Atrium Health Wake Forest Baptist | Comprehensive Cancer Center

2024 Investigator-Initiated Clinical Trials Boot Camp
Request for Applications

Purpose

The Cancer Research Training and Education Coordination (CRTEC) program of the Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC) is pleased to announce the availability of funds to support new investigators interested in a training program to develop and lead an investigator-initiated clinical trial at AHWFBCCC.

This early career (Assistant Professor or Fellow) training opportunity is available to all AHWFBCCC Members, regardless of Program affiliation and any non-members who wish to collaborate with an AHWFBCCC member or are considering membership. Non-members that are selected to participate will be expected to become members prior to receiving any funds.

This 2-day, in-person, training opportunity will be held Thursday, September 12, 2024, through Friday, September 13, 2024, at Graylyn Conference Center (https://graylyn.com/) in Winston-Salem, NC. Each applicant will submit a basic proposal (2-page max) for an investigator-initiated clinical trial suitable for AHWFBCCC **to be fully developed during boot camp activities**. Protocols that are largely written before the boot camp are likely not appropriate. The 2-day program will offer didactics related to clinical trial design, regulatory and approval processes, recruitment of diverse populations, statistical considerations, and available AHWFBCCC shared resources. Boot camp lectures are mixed with intensive mentoring and feedback sessions from experienced investigators; active group participation through questions and feedback to others is expected of all participants.

Accepted trainees will work with a mentoring team comprised of boot camp faculty with expertise in clinical care, trial management, biostatistics and study design, and research and patient advocate perspectives. Additional mentors will be incorporated as needed to meet trainee needs, i.e., radiation or surgical oncology, hematology, adolescent and young adult (AYA) research, etc. The Clinical Trials Office (CTO) will provide additional perspectives on feasibility and trial implementation.

The desired outcome of the 2-day in-person workshop will be an updated 2-page trial outline ready for development into a trial protocol to be conducted at AHWFBCCC. Following the workshop, participants will meet monthly with mentors and peers for one year to include additional core content to facilitate trial design, review regulatory processes, and meet milestones of protocol development to develop the desired final trial protocol with approvals by respective disease group(s) (DGs), the Protocol Review Committee (PRC), and Institutional Review Board (IRB). Part of subsequent training will include assistance in developing a timeline and budget for these trials. Upon successful completion of the course and final protocol IRB approval within the first year of training, pilot funds will be provided to conduct the study.

Special consideration will be given to projects that address the needs of our-county catchment area and are expected to reduce disparities across the cancer control continuum.

Eligibility

Applications will be considered responsive to the call if they meet the following criteria:

- Assistant level faculty in any oncology specialty, including medical, surgical, radiation, gynecologic, and pediatric oncology, or faculty from other departments conducting cancer clinical research.
- Senior fellows with AHWFBCCC faculty commitment from any oncology subspecialty may also apply (letter of support from chairperson required).
- Must have a pilot proposal as part of application that is feasible to open at AHWFBCCC and could reasonably enroll within 24 months.
- Priority will be given to interventional trials, although others may be considered.

Key Dates

Date	Detail
06/03/2024	Full Application Deadline
09/01/2024 – 09/01/2025	Training Period (2-day workshop and monthly team and peer meetings – 2 hr/month)
09/01/2025	Trial Activation Date and Release of Pilot Funds
09/01/2026	12-month Progress Report Due (1-year pilots)
09/01/2027	24-month Progress Report Due (2-year pilots)

Funding

Up to 5 applications will be funded with a maximum funding of $50,000 for 24 months. Funding is contingent on the successful completion of the Boot Camp 2-day program, active participation in post-boot camp monthly mentoring/training sessions, design of an investigator-initiated pilot trial or ancillary study, development of an appropriate budget created in partnership with the CTO financial team (to be completed during post-boot camp training), and final protocol approval by respective disease group(s) (DGs), the Protocol Review Committee (PRC), and Institutional Review Board (IRB). Protocols should be submitted to the IRB by September 2025.

Application Procedure

Full Application Deadline: Monday, June 3rd, 2024 (06/03/24) at 5 pm EST

The application can be submitted through REDCap, by the deadline noted above. Application instructions are summarized below.

Format Specifications

- Arial font and no smaller than 11 point.
- Margins at least 0.5 inches (sides, top and bottom).
- Single-spaced lines.
- Consecutively numbered pages.

Submission/Applicant Information

- Project Title
- Submitting Principal Investigator/Trainee, Co-Principal Investigator (if applicable), Co-Investigator(s), and other Key Personnel

Research Plan (limited to 3 pages total; 2 pages for the Study Description, ½ page for feasibility and timeline, and ½ page for Personal Statement)

- Study Description (2 pages)
  We are looking for straightforward trials and intervention studies that can be done in a reasonable time period within AHWFBCCC (generally not Phase III trials or adjuvant trials with necessary long-term follow-up). This must be a new and original idea without a fully written protocol. Please include:
  - Title
  - Concept and Rationale
  - Primary and Secondary Objectives
  - Study Population (stage, site, recurrent, initial diagnosis, etc.)
  - Broad Study Design (i.e. number of groups, is there a control, etc.) We realize this will develop as part of the workshop so not expected to know all details yet)
  - Correlative Studies, if applicable
- Feasibility/Timeline (1/2 page)
  - Whether or not you currently have access to, or permission to use, the drug(s)/device(s)/interventional materials(s) proposed.
  - Number of potentially eligible patients at AHWFBCCC
  - Timeline: Estimate how long you believe it will take to complete your study (including enrollment and follow-up).
- Personal Statement (1/2 page)
  Explain your interest in participating in this boot camp. Please include:
  - A description of your previous research background.
  - An explanation of how participation in the boot camp will help you to design and conduct the trial to be outlined in your protocol.
  - A commitment to participate in all boot camp activities and in long-term evaluations by maintaining contact with organizers and responding to questionnaires when requested.

NIH-style biographical sketch (*for primary applicant ONLY)*

Budget Guidelines

Budget will be developed after the RFA as part of post-boot camp training with CPDM/CTO financial team. At that time, more information will be given regarding budget criterion.

Review Criteria and Process

Proposals will be evaluated by the Pilot Grant Review Committee (PGRC). Funding decisions will be made based on the reviews of an evaluation of the projects' connection with the goals of the AHWFBCCC. Final award approval will be at the recommendation of AHWFBCCC Leadership. Any IACUC and/or IRB protocols must be approved prior to funding of the approved pilot.

Reviewers will score applications from 1 to 9 based on:

1. Significance of the problem to be addressed
2. Is the project able to be executed and completed in a timely manner (approximately 2 years to complete). Is it appropriate for our catchment area/patient population at AHWFBCCC.
3. Overall quality of the applicant (i.e., how committed is the applicant to conducting clinical research, will this boot camp benefit their training and career goals, will they be engaged in recruiting the patients to the study?

Other elements to be considered in the review include: the likelihood that the investment will lead to external funding, early-career faculty involvement, race/gender inclusiveness of the research team and inclusion of women, minorities, older adults, and children as potential participants.

Program Expectations

Should any significant issues arise, the study team will be required to work with the AHWFBCCC Director to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include (not a complete list):

- Key preliminary data needed for a revised extramural grant application.
- Proof of concept data to establish a novel scientific hypothesis or approach.
- A completed application to an extramural RFA.
- A publication establishing a new collaboration.

Other Guidelines

1. Prior to receiving funds, research involving human subjects must have appropriate approval from the IRB. Either an IRB approval letter or an IRB response to a "Determination Whether Research or Similar Activities Require IRB Approval" must be submitted to the AHWFBCCC prior to funds being released. Human subjects must be reviewed in accordance with the institution's general assurances and HIPAA. All key personnel must have certification of training in the protection of human subjects prior to the start of the grant period.
2. It is expected the PI will report outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations, and patents, including participation in relevant Program activities such as research updates at Program meetings or retreats.
3. Any awardee who leaves his or her position should contact the AHWFBCCC to discuss future plans for the project.

Grant Administration

Training will be completed during the first year and clinical trials that meet all approval guidelines will be for a 24-month period unless otherwise stated. A progress report will be required at the end of the 12 months and 24 months and no-cost extensions may be requested at that time with sufficient justification and remaining funds**.**

Contacts

Questions about your training application and/or proposed clinical trial should be directed to Emily Dressler, edressle@wakehealth.edu or Heidi Klepin, hklepin@wakeheatlh.edu.

Questions about the REDCap system should be directed to Natalie Barrett, nbarrett@wakehealth.edu.