Critical Illness, Injury, and Recovery Research Center (CIIRRC)
Request for Applications for Pilot Awards

Overview

The CIIRRC is an institutionally sponsored research center that seeks to improve the burden of critical care related disorders on human health. Our mission is to unite distinguished, multidisciplinary investigators to become a unique and cohesive venture focused on developing and fostering team science. Using a discovery-based model we seek to bridge the translational research spectrum of basic, clinical, epidemiologic and health policy sciences related to the prevention, treatment and recovery of critical illness and injury. CIIRRC will accomplish this mission by: attracting and training new investigators in basic and clinical critical care research; connecting with local and national communities; implementing policy through evidence-based knowledge; leveraging resources across multiple Departments, Institutes and Centers, and extending value to other academic medical centers.

Purpose

CIIRRC seeks innovative interdisciplinary applications for clinical, and translational **pilot** research projects related to critical illness and injury. Existing or newly formed inter-disciplinary teams are encouraged to apply. Preliminary/pilot data are not required. Pilots in this cycle should address key issues within acute and critical care environments that can be addressed using pragmatic trial designs. The pilot grant proposal could conduct a pilot pragmatic trial or generate key preliminary data for an external proposal for a larger pragmatic trial.

Comparative effectiveness studies that evaluate variations in usual care are optimal for this pilot. Study designs should consider participant enrollment that includes using waiver of informed consent approaches. Pre-submission discussion with the Wake Forest IRB prior to submission is recommended. Funded pilots can capture cohort demographics and study outcomes by fully or partially leveraging the Critical Illness, Research and Recovery data analytics platform. Successful pilot studies will receive up to $9,000 total, to be spent within a six-month project period.

The application must include:

- A multi-disciplinary team
- A Wake Forest faculty member serving as PI
- A commitment to use pilot data to develop a subsequent, larger team-oriented grant application
- Applicants should describe how the proposed project relates to and addresses health care needs of patients experiencing, or at risk for critical illness and injury.
- A “pragmatic” trial design

Eligibility

This award is only open to Wake Forest School of Medicine and Wake Forest University faculty in the PI role; however, research teams may include other investigators outside of Wake Forest.

Key Dates

Date	Detail
12/18/19, 11:59 pm	Full Application Deadline
2/1/2020	Selection of Awardees
3/1/2020	Project Start Date
9/1/2020	Latest Project End Date

Funding

The CIIRRC will fund up to $9,000 in direct costs per project. See section on Budget Guidelines for more details on allowable and non-allowable budget items.

Application Procedure

Full Application Deadline: 12/18/19, 11:59 pm

Investigators are invited to apply by submitting their application through the ePilot electronic submission system, 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 Investigator, Co-Investigator(s), and other Key Personnel information

Abstract (300 words max)

Research Plan (4 pages max)

- A brief description of the hypotheses/aims of the overall project.
- A brief description of the design of experiments/project.
- Description of how pilot data will be used to develop a subsequent, larger team-oriented grant application.
- The anticipated outcomes and interpretation. Describe how the proposed project relates to and addresses health care needs of patients experiencing, or at risk for critical illness and injury.
- Contribution of each team member (1 page max)

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.

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

- Complete the budget template form provided 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 (new style)

Budget Guidelines

The budget period is for 6 months ending no later than 09/01/2020. Up to $9,000 in direct costs may be requested.

Grant funds may be budgeted for:

- Research support personnel (including undergraduate and graduate students)
- Travel necessary to perform the research
- Small equipment, research supplies and core lab costs, or
- Other purposes deemed necessary for the successful execution of the proposed project

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

- Faculty or other investigator effort
- Office supplies or communication costs, including printing
- Meals or travel, including to conferences, except as required to collect data
- Professional education or training
- Computers or audiovisual equipment, unless fully justified as a need for the research
- Manuscript preparation and submission, or
- Indirect costs

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 Critical Illness, Injury, and Recovery Research Center funds. The CIIRRC 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

CIIRRC proposals are competitive and peer-reviewed. Proposals will be evaluated by faculty and based on NIH review criteria and scoring. Final award approval will be at the recommendation of Critical Illness, Injury, and Recovery Research Center 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 in 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

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

Specific Deliverables Include:

- Joint CIIRRC membership
- Provide a mid-term progress report and final report
- Work with CIIRRC members to develop a larger, team-oriented grant application

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 CIIRRC 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. We expect PIs to report over the lifetime of the work the outcomes achieved due to the pilot award, e.g., subsequent external funding, publications, presentations and patents.
3. All publications that are the direct result of this funding must reference: “Research reported in this publication was supported by the Critical Illness, Injury, and Recovery Research Center, Wake Forest School of Medicine.” Publications must also be registered in PubMed Central.
4. Any awardee who leaves his or her position should contact the CIIRRC 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 6-month period of time.

Contacts

Substantive questions about your proposed research project should be directed to Clark Files at Clark.Files@wakehealth.edu.

Questions about the ePilot electronic submission system should be directed to Brittney Jackson (britjack@wakehealth.edu).