Purpose
The Center for Research on Substance Use and Addiction is seeking proposals for pilot studies involving meaningful collaboration of basic, clinical, and population-based researchers in the area of alcohol and substance use. The ultimate aim of this pilot program is to make research investments that maximize healthcare value and improve health. The immediate aim is to allow investigators to develop, test, or disseminate novel approaches to a translational research question and obtain preliminary data in support of larger follow-up investigations. Examples of pilot studies include feasibility studies, secondary analysis of existing data, development of new research methodology and/or new tools, dissemination of effective tools, methods, processes, or early development of new therapy/technology. Priority will be given to applications that include colleagues from both Wake Forest Baptist and Atrium Health.

Eligibility
These awards are open to all faculty with a rank of instructor or higher, as well as any other individuals eligible for NIH R-series awards at Wake Forest School of Medicine and Atrium Health.

Key Dates

<table>
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<th>Date</th>
<th>Detail</th>
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<tbody>
<tr>
<td>12/15/21, 11:59 pm</td>
<td>Full Application Deadline</td>
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<tr>
<td>01/17/22</td>
<td>Selection of Awardees</td>
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<tr>
<td>02/01/22</td>
<td>Project Start Date</td>
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<tr>
<td>01/31/23</td>
<td>Latest Project End Date</td>
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Funding
Award amounts are anticipated to range from $10,000 to $40,000. Requested funding should be in close alignment with the budget needed to carry out the proposed project. Please see section on Budget Guidelines for more details on allowable and non-allowable budget items. Since Center for Research on Substance Use and Addiction funds cannot be carried over from one budget period to the next, requests for no-cost extensions will not be approved.

Application Procedure
Full Application Deadline: 12/15/2021, 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 (6 pages max)
- Specific Aims
- Significance – Explain how the project addresses an important problem, how it will improve scientific knowledge, technical capability and/or clinical practice. In addition, use this section to demonstrate that the proposed project is a critical step in preparing a competitive proposal in response to a specific, identified funding opportunity for extramural funding.
• **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.

• **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 and benchmarks for success.

• **Timeline** – Present a reasonable and feasible timeline for achieving the study aims within the 12-month (maximum) project timeline.

**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).

**Information Regarding Live Vertebrates**

- 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 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 12 months ending no later than 01/31/2023. Award amounts are anticipated to range from $10,000 to $40,000. Requested funding should be in close alignment with the budget needed to carry out the proposed project.

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 Center for Research on Substance Use and Addiction funds. The Center for Research on Substance Use and Addiction reserves the right to revoke funding in the event it is determined that funds were not spent in accordance with the approved protocol.

**Timeline**
Include a 12-month timeline on achieving the Aims of your proposal.
Review Criteria and Process
Proposals submitted in response to this RFA are competitive and will be peer reviewed.

The most competitive proposals will:

- Rate highly on the standard NIH review criteria of significance, investigators, innovation, approach, and environment.
- Involve a meaningful collaboration between a basic science and a clinical investigator, a clinical investigator and a population science investigator, or a basic science and a population science investigator. Please go to the Center website for list of Members and their Faculty Links: http://www.wakehealth.edu/Research/Center-for-Research-on-Substance-Use-and-Addiction/Membership.htm.
- Lay out a project plan that is feasible to complete in the 12-month project period (note that this period includes the time needed to obtain IACUC and IRB approvals, if required; also note that there will be no opportunity to request carryover).
- Demonstrate that the proposed project is a critical step in preparing a competitive proposal in response to a specific, identified funding opportunity (program announcement or request for applications) for extramural funding (e.g., from the National Institutes of Health, Department of Defense, Patient-Centered Outcomes Research Institute, Robert Wood Johnson Foundation). (Note: This should be explicitly addressed in the Significance section of the pilot proposal.)

Final award decisions will be made by the leadership of the Center for Research on Substance Use and Addiction.

Program Expectations
If any significant issues arise, the study team will be required to work with the Center for Research on Substance Use and Addiction to define an intervention strategy for the study to be successfully completed (or in rare cases, terminated).

Specific Deliverables Include:
- Presentation of results at a seminar sponsored by the Center for Research on Substance Use and Addiction.
- Disclosure of implementation/dissemination results and efforts to seek extramural funding beyond the pilot grant and subsequent notification of any funds obtained and/or related publications or significant collaborations from the project for a minimum of 4 years.

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 Center for Research on Substance Use and Addiction 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. Prior to receiving funds, research involving live vertebrates must have appropriate approvals from IACUC. Either an IACUC approval letter or documentation on why activity does not require IACUC approval must be submitted to the Center for Research on Substance Use and Addiction prior to funds being released.
3. Center for Research on Substance Use and Addiction staff will work closely with funded teams throughout the grant period to monitor progress and, when necessary, provide assistance. A final progress report will be required. 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.
4. All publications that are the direct result of this funding must reference: “Research reported in this publication was supported by the Center for Research on Substance Use and Addiction, Wake Forest School of Medicine.” Publications must also be registered in PubMed Central.
5. Any awardee who leaves his or her position should contact the Center for Research on Substance Use and Addiction to discuss future plans for the project.

**Grant Administration**
The Principal Investigator is responsible for the administration of grant funds. Projects can be up to a 12-month period of time.

**Contacts**
Substantive questions about your proposed research project should be directed to Michael Nader (mnader@wakehealth.edu; 3-7172).

Questions about the ePilot electronic submission system should be directed to Jessie Barnett (jcbarnet@wakehealth.edu)