

# 30 Day Rule for CIRB Approved Amendments

## Addendum to NCI/CTMB Audit Guidelines

- Direct result of multiple Groups seeking CTMB input on how many days/weeks would be appropriate for consent form at the site to be updated after the CIRB has approved the amendment
- Discussion item at the Group Administrators Meeting in May 2016, decided it would be 30 days
- Decision was formalized via an addendum to the audit guidelines sent to the Group Audit Coordinators in February 2017; also posted on CTEP/CTMB Website

## Rule only applies to CIRB approved amendments

- Consent form not updated by the site within 30 days of amendment approval date (date posted on CTSU website), will be deemed a **Lesser** deficiency
- Groups have the option to make this rule more strict and assign a **Major**.