CTSU Updates

SWOG Spring Meeting
April 2019

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Agenda

- Accrual in OPEN
- Delegation of Tasks Log (DTL)
- Source Document Portal (SDP)
- Data Quality Portal (DQP)
- CIRB Use Requirements
- Roster Reminders
- Questions

OPEN ACCRUAL

How to find accrual (and other) information using OPEN

April 2019

Accrual Details - OPEN

- New accrual columns were added to the OPEN history screen
  - Step type
  - Count towards

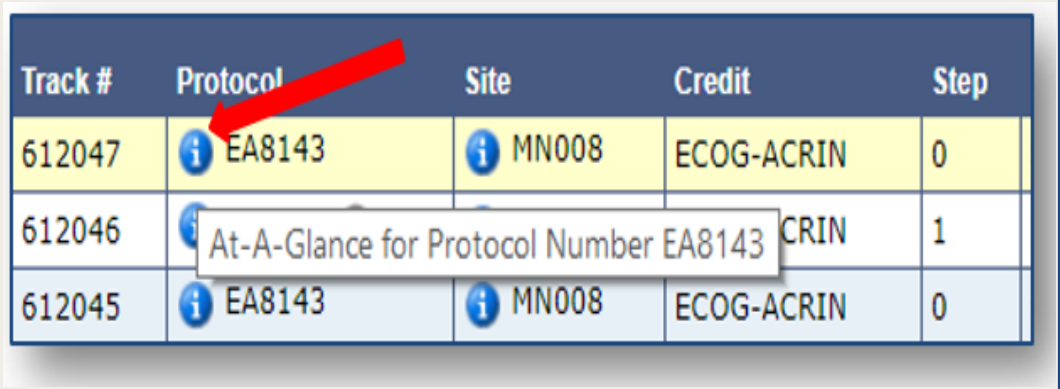
- Each enrollment step will display on a separate row
  - Includes the step type
  - Indicates if the enrollment will be counted towards the step type

OPEN History Screen

Protocol	Site	Credit	Step	Step Type	Count Towards
EAY131		ECOG-ACRIN	0	SCREENING	Y
EA8143		ECOG-ACRIN	1	INTERVENTION	Y
EA8143		ECOG-ACRIN	0	SCREENING	Y
EA8143		ECOG-ACRIN	1	INTERVENTION	Y
EA8143		ECOG-ACRIN	0	SCREENING	Y
EAQ171CD		ECOG-ACRIN	0	SCREENING	Y
EAQ171CD		ECOG-ACRIN	2	INTERVENTION	N
EAQ171CD		ECOG-ACRIN	1	INTERVENTION	Y

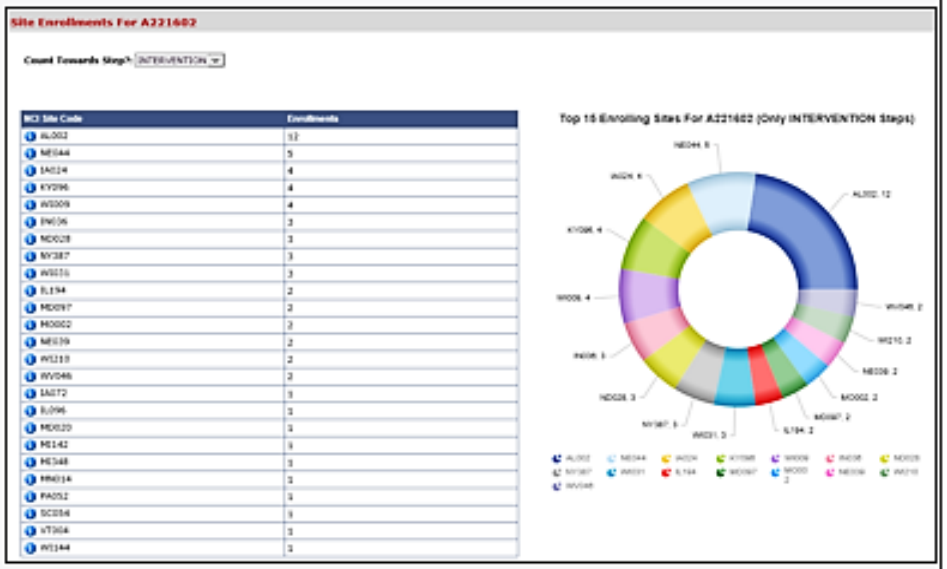
‘i’ Button in OPEN

- At-A-Glance information for the protocol
- Pop-up box includes:
  - General protocol information
  - Registration steps
  - OPEN person types
  - Funding information
  - Site enrollment information



At-A-Glance Pop-Up Box

Protocol: A221602
Title: Olanzapine With or Without Fosaprepitant for the Prevention of Chemotherapy Induced Nausea and Vomiting (CINV)in Patients Receiving Highly Emetogenic Chemotherapy (HEC):
GRP Prot Status: Active
PIO Status: Active
Network Group: ALLIANCE
Legacy group:
Restrict Sites: N
Auto QA: Y
Rave study? Y
Rave Study Group: MAYO
PMB Dist? N
UUID? ef385198-77c2-480c-91dd-18abc3090ffe
CTSU Web Post: N
Menu Date:
Study Type: G
OPEN protocol? Y
OPEN to load to Rave? N
OPEN Slot Reservation? N
OPEN Activation Date: 15-Oct-2018 12:00:00 AM EDT
OPEN to Load to caAERS? N
OPEN to Submit CDUS? Y
TRIAD Protocol? N
TRIAD Activation Date:
RT QA Flag? N
CIRB Posting Flag? Y
Financial Posting Flag? Y
CTA? N
CTA Holder
DQP Supported
Balance Study? N
DTL Required? N
Central Monitoring? N
EPRO Study? Y
Express Courier: Not Required
Monitoring Method: CDUS - Abbreviated



Registration Steps:

Step	Description	Step Type	Required?	Load To	FMT	Count Towards?
1	Randomization	INTERVENTION	Y	NONE	Y	Y
2	Re-Registration	INTERVENTION	N	NONE	N	N

Open Person Types:

Person Type	Registration Type
Consenting Person	Non-Physician Investigator
Consenting Person	Investigator
Consenting Person	Associate Plus
Credit Investigator	Investigator
Site Registrar	Non-Physician Investigator
Site Registrar	Associate Plus
Site Registrar	Investigator
Treating Investigator	Investigator

DELEGATION OF TASKS LOG (DTL)

New task options – Person Minimum, Task Restrictions, Training Documentation Required

April 2019

New Task Options for DTL Templates (1)

- **Person Minimum-** assigns a minimum number of persons to a task
- **Task Restrictions-** restricts a person from being assigned certain tasks, if that person is also assigned another task on the DTL
  - Example: Cannot assign a person the Unblinded Study Personnel task and the Rave CRA task at the same site or any other site.

New Task Options for DTL Templates (2)

- **Training Documentation Required-** requires documentation of training for each person assigned to a particular task
  - Sites must upload training documentation using the site DTL
  - A reviewer will review and approve / reject documentation
  - Status of review will be available on the DTL
  - Tasks will remain in Pending status until approval occurs
  - Notification will be sent to the DTLA if documentation is rejected
  - Training documentation can be used across site DTLs

Unblinded Study Personnel Task – NRG-GY018

- **Two Person Minimum-** At least two persons must be assigned, sites cannot order drug until Pharmacy Agreements are reviewed and approved
- **Task Restrictions-** Persons assigned to this task cannot be assigned to other tasks on the DTL; except for Investigational Agent Accountability
- **Training Documentation Required:** Pharmacy Agreement must be uploaded to training documentation field on the DTL for each person assigned to this task

SOURCE DOCUMENT PORTAL (SDP)

An overview, new enhancements, and a refresher on annotations and redactions

April 2019

SDP Overview

- An application on the CTSU website in Auditing & Monitoring section
- Allows the upload and storage of source documents to support activities such as Central Monitoring and Patient Eligibility Review
- Provides ability to redact Personally Identifiable Information (PII) electronically during the upload
- Currently piloted for use in Central Monitoring on several studies

SDP Enhancements

- Automatic annotation of form with study, site, and patient identifier
- Allow document type identification of *and/or*
- New document type of *Relevant Document*
- Ability for the monitor to redact PII after triaging
- Central monitoring activity report showing Rave status

Upload, Annotate, and Redact

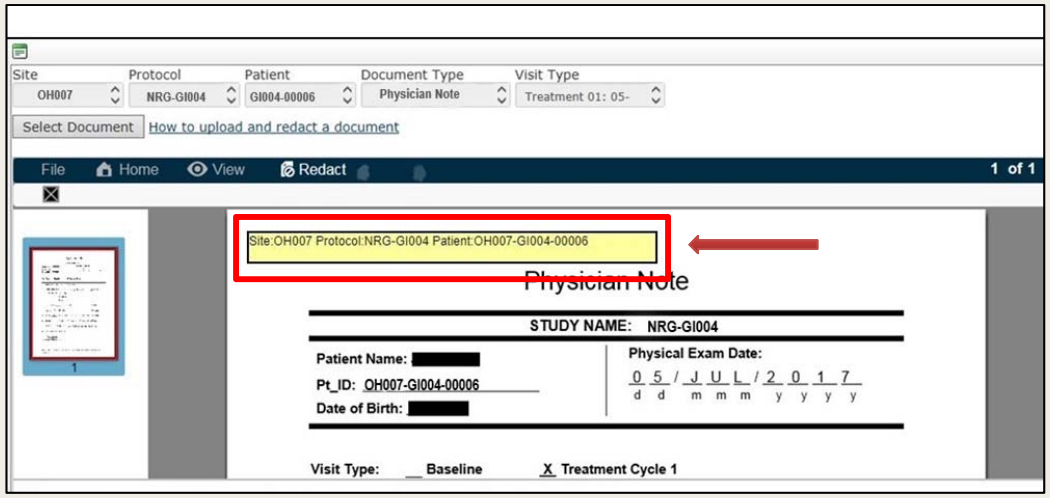
Document upload includes automatic annotation and allows redaction within the SDP

- Upload source documents as PDF (represents a single patient and visit)
- Automatically annotated with study, site, and patient identifier
- Redact PII using redaction tool
- Save document

*Note: *Once an uploaded document is saved, the redacted fields and annotations are burned onto the document and cannot be changed.*
To make changes to a saved document you must delete the document and upload it again.

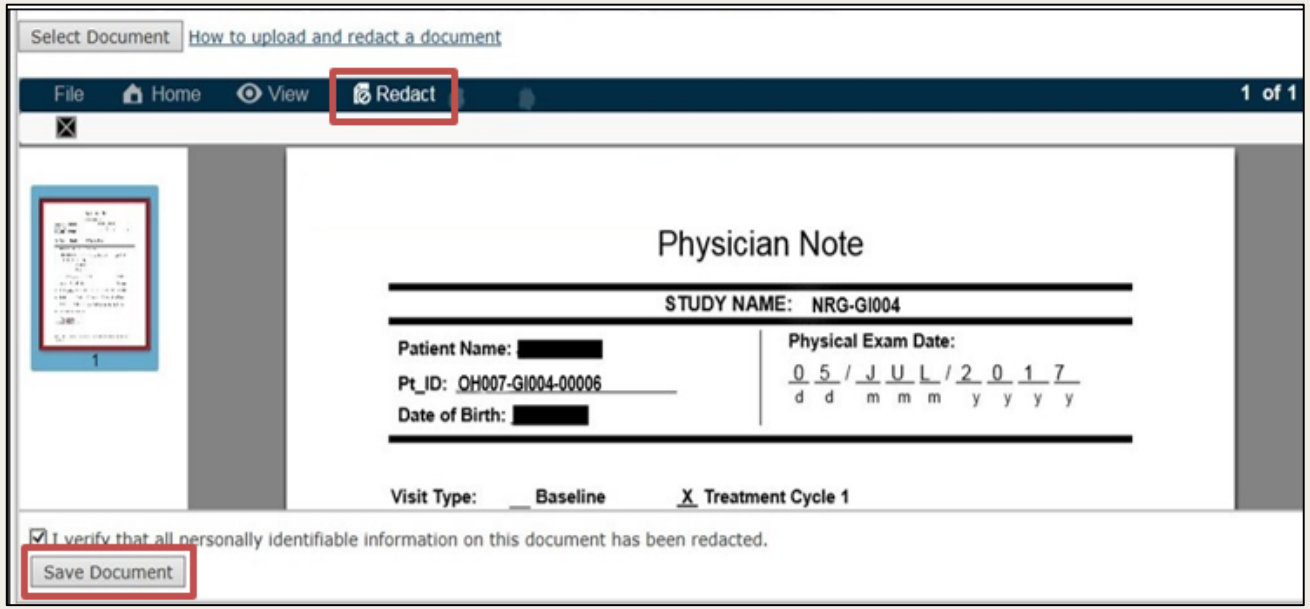
Automatic Annotation

- Displayed at time of document upload
- Cannot be deleted but can be hidden from view
- Can be moved if the default position if blocking information on the document
  - Moving annotations must be managed separately on each page and done ***prior*** to saving the document



Redact PII

- Select **Redact**
- Click and drag cursor over PII to redact
- After review and PII redaction, save the document
- Check the verify checkbox at the bottom left of the Document Upload screen to confirm all PII was redacted
- Click *Save Document* to complete the upload



DATA QUALITY PORTAL (DQP) AWARENESS FAQS

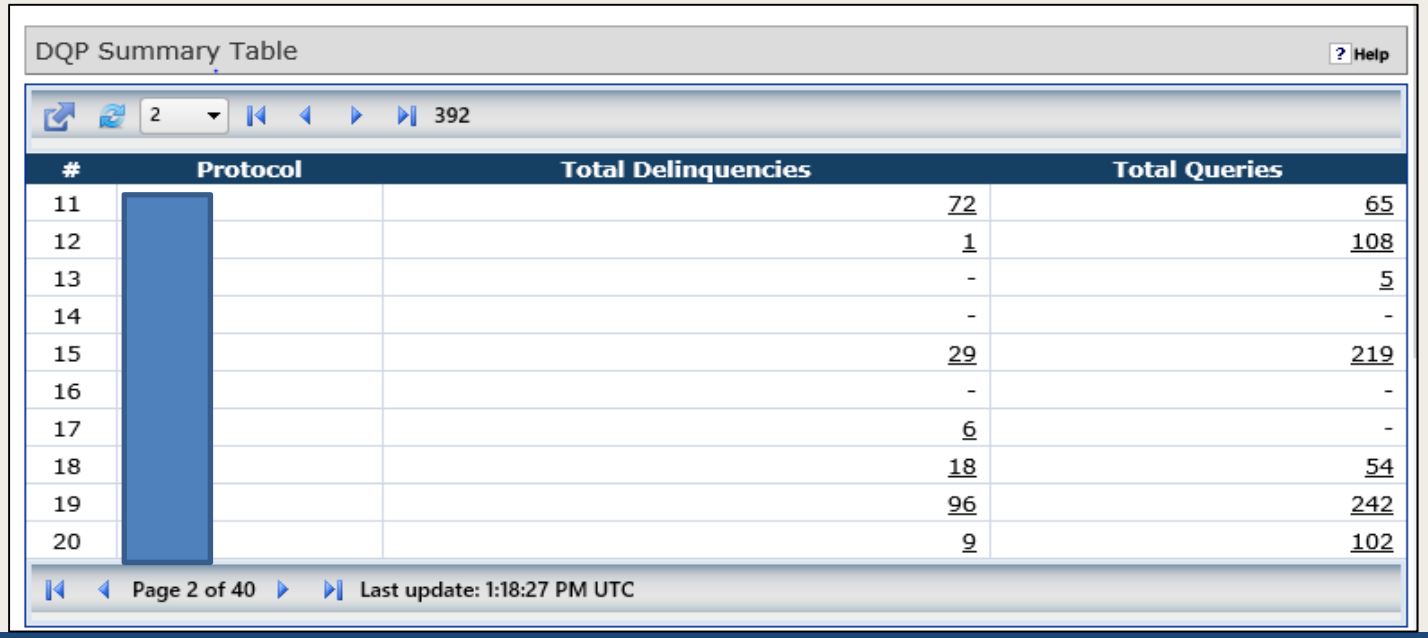
April 2019

Available DQP Reports

- DQP Summary Table
- Aging Report Summary
- Rave Delinquencies/Queries by Form
- Rave Delinquencies/Queries
- DQP Timeliness Reports

DQP Summary Table

- Located in Data Management > Rave Home Page
- Provides summary counts of total delinquencies and total queries for each protocol
  - "-" = there are no delinquent forms or queries for the protocol
  - "n/a" = Rave calendaring is not used by the LPO for the protocol, no delinquent form information is available


DQP Summary Table

Help

2 392

#	Protocol	Total Delinquencies	Total Queries
11	[redacted]	72	65
12		1	108
13		-	5
14		-	-
15		29	219
16		-	-
17		6	-
18		18	54
19		96	242
20		9	102

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DQP Timeliness Reports

- Form and Query Timeliness reports are available in the DQP Reports module
- Provide metrics of expected and received forms/queries for all protocols for all sites *or* for a specific site the user is rostered to
- Posted quarterly to the DQP, not updated after posting

Cancer Trials Support Unit
A SERVICE OF THE NATIONAL CANCER INSTITUTE
Linking practice to progress

Form Metrics for [redacted]

Site	Protocol	Quarter (2018, Q4) Total Number of Expected Forms [A]	Quarter (2018, Q4) Total Number of Forms Received On Time [B]	Quarter (2018, Q4) Total Number of Forms Received Late	Quarter (2018, Q4) Total Number of Forms Not Received	Cumulatively Total Number of Forms Not Received [C]	Form Timeliness Metric (%) [B]/([A]+[C])
[redacted]	[redacted]	*There are no Form Metrics to Display*					
		45	32	12	1	1	70%
		4	4	0	0	0	100%
		There are no Form Metrics to Display					
		5	0	5	0	0	0%
		30	30	0	0	0	100%
		2	0	2	0	0	0%
		There are no Form Metrics to Display					
		40	19	11	10	10	38%
		There are no Form Metrics to Display					
		0	0	0	0	2	
		10	5	4	1	1	45%
		4	4	0	0	0	100%
		There are no Form Metrics to Display					
		There are no Form Metrics to Display					
		There are no Form Metrics to Display					
[redacted]	**Totals**	140	94	34	12	14	61%

DQP FAQ #1

Why is my form still specified as delinquent on the DQP after I already entered it in Rave?

To be considered as received, data entry must be complete ***and*** *all initial* ***Site from System*** *and* ***Non Conformant*** *queries on a form must be answered.*

Allow 24 hours since a DQP system refresh runs on a nightly basis to remove received forms from the DQP.

If your form is still listed as delinquent on the DQP after the nightly refresh, and all initial ***Site from System*** *and* ***Non Conformant*** *queries have been answered, contact the data manager for the organization leading the study.*

Slide 22

GR9 Should this date be removed?
Ginger Riley, 3/26/2019

DQP FAQ #2

Why does the DQP say I have delinquent forms/ queries, but are there no delinquent forms/queries specified in the Rave Task Summary?

Delinquent (or Overdue, as per Rave) forms and queries may not always be displayed in the Site or Patient Rave Task Summary or at the Rave folder level.

The CTSU recommends to always review your delinquent forms and queries in Rave at the form/field level, as delinquent forms and queries requiring site management are always displayed at the Rave form/field level.

Slide 23

GR8 Should this date be removed?
Ginger Riley, 3/26/2019

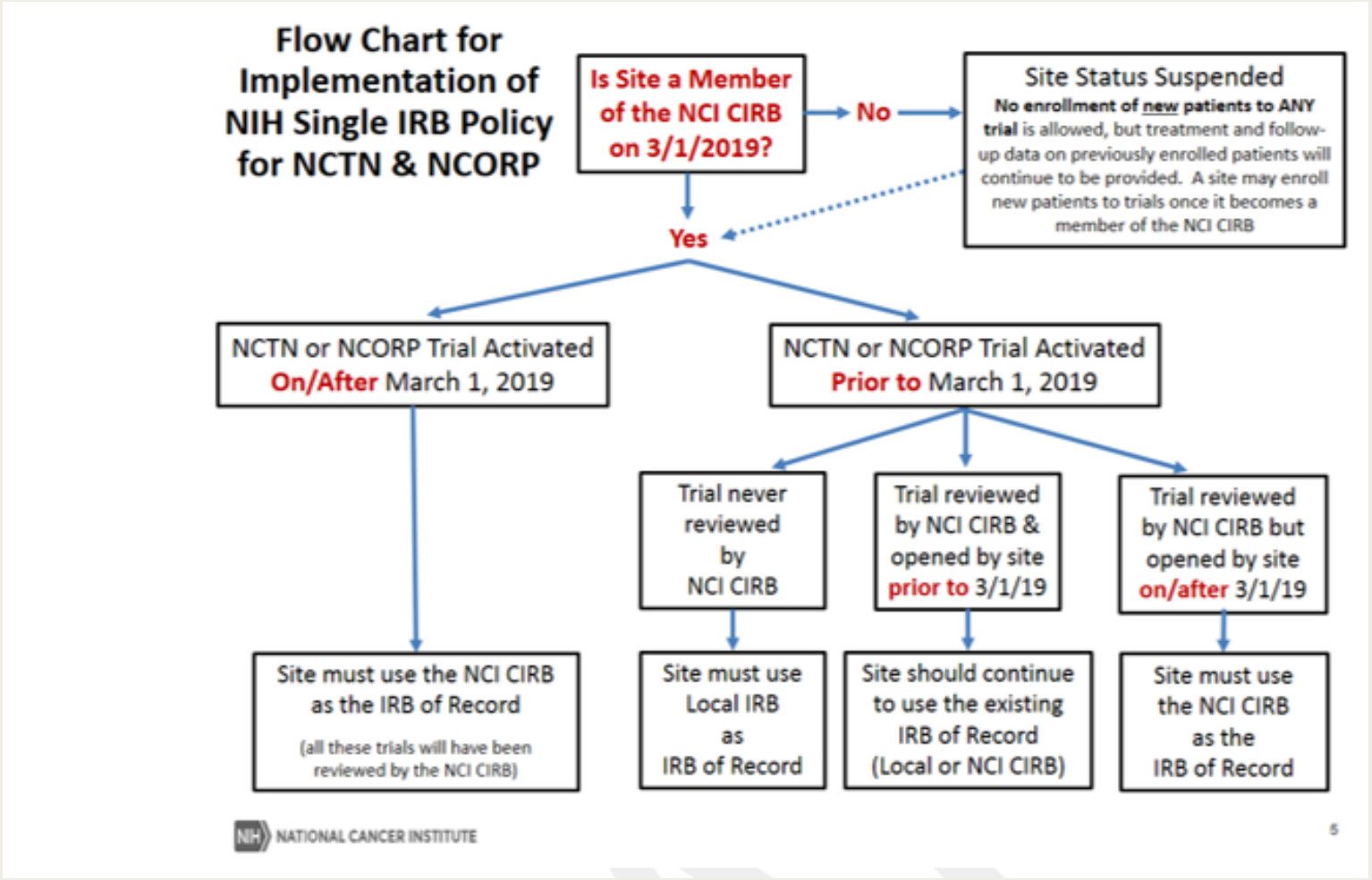
CIRB USE REQUIREMENTS

April 2019

CIRB Requirement

- All U.S. sites participating on trials through the NCTN and NCORP must be or must become members of the NCI CIRB to continue to enroll patients on trials.
- The requirements is based on the NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094).
- The implementation date of this policy was **March 1, 2019**.
- Sites not members of the CIRB at that point were *Suspended*.
  - This affects their participation on <u>all</u> trials, *even those not covered by the CIRB*.
  - Sites not joining the CIRB can continue to treat and follow previously-enrolled patients, but cannot enroll new ones.
- All new NCTN and NCORP studies will be covered by the CIRB.

Implementation of the Policy



ROSTER REMINDERS

Information on removing persons, site-protocol PI checks, close/transfer site checklists, and more

April 2019

Hmmm…Dr. Jones left, what is the best way to remove her from our roster?

First, is Dr. Jones doing any of the following?	
Site-Protocol PI:	Submit PI change request to CIRB for CIRB reviewed studies, or to the CTSU Regulatory Office for local reviewed studies
Treating, credit or drug shipment investigator in OPEN:	Use the Transfer and Update Module in OPEN to update investigator assignments
Acting as the Clinical Investigator (CI) on the site Delegation of Task Log:	Reassign the CI role
Other role assignments:	Reassign to other staff with the appropriate registration type

Next Steps

- Your site Registration Coordinator (RC) should contact the Registration and Credential Repository (RCR) Help Desk to inform them the individual has relocated or is no longer practicing
  - This should set the individual to withdrawn at all treatment sites
- Use NCORP-SYS or the Roster Update Management System (RUMS) to withdraw from individual rosters

Site-Protocol PI Checks and How To Resolve Issues

Because the frustration is real!

Check	Resolution
✓ Practice site is listed in the Site-Protocol PI's RCR profile	Update RCR to include the site
✓ IRB number is listed in the Site-Protocol PI's RCR profile	Update RCR to include the IRB number
✓ Site-Protocol PI is active with CTEP	Update RCR registration
✓ Site-Protocol PI is on a participating roster at the practice site	Add the Site-Protocol PI via NCORP-SYS or RUMS to the practice site
✓ Site-Protocol PI is the correct registration type and/or task access for the protocol	Select another investigator with the appropriate registration type
✓ Site-Protocol PI is on the Signatory roster for sites deferring to CIRB approval	Add the Site-Protocol PI to the Signatory roster in RUMS

Closing a Site - Checklist

- Determine the status of all patients
  - Off-study or transferring
- Contact Lead Protocol Organizations (LPOs) to ensure data entry/queries are complete
- Notify your network administrator (i.e., Main Member site, NCORP, or LAPS admin)
- Notify grant holder of closure
  - For LAPS contact NCTNProgram@mail.nih.gov
  - For NCORPs follow NCORP guidelines
  - Main Member sites notify affiliated NCTN Groups
- Withdraw site from CIRB Signatory (if applicable)
- Submit withdrawal of all site registration records to the CTSU Regulatory Office

Transferring a Site - Checklist

- Determine the status of all patients
  - Off-study, transferring, remaining at the site in followup or under new network
- Determine status of IRB coverage
  - Update CIRB Signatory or local IRB approvals as appropriate
  - Withdraw studies that will not remain open under new network
- Withdraw network staff via NCORP-SYS or RUMS
- Notify your network administrator (i.e., Main Member site, NCORP, or LAPS admin)
- Notify grant holder of closure
  - For LAPS contact NCTNProgram@mail.nih.gov
  - For NCORPs follow NCORP guidelines
  - Main Member sites notify affiliated NCTN Groups

More Information & Questions

- A version of this slide set with additional content will be posted to the CTSU website
  - Available in early May; will be announced in the Bi-Monthly Broadcast
  - Location: Resources >Educational Multi Media >Slide Sets
- Questions?