

Policy on the Issuance of Waivers for Protocol Deviation(s)

Approved May 15, 1996; Revised September 3, 1996; Streamlined August 13, 2025

CTEP will not issue or approve any waivers for protocol deviations.

This policy applies to all components of CTEP-approved protocols, including eligibility criteria, treatment schedules, dose modifications, toxicity assessment, response criteria, and statistical aspects.

If a change to a CTEP-approved protocol is necessary, the lead organization must submit an amendment to the protocol. The amendment must be approved in writing by CTEP and by the NCI CIRB (or other IRB of record) prior to its activation.