**Procedure for Requests for Grant Letters for Drug Supply**

Investigators submitting grants to support clinical trials are usually required to have a commitment of drug supply for the proposed study. Consequently, PIs request letters from CTEP indicating commitment of the CTEP-supplied investigational agent.

CTEP’s policy has been to provide provisional approval for LOIs containing such requests, contingent upon receipt of grant funding, when the grant was reviewed by an NIH review panel. LOIs are placed on hold, pending grant review. In addition, a letter has been provided indicating that CTEP would provide drug for NIH-supported grant studies, provided the industry collaborator has agreed to provide study agent and a sufficient supply of the investigational agent is available.

Due to OEWG timelines, it is no longer possible to approve LOIs that are contingent on grant funding, due to the length of time of the grant review cycle. Consequently, CTEP has developed a new process for LOIs pending grant approvals that are submitted to CTEP.

In place of the standard LOI form, investigators now will complete the **Grant Letter Request (GLR) LOI**. PIO will assign the GLR LOI a number and assign it for IDB review meetings. If the proposal is found to be acceptable, the PI will be furnished with a grant letter as described above. Once the GLR LOI is approved, it will enable PIO to track the request when the PI resubmits the proposal as a full LOI once the grant has been approved. The PI will be asked to reference the GLR LOI number with the new submission, and a new LOI number will be assigned, but the GLR LOI number will be noted in the review packet. The GLR will remain “in review” in the CTEP database until the full LOI is received, when it will be changed to approved. If no LOI is received within 1 year, PIO will change the status to disapproved.

General guidelines:

* In general, CTEP will provide a provisional drug commitment letter for U.S. government-granting programs (NIH, DOD). The decision to provide letters for other peer-reviewed granting organizations will be made on a case-by-case basis.
* CTEP must be able to assess proposals before agreeing to provide a provisional drug commitment letter.
* The grant submission should be attached to the GLR LOI.
* Once investigators obtain grant funding they should submit an LOI, referencing their previous request. CTEP will review the LOI and, following provisional approval, forward the LOI to the company for commitment of drug supply.
* The GRL LOI must be received by CTEP at least 2 weeks prior to the grant submission deadline to allow sufficient time for the CTEP review.