PILOT AND FEASIBILITY PROJECT PROGRAM
REQUEST FOR APPLICATIONS (RFA) and APPLICATION SUBMISSION GUIDELINES
2016-2017 FUNDING CYCLE

RFA Release Date: Tuesday, April 5, 2016
Statistical Consultation Request Priority Date: Friday, April 15, 2016
Letter of Intent Due Date: Tuesday, April 19, 2016
Application Due Date: Noon, Friday, April 29, 2016
Funding Period: June 1, 2016 – May 31, 2017

The Center for Oral Health Research (COHR) Pilot and Feasibility Project Program aims to facilitate innovative basic, translational and clinical research specifically in the area of oral and craniofacial biology. The ultimate goal of the program is to provide adequate resources and training for pilot investigators to develop sufficient preliminary data to prepare a competitive extramural research grant application that will directly utilize one or more of the COHR Cores. The program will have a three part focus with a mission to: 1) attract junior faculty without prior extramural funding to oral health-related research; 2) enable established COHR investigators to explore an area that represents a significant departure from their current work, and 3) entice established investigators in other areas of biomedical research to apply their expertise to an oral health-related problem. It is envisioned that the program will enable investigators to form interdisciplinary, interactive, and sustainable research studies that will impact oral and craniofacial health.

Four Grant Categories: All awards are up to one year period

**Early Career Pilots**
- Discovery grant for junior faculty within 6 years of first full time faculty appointment and no prior extramural funding as Principal Investigator. Open to MUSC faculty at the rank of Instructor or Assistant Professor. Mentor required. Up to $30,000.

**New Direction Pilots**
- High impact/high risk projects or projects that are a significant departure from a faculty members normal research program. Open to MUSC faculty of any rank. Up to $30,000.

**Collaborative Pilots**
- Projects that stimulate basic scientist-clinical investigator collaborations, increase collaboration between MUSC and other academic institutions, or support the movement of promising technologies to clinical application. Open to faculty of any rank from COBRE participating institutions. Up to $30,000.

**Fast-Forward Seed Pilots**
- Awards are limited to investigators who have submitted an extramural grant application, received a summary statement and need additional critical data for a successful resubmission. Open to MUSC faculty of any rank. Up to $15,000.

TO APPLY:
Access the application submission portal at:
http://academicdepartments.musc.edu/sctr/programs/pilot_projects

PROGRAM QUESTIONS:
Caroline Westwater, PhD
Email: westwatc@musc.edu
Phone: 843-792-7703

SCIENTIFIC SCOPE AND COHR CORES:
Further information can be found at:
http://academicdepartments.musc.edu/cohr/
KEY ELEMENTS OF THE COHR PILOT AND FEASIBILITY PROJECT PROGRAM

The main objective of the program is to promote the growth of the COHR through the development of new extramural funding and the utilization, enhancement and advancement of critical technologies and COHR Core services. The pilot project program is not designed to provide ongoing support for a long-term project or to provide supplemental support to ongoing funded research projects.

PILOT PROJECTS MUST AIM TO:

• Address an important question in basic, translational and/or clinical research that impacts oral and craniofacial biology-related science (ALL Grant Categories).
• Generate critical preliminary data to support the submission of a competitive extramural grant application that will directly utilize one or more of the COHR Cores (ALL Grant Categories).
• Include a collaborative, synergistic team of researchers from different institutions, different colleges within MUSC and/or multidisciplinary investigators (Collaborative Category).
• Propose research that is new to the team members (New Direction Category). Please note that COHR pilot project grants do not support ongoing funded projects. One exception to this may be for Fast-Forward Seed Grants.

PROGRAM ELIGIBILITY

• The Principal Investigator (PI) of a pilot project in any category must be a full-time faculty member of a COBRE participating institution. The Principal Investigator (PI) of a pilot project in the Early Career, New Direction and Fast-Forward Seed category must be a full-time faculty member of MUSC.
• Applicants for Early Career Pilot Grants may not have been or currently be PI of a NIH R01, P01 subproject or equivalent, and should be within six years of their first full-time faculty appointment at the rank of Instructor or Assistant Professor.
• Established investigators may serve as a Pilot Project Mentor for only one Early Career Pilot Grant per annual funding cycle. The Mentor must have recognition as an accomplished scientist in his/her chosen field, a strong history of competitive research support, and track record of success in training independent investigators. The Pilot Project Mentor may be from inside or outside MUSC, but cannot be a prior or current supervisor or preceptor.
• Applicants for New Direction Pilot Grants may be faculty of any rank at MUSC and should have a record of accomplishment in their chosen field. PIs of New Direction Pilot Grants may have current NIH or extramural funding; however, they must propose a new research direction that is substantially different from current or previous line(s) of investigation. Proposals in this category must include a compelling rationale and timeline that clearly establishes the direct relevance to the COHR’s mission, the PIs qualifications and resources to undertake a new line of investigation and a viable plan for obtaining competitive extramural grant funding.
• Investigators may serve as the PI or co-PI of only one proposal per grant category per annual funding cycle. Investigators may serve as co-investigator on multiple applications. Co-investigators are defined as substantial contributors who helped conceive of the experimental idea, contributed to the intellectual development of the concept, and/or designed the study or part thereof (scientific or technical details).
• One co-PI is allowed per proposal; however, a co-PI should have a significant role in the proposed project to be named as the co-PI. The co-PI should be clearly identified in the application, narrative, budget and budget justification.
• PIs who have been funded previously by COHR grant mechanisms may not be eligible to apply until they complete the currently funded project and submit a completed progress report to Dr. Westwater (westwatc@musc.edu). If the previously funded project was not productive, the COHR Pilot Program may deny further funding to those PIs.
• Previous recipients of Early Career, New Direction, and Collaborative Pilot Grants are not eligible to compete again for additional funding in the same category. However, an Early Career grantee could conceivably apply for a future New Direction or Collaborative grant.
THE APPLICATION PROCESS

Letter of Intent
Although a Letter of Intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows us to estimate the potential review workload and plan the review. Prospective applicants are asked to submit a Letter of Intent that includes the following information:

- Descriptive title of proposed research.
- Name, email address, and telephone number of the PI and Co-PI (if applicable).
- Complete listing of the investigative team, their academic titles, primary department and proposed role on the project.
- Pilot grant category (Early Career, New Direction, Collaborative, Fast-Forward Seed).

The Letter of Intent should be submitted by email to the COHR Pilot Project Program office (westwatc@musc.edu) by Friday, April 15, 2016.

Resubmission of an Application
Applicants will have the opportunity to submit one revised application in response to review comments. Revised applications should be submitted during the following COHR RFA cycle. Investigators submitting an amended application will be expected to thoroughly address the review critiques using the NIH modeled Introduction to Resubmission Application. The Introduction must summarize the substantial additions, deletions and changes to the application (1-2 pages). The Introduction must also include a response to the issues and criticisms raised in the Summary Statement. To facilitate the re-review process the revisions must be highlighted throughout the revised application. The substantial scientific changes must be marked in the text of the application by bracketing, indenting, or changing typography. Do not underline or shade the changes. Deleted sections should be described but not marked as deletions. If the changes are so extensive that essentially all of the text would be marked, explain this in the 1-2 page Introduction. Additional guidance can be found in section 2.7 “Resubmission” Applications, of the NIH Application Guide SF424 (http://grants.nih.gov/grants/funding/424/index.htm).

Full Application
Applicants should submit the application materials through the SCTR website (http://academicdepartments.musc.edu/sctr/programs/pilot_projects) by clicking the appropriate “Apply” link. All applications consist of an online form and four PDF uploads.

Online Form (Questions with an * are required fields)
- PI Name*
- PI eRA Commons User Name*
- Degree*
- PI Faculty Rank/Position*
- PI Tenure Track*
- PI Home Institution*, College/School*, Department*, Center Affiliation and Division within institution.
- PI NIH Specialty Code*
- PI Phone Number*
- PI Email Address*
- PI Mailing Address*
- Business Manager Name*, Phone Number*, Email Address*, Mailing Address*
Optional Contact Person Name, Phone Number, Email Address

On the online application, list a co-PI as the first co-I and include (co-PI) within parentheses after the co-Pls last name.

Co-I information (similar to information captured for the PI)

Project information (e.g. IRB, IACUC). Please note that funding cannot be released until all applicable institutional human, animal, and biosafety protocols (such as IRB, IACUC, IBC), and any other required regulatory documents (such as INDs, IDE, and CITI Training) have been approved and copies sent to the COHR Pilot Project Program office (westwatc@musc.edu). Investigators are strongly encouraged to begin the regulatory approval process prior to submitting the pilot project application.

Child Health Component

Intellectual Property Potential

Have you ever applied for funding or published with any of the co-I(s)?

Funding Entity Code* Select COBRE- Oral Health

Project Title*

Grant Category* Select Discovery (for New Direction and Collaborative category), Early Career, or Fast-Forward Seed

PDF Upload 2: Project Description*

30 lines of text for Project Summary, Arial font size 11, at least 0.5 margins, PDF only.

The Project Summary should serve as a succinct and accurate description of the proposed work when separated from the application. State the application's broad, long-term objectives and specific aims, making reference to the oral health relatedness of the project. Describe concisely the research design and methods for achieving the stated goals. This section should be informative to others working in the same or related fields and understandable to a scientifically or technically literate reader. Using no more than two or three sentences, describe the Relevance of this research to public health. The Relevance statement should be succinct and written using plain language that can be understood by a general, lay audience.

PDF Upload 3: Budget and Justification*

For the budget, please use PHS 398 Form Page 4: Detailed Budget for Initial Budget Period in MS Word Version (1 page) at http://grants.nih.gov/grants/funding/phs398/phs398.html and use continuation pages as needed for the budget justification. Upload the budget and justification as a single PDF file. The COHR reserves the right to reduce requested award amounts.

Personnel Support: Faculty salaries are not an allowable expense. Salary and fringe benefits are allowed for technical support, such as: Postdoctoral Fellows, Research Specialists and Study Coordinators.

Non-personnel Research Expenses: Allowable expenses include research supplies, animal purchase and per diem, institutional core service fees, research subject compensation and transportation, and data analysis/statistical support. All expenses must be directly related to the proposed research.

Unallowable Costs: Research equipment, professional travel, general office supplies, computers and laptops, membership dues and fees, publication costs, subscription costs, mailing costs, and rent. Faculty salaries are not an allowable expense.

Facilities and Administrative Costs: Facilities and administrative costs, also known as indirect costs, are not permitted.

Subawards to COBRE participating institutions: No signed documents are needed at the time of submission from subaward institutions. The COHR Pilot Project Program office will work with the respective PIs to establish subawards once an application is approved for funding. A detailed subaward budget and justification should be included at the time of initial submission. Failure to include these documents will result in the application being deemed incomplete.

PDF Upload 4: Proposal*
- 6 page limit (1 page for Specific Aims, 3 pages for Research Strategy, 1 page for Statistical Considerations, and 1 page for Additional Review Considerations), Arial font size 11, at least 0.5 margins, PDF only. Revised applications must include a 1-2 page Introduction at the beginning of the Research Plan (see Resubmission of an Application section for further details).
- The Specific Aims should state concisely the goals of the proposed research and summarize the expected outcome(s) including the impact that the results of the proposed research will exert on the research field(s) involved. List succinctly the specific objectives of the research proposal, e.g., to test a stated hypothesis, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new technology. **The Specific Aims section must be limited to one page.**
- The Research Strategy should follow the standard NIH format, which includes Significance, Innovation, and Approach. Further information can be found in Section 5.5.3 of the PHS Grant Application Guide ([http://grants.nih.gov/grants/funding/424/index.htm](http://grants.nih.gov/grants/funding/424/index.htm)). The research proposal should be informative enough for reviewers to understand the proposed research without any supporting documents. Applicants should include all the required details based on the grant category and its review criteria within the proposal without referring to additional pages/documents. **The Research Strategy section must be limited to three pages.**
- The Statistical Considerations section should describe how the data will be analyzed and used to make inferences regarding the Specific Aims. A justification of sample size should be included for animal studies and any aims that include human tissue samples, patients, or healthy volunteers. Statistical considerations should be outlined in a separate section (1 page limit) after the Research Strategy section (3 page limit). Statistical consultations are available through the SCTR Biostatistics, Epidemiology and Research Design Program ([http://academicdepartments.musc.edu/sctr/programs/biostatistics.html](http://academicdepartments.musc.edu/sctr/programs/biostatistics.html)). Investigators wishing to use this service should submit a request through SCTR SPARC Services Catalog ([https://sparc.musc.edu/](https://sparc.musc.edu/)). Please submit statistical consultation requests by **Friday, April 15, 2016.**
- The Literature Cited section should be placed at the end of the Research Strategy and is not included in the page limit.
- The Early Career Support Letter should be placed at the end of the Literature Cited section and is not included in the page limit. A detailed letter of commitment from the Pilot Project Mentor should describe the mentoring arrangement (e.g. frequency of meetings, access to space and/or equipment) and focal areas (knowledge, techniques or skills) critical to the project’s outcome and the pilot investigator’s career development (Early Career Category ONLY).
- The Summary Statement (Fast-Forward Seed Grants ONLY) should be placed at the end of the Literature Cited section and is not included in the page limit.
- The Additional Review Considerations section should include a response, if applicable, to the five points listed below. **The Additional Review Considerations section must be limited to 1 page (page limit excludes Early Career Support Letter and Fast-Forward Seed Summary Statement).**
  1. State how you plan to utilize the COHR Cores in this proposal.
  2. State how you plan to secure future extramural funding and how you plan to utilize the COHR Cores in future grant proposals. Please be sure to state the funding agency, mechanism and timeline (ALL Grant Categories).
  3. State how the proposed research is substantially different from current or previous lines of research already pursued by your laboratory (New Direction Category ONLY).
  4. State how the proposed experiments will address a major criticism raised in the Summary Statement (Fast-Forward Seed Category ONLY).
  5. State how the investigative team has complementary and integrated expertise (Collaborative Category ONLY).
**Incomplete applications, late applications or applications that are not responsive to the RFA will not be reviewed.**

Each application will be assigned to at least two reviewers with appropriate expertise and without conflict of interest. Reviewers are instructed to evaluate the quality of the research (significance, investigator(s), innovation, approach, environment) using the 9-point NIH rating scale (1= Exceptional to 9= Poor). The reviewers will address the ‘Additional Review Considerations’ listed below for each application as applicable, and will generate an Overall Impact Score based on the quality of the research and the ‘Additional Review Considerations’. The COHR Steering Committee will prioritize the applications based on the overall impact score, Summary Statement, and also on the programmatic needs of the COHR. Funding recommendations will be forwarded to the COHR External Advisory Committee for final funding decisions.

**Additional Review Considerations for ALL Grant Categories**

- Does the proposal address an important oral health-related problem and, if successful, will the results have a substantial impact on oral and craniofacial health?
- Does the proposal utilize one or more COHR Cores?
- Is the project focused, feasible, and achievable, and does it have a high potential to secure future extramural funding that will utilize one or more COHR Cores?
- Does the proposal stimulate collaborations with COHR members that might otherwise not have taken place?
- For clinical and animal studies, do applications include a statistical power analysis? Does the proposal describe statistical methods required for analysis of study data? Although applications will primarily be pilot projects, they must be adequately powered to provide meaningful information about the feasibility and size for planned future extramural grant applications.
- Does the proposed research incorporate ideas and aims that are substantially different from those already being pursued by the investigator?
- Has the investigator defined a need for funding to support the proposed direction of research?
- Does the project have high potential to secure future extramural funding?

**Additional Review Considerations for Early Career Pilot Grants**

- Does the proposal include a support letter describing a clearly defined mentorship plan with a senior/established investigator?
- Will the investigator receive adequate supervision and mentoring?
- Does the proposal describe a plan for achieving research independence and potential to lead to extramural independent funding?

**Additional Review Considerations for Collaborative Pilot Grants**

- Are the PIs, collaborators, and other researchers well suited to the project? Do they have established roles, skills and experiences to carry out the project?
- Is there clearly new trans-disciplinary collaboration? This includes collaboration between at least two of the following: basic scientists, clinicians/clinical scientists, health professionals, and population scientists
- If the project is collaborative, do the investigators have complementary and integrated expertise; is their organizational structure appropriate for the project?

**Additional Review Considerations for Fast-Forward Seed Pilot Grants**

- Does the proposed experiments address a major criticism raised in the Summary Statement?