

# CTEP Amendments

1. NEW FORM
2. FEASIBILITY ROUTING

Friday, February 19, 2021

# NCI Protocol Amendments - Background

Since 2015, NCI funded studies rely on NCI CIRB  
ETCTN/NCTN/COG trials

Since 2017, studies under the NCI CIRB must have  
sponsor amendments implemented (activated)  
locally within 30 days of the posting date on the  
network group broadcast

At the time of audit, amendments implemented  
late will result in audit findings

# Amendment Notifications

- Bi-Monthly CTSU Broadcasts are released on the 2<sup>nd</sup> and 4<sup>th</sup> week
- Alliance, NRG, ECOG-ACRIN and COG also send email updates
- Posted on the CTSU website regularly
- All CIRB amendments are required to be activated within **30 days (calendar)** of posting date on the CTSU website
- Review and submission in iRIS timeline:
  - Research teams must submit CIRB amendments in iRIS within 5 Calendar days of posting regardless of weekends, holidays, vacations, etc.

# CTEP Amendment Form

The new CTEP Amendment form to be released February 19, 2021

- More parallel reviews
- Streamlined specific to CIRB Submissions
- Easier identification

External IRB	
<input type="radio"/>	sIRB Amendment
<input type="radio"/>	<b>CTEP Amendment</b>
<input type="radio"/>	Progress Report

# Comparison to SIRB and DFCI IRB Amendments

## What stays the same?

- Applicable committees are routed based on *how* the form is completed
- Core site must circulate amendment documents to all sub-sites at the time of iRIS submission
- The institution-specific Pharmacy Feasibility outcome determines if the amendment will route to Order Sets/OMS for that institution

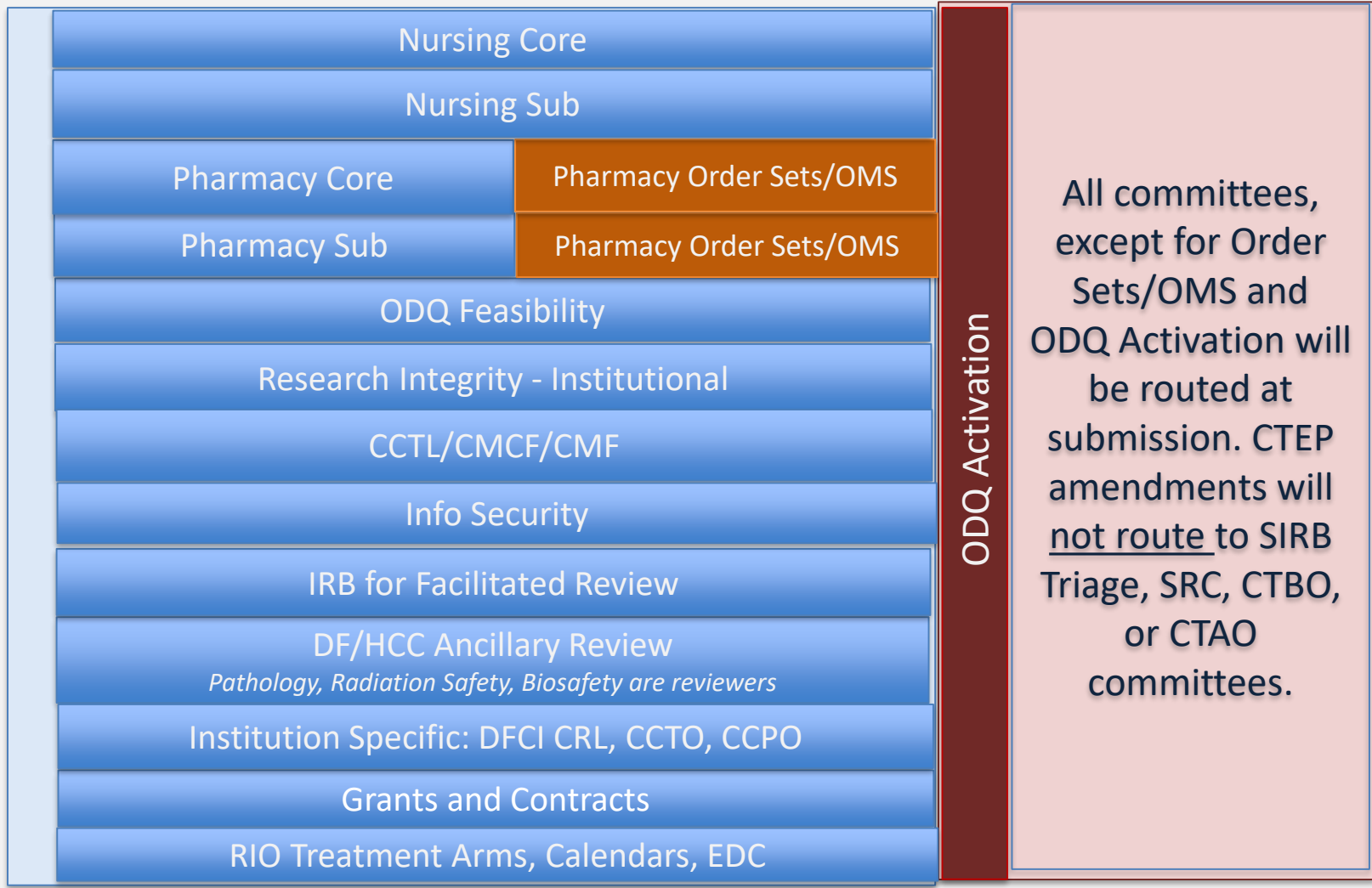
# Comparison to SIRB and DFCI IRB Amendments

## What is different?

- SRC, SIRB Triage, CTBO, and CTAO committees will not be routed
- All reviews occur in parallel
  - Except Order Sets/OMS and ODQ Activation
- There is no Operational Readiness Checklist
- The CTEP amendment form has similar questions to the SIRB amendment form with a few changes
- Timeline expectations


# CTEP Amendment Routing Path

Submission 




# CTEP Amendment Form: Important Dates


**A. Date Posted to CTSU Website:**

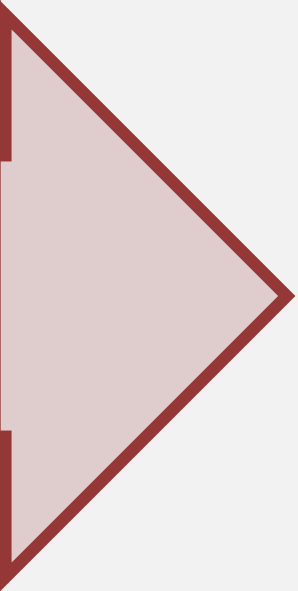


**B. Required Local Activation Date:**



**C. Amendment Version Date:**





**Study teams will need to calculate the 30 day activation deadline = 30 calendar days from date of posting on CTSU website**

**For Example:**

**Date Posted to CTSU Website: 01/09/2021**







**Required Local Activation Date: 02/08/2021**



# Study Team Requirements for Consent Forms

- Page Numbers
- Use of NCI CIRB Model Consent without the following DF/HCC Templated Language:
  - HIPAA
  - Injury Language
  - Standard Signature Block
- Combining Large Flow Charts
- Inclusion of Contact Information

# iRIS: Uploading Consent Forms

Title/Category	Version	Language	UnApproved Consent	Approved Consent	Consent Outcome	Approval Date	Expiration Date	Checkout By	Create a Revised Document
Consent clean 15 Aug2018									
	1.2 08/15/2018	English			Approved	01/09/2021	03/11/2021		 Add Revision
Consent tracked 15Aug2018									
	1.0 08/15/2018	English							 Add Revision
HIPAA Authorization Form *Added by the Review									
	1.0 09/17/2020	English			Approved	10/08/2020	03/11/2021		 Add Revision

- When uploading a consent form in iRIS, the research team will want to open the consent form that was previously reviewed and acknowledged by the DFCI IRB and click on **Add Revision**.
- The revised consent form **should not** indicate that it is version 1.0, unless a **new** or **model** consent form is being added to the study.

# HIPAA Authorization Form(s)

- OHRS will create the HIPAA Authorization Form
- OHRS will revise the HIPAA Authorization form if there is a change in:
  - Title
  - CORE or Site Principal Investigator
  - Sponsor

# Translated HIPAA Authorization Form(s)

- **Current Languages**

- Arabic
- Cape Verdean Creole
- Haitian Creole
- Portuguese
- Spanish
- Vietnamese

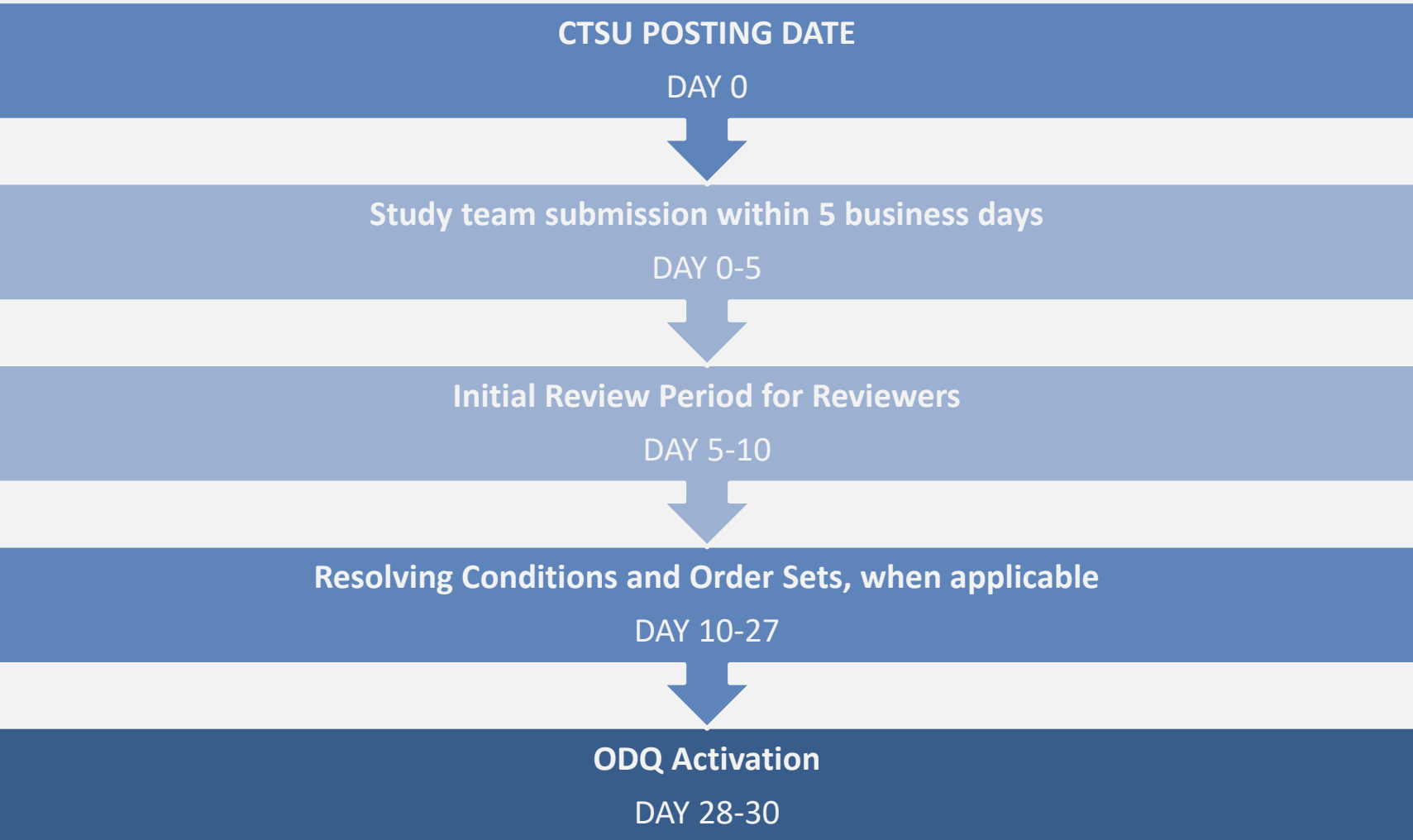
- **Timeline**

- **Languages Above:** ~ 1 business Hour
- **New Language Translation:** ~ 5 business days

# Alert Page

- Allowable for NCI CIRB studies
  - Not reviewed or approved by the NCI CIRB
- **Who Grants Approval for Use?**
  - **PEDI**: Core Principal Investigator
  - **ADULT**: Study Chair
- **Role of DFCI IRB**
  - Review Study Chair or Core PI correspondence
  - Acknowledge document in iRIS

# CTEP Amendment: Important Timelines



# Key Takeaways

NEW as of 12/16/2020

- NEW CTEP Amendment form, February 19, 2021
- Use CTEP AM for ALL NCI CIRB AMs
- Study teams must submit in 5 days regardless of holidays, vacations, or weekends
- Study teams need to calculate the 30 day (calendar) required local activation date
- Use of the iRIS Current Active Submission Report

# Thank you!

Please reach out to  
[OHRSCentral\\_IRB@dfci.harvard.edu](mailto:OHRSCentral_IRB@dfci.harvard.edu)  
with questions about the content of this  
presentation.