

**NAFTNet Study Concept Proposal Outline**

* Submit electronically as an attachment to the Board of Directors Chairperson info@naftnet.org.
* **Deadlines for Concept Form Proposal Submission are as follows:**
	+ December 1 for the Spring Meeting
	+ June 1 for the Fall Meeting
* The Chairperson will distribute a blinded copy of the concept proposal to the Board of Directors for review. A simple majority approval moves the concept proposal forward to the Scientific Review Subcommittee.
* If the concept proposal is accepted, the applicant is notified within 15 days and invited to submit a complete research proposal to the Scientific Review Subcommittee for review and preparation for the Steering Committee presentation. Questions and concerns about the proposal may be included in the notification letter.

Title of Study:

Primary investigator (s):

NAFTNet Center Affiliation:

NAFTNet Steering Committee Representative Sponsor Name:

Date:

Overall study hypotheses:

Objectives:

Primary objective:

Secondary objectives:

Exploratory objectives:

Study Endpoints:

Primary Endpoint:

Secondary Endpoints:

Other Endpoints:

Background and significance of problem to be studied:

Study design

* Study population

Inclusion criteria

Exclusion criteria

Study methods

Sample size calculation

Plans for long-term follow-up (methods and length of follow-up)

**Budget**

**References**

1.

2.

3.

**Approved Study:**
If a research proposal has been approved as a NAFTNet protocol, the Board of Directors Chairperson will send a letter of Network’s commitment to participate to the PI to accompany any submitted grant applications or requests for funding. Information about participating NAFTNet Centers and NIH Biographical Profiles of the designated primary NAFTNet member from the centers will be available to the study PI to download from the NAFTNet website to accompany their funding application.

**Supported Development:**
For proposal obtaining support to move forward but requiring further revisions, the Scientific Review Subcommittee Chairperson will appoint a 4-person working group (chaired by one member of the Scientific Review Subcommittee) to support the PI.

There will be a conference call between the members of the working group within 30 days of the Steering Committee meeting to discuss desired improvements to the study. Ongoing feedback will be given to the PI by the working group following each revision until all issues are resolved and the working group feels it is ready for final presentation, aiming for completion of this process within 15 days of the next Steering Committee meeting.

The working group chair will provide the Scientific Review Subcommittee Chairperson with a progress report 2 and 4 months after the Steering Committee meeting, describing progress and challenges.

The PI will submit the final edited research proposal within 15 days of the next meeting for distribution and review by the full Steering Committee.

The PI will re-present the proposal to the next Steering Committee meeting outlining changes made to address the issues raised at the initial presentation. Following further discussion, the study proposal will be voted on for Network support. An anonymous vote with a 2/3 majority approving Network support is required. Otherwise, the study will not be a NAFTNet supported study.