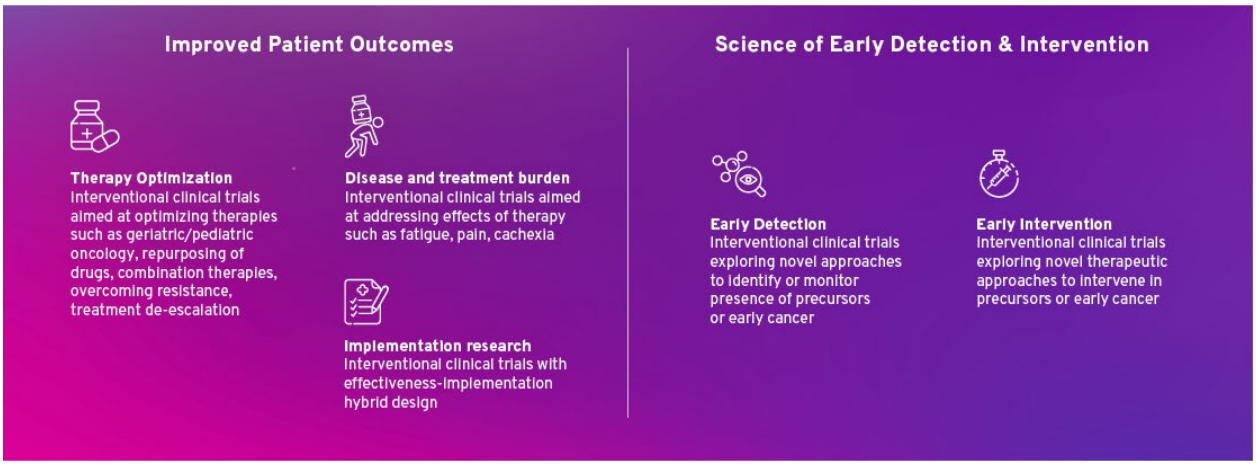
RISING TIDE.
Foundation for Clinical Cancer Research

FUNDING GUIDELINES

Rising Tide Foundation for Clinical Cancer Research (RTFCCR) supports truly innovative and unique patient-centered clinical trials with the potential to timely impact the lives of cancer patients. Our overall goal is to improve treatment options and quality of life for cancer patients by funding clinical studies focused on detection, treatment, and survivorship. We fund phase I to phase III interventional clinical trials and do not support basic research or phase IV trials, nor observational or epidemiological studies.



RTFCCR focus areas. For more information, please refer to our website:
Funding Approach (risingtide-foundation.org)

Eligibility

The principal investigator for the proposed research must hold a doctoral degree, have completed a postdoctoral training fellowship, and have faculty appointment (or equivalent) with an academic institution, including research institutions that are not formally associated with a university, at the time of the award term. Both new and established investigators are encouraged to apply.

An applicant must be an independent, self-directed researcher for whom their institution provides space and other resources customary for independent investigators. The application must convey the commitment of the institution to both the applicant and the proposed research activities. An applicant with an existing award from Rising Tide concurrent with the new application is precluded from applying.

All investigators requesting pilot funds should demonstrate how the proposed study is a departure from ongoing funded work. New studies may be an extension of other work but should not overlap any funded study unless the applicant clearly demonstrates that new funding will not duplicate existing support. Rising Tide will require the return of all issued funds found to be a duplication of other funding sources.
The following criteria must be met for the proposed clinical trial:

- Clinical trials need to be interventional trials and may include secondary non-clinical endpoints.
- Pharmaceutical agents used in the study can be generic (off patent), registered for this

indication, or under development by an academic institution.
- Open for early stage first in human clinical trials to late-stage clinical trials (Phase 1, 2 and 3) where creation of a patient-initiated protocol is possible.

Please note:
- Clinical trials testing immunotherapies need to be discussed with Rising Tide before submission of any application.
- Final selection will be contingent on scientific review and availability of funds.
- Rising Tide does not have any geographical nor cancer type restrictions.
- International teams are welcomed.
- The application must be submitted in English.
- If the applicant wishes to apply for funds to conduct correlative studies that are translational in nature and form part of the interventional clinical trial, we encourage him/her to reach out to us to confirm eligibility. Such projects should clearly demonstrate the potential to lead directly to improved outcomes for patients or lead directly to a clinical trial. Applicants will be asked to estimate the time frame for their research to result in a clinical trial.

Applicants can contact us at rtfccrteam@risingtide.ch to clarify any questions or doubts.

Use of funds

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

Maximum award and duration

The amount granted will be based on the objectives of each grant and the availability of funds. The duration of an award is up to five years. Rising Tide will disburse awarded funds only if the recipient maintains strict compliance with reporting and participant accrual requirements as outlined in Rising Tide's Research Funding Terms and Conditions (included in the RTFCCR Grant Award Letter).

Sharing of knowledge

Rising Tide will actively foster the dissemination of information generated by our grantee institutions. Per our terms and conditions, it is expected that grant recipients share, disseminate, and publish all meaningful results and findings of their work with the public expeditiously. RTFCCR staff will actively follow up on the publication plan provided with the grant application.

Measuring impact

With a steadily growing portfolio of research grants, it is important for Rising Tide to have a well-defined set of measurements aligned with our funding strategy and supporting the attainment of our core values. As part of monitoring grant progress, grantees are asked to collect a pre-defined set of outcomes and impact measures. These will be used to communicate the resulting contribution each

project brings to the fulfillment of the foundation mission and objectives.

Patient involvement in research

We define patient involvement as meaningful involvement of patients in the development of detection, therapeutic, or symptom management approaches. It encompasses the active, meaningful, and collaborative interaction between patients and researchers across all stages of the research process, where research decision-making is guided by patients' contributions as partners, recognizing their specific experiences, values, and expertise.

We adopt the definition of patient partner provided by Patient-Centered Outcomes Research Institute (PCORI). PCORI's definition of patient partners includes patients (those with lived experience), family members, caregivers, and the organizations that are representative of the population of interest in a particular study.

It is important that patient partners are not confused with trial participants; patient partners are members of the research team and involved in the planning, conducting, and dissemination of the research, whereas trial participants are those individuals actually enrolled in the study.

The strategy, modalities, and budgets for patient involvement, related deliverables, and expected outcomes can be included in the grant budget, as long as they are clearly described in the grant application.

Guidance for planning patient involvement in research

Early involvement of patient partners, based on co-design principles, allows for a better formulation of relevant research questions, more credibility of the knowledge produced, identifying, and solving potential challenges faced during the trial, and better application of outcomes to specific contexts.

Here is a checklist to help plan patient involvement and complete the Patient Involvement Plan required with the Letter of Intent (LOI). It encompasses points that should be considered for the application phase, during the implementation of the project, and beyond the project.

Before the project starts:

- Patient involvement is planned across the entire project lifecycle.
- The most appropriate Patient Involvement model is selected.
- The appropriate patient partners are involved early in formulating the concept and hypothesis of the study.
- The appropriate budget for Patient Involvement activities and compensation of patient partners is reflected in the Patient Involvement Plan and the overall grant budget request.

During the project:

- The assessment of needs of trial participants by patient partners is included.
- The trial and procedures are adapted where necessary to meet trial participants' needs.
- An assessment of the impact of Patient Involvement is considered at the mid-term and end of the project.

Beyond the project:

- Communication and dissemination of study outcomes with patient / public partners is planned

after project end.
- Collaboration with the patients' community on trial outcomes is planned.

For more information, please download the document "DIA Consideration Guide to Implementing Patient-Centric Initiatives in Health Care Product Development" here.

Choice of model of Patient Involvement in research projects

Research teams should think carefully about activities across the whole project lifecycle that patient partners could undertake. Short term activities are easy to define upfront, but it is more challenging to think about sustained involvement across the entire project. Therefore, depending on the research project, it is important to think about the most applicable role of a patient partner for contributing to the clinical research project. Applicants will be asked in the full application to provide a detailed explanation to justify the patient role selected for the project.

Patient role	Examples	Involvement level
CONSULTANT	• Patients provide a priori and continuous consultation on outcomes of importance, study design, etc. • Patients are paid investigators or consultants. • Patients have a governance role – "a seat at the table".	High
ADVISOR	• Patients serve as advisory committee members or provide a priori consultation on outcomes of importance and study design but have no leadership role or governance authority.	Moderate
REACTOR	• Patient input is collected distally through surveys, focus groups, or interviews, but patients are not consulted directly or a priori on such things as study design and outcomes of importance. • Patients are asked to react to what has been put before them rather than being the origin of the concepts of interest.	Low

Patient Involvement Plan

We require the submission of a Patient Involvement Plan as part of the LOI. It should then be revisited or adapted for the Full Application. The plan should describe patient involvement processes during the generation of the project application as well as during the implementation of your project. It describes involvement, such as how you engage with the patient community when your research question is defined, while the proposal is written, when it is being submitted and resubmitted, and which patient involvement model you chose for the implementation of the project.

When developing the project budget, please make sure that adequate and realistic resources for patient involvement are reflected in the Patient Involvement Plan and the overall grant budget request. This could include an appropriate budget for work time (staff or contractors in patient organizations) as well as project-related pass-through costs (e.g. travel expenses and meeting venue costs).

In summary, different phases of research will need different activities to ensure patient involvement is implemented in the way defined in this document, for example Phase I first-in-human studies may

require a different approach than a survivorship study.

We accept different formats for Patient Involvement Plans, as long as:

- Activities proposed are listed and properly described.
- Activities proposed are designed for patients and with patients.
- The results of these activities are implementable in the clinical trial design or execution to ensure patient needs are met.

Be very clear at the outset about what you expect to achieve and what metrics – both quantitative and qualitative – will be used to measure progress and achievement of both overall research goals and specific patient-centricity goals.

Application process

The application process involves the following steps:

- Letter of Intent (LOI): We accept LOIs from highly qualified and dedicated institutions all year round. LOIs are submitted online through our grant management system, SmartSimple (https://ccr.eu-1.smartsimple.eu/welcome/CCR/?u=1) and are assessed by internal staff and advisory board members.
- Full Grant Application: Only the most promising applications that align with our focus areas and have the highest potential for sustainable, transformative, and direct patient impact in the shortest possible time will be invited to submit a full grant application online.
- Grant Review Committee: Full grant applications are reviewed by our grant review committee, a panel of external experts that carries out a comprehensive scientific review. Each application is independently analyzed and ranked by the scientific peer reviewers, patient experts, and a biostatistician on the panel. The review meeting takes place six weeks before the Rising Tide Board of Directors meeting.
- Rising Tide Board of Directors Meeting: Recommendations made by the grant review committee and RTFCCR advisory board are submitted to the Rising Tide Board of Directors for final funding approval. Upon 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.

Application requirements

Please note, all applications should include the following as requested in the SmartSimple platform:

- The curriculum vitae (CV) of the principal investigator and co-investigators (max 2 pages each; please upload all CVs as PDF files in SmartSimple)
- A description of the proposed research project (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
    - Statement of objectives regarding how the study can change the current standard-of-care for today's patients or how it will create evidence to improve prevention and early detection of cancer

  - Detailed schedule of activities for a patient in the study
  - Explanation of why the treatment may be helpful to patients enrolled
  - Description of criteria used in determining positive results and how quality-of-life improvements will be quantified
  - Statistical analysis section outlining approach taken to make study scientifically valid
  - Amount of time before the opening of the study upon approval for funding
  - Statement of next steps for research upon achieving positive or negative results
  - Description of how milestone achievements for the study are achieved
- Completed Patient Involvement Plan
- 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" included on the form)
- Current, active Institutional Review Board (IRB) or Ethical Committee (EC) approval letter for the study (if the IRB/EC has not been obtained at the time of proposal submission, please indicate the expected timeline for obtaining the approval)
- Letter from department head stating institutional commitment to the project, no competing studies, and verification to accrue a valid patient population
- Explanation of alignment with RTFCCR Focus Areas
- Detailed budget including costs for patient partner compensation and travel expenses
- List of other sources of financial support for the project (include all sources applied – pending and/or active with dates of start and expected end)
- Industry letter stating permission for the use of the investigational agent, who is supplying that agent for the study, and the in-kind amount of that contributed agent [if applicable]
- List of literature cited.

Conditions of continued funding upon approval

- Demonstration of satisfactory progress as defined in grant award documentation (milestones met as officially agreed, approved, and expected; proof and explanation of each patient status and response)
- Agreement to and compliance with Rising Tide's Research Funding Terms & Conditions
- Regular communication with Rising Tide staff with regards to the funded clinical study
- Notification of any modifications to the approved study, its Patient Involvement Plan, 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 IRB/EC, the FDA, and/or any other funding sources for the study)
- Demonstration of ongoing study results (with milestones and deliverables)
- Willingness to talk to and meet Rising Tide staff, Board members, or anyone else pertinent to the continued funding of the study
- Facilitation of initial introduction with the study's patients interested in talking to Rising Tide