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December 1, 2016

TO: ALL NCTN MEMBERS

FROM: SWOG Operations Office

RE: Implementation dates for protocol changes

MEMORANDUM

IRB Review Requirements
( ) Full board review required
( ) Expedited review allowed
(√) No review required

Status Change
( ) IRB Review only
( ) Activation
( ) Closure
( ) Reactivation

Protocol changes
( ) Eligibility changes
( ) Treatment / Dose Modification / Study Calendar changes
( ) Informed Consent changes
  ( ) Patient notification not required
  ( ) Patient notification required
( ) Scientific / Statistical Consideration changes
( ) Specimen Submission changes
( ) Data Submission / Forms changes
( ) Editorial / Administrative changes
( ) Other

MEMORANDUM

The NCI Central IRB (CIRB) Initiative was designed to help reduce the administrative burden on local IRBs and investigators and to enable investigators to enroll patients onto NCI-sponsored clinical trials significantly faster than when employing the traditional method of local IRB review.

We have discovered that there are sites using the CIRB as their IRB of record that are required to submit protocol modifications for local IRB oversight prior to implementation of any changes. This was not the intent of the CIRB Initiative as it can slow down the implementation of new protocols, protocol modifications and revised consent forms. There has also been confusion as to allowed timeframes for implementing protocol modifications and revised consent forms.

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In order to facilitate the process of implementing protocol modifications in a timely manner (as intended by the CIRB Initiative), **sites using the NCI CIRB as their IRB of record, will now be required to implement amendments and revisions within 30 days** of the CIRB posting date (date of the CIRB Acknowledgment Letter).

For sites not using the NCI CIRB, per NCI-CTMB Guidelines, protocol amendments and revisions must be approved by local IRBs within 90 days of distribution of the notice and the changes are effective upon approval by the local IRB; however, **eligibility changes will now become effective 6 weeks after distribution of the notice. If approval is not granted within 6 weeks, accrual must be suspended until local approval is obtained.**

Sites will be held to these standards for audit and patient registration purposes starting December 15, 2016. For comments or questions, please contact Elaine Armstrong at the SWOG Operations Office at (210) 614-8808 or qa@swog.org.

This memorandum serves to notify the NCI, CIRB and the SWOG Statistical Center.