

	NACHO Protocol Concept Proposal Form	
	Effective Date: 12/18/2018	Approved by: NACHO Executive Committee
	Revised Date: 10/22/2020	Page: 1 of 1

NOTE: Please refer to NACHO SOP "Protocol Concept Proposal Submission" for more information.

Concept Leader / Institution:

Concept Title:

Email address:

NACHO Collaborators:

Proposal date:

Other Collaborators:

1. Project Type

- | | |
|--|---|
| <input type="checkbox"/> Therapeutic prospective protocol, Phase _____ | <input type="checkbox"/> Retrospective data analysis |
| <input type="checkbox"/> Non-therapeutic prospective protocol | <input type="checkbox"/> Biology study (human samples) |
| | <input type="checkbox"/> Laboratory study (pre-clinical research) |

2. Protocol Summary

Please attach a summary (not more than 5 pages) of the study concept which includes background, hypothesis, objectives, design/methods, intervention (if applicable), and references.

3. What conflicts exist between this proposed study and current NACHO protocols or approved protocols in development, and what is the plan to mitigate the conflicts?

4. Project Funding

Have funding sources been identified for this project? **Yes / No**

If yes, describe:

If no, what are the plans to secure funding?

If study drug is required, has the pharmaceutical company been contacted?

If no, what are the plans to secure study drug?

5. Submission

Please submit the completed form and attachments along with a completed Conflict of Interest Form for each Chair and co-Chair to: NACHO.OperationsCenter@stjude.org The completed Concept Form will be forwarded to the current chair of the Scientific Committee (SC). Clarifications and changes may be requested by the SC during the 45-day review period. The SC will notify the EC of their recommendation within 70 days. The submitting NACHO member will be notified by the SC when the EC has finalized the decision.