



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

