

UAB MEDICINE

O'Neal Cancer Center

Investigator Initiated Trial Award In honor of Francisco Robert, M.D.

The O'Neal Cancer Center's **Investigator Initiated Trial Awards** provide investigators with the opportunity to carry out interventional treatment trials that will benefit from local expertise and are highly relevant to our catchment area. Trials which originate from UAB research are highly encouraged.

Scope of Award

Each award will provide up to \$100,000 for an interventional trial. Costs for trial related activities including regulatory submission, monitoring, trial activation, coordination, and data management will be built into the award budget. Funds may be used for correlative studies, other resources within UAB, and publication fees. These funds may not be used for salary support for the PI or mentor.

The IIT Award can only be used for the costs at UAB (an exception being for publication costs). For multi-site IIT trials, the award cannot be used for trial costs at non-UAB sites. Monitoring is a requirement for multi-site IITs and the associated costs must be covered. If the IIT Award is being leveraged in conjunction with other sources of funding, the duration and scope of the trial may include multiple sites and a longer timeline. A plan for the trial to be fully funded is required at the time of application.

Eligibility

One of the PIs must have an M.D. and be a faculty member in a clinical department at UAB. Trainee applications must include a letter from their Division Director or Department Chair indicating that the trainee will remain at UAB beyond completion of training and/or outlining how another PI will complete the trial. Trainees cannot be the PI of treatment trials. Multi-PI proposals are encouraged.

Selection Process

Awards will be contingent on the availability of funds and the quality and diversity of the applications. The selection committee will include the AD of clinical research and other senior members of O'Neal based on areas of expertise and experience in clinical trials. Applications will be reviewed on a rolling basis. The following criteria need to be met in the application:

- a) Relevance to a population with cancer in our catchment area
- b) High scientific quality of the proposal (novel therapy, endpoint, image or laboratory-based correlative).
- c) Potential impact on the PI's career development
- d) Interdisciplinary collaboration
- e) Inclusion of all populations historically underrepresented in clinical trials
- f) Accrual timeline (no more than 2 years)
- g) Potential for future extramural funding

Application

Prior to application, investigators must present their idea at the IIT concept meeting. Please contact Brittany Harris, IIT Navigator (brittanybharris@uabmc.edu), to be added to and upcoming IIT concept meeting agenda. You will be asked to work with the budget team to develop a budget, as well as a biostatistician to assess your design. Applications will be accepted, reviewed, and awarded on a rolling basis.

Applications should be in 11-point font, with a smaller font (9 pt) allowed for figure legends. All the sections of the application must be combined into one PDF and send to Susan Ruppert the O'Neal Pilot Program

administrator (sruppert@uab.edu) for the review assignment.

Applications must contain the following elements:

- a) Curriculum vitae of the PI and identified mentor (if applicable)
- b) Letter of support from mentor detailing the mentoring plan (if applicable)
- c) One-page letter from Division Director or Department Chair (if the PI is a trainee)
- d) Clinical trial Proposal (in no more than 10 pages):
 1. Background
 2. Objectives and corresponding endpoints
 3. Eligibility
 4. Study design
 5. Treatment plan
 6. Condensed statistical analysis plan including sample size calculation developed with our biostatisticians (contact Charity Morgan, PhD for assistance charitymorgan@uabmc.edu)
 7. Study timeline to include estimated time for protocol development, regulatory submission, activation, completion of accrual (**2-year limit**), data collection, analysis and publication plan.
- e) Simplified budget (no more than one page) developed in conjunction with Courtney cbravenfeld@uabmc.edu and Amber akoconnor@uabmc.edu on the budget team. Please complete the budget intake form at the link below to begin the budget process:
https://uab.co1.qualtrics.com/jfe/form/SV_bemA8FtFYI2Egv4
- f) Funding plan for the whole trial to include any aspects not covered by the Robert Award (if applicable).

Terms and conditions of the Francisco Robert Award

The two-year time limit starts when the study opens to accrual. Each of the requirements below are based on that date. **Enrollment must be completed within 2 years.**

- a) Investigators are encouraged to present at “trial in progress poster” at the annual O’Neal research retreat in October.
- b) When the study has been open for 1 year, the PI must present a progress update at the IIT concepts meeting. This should include updates about enrollment, future funding, publications, and translation.
- c) Per the DSMP, all IITs are required to remit 6-month reports to the Data Safety and Monitoring Committee. Your IIT may be paused if this reporting is missed. Also note, that Quality Management will monitor all IITs and provide reports to the PI and DSMC to ensure the safety of our patients and the integrity of your data (based on the Risk Table in the DSMP).
- d) You will receive periodic updates about the study costs and enrollment. You may be asked for updates if delays or spending issues arise. Your study may end early if funding is depleted prematurely.
- e) When enrolment is complete you will provide a publication plan for submitting a paper within 2 years of the last enrollment (and not more than 4 years after the start of the award).

