PILOT AND FEASIBILITY PROJECT PROGRAM
REQUEST FOR APPLICATIONS (RFA) and APPLICATION SUBMISSION GUIDELINES
2013 FUNDING CYCLE

KEY DATES
RFA Release Date: Wednesday, July 15, 2013
Letter of Intent: August 2, 2013
Application Due Date: September 20, 2013
Earliest Anticipated Funding Date: November 1, 2013

OVERVIEW
The Medical University of South Carolina Center for Genomic Medicine (CGM) is launching its first pilot project initiative with the goal of developing new research in genomic medicine that makes use of genomics technologies, including next generation sequencing (NGS) and bioinformatics capabilities recently developed on campus. The overall aim of this pilot initiative is to stimulate basic, translational, and clinical research in genomic medicine with a goal of identifying faculty who may become members in the Center for Genomic Medicine.

The main objective of the program is to promote the growth of the Center for Genomic Medicine and to foster new users of the Genome sequencing and Bioinformatics Core facilities, to allow investigators to obtain genomic data, including NGS based data, to be used in currently pending or future grant applications.

PILOT PROJECT CATEGORIES: There will be two types of awards associated with this mechanism. We expect to make one award in the amount of up to $30,000 to support a new pilot project. For this award, obtaining matching funds for the proposed work is highly encouraged. We will also make smaller awards of up to $10,000 each that can be used as supplemental funds to expand the scope of existing projects using genomics technologies. When submitting your LOI, be sure to indicate which award mechanism you are interested in applying for.

<table>
<thead>
<tr>
<th>Grant Categories</th>
<th>Brief Description</th>
<th>Award Amount</th>
<th>Award Duration</th>
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</thead>
<tbody>
<tr>
<td>New Pilot project award</td>
<td>Intended to drive the development of new genomics research to obtain preliminary data using genomics technologies.</td>
<td>Up to $30,000</td>
<td>Up to 1 year</td>
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<tr>
<td>Supplementary funding award</td>
<td>Intended to provide funds for use in the Genomics core to obtain genomics data toward existing projects</td>
<td>Up to $10,000</td>
<td>Up to 1 year</td>
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Genomics Shared Resource web page can be found at: http://hcc.musc.edu/research/resources/genomics.htm

PROGRAM QUESTIONS:
Stephen P. Ethier, PhD
Email: ethier@musc.edu
Phone: 843-876-2298

ADMINISTRATIVE QUESTIONS:
Contact Virginia Davis
Email: daviv@musc.edu
Phone: 843-876-2298
KEY ELEMENTS OF THE CGM PILOT PROJECT PROGRAM
The main objective of the program is to promote the growth of the CGM through the development of new extramural funding, and the utilization of critical technologies and CGM Core services. The pilot project program is not designed to provide ongoing support for a long-term project.

PILOT PROJECTS MUST AIM TO:
• Address an important question in Genomic Medicine.
• Generate critical preliminary data to support the submission of a competitive extramural grant application that will directly utilize one or more of the CGM Genomics and Bioinformatics Cores.

PROGRAM ELIGIBILITY
This is a University-wide initiative that is open to all MUSC faculty.

THE APPLICATION PROCESS
Letter of Intent (LOI)
A 1-page letter of intent is due by 3 pm on Friday, August 2, 2013. Letters should be sent to Virginia Davis (daviv@musc.edu)
The following information should be included:
• Preliminary title
• Brief outline of the study plan and its relatedness to genomic medicine
• The need for specific genomics technologies for completion of the project
• Complete listing of the investigative team, their academic titles, primary departments, and roles on proposed project.
All LOIs will be reviewed by the Center for Genomic Medicine Internal Advisory committee (see attached committee roster). Those who submit a LOI will be notified by August 15th, 2013 on whether they are being invited to submit a full application.

Full Application
Full applications from those invited to submit them are due Friday, September 20th, 2013 by 3 pm. Applicants for a full award are required to consult with Dr. Robert Wilson in the Genomics core prior to submission of the application so that budgets can be properly planned, and to ensure that the proper technologies are available. In this regard, note that the Center for Genomic Medicine will provide bioinformatics support for funded individuals at no cost, so there will be no need to include bioinformatics in the budget. Applications received by the deadline will be scientifically peer-reviewed by one member of the Internal Advisory Committee and one member of the External Advisory Committee (see attached roster). Notifications of awards will be made by the end of October, 2013, with an anticipated start date of early November, 2013, depending on the status of human and animal studies approvals.

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)
 o PI Name*
 o PI eRA Commons User Name*
 o PI Biosketch*. Please use PHS 398 Form 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.
 o Degree*
 o PI Faculty Rank*
 o PI Tenure Track*
 o PI Home Institution*, College/School, Department*, Center Affiliation and Division within institution.
 o PI NIH Specialty Code*
o PI Phone Number*
o PI Email Address*
o PI Mailing Address*
o Business Manager Name*, Phone Number*, Email Address*, Mailing Address*
o Optional Contact Person Name, Phone Number, Email Address
o Co-I information (similar to information captured for the PI)
o 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 Center for Genomic Medicine (daviv@musc.edu).

Investigators are strongly encouraged to begin the regulatory approval process prior to submitting the pilot project application.

o Child Health Component*
o Intellectual Property Potential*
o Have you ever applied for funding or published with any of the Co-I(s)?*
o Project Title*
o Grant Category* Select either New Pilot Project or Supplementary Funding

PDF Upload 2: Project Summary and Relevance
o 30 lines of text for Project Summary, Arial font size 11, at least 0.5 margins, PDF only.
o 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 genomic technologies including next generation sequencing (NGS). 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 Genomic Medicine. 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 – 3 pages
o Specific Aims: State concisely the specific aim(s) to be achieved during the one year project period.
o Research Strategy
  a. Approach
  b. Significance of the work to genomic medicine
  c. Translational potential of the work
o Literature Cited: Select only those references pertinent to the proposed research. This is not included in the 3-page limit.
o The Additional Review Criteria section should include a response, if applicable, to the points listed below. The Additional Review Criteria section must be limited to 1 page and 1 support letter.

1. The use of the funds for genomic analysis of experimental or clinical samples, preferably using technologies available in one of the on-campus genomics core labs
2. The likelihood that the work will lead to data that will be used in future grant applications in areas related to genomic medicine
3. The track record of the candidate in obtaining extramural funding. For junior investigators applying for funds, the track record of a faculty mentor will be strongly considered.
4. Translational potential of the work
5. Scientific merit of the specific aims and the proposed experimental approach
6. Though not a requirement for funding, availability of matching funds from another MUSC department or Center is to be considered a strength
PDF Upload 4: Budget and Justification

Use PHS 398 from page 4 (http://grants.nih.gov/grants/funding/phs398/phs398.html) followed by a written justification. Budget cap is $60,000 direct costs (which includes the matching funds) for new pilot projects and $10,000 for supplemental projects. Include direct costs only; there are no indirect costs associated with this grant. No faculty salaries should be included. Any faculty effort related to this award must be listed and supported by the respective department as cost share. By signing the cover page, the departmental business managers verify and approve this cost share. While some salary support for laboratory personnel, post-doctoral fellows, study coordinators, etc. may be included, the majority of the funds must be used to support the use of genomics technologies in the experiments associated with the project. Include justification for all budget requests. Every budgeted item must be classified into a category with unit costs specified and defined. Equipment is not allowed. Travel expenses will not be allowed.

APPLICATION REVIEW CRITERIA AND PROCESS

Overview
Each application will be assigned to two reviewers and one expert in bioinformatics. One reviewer will be from the Internal Advisory Committee and one from the External Advisory committee, plus one reviewer with expertise in bioinformatics. 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 CGM Internal Advisory Committee will prioritize the applications based on the overall impact score, Summary Statement, and also on the programmatic needs of the CGM.

Additional Review Considerations for ALL Grant Categories
- The use of the funds for genomic analysis of experimental or clinical samples, preferably using technologies available in one of the on-campus genomics core labs
- The likelihood that the work will lead to data that will be used in future grant applications in areas related to genomic medicine
- The track record of the candidate in obtaining extramural funding. For junior investigators applying for funds, the track record of a faculty mentor will be strongly considered.
- Translational potential of the work
Center for Genomic Medicine – Internal Advisory Committee

Raymond F. Anton, M.D.
Distinguished University Professor
Department of Psychiatry & Behavioral Sciences
antonr@musc.edu
792-1226

Judy Dubno, Ph.D.
Professor
Department of Otolaryngology – Head & Neck Surgery
dubnojr@musc.edu
792-7978

Darwin P. Bell, Ph.D.
Professor, Director, Renal Research
Endowed Chair, Nephrology Research
Division of Nephrology, Department of Medicine
bellpd@musc.edu
876-2372

Jacqueline F. McGinty, PhD
Associate Dean, College of Graduate Studies
Department of Neurosciences/Neuroscience Research
mcginty@musc.edu
792-9036

Carolyn D. Britten, M.D.
Associate Professor
Department of Hematology/Oncology
britten@musc.edu
792-4271

Shashidhar G. Pai, M.D.
Professor
Director, Division of Genetics, Department of Pediatrics
pais@musc.edu
876-1516

Christopher Davies, Ph.D.
Professor
Department of Biochemistry & Molecular Biology
davies@musc.edu
876-2302

Steven Rosenzweig, Ph.D.
Professor
Department of Pharmacology
roenzsa@musc.edu
792-5841

Harry A. Drabkin, M.D.
Professor
Director, Division of Hematology/Oncology
drabkin@musc.edu
792-4271

Daynna J. Wolff, Ph.D.
Professor
Department of Pathology & Laboratory Medicine
wolffd@musc.edu
792-3574
Center for Genomic Medicine – External Advisory Committee

Mr. Mark Burke, MS
Senior Director of Information Resources & Bioinformatics
David H. Murdock Research Institute
150 Research Campus Drive, Kannapolis, NC 28081
Phone: (704) 250-2600
e-mail: mburke@DHMRI.org

Dr. Howard Edenberg, Ph.D.
Director of Center for Medical Genomics
Department of Biochemistry and Molecular Biology
Indiana University School of Medicine, John D. Van Nuys Medical Science Building
635 Barnhill Drive, Room 4063E, Indianapolis, Indiana 46202
Phone: 317-274-2353
e-mail: edenberg@iu.edu

Dr. Geoffrey Ginsburg, MD, Ph.D.
Director, Genomic Medicine
Duke Institute for Genome Sciences & Policy, Duke University Medical Center
101 Science Drive, Room 2111, Box 3382, Durham, NC 27708
Phone: (919) 668-6210
e-mail: geoffrey.ginsburg@duke.edu

Dr. Howard Jacob, Ph.D.
Director, Human and Molecular Genetics Center
Medical College of Wisconsin
8701 Watertown Plank Road, Milwaukee, WI 53226
Phone: 414-456-4887
e-mail: jacob@mcw.edu

Dr. Stephen Kingsmore, MB, BAO, ChB, DSc, FRDPath
Director, The Center for Pediatric Genomic Medicine
Children’s Mercy Hospitals & Clinics
2420 Pershing Road, Kansas City, MO 64108
Phone: 816-234-3059
e-mail: sfkingsmore@CMH.edu

Dr. Paul Meltzer, M.D., Ph.D.
Head, Molecular Genetics Section Branch Chief
National Center for Genome Research
National Cancer Institute, Building 37, Room 6138, Bethesda, MD 20892
Phone: 301-496-5266
e-mail: pmeltzer@mail.nih.gov

Dr. Steven Skinner, M.D., Director
Greenwood Genetic Center
106 Gregor Mendel Circle, Greenwood, SC 29646
Phone: 864-941-8164
e-mail: sas@ggc.org