

PROGRAM SUMMARY

Congratulations on reaching the second step of the Foundation's clinical trials program application! We look forward to seeing your full proposal.

PROPOSAL GUIDELINES

1. Proposal Format:

- a. Single-spaced or greater with a minimum of 12-point font. Proposals should not exceed 10 pages. Ideally, proposals will be roughly 6 pages excluding letters of support. Neither budget nor biographical information documents will be included in the page count.
- b. The full proposal must be converted to a single PDF document that includes all attachments.
- c. The order of the proposal should follow the outline below, including use of numbering and headings.
- d. Acronyms and similar terminology should be defined on the first usage.

2. Proposal Outline

- a. Title
- b. Hypothesis and Objectives: Be precise and enumerate specific, testable hypotheses with realistic objectives to be met within the timeline and budget of proposal.
- c. Significance and Literature Review: Clearly describe the background of the problem, justifying the need for the research; reference important papers in existing literature and identify gaps in existing research; explain the importance of expected findings and describe how the proposed trial challenges and seeks to shift current clinical practice paradigms.
- d. Preliminary data: Briefly describe previous research (if any) by the investigator which supports the proposed research.
- e. Experimental Methods and Design: Describe the proposed experimental approach, including data sources, statistical design and power, sampling methods, empirical analysis of methodologies that will be used to answer the research question, participant follow-up procedures, and number of patients included in the study.
- f. Work Plan: Describe all enrollment and exclusion criteria, briefly summarize a recruitment and retention plan, outline the sequence and schedule of experiments and duration of the project, identify who will have what duties and responsibilities, and define key milestones. If the project requires multi-centric data collection, include the hospital information system in place at each collection site and how the data collected will be standardized across these systems. and existing medical records systems at all collection sites.
- g. Animal Involvement Justification: Include the required animal involvement justification form.
- h. Client Release Form: Include an approved (if required by your institution) client release form developed specifically for the proposed project. If an applicant is a primary care

doctor and does not have access to such a form at the time of application submission, he/she may request assistance from the Foundation to create the form prior to submitting the application.

- i. Cited References: Include complete citations referenced in the proposal.
- j. Budget: Complete the budget template located in the Resources section. Include the role and percent of each individual for whom salary funds are requested. Add comments where additional detail is needed to justify budget lines.
 - 1. Indirect costs: By policy, the Foundation permits 10% of the budget to be applied to indirect costs, if an applicant's institution charges for these costs.
- k. Previous Spectrum of Care projects: Describe (and, if published, provide citations for) previous work by the researcher on spectrum of care related matters.
- l. Biographical Information: Include a Curriculum Vitae for the primary investigator and Co-investigators to include place of employment and position, completed degree work, years of experience, and prior research experience (if any).
- m. Letters: If a university-based applicant, please include a Letter of Support from Department Head (or equivalent). This letter should:
 - 1. Demonstrate the department's approval of the research plan.
 - 2. Confirm that the applicant is a full-time permanent employee.
 - 3. Confirm that the applicant will be allowed adequate time to conduct the proposed research.