

	NACHO Protocol Concept Proposal Form	
	Effective Date: 12/18/2018	Approved by: NACHO Executive Committee
	Revised Date: NA	Page: 1 of 2

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

Concept Leader / Institution: _____

Email address: _____

Proposal date: _____

Concept Title: _____

NACHO Collaborators: _____

Other Collaborators: _____

1. Project Type

- Therapeutic prospective protocol, Phase _____
- Non-therapeutic prospective protocol
- Retrospective data analysis using data from NACHO studies
- Biology study (human samples)
- Laboratory study (pre-clinical research)
- Other Explain: _____

2. Protocol Summary

Please attach a summary (not more than 5 pages) of the study concept which includes background, hypothesis, objectives, design/methods, sample size, 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

- | | |
|--------------------------|----------|
| NACHO resources required | Yes / No |
| Biostatistician | Yes / No |
| Data Management needed | Yes / No |
| IND needed? | Yes / No |
| Other | Yes / No |

If yes, describe:

Will this be a multi-site study? Yes / No

If yes, describe:

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

If yes, describe:

If no, what are the plans to secure funding?

5. Submission

Please submit the completed form and attachments to: NACHO.OperationsCenter@stjude.org who will forward to the current chair of the Scientific Committee (SC). Clarifications and changes may be requested by the SC during the forty-five (45) day review period. The SC will notify the Executive Committee (EC) of their recommendation within forty-five (45) days. The submitting NACHO member will be notified by the SC when the EC has finalized the decision.