



CLINICAL CANCER RESEARCH PROGRAMMATIC GUIDELINES

Our Funding Focus

Rising Tide Foundation supports truly innovative, unique, patient-centered research that has the potential to positively impact the lives of cancer patients in near future. We fund early stages clinical studies and translational research that can demonstrate the potential for quick and meaningful impact. **We do not support basic research or phase III/IV trials.**

Our primary consideration in grant support is to improve treatment options and quality of life of cancer patients. We work to drive immediate results for cancer patients and want our investigators to commit and advance research towards a cure. Our Foundation is not a source of funding for traditional studies and trials as there are existing resources available for incremental improvements in cancer therapy.

Rising Tide Foundation will only support truly innovative and unique clinical trials that have the potential to immediately impact the lives of cancer patients. Applicants are encouraged to pay close attention to the mission of our Foundation. We are only interested in providing support to funding support is not being used strategically, efficiently, and purposefully for the achievement of our mission, all funding may be terminated.

Purpose

The overall goal of our cancer research funding program is to improve treatment options and quality of life for cancer patients by funding clinical studies focused on prevention, detection, treatments and aftercare. We seek to accelerate and support innovative and creative studies that have the high probability to change the paradigm for how cancer is treated today. Our grant application is the vehicle by which proactive investigators may focus directly on their cancer patients' clinical problems and deliver clinical treatments that may prove successful quickly. We are particularly interested in identifying and funding clinical investigators who:

1. Have outstanding clinical treatment ideas relevant to today's cancer patients with a direct, meaningful therapeutic impact for enrolled patients.
2. Are driven to deliver new and better treatment options for their patients today through clinical trial studies directly relevant to our Foundation's mission.
3. Have collaborated to design novel, new, or pilot projects distinctly removed from currently funded research projects.

Funding from other granting agencies is encouraged as long as (i) the funding agencies are disclosed and accepted as funding partner by Rising Tide Foundation, and (ii) there is no overlap or duplication of funding for the proposed study.

Eligibility

Both new and established investigators are encouraged to apply. All established investigators requesting pilot funds should demonstrate how their study is a departure from ongoing funded work. New studies may be an extension of other work but cannot overlap any funded study unless the applicant clearly demonstrates that new funding will not duplicate existing support. Rising Tide Foundation will require the return of all issued funds if found to be a duplication of other funding

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Primary Investigator Printed Name: _____

Primary Investigator Signature: _____

Date: _____

sources. The intent of your proposed study should be to provide preliminary data for future support from other funding sources, thereby driving new and better treatment options to market.

Use of funds

Awarded funds will be paid on a milestone-driven or pay-by-patient basis. It should be used for non-reimbursable approved treatment- and study-related patient-care costs, including extraordinary laboratory and imaging studies and supplies. Funds may also be used to support the portion of salary devoted to the approved project by the Principal Investigator and other key personnel. Full documentation and disclosure is required in your budget worksheet. Equipment will be funded only in extremely rare circumstances and should be fully justified in your budget. Maintenance of equipment will only be funded if use is demonstrated to be entirely related to your funded project by Rising Tide Foundation. Kindly note that indirect costs are not covered.

Maximum award and duration

The amount of each award is based on the availability of funds. The duration of the award is up to five years or less as specified in the grant award letter. Rising Tide Foundation will disburse awarded funds only if the recipient maintains strict compliance with reporting and participant accrual requirements as outlined in our Research Funding Terms and Conditions.

Application process

The application process involves the following steps:

- **Pre Grant Application:** As potential breakthrough ideas can occur every day, we accept letters of intent from highly qualified and dedicated institutions all year round. Letters of Intent are submitted online via <https://proposalcentral.altum.com/> and are assessed by internal staff.
- **Full Grant Application:** Only the most promising applications with the highest potential for sustainable, transformative impact will be invited to submit a full grant application online. The applicant should submit both, the 'Guidelines' and the 'Full Grant Application' templates. These documents are available online and should be submitted through the website.
- **Scientific Board:** Full grant applications are reviewed by our Scientific Board, a panel of external experts that carry out a comprehensive scientific review. Each application is independently analyzed and ranked by the peer reviewers on the panel. Recommendations made by the Scientific Board are submitted to the Rising Tide Board of Directors for final funding approval. The Pannel Meeting takes place six weeks before the Board Meeting.
- **Rising Tide Board Meeting:** After approval from the Board of Directors, we will send out the award notification to award recipients no later than a month after the board meeting. Declination letters will be sent to those who were not successful in their application. Board meetings normally take place three times a year.

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All applications should include the following:

- 'Guidelines' document signed in entirety [to be submitted online as pdf]
- 'Full Grant Application' filled out and signed in entirety [to be submitted online as pdf]
- The curriculum vitae of the principal investigator and co-investigators limited to a MAXIMUM of 2 pages per individual. All CVs should be included in one pdf file to be uploaded online.
- A description of the proposed research project. The description of the proposed research project should be organized in a manner similar to that required by the US National Institute of Health [PHS 398], including:
 - Specific aims
 - Background and significance
 - Preliminary results, studies explaining the significance and potential for success
 - Experimental design and methods
 - Statistical analysis section outlining approach taken to make it scientifically valid
 - Statement of your objectives regarding how your study can change the current standard-of-care for today's patients
 - How much time will elapse between your approval for funding and opening of your proposed study
 - Statement of next steps for your research upon achieving positive or negative results
 - Description of how milestone achievements for this study are achieved
 - List of other sources of financial support for this project; please include all sources *applied, pending, and/or active* with dates of start and expected end (see page 10)
 - Industry letter stating permission for the use of the investigational agent [provide where applicable] and list literature cited.

If the proposed study is a clinical trial, please include the following in addition to the above referenced information:

- Number of patients enrolled to achieve statistical significant findings
- Enrollment inclusion and exclusion criteria
- A detailed schedule of activities for a patient in this study
- Explain why this treatment may be helpful to those patients enrolled
- Describe criteria used in determining positive results and how you will be quantifying quality-of-life improvements
- A copy of the Patient Consent Form, if available, acknowledging funding in whole or in part by Rising Tide, including a statement to the effect of "If you are interested, Rising Tide would like permission to communicate with you regarding your experience and any other information you would like to share regarding the treatments received while participating in this clinical trial. Please acknowledge yes by checking here _____" must be included on the form.
- Timeline for patient treatment, including milestones for completing this study as a "fee per patient" study
- Current, active IRB Approval letter for this study. If your application is reviewed and considered "approved pending IRB approval" by Rising Tide's Board of Directors, you acknowledge that proof of IRB approval must be in the hands of Rising Tide prior to any payment of Rising Tide's funds.

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Conditions of continued funding upon approval:

1. Demonstration of satisfactory progress as defined in grant award documentation
2. Agreement to and compliance with Rising Tide's Research Funding Terms & Conditions; milestones met as officially agreed, approved, and expected; proof and explanation of status of each patient and their responses demonstrated.
3. Regular communication with Rising Tide staff in regards to the funded clinical study.
4. Notification of any modifications to your approved study, its protocol, timeline, expectations, funding sources, patient status and exact reason for any patient's discontinuation of study participation, etc.; include copies of documents supplied to your IRB, the FDA, and/or any other funding sources for this study.
5. Demonstration of ongoing study results (e.g. symptoms records and patient impact in clinical trials).
6. Willingness to talk to and meet Rising Tide's staff, Board members or anyone else pertinent to the continued funding of your study.
7. Facilitation of initial introduction with your study's patients who are interested in talking to Rising Tide.

Rising Tide may cease funding any project at any time. Rising Tide shall have no legal or contractual obligation to fund any grant or project, even after approval. This application does not constitute consideration for obligation or liability by Rising Tide.

Other Information

The following information must be answered in the body or cover letter of your application:

1. If your study involves the use of an investigational agent, we must receive an industry letter stating permission for the use of that agent, who is supplying that agent for your study, and the in-kind amount of that contributed agent.
2. We must have verification that the investigator will be able to conduct the proposed study to meet the parameters and timeframe of the project. [i.e. letter from your department head stating institutional commitment to this project, that there are no competing studies, verification to accrue a valid patient population, etc.)

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