SWOG CANCER RESEARCH NETWORK

March 1, 2019

TO: ALL NATIONAL CLINICAL TRIALS NETWORK (NCTN) MEMBERS AND ALL NCORP COMPONENTS AND SUBCOMPONENTS

FROM: SWOG Operations Office (E-mail: protocols@swog.org)

RE: Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research

MEMORANDUM

IRB Review Requirements
(√) No review required

MEMORANDUM

The purpose of this memorandum is to inform sites of the Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research and its ramifications for SWOG sites participating in studies funded by our NCTN and NCORP grants.

The policy is effective for grants submitted to NIH on or after January 25, 2018 and requires multi-site research centers/groups to establish the expectation that a single IRB (sIRB) of record will be used in the ethical review of non-exempt human subject's research protocols funded by the NIH that are carried out at more than one site in the United States.

In order to comply with this policy, the National Cancer Institute (NCI) has determined that beginning on 3/1/19 (the earlier date of funding for the affected NCTN and NCORP grants) each NCTN and NCORP sites must be a member of the NCI CIRB in order to continue registering patients to studies in the NCTN/NCORP network.

Attached please find a flow chart provided by the NCI for use in determining which sites and studies are affected. Sites are encouraged to review this chart to determine whether and how you will be affected by this transition to ensure that you remain eligible to continue patient enrollment to NCTN and NCORP studies.

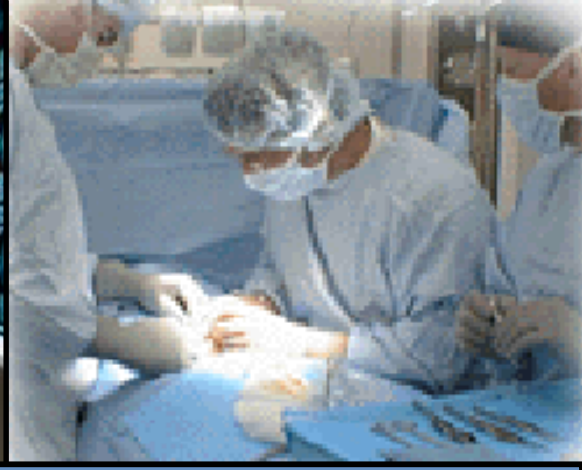
Information regarding CIRB, instructions for becoming a CIRB signatory site, and additional resources regarding the CIRB process are available at https://ncicirb.org/institutions.

The complete text of the Final NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research is available at https://grants.nih.gov/grants/guide/notice-files/not-od-16-094.html.

This memorandum serves to notify the NCI, CIRB, and SWOG Statistics and Data Management Center.

cc: PROTOCOL & INFORMATION OFFICE

National Cancer Institute



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

Division of Cancer Treatment & Diagnosis
Division of Cancer Prevention
National Cancer Institute
September 26, 2018

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