

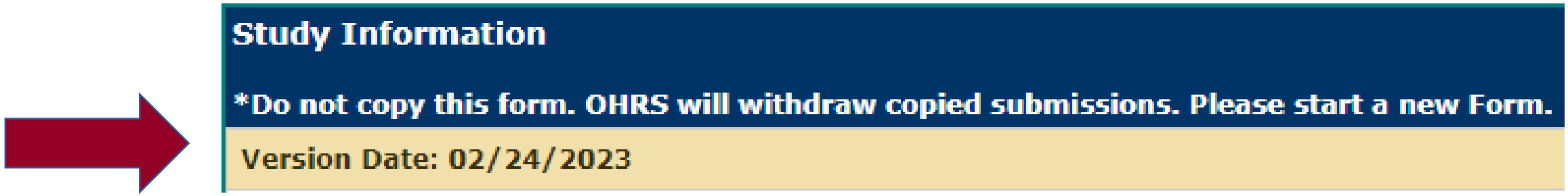
https://wiki.dfci.harvard.edu:8443/prms/iris-updates

Reminder to not copy old versions of CR/Progress Reports

Reminder to not copy old versions of CR/Progress Reports

- Please do not copy CR and Progress Reports from previous years in iRIS.
  - Copying old versions leads to missing updates/questions and inconsistent data, which in turn results in conditions for approval and delayed review times.

- Forms now have the version number included so that OHRS can tell if a previous form has been copied.



- These submissions **will be returned** in iRIS and will not be reviewed until a new form has been created.

Reminder: IND Training – Activation Requirement

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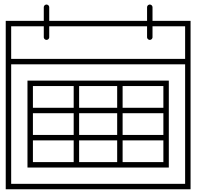
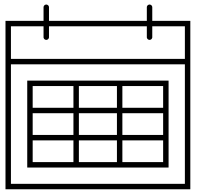


March 1, 2023



Investigators holding an IND must be compliant with this training requirement **prior to activation of any applicable new submission or amendment changing the sponsor-investigator**

How do I fulfill this training requirement?

- IND training is provided at the institutional level – format varies based on PI's home institution
  - Designated institutional contacts are listed in the New Research Staff Checklist, and the Education and Training Page (under PI Training Requirements)

How do I check a PI's training status?

- Training credential is listed in OnCore staff profiles, OR
- Reach out to ODQEducation@dfci.Harvard.edu or your designated institutional contact

Questions?

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

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

Panelists:

Ryan Williams (RIO)
Jon Matichak (RIO)
Nick Farley (ODQ)
Claire Sulkowski (ODQ)
Olivia Wood (ODQ)
Lara Sloboda (OHRS)
Jackson Norton (OHRS)
Elke Backman (Pharmacy)