

# NCI SWOG Site Operations Update

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**NCI**

**National Clinical  
Trials Network**

a National Cancer Institute program



Planned Implementation  
of NIH Policy on  
Single IRB (NCI CIRB)  
for US Sites Participating  
in the NCTN & NCORP  
Clinical Trials Networks

## Underlying Principles for Implementation

**Membership in the NCI CIRB is necessary for US sites in the NCTN and NCORP Clinical Trials Network Programs by the implementation date for new enrollments to any “new” or “legacy” NCTN/NCORP trial regardless of when the trial was activated by NCTN Grp/Network (CTSU)**

***Rationale:** Membership signals the site’s commitment to participating in the NCTN and/or NCORP Network Program(s) going forward*

**Date for implementation is March 1, 2019** for the implementation of the NIH policy as it is the earliest date of the competitive renewal (i.e., date of funded awards) between the NCTN and NCORP Programs

***Rationale:** Given the integration of the site rosters for the NCTN and NCORP Programs in the CTSU, a single, fixed date had to be set for both Programs using the earliest renewal date for funded awards – March 1, 2019 - which is the competitive renewal date for funded awards under the NCTN Program*

## Implementation Rules

In order to address the mix of IRBs (local IRB or NCI CIRB) used by sites for specific NCTN/NCORP trials, rules for the upcoming implementation on March 1, 2019 are explained below using the following definitions:

**Activation Date** = Initial date that the trial was activated by the NCTN Group/Network (CTSU)

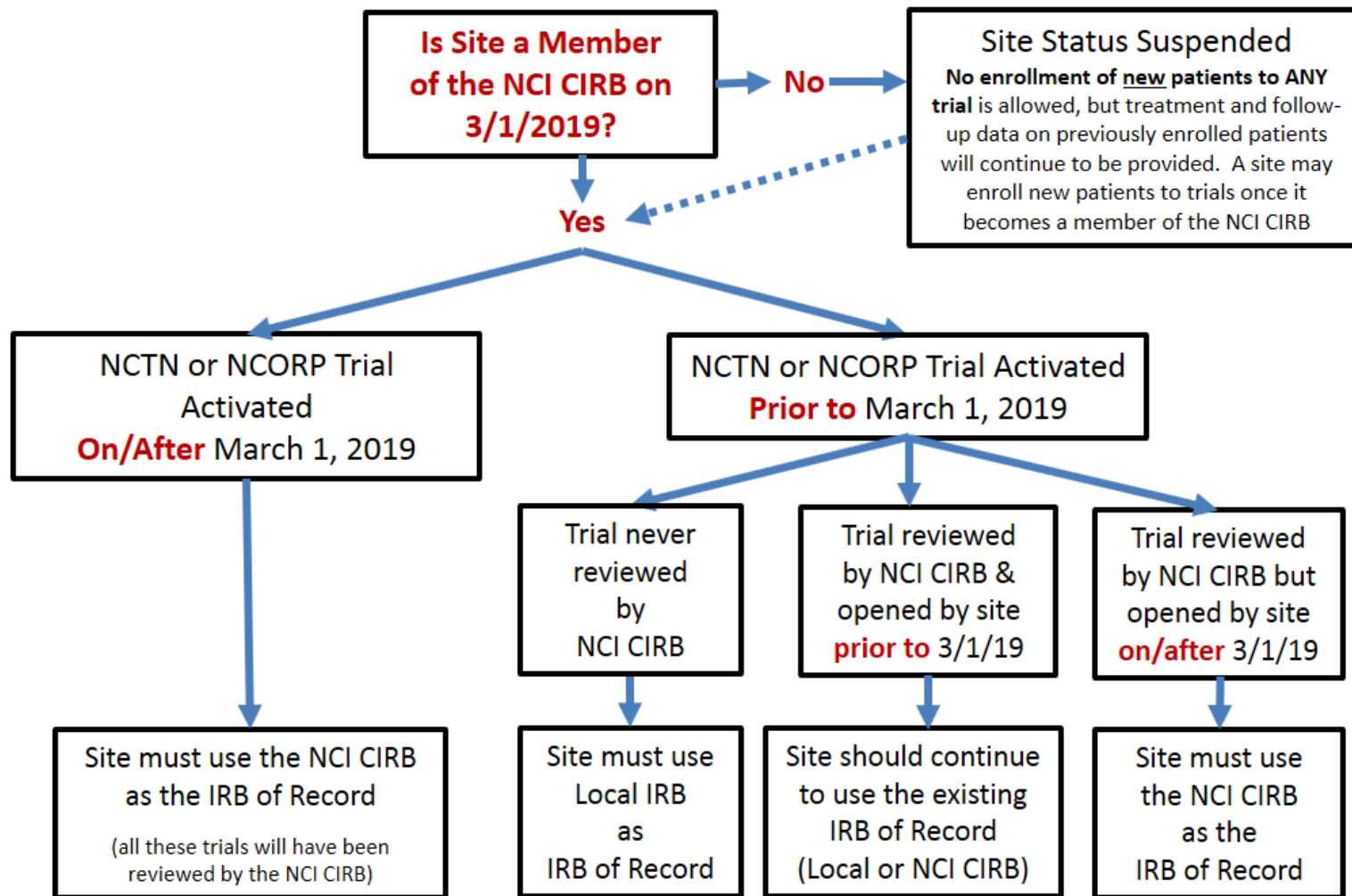
**Opened Date** = Initial date the trial was opened by a site regardless of when the trial was “activated” by the NCTN Group/Network (CTSU)

**NCTN/NCORP Trials with Activation Dates On or After 3/1/2019:**  
Sites must use the NCI CIRB as the IRB of Record for all NCTN and NCORP trials activated on or after March 1, 2019.

# Implementation Rules: NCTN or NCORP Trials with Activation Dates Prior to 3/1/2019

- FDA guidance (“Considerations When Transferring Clinical Investigation Oversight to Another IRB”) states that to “prevent lapses in human subject protection, it is generally preferred that the same IRB retain oversight responsibility throughout the conduct of the trial, if possible.”
- NCTN/NCORP trials never reviewed by the NCI CIRB will not be transitioned to the NCI CIRB; participating sites will continue to use their local IRBs as the IRB of Record for all enrollments until those trials are completed (and any site opening one of those trials after 3/1/19 would also use its local IRB as IRB of Record).
- Sites participating in NCTN/NCORP trials reviewed by the NCI CIRB but opened at their site prior to the implementation date of 3/1/19 under their local IRB as the IRB of Record should continue to use their local IRB until those trials are completed, unless there is a compelling reason to transfer the trial to NCI CIRB.
- Sites that open NCTN/NCORP trials reviewed by the NCI CIRB at their site on or after the implementation date of 3/1/2019 must use the NCI CIRB as the IRB of Record.

# Flow Chart for Implementation of NIH Single IRB Policy for NCTN & NCORP



# Steps for sites that will no longer actively participate in NCTN or NCORP trials after March 1, 2019

Note: sites are still expected to provide follow-up information for patients that are in follow-up.

Site Type	Site Is Following Patients	Site Is Not Following Patients
<b>Rostered Site (not an NCORP or LAPS site)</b>	Notify affiliated NCTN groups that the site will no longer be an active member but will complete patient follow-up. (Site will be put in follow-up status in Regulatory Support System (RSS) to allow patient follow-up.)	Notify affiliated NCTN groups to withdraw the site in RSS.
<b>NCORP Site</b>	NCORP administrator will submit a request to withdraw the site in NCORP-SYS. Once approved by DCP, NCORP-SYS will automatically notify RSS to set the site to follow-up status. (Site will be put in follow-up status in RSS to allow patient follow-up.)	NCORP administrator will submit a request to withdraw the site in NCORP-SYS. Once approved by DCP, NCORP-SYS will automatically notify affiliated NCTN Groups and/or DCP Research Bases to withdraw the site in RSS.
<b>LAPS Site</b>	Notify CTEP at via the NCTN email box that site should be removed from the LAPS grant roster. (Site will be put in No Longer Funded (NLF) status in RSS to allow patient follow-up.)	Notify CTEP to remove the site from the LAPS grant roster; then notify affiliated NCTN Groups to withdraw the site in RSS.

## Relevant Policies and Resources

- NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research (NOT-OD-16-094):  
<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-094.html>
- NIH Website on Single IRB Policy for Multi-site Research:  
<https://grants.nih.gov/policy/clinical-trials/single-irb-policy-multi-site-research.htm>
- FDA Guidance on “Considerations When Transferring Clinical Investigation Oversight to Another IRB”:  
<https://www.fda.gov/downloads/regulatoryinformation/guidances/ucm307779.pdf>
- NCI CIRB Website: <https://ncicirb.org/>





# Resource Reminders

# CTSU Website Resources

# CTSU Website – Webinars

The screenshot shows the CTSU website interface. At the top, the logo for the Cancer Trials Support Unit (CTSU) is displayed, along with navigation links for Home, Contact, and Feed. A user login area shows 'Welcome Grace Mishkin. Your password will expire in 78 days.' A search bar is present on the right. The main navigation menu includes Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, RUMS, Delegation Log, Resources (highlighted with a yellow circle), Collaboration, and Reports. Below the navigation, the 'Resources Browser' sidebar is visible, with 'Educational Multimedia' and its sub-item 'Webinars' highlighted with a yellow circle. The main content area displays a table of webinars.

#	Title	File Date	Format	Post Date
1	<a href="#">CTSU National Coverage Analysis (NCA) for NCI Clinical Trials Session II – Slides – August 15, 2018</a> ★	15-Aug-2018	PDF	22-Aug-2018
2	<a href="#">CTSU National Coverage Analysis (NCA) for NCI Clinical Trials Session II –Recording – August 15, 2018</a> ★	15-Aug-2018	MPEG-4	22-Aug-2018
3	<a href="#">CTSU National Coverage Analysis (NCA) for NCI Clinical Trials Session I – Slides – August 8, 2018</a> ★	08-Aug-2020	PDF	17-Aug-2018
4	<a href="#">CTSU National Coverage Analysis (NCA) for NCI Clinical Trials Session I –Recording – August 8, 2018</a> ★	08-Aug-2020	MPEG-4	17-Aug-2018
5	<a href="#">CTSU National Coverage Analysis (NCA) for NCI Clinical Trials Session I – Q and A from Sites – August 8, 2018</a> ★	08-Aug-2018	PDF	06-Sep-2018
6	<a href="#">NCTN Lymphoma Clinical Trials - Slides - April 3, 2018</a> ★	10-Apr-2018	PDF	11-Apr-2018
7	<a href="#">NCTN Lymphoma Clinical Trials - Recording - April 3, 2018</a> ★	Not Applicable	Web Link	11-Apr-2018

# CTSU Website – Group Meeting Slides

The screenshot shows the CTSU website interface. At the top, the logo for the Cancer Trials Support Unit (CTSU) is displayed, along with the text 'A SERVICE OF THE NATIONAL CANCER INSTITUTE'. Navigation links for Home, Contact, and Feedback are visible. A user login area shows 'My Account' and 'CRISP' with a welcome message for Grace Mishkin. A search bar is present on the right. The main navigation menu includes Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, RUMS, Delegation Log, **Resources** (highlighted with a yellow circle), Collaboration, and Reports. Below the navigation, the 'Resources Browser' section is active, showing a search bar and a list of folders. The 'Researcher Resources' folder is highlighted with a yellow circle. The main content area displays a table of 'Slide Sets' with columns for #, Title, File Date, Format, and Post Date.

#	Title	File Date	Format	Post Date
1	<a href="#">CTSU Presentation for Spring 2018 NCTN Group Meetings</a> ★ <b>NOTE:</b> Versions of this slide set were presented at the Spring 2018 NCTN Group Meetings.	23-May-2018	PDF	30-May-2018
2	<a href="#">CTSU Presentations for Fall 2017 NCTN Group Meetings</a> ★ <b>NOTE:</b> Versions of this slide set were presented at the Fall 2017 NCTN Group Meetings.	15-Nov-2017	PDF	21-Nov-2017
3	<a href="#">ePRO Overview</a> ★	27-Sep-2017	PDF	11-Oct-2017
4	<a href="#">Introduction to CTEP's Registration and Credential Repository (RCR) Slide Set</a> ★	28-Aug-2017	PDF	08-Sep-2017
5	<a href="#">CTSU Presentation for Spring 2017 NCTN Group Meetings</a> ★ <b>NOTE:</b> Versions of this slide set were presented at the Spring 2017 NCTN Group Meetings	02-May-2017	PDF	20-Jun-2017
	<a href="#">CTSU Presentations for Fall 2016 NCTN Group Meetings</a> ★			

# CTSU Website – DTL FAQs

The screenshot shows the CTSU website interface. At the top, the CTSU logo and "Cancer Trials Support Unit" are visible. A navigation bar includes links for Home, Protocols, Dashboard, Regulatory, OPEN, Data Management, RUMS, Delegation Log, Resources (highlighted with a yellow circle), Collaboration, and Reports. A search bar is present with a "Go!" button. The left sidebar contains a tree view of folders, with "Frequently Asked Questions (FAQs)" and "Delegation of Tasks Log (DTL)" highlighted with yellow circles. The main content area displays a search bar for FAQs and a list of five frequently asked questions regarding DTLs.

**Search for...**

**Resources**

Search FAQs:

- 1. Which protocols will require a DTL?**

The initial focus of the DTL is for protocols under a CTEP Investigational New Drug (CTEP IND) that may support Food and Drug Administration (FDA) registration. The National Cancer Institute (NCI) will determine when a protocol requires a DTL.
- 2. Does each site under our network need a DTL?**

Yes, DTLs are protocol and site specific. Each site under the network that will enroll to a protocol must have its own DTL.
- 3. Will there be a DTL for all new protocols?**

There is no formal decision on the eventual scope of the DTLs.
- 4. How will the DTL process work for NCORPs or other networks?**

Each component, sub-component, integrated component, affiliate or sub-affiliate that will accrue to the study must have its own DTL.
- 5. Will DTLs apply to other networks like the ETCTN?**

The initial focus is on NCTN trials under a CTEP IND. No decision has been made regarding roll-out of the DTL to other

# Disease Diagrams

## NCTN Trial Portfolios by Disease

- Posted as separate PDFs by disease area: <https://go.usa.gov/xQT4q>  
([https://ctep.cancer.gov/initiativesPrograms/nctn\\_trials\\_by\\_disease.htm](https://ctep.cancer.gov/initiativesPrograms/nctn_trials_by_disease.htm))
- Each document heading includes the date the diagrams were last updated; diagrams will be reviewed for accuracy monthly
- Can be viewed on the computer
  - Hover over the trial number to see the protocol title
  - Click the trial number to go to the protocol's ClinicalTrials.gov webpage
- Can be printed out and used in hardcopy format
  - First page(s) include disease diagram
  - Last page includes a table with the protocol number and title for reference

# NCTN Trial Portfolios by Disease

[https://ctep.cancer.gov/initiativesPrograms/nctn\\_trials\\_by\\_disease.htm](https://ctep.cancer.gov/initiativesPrograms/nctn_trials_by_disease.htm)

The screenshot shows the NIH National Cancer Institute (DCTD) website. The main header includes the NIH logo, 'NATIONAL CANCER INSTITUTE', and 'DCTD Division of Cancer Treatment & Diagnosis'. Navigation links for Home, Sitemap, Contact CTEP, and Secure Access Login are present, along with a search bar. A dark blue banner reads 'CTEP Cancer Therapy Evaluation Program'. Below this is a navigation menu with dropdowns for Home, Investigator Resources, Protocol Development, Industry Collaborations, Initiatives / Programs, More Links, and About CTEP. The main content area is titled 'Initiatives/Programs' and 'NCTN Trial Portfolios by Disease', with a 'Last Updated: 08/31/18' timestamp. The page text explains that NCI's National Clinical Trials Network (NCTN) is conducting trials in various areas and provides a list of these areas. A note recommends downloading PDF files. The list of cancer trials by disease area includes: Brain, Breast, Gastrointestinal, Genitourinary, Gynecological, Head and Neck, Leukemia, Lymphoma, Myeloma, Sarcoma, Skin (Mainly Melanoma), Thoracic, and Adolescent and Young Adult (AYA). A left sidebar contains various links, with 'NCTN Trials by Disease' circled in yellow.

NIH NATIONAL CANCER INSTITUTE  
DCTD Division of Cancer Treatment & Diagnosis

Home | Sitemap | Contact CTEP | Secure Access Login

Search this site

CTEP Cancer Therapy Evaluation Program

Home | Investigator Resources | Protocol Development | Industry Collaborations | Initiatives / Programs | More Links | About CTEP

Experimental Therapeutics  
Clinical Trials Network (ETCTN)

National Clinical Trials  
Network (NCTN)

**NCTN Trials by Disease**

NCTN Core Coordinating  
Sciences Committee  
(NCTN-CCSC)

Overview

Proposal Submission  
and Instructions

Expanded Evaluation  
Guidelines

FAQs & Funding  
Opportunities

NCI Drug Development  
Project Teams

The NCI Formulary

CTEP Branches  
and Offices

Clinical Investigations Branch

Clinical Trials Monitoring Branch

Clinical Trials Operations  
and Informatics Branch

Investigational Drug Branch

Pharmaceutical Management  
Branch

Regulatory Affairs Branch

Initiatives/Programs Last Updated: 08/31/18

## NCTN Trial Portfolios by Disease

NCI's **National Clinical Trials Network** (NCTN) is conducting trials of cancer treatment therapies in the areas listed below. To see trials that are **active** for a specific disease area, please click that disease area from the following list.

*Note: For full functionality, it is recommended that users download the PDF file, and open with a PDF reader.*

**NCTN Trial Portfolio (including all disease areas)** (pdf)

**Cancer trials by disease area:**

- **Brain** (pdf)
- **Breast** (pdf)
- **Gastrointestinal** (pdf)
- **Genitourinary** (pdf)
- **Gynecological** (pdf)
- **Head and Neck** (pdf)
- **Leukemia** (pdf)
- **Lymphoma** (pdf)
- **Myeloma** (pdf)
- **Sarcoma** (pdf)
- **Skin (Mainly Melanoma)** (pdf)
- **Thoracic** (pdf)
- **Adolescent and Young Adult (AYA)** (pdf)



# NCTN Trial Portfolios by Disease

[NCTN Trial Portfolio \(including all disease areas\) \(pdf\)](#)

Cancer trials by disease area:

- [Brain \(pdf\)](#)
- [Breast \(pdf\)](#)
- [Gastrointestinal \(pdf\)](#)
- [Genitourinary \(pdf\)](#)
- [Gynecological \(pdf\)](#)
- [Head and Neck \(pdf\)](#)
- [Leukemia \(pdf\)](#)
- [Lymphoma \(pdf\)](#)
- [Myeloma \(pdf\)](#)
- [Sarcoma \(pdf\)](#)
- [Skin \(Mainly Melanoma\) \(pdf\)](#)
- [Thoracic \(pdf\)](#)
- [Adolescent and Young Adult \(AYA\) \(pdf\)](#)

CTEP updates monthly based on activated and closed trials

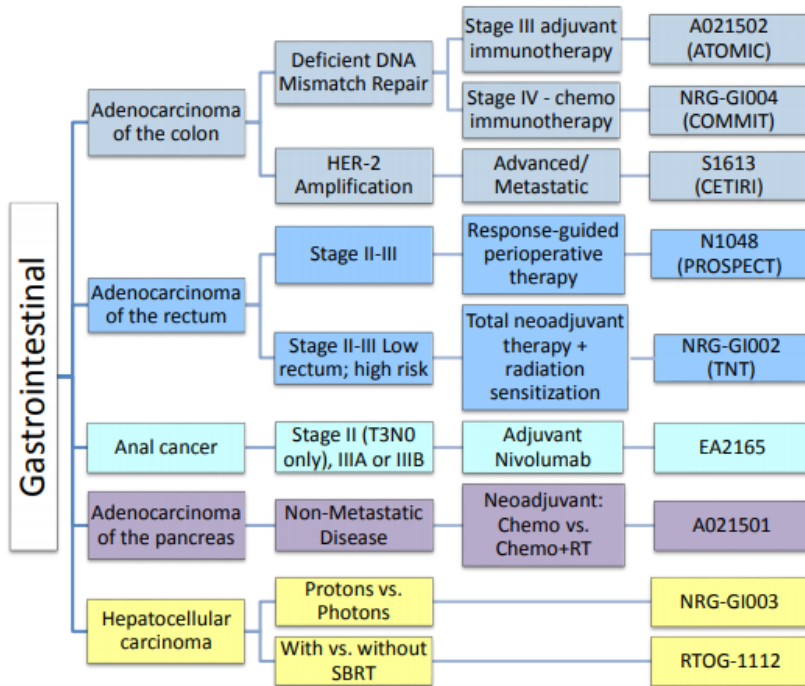
Updates are reviewed by CTEP Disease Leads before posting

# New NCTN Trial Portfolios by Disease: GI

## NCTN Gastrointestinal Cancer Trials Portfolio (Open as of 9/17/2018)

Hover over Trial Number for Protocol Title.

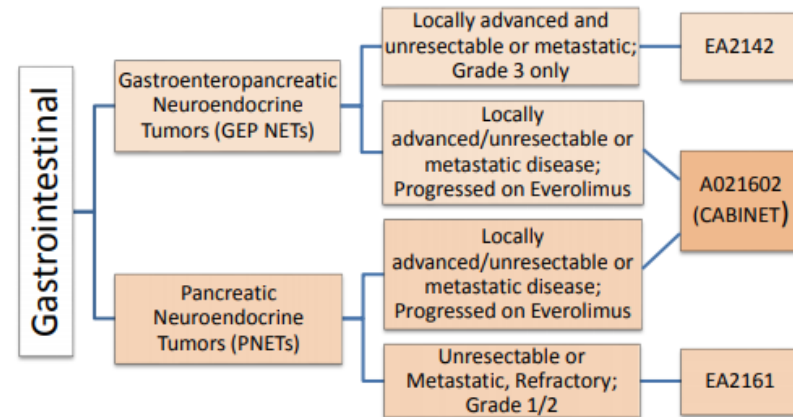
Click Trial Number to go to the associated ClinicalTrials.gov webpage.



## NCTN Gastrointestinal Cancer Trials Portfolio (Open as of 9/17/2018)

Hover over Trial Number for Protocol Title.

Click Trial Number to go to the associated ClinicalTrials.gov webpage.



Cross-disease trials:

EA2131 (MATCH)

S1609 (DART)

# Trial Portfolios by Disease: Leukemia

## NCTN Leukemia Trials Portfolio (Open as of 9/17/2018)

Hover over Trial Number for Protocol Title.

Click Trial Number to go to the associated ClinicalTrials.gov webpage.

