

CTEP Informed Consent Form Posting Requirement Policy

NCI's Cancer Therapy Evaluation Program (CTEP) is implementing new requirements for posting of the study Informed Consent form to ClinicalTrials.gov to comply with the revised Common Rule requirements at 45 CFR 46.116(h).

This policy applies to all CTEP-supported studies, including but not limited to studies conducted through the National Clinical Trials Network (NCTN), Experimental Therapeutics Clinical Trials Network (ETCTN), Pediatric Early Phase Clinical Trials Network (PEP-CTN), Adult Brain Tumor Consortium (ABTC), Pediatric Brain Tumor Consortium (PBTC), and the Cancer Immunotherapy Trials Network (CITN). CTEP is making this new policy effective April 15, 2019. However, as, noted below, this policy applies to any CTEP-supported trial with a trial activation date on or after January 21, 2019.

Definitions

Trial Activation Date: Initial date that a trial was activated in the CTEP systems (e.g., for the CTEP-supported clinical trial network programs, this is the date of activation in the Cancer Trials Support Unit (CTSU)).

Lead Protocol Organization (LPO): Organization that developed and is overseeing the conduct of the trial.

Closed to Accrual and Treatment: CTEP Protocol Status Update Form refers to this as Closed to Accrual, All Patients have Completed Treatment/Intervention: The protocol has been closed to patient accrual. All patients have completed therapy/intervention, but patients are still being followed according to the primary objectives of the study. No additional investigational agents are needed for this study.

Informed Consent Form Posting Requirement for CTEP-Supported Studies

All CTEP-supported studies with a trial activation date on or after January 21, 2019, must post the most recent CIRB-approved model consent form to ClinicalTrials.gov within 60 days of the study status changing to "Closed to Accrual and Treatment."

The trial activation date of January 21, 2019 was chosen to align with the implementation date for the revised Common Rule requirements. Although the revised Common Rule requirements apply to studies with an initial IRB approval date on or after January 21, 2019, CTEP has decided to apply this policy based on the trial activation date. The trial activation date was chosen because this date is consistently tracked in CTEP systems and will include all studies subject to the revised Common Rule requirements.

For studies where CTEP is the IND sponsor, NCI will post the most recent CIRB-approved model consent form to ClinicalTrials.gov within 60 days of the study status changing to "Closed to Accrual and Treatment."

- Lead Protocol Organizations must ensure that the study status is promptly updated in CTEP systems to "Closed to Accrual and Treatment" at the appropriate time by emailing the CTEP Protocol Information Office (PIO) with the study status change as soon as study treatment ends. This is necessary so that CTEP can ensure compliance with this requirement.

- When the study status changes to “Closed to Accrual and Treatment,” CTEP will provide all industry partners the most recent CIRB-approved model consent form and allow 30 days for them to request redactions before finalizing the consent form for posting.

For studies where CTEP is not the IND sponsor and for studies that are IND-exempt, the Lead Protocol Organization will post the most recent CIRB-approved model consent form to ClinicalTrials.gov within 60 days of the study status changing to “Closed to Accrual and Treatment.”

Guidance for Local Sites Transitioning CTEP-Supported Studies that Activated Before January 21, 2019, to the Revised Common Rule Requirements

Lead Protocol Organizations should notify their member sites of the following guidance and provide any additional LPO-specific requirements.

Studies approved and activated under the prior Common Rule requirements were done so in good faith that they were ethically and regulatorily sound when approved. CTEP will not be transitioning studies to the revised Common Rule requirements and discourages sites from transitioning CTEP-supported studies opened using the local site’s IRB as the IRB of record to the revised Common Rule requirements.

With this policy, CTEP is requiring posting of the Informed Consent Form for studies activated on or after January 21, 2019. Should a local site’s institution decide to require a study activated before that date (which is using the local site IRB as the IRB of record) to be transitioned to the revised Common Rule, the site must comply with the requirements described below.

Local sites will not be able to post the consent form to ClinicalTrials.gov because they are not the study sponsor. Instead, they can take advantage of alternative sites that the Office for Human Research Protocols (OHRP) has determined meet the Common Rule Requirement.

Local sites should note the following stipulations:

- If a transitioned study is under CTEP IND, the site must email a copy of the consent form intended for posting to CTEP’s Regulatory Affairs Branch (RAB) at NCICTEPpubs@mail.nih.gov within one week of the study status changing to “Closed to Accrual and Treatment.” The Regulatory Affairs Branch will provide the consent form to all industry partners and allow them 30 days to request redactions. The Regulatory Affairs Branch will then provide to the site a redacted consent form that is cleared for posting.
- If a transitioned study is under a non-CTEP IND, the Lead Protocol Organization may have additional requirements before the consent form can be posted.

Relevant Policies and Resources:

OHRP Revised Common Rule Educational Materials: <https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/index.html>

OHRP Common Rule FAQs for Informed Consent: <https://www.hhs.gov/ohrp/education-and-outreach/revised-common-rule/revised-common-rule-q-and-a/index.html#informed-consent>

CTEP Protocol Status Update Form: <https://ctep.cancer.gov/protocolDevelopment/amendments.htm>