

Ancillary Study Proposal Review Process Summary

Before ancillary studies that are not an integral part of a protocol can be endorsed by the BMT CTN, proposals must go through the review process delineated below and be approved by the BMT CTN Executive and/or Steering Committee. Investigators should allow a **minimum of 30 business days** for the appropriate teams and committees to complete their review and provide a final determination regarding study approval.

- Proposals for ancillary studies using stored biospecimens must be presented in writing to the Protocol Team. Written proposals must be prepared by using the BMT CTN Ancillary Study Proposal Summary Form provided on the BMT CTN public website. The investigator must indicate potential sources of funding for the study, and indicate if funds are currently available or being sought.
- For ancillary study proposals limited to one protocol, the initial review is conducted by the Protocol Team. An important factor in the review of ancillary study proposals is the determination that the objectives and implementation of the primary study are not compromised. Protocol Team members individually review ancillary study proposals and evaluate them for:
 - Significance and appropriateness of the proposed research question
 - Design of the proposed research
 - Availability of funding and by whom
 - Availability of biospecimens, if required for the study
- The Biomarkers Committee provides a second level of review, when necessary, focusing on the laboratory aspects of the proposal in terms of feasibility and scientific merit and putting the proposal in the context of other laboratory studies approved or ongoing on BMT CTN clinical trials. The Biomarkers Committee sends its evaluation back to the Protocol Team for their review. The Protocol Team may amend its evaluation of the proposal based on this critique. For ancillary studies involving biospecimens but applying to several protocols, the primary review is done first by the Biomarkers Committee, which then presents its recommendations to the BMT CTN Protocol Teams.
- The Protocol Team then presents its recommendations regarding the proposed study to the BMT CTN Executive Committee and/or Steering Committee for final approval.

