



## 2024 Wake Forest Organoid Research Center Pilot Request for Applications

### Purpose

The Wake Forest Baptist Comprehensive Cancer Center (CCC) is soliciting applications for projects focused on **Organoid Research for Wake Forest Organoid Research Center (WFORCE) Pilot**. This pilot project opportunity is available to all CCC investigators. We continue to be interested in projects that highlight the “value-added” aspects of the CCC, such as those focused on inclusion of investigators from multiple programs, new investigator pairings, novel use of technology platforms, translational research, and use of CCC Shared Resources. We also encourage pilots that increase inter- and intra-programmatic collaborations, especially those that can lead to multi-PI extramural grant applications (R01s, P01s and SPORes). Applications will be reviewed by an internal review committee. Up to two meritorious applications will be awarded \$100K each. This pilot project opportunity is available to all WFSOM faculty and WFBCCC members, and those who wish to collaborate with investigators outside WFSOM and WFBCCC as Co-I.

WFORCE areas of interest:

- 1) Develop tumor organoids from common and rare cancers. Identify driver mutations, determine drug susceptibility and resistance in clonal populations.
- 2) Use of tumor organoids to identify critical signaling pathways involved in cancer pathogenesis and develop agents against these pathways/targets.
- 3) Use of tumor organoids to develop cancer treatment resistance mechanisms and prediction
- 4) Tumor organoids for adoptive T cell transfer and humoral immunity.
- 5) Generation, screening and fine tuning of CAR-T cell efficacy in Tumor organoids platforms.
- 6) Develop organoids from Circulating Tumor Cells for application in clinical correlation companion diagnostics
- 7) Exosome and stem cell signaling modification in organoid structures.
- 8) Generation of organoid derived correlative data for translational applications of medical technology

### Eligibility

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

- For pilot project funding, includes a strategy for submission of a larger grant application to further the work developed in this pilot.
- For project support funding, a clear description of how these funds will align with the funded project and will successfully expand this work to other populations.
- Submission by a CCC member (Partnerships with Levine Cancer Institute researchers are encouraged but require collaboration with a CCC member).

## Key Dates

Date	Detail
2/01/2024, 5p EST	Full Application Deadline
03/21/2024	PGRC Review
03/27/2024	RLC Review
04/05/2024	Project Start Date
10/01/2024	6-month Progress Report Due
4/30/2025	Project End Date – 12 Month Progress Report Due

## Funding

The CCC will fund up to \$100,000 in direct costs per project. See section on Budget Guidelines for details on allowable and non-allowable budget items.

## Application Procedure

### Full Application Deadline: February 1, 2024, 5 pm EST

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

#### Research Plan (2 pages max)

- *Specific Aims* – Describe the goals of the pilot project.
- *Significance* – Explain how the project addresses an important problem, how it will improve scientific knowledge, technical capability and/or clinical practice.
- *Innovation* – Explain how this project uses novel concepts, approaches or methodologies, instrumentation, or interventions.
- *Approach* – Describe the overall strategy for this project, including potential problems, alternative strategies, statistical analysis and benchmarks for success.
- *Investigator(s)* – Describe how each member of the team will contribute to the project. Include their expertise and experience that will be utilized on this project.
- Describe how the results of the pilot award will support specific plans for extramural funding

**Projected quarterly timeline.** Including specific milestones (no page limit)

**References** (no page limit)

#### Information Regarding Human Subjects

Address the following if the project **involves human subjects**.

- Provide a one-page document addressing the Protection of Human Subjects, if applicable.
- IRB Approval Status (please note: IRB approval is not required for full application submission, however **a delay in IRB approval does not alter the project end date**) Pre submission discussion with the Wake Forest IRB is strongly suggested.

#### Information Regarding Live Vertebrates if applicable.

- IACUC Approval Status (please note: IACUC approval is not required for full application submission, however **a delay in IACUC approval does not alter the project end date**)

**Budget and Justification** (budget template plus 1-page justification)

- Complete the budget template form provided in REDCap along with a brief justification for the funds requested for this RFA. Please include explanation of other resources that may be leveraged to support the project.
- Sub-awards to other institutions to carry out work on a project are not allowed.

**NIH-style biographical sketch for all Key Personnel****Budget Guidelines**

The budget period is for 12 months. Up to \$100K in direct costs may be requested.

Grant funds may be budgeted for:

- Research support personnel (including undergraduate and graduate students)
- Faculty salary support may also be included but should be well-justified with a recommended cap of \$15K.
- Describe the allocated funds to prepare tumor organoids at WFORCE, if organoid development not available at submitting investigator's lab.
- Travel necessary to perform the research (limited to \$1,000)
- Small equipment, research supplies and core lab costs, or other purposes deemed necessary for the successful execution of the proposed project (limited to \$5,000)

Grant funds may **not** be budgeted for:

- Office supplies or communication costs, including printing
- Professional education or training
- Computers or audiovisual equipment
- Indirect costs
- Manuscript submission

Awarded funds must be used to conduct the work proposed. All direct charges to this award must adhere to federal regulations and requirements regarding the use of CCC funds. The CCC leadership reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved protocol.

**Review Criteria and Process**

Proposals will be evaluated by an internal review committee. Funding decisions will be made based on the evaluation of the projects' connection with the goals of the CCC. Final award approval will be at the recommendation of CCC 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. Innovation the proposed solutions.
3. Strength and breadth of the investigative team.
4. Methodological rigor and feasibility with clear milestones.
5. Likelihood the innovation will be broadly applicable and have impact on translational research, and.
6. A reporting plan regardless of whether the study yields positive or negative results.
7. Other elements to be considered in the review include: the likelihood that the

investment will lead to external funding or a licensable innovation, 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 CCC 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 for extramural funding.
- A publication establishing a new collaboration.

### **Other Guidelines**

1. Prior to receiving funds, research involving human subjects must have appropriate approvals 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 CCC 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.
3. Any awardee who leaves his or her position should contact the CCC Director to discuss future plans for the project.

### **Grant Administration**

The Principal Investigator is responsible for the administration of grant funds. Projects will be for a 12-month period of time.

### **Contacts**

For further information, please contact Kostas Votanopoulos: [kvotanop@wakehealth.edu](mailto:kvotanop@wakehealth.edu) or Shay Soker: [ssoker@wakehealth.edu](mailto:ssoker@wakehealth.edu)

Questions about the REDCap system should be directed to Jackie Turner, [jeturner@wakehealth.edu](mailto:jeturner@wakehealth.edu)