

TRIGR Ancillary Studies Guidelines

The TRIGR Scientific Advisory and Ancillary Studies Committee focuses on the following aspects of your study in relationship to the TRIGR Study. It is important to have a letter specifically addressing each of the items below, as well as a protocol, consent form, and IRB / Ethics Committee or Animal Care and Use Committee approval, if applicable:

1. The scientific merit of the proposal and the potential contributions that your proposal will make to TRIGR overall.
2. That the ancillary study does not cause a deviation from the defined study protocol.
3. That the proposed study does not complicate the interpretation of the results of TRIGR.
4. That it does not adversely affect subject cooperation and participation.
5. That the volume of whole blood or sera taken from subjects does not exceed safe or prudent limits.
6. That your study does not create a significant diversion from TRIGR.
7. That the study does not divert or expend resources from TRIGR either locally or at the coordinating center.
8. That the study does not adversely influence the cooperative spirit of the collaborating investigators.
9. That your study does not compromise the scientific integrity of TRIGR.
10. That adequate resources are available to complete the proposed study or are requested from granting agencies.
11. That techniques and assays essential to the study are well established in your laboratory.
12. Your study must include a member of TRIGR as investigator or co-investigator.

Ancillary studies must be funded from sources other than funds provided to the TRIGR Study Group for execution of the core TRIGR protocol. If resources for your proposed study are not currently available but are being sought through granting agencies, please inform us in writing, with the name of the agency and the date on which the proposal will be reviewed. Also indicate if this agency requires a letter of approval from the TRIGR Scientific Advisory and Ancillary Studies Committee prior to review.

Once your proposal has been received, it will be forwarded to all committee members with two members assigned as primary reviewers. Allow up to 4 weeks for Ancillary Studies review.

TRIGR requires that the proponent(s) of an ancillary study have representation in the TRIGR Study Group (TSG). This requirement is satisfied if you or another proponent of your study is a current member of the TSG or if a member of the TSG agrees to provide liaison with you. Further, if your study is approved and you utilize the resources of TRIGR, you are a partner in this study.

As a partner in TRIGR, all manuscripts, abstracts, presentations at scientific meetings based on ancillary study data must be reviewed and approved by the TRIGR Publications and Presentations Committee (PPC) before presentation or publication. For further information with regard to publication and presentation, please contact Dr. Outi Vaarala, Chair of the PPC, at the National Institute for Health and Welfare, Helsinki, Finland – email: outi.vaarala@thl.fi.

A yearly progress report summarizing your study results and the impact of the study on TRIGR trial must be submitted to the Ancillary Studies Committee.

To submit your proposal or if you should have any questions regarding the information presented in this policy guideline, please contact the Chair of the Scientific Advisory and Ancillary Studies Committee, Dr. Jerry P. Palmer, at JerryP@medicine.washington.edu, tel.: 206-764-2495 or fax: 206-764-2693.