PILOT AND FEASIBILITY PROJECT PROGRAM
REQUEST FOR APPLICATIONS (RFA) and APPLICATION SUBMISSION GUIDELINES
2014-2015 FUNDING CYCLE

KEY DATES

- RFA Release Date: Monday, March 17, 2014
- Statistical Consultation Request Priority Date: Wednesday, April 9, 2014
- Letter of Intent Due Date: Wednesday, April 9, 2014
- Application Due Date: Wednesday, April 23, 2014
- Earliest Anticipated Funding Date: June 2014

OVERVIEW

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.

PILOT PROJECT CATEGORIES

The COHR Pilot and Feasibility Project Program will support three general grant categories: Early Career, New Direction, and Novel Methods & Technologies.

<table>
<thead>
<tr>
<th>Grant Categories</th>
<th>Brief Description</th>
<th>Award Amount</th>
<th>Award Duration</th>
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<tbody>
<tr>
<td>Early Career</td>
<td>Discovery grant for junior faculty within 6 years of first full time faculty appointment and no prior extramural funding as Principal Investigator. Mentor required.</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
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<tr>
<td>New Direction</td>
<td>Faculty of any rank who are substantially changing research direction.</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
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<tr>
<td>Novel Methods &amp; Technologies</td>
<td>Faculty of any rank who wish to develop a novel method or technology. Business plan may be required.</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
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TO APPLY:

Access the application submission portal at: https://sctr.musc.edu/index.php/programs/pilot-projects

SCIENTIFIC SCOPE AND COHR CORES:

Further information can be found at: http://academicdepartments.musc.edu/cohr/

PROGRAM QUESTIONS:

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

ADMINISTRATIVE QUESTIONS:

Contact LuAnne Harley
Email: harleylu@musc.edu
Phone: 843-792-2327
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 (Early Career and New Direction grants).
- Develop a new method or technology that will directly enhance, advance or replace one or more functions or services within a designated COHR Core (Novel Methods & Technologies grants).

PILOT GRANT CATEGORIES

1. Early Career Pilot Project (up to $30,000/project/year)
   Early Career Pilot Grants will be available to newly independent faculty members with no prior significant external grant support as Principal Investigator who wish to develop an independent program of research that complements the focus of the COHR. For this mechanism, significant external grant support is defined as a NIH R01, P01 subproject or equivalent. Applications in this category must include a Pilot Project Mentor who will provide a detailed letter of commitment describing 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 research career development. The Pilot Project Mentor may be from inside or outside MUSC, but cannot be a prior or current supervisor or preceptor. The Pilot Project Mentor may receive a $3,000 COHR Core Voucher per year as recognition/compensation for their mentorship.

2. New Direction Pilot Project (up to $30,000/project/year)
   New Direction Pilot Grants will be available to faculty members of any rank whose proposal is directly relevant to the COHR mission. To be considered a “new direction,” the proposed research must incorporate ideas and aims that are substantially different from those already being pursued by the investigator. Proposals in this category must include a compelling rationale and timeline that clearly establishes the direct relevance to the COHR’s mission, the Principal Investigator’s qualifications and resources to undertake a new line of investigation and a viable plan for obtaining competitive extramural grant funding.

3. Novel Methods & Technologies Pilot Project (up to $30,000/project/year)
   Pilot Grants for Novel Methods & Technologies will be available to faculty members of any rank, including but not limited to existing COHR Core personnel, who are in a position to carry out a feasibility study to demonstrate the utility, practicality and potential advantages of an innovative methodology or technology that would directly enhance, advance or replace one or more functions or services of a designated COHR Core. Proposals in this category must include information on the novelty of the target method or technology and its potential application to oral health research and data supporting the potential advantages (e.g., efficiency, cost-saving, time-saving, accuracy, resolution). If the new method or technology is likely to be included in an existing COHR Core, the proposal should include a support letter from the respective Core Director describing how the proposed methodology or technology would be incorporated and managed, including, if appropriate, a pro forma cost analysis and fee schedule. Pilot project funds in this category may be used to purchase instrumentation and/or licenses necessary to implement and test the proposed method(s) or technology. Funds not required for acquisition, may be used for personnel, supplies, training and other appropriate expenses directly applicable and allocable to the new technology. Funds may not
be used to support routine maintenance, repairs or operating costs of the research core hosting the proposed methodology or technology. Proposals in this category should include an Advisory Committee of internal and at least one external member with scientific and technological expertise to provide objective, critical, constructive evaluation and advice regarding the use and effectiveness of the proposed methodology and/or technology.

PROGRAM ELIGIBILITY

• The Principal Investigator (PI) of a pilot project in any category must be a full-time faculty member at 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. Applicants for New Direction or Novel Methods & Technologies 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.

• **Investigators may serve as the PI or co-PI of only one proposal per grant category** (Early Career, New Direction or Novel Methods & Technologies) 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).

• Previous recipients of Early Career and New Direction 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 grant and recipients in either category might develop a future proposal addressing Novel Methods & Technologies.

• 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.

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.
- Complete listing of the investigative team, their academic titles, primary department and proposed role on the project.
- Pilot grant category (Early Career, New Direction or Novel Methods & Technologies).

The Letter of Intent should be submitted by email to the COHR Pilot Project Program office (westwacht@musc.edu) by **April 9, 2014**.

**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 criticism 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://sctr.musc.edu/index.php/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*
- PI Biosketch*. Please use PHS 398 Biographical Sketch Format Page (PDF upload 1: Biosketch) at http://grants.nih.gov/grants/funding/phs398/phs398.html. Follow the 4-page limit, include a personal statement and select up to 15 publications based on recency, importance to the field and/or relevance to the proposed research. Use the PHS 398 MS Word forms, and convert to PDF format to upload.
  - Degree*
  - PI Faculty Rank*
  - 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
  - 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 (harleylu@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)?*
  - Project Title*
  - Grant Category* Select COBRE- Oral Health

PDF Upload 2: Project Summary and Relevance
- 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: Research Plan
- 6 page limit (1 page for Specific Aims, 3 pages for Research Strategy, 1 page for Statistical Considerations, and 1 page for Additional Review Criteria), 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/phs398/phs398.html). 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 (https://sctr.musc.edu/index.php/programs/biostats). Investigators wishing to use this service should submit a request through SCTR SPARC Services Catalog (https://sparc.musc.edu/). Please submit statistical consultation requests by April 9, 2014.
- The Literature Cited section should be placed at the end of the Research Strategy and is not included in the page limit.
- The Additional Review Criteria section should include a response, if applicable, to the four points listed below. The Additional Review Criteria section must be limited to 1 page and 1 support letter.
  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 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. Provide a detailed letter of commitment from the Pilot Project Mentor describing 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).
  5. Provide a detailed letter of support from the respective COHR Core Director describing how the proposed methodology or technology would be incorporated into the existing COHR Core and managed. Include, if appropriate, a pro forma cost analysis and fee schedule (New Methods & Technologies Category ONLY).

PDF Upload 4: 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](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. Funds for research equipment and/or professional travel may be requested only with specific justification describing exceptional circumstances with documentation of critical need and absence of feasible alternatives.

- **Unallowable Costs:** 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.

**APPLICATION REVIEW CRITERIA AND PROCESS**

**Overview**

Each application will be assigned to at least two reviewers with appropriate expertise and without conflict of interest, who are faculty members at MUSC or outside academic institutions. 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 otherwise might 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.

**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?
- Has the investigator defined a need for funding to support the proposed direction of research?

**Additional Review Considerations for New Direction Pilot Grants**
- 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?

**Additional Review Considerations for Novel Methods & Technologies Pilot Grants**
- What is the likelihood that the new method or technology will directly enhance, advance or replace one or more functions or services within a designated COHR Core?
- Does the novel method/technology have potential value to multiple investigators, if so, how many potential users?
- Does the novel method/technology have the potential to support extramurally funded research projects?
- Does the application include a support letter from a COHR Core Director describing how the proposed method/technology would be incorporated into the existing COHR Core and managed?