

Jackson State University
RCMI - Center for Environmental Health
PILOT PROJECT PROGRAM
Request for Applications (RFA) for Pilot Projects Grants

RELEASE DATE: **August 22, 2013**

APPLICATION RECEIPT DATE: **September 23, 2013 by 5:00 p.m. Central Time**

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PEER REVIEW PERIOD: September 23-30, 2013

EARLIEST ANTICIPATED AWARD DATE: **October 01, 2013**

Purpose of this RFA

The overarching goal of the Research Centers in Minority Institutions (RCMI)–Center for Environmental Health (CEH) at Jackson State University (JSU) is to develop an efficient and robust biomedical infrastructure that would allow JSU investigators to conduct innovative research that addresses biomedical and environmental health issues of concern to minority and underserved communities. The Center also envisions to develop a critical mass of JSU investigators who become more competitive in obtaining mainstream independent grants from NIH and other funding agencies. **Therefore, the major goal of the Pilot Project Program (PPP) is to provide a financial and technical support mechanism for the implementation of basic, clinical, socio-behavioral and/or translational research activities that leverage the unique nature of the RCMI-CEH resources to address important environmental health and health disparities issues.** Specifically, this RCMI-CEH PPP provides a unique opportunity for early stage, mid-career and senior investigators to create new knowledge, advance science, and provide a rational basis for improving human health.

Research Priority Areas of Focus

Many environmental agents, acting either independently or in combination with other toxins, may induce a wide range of adverse health outcomes. These can include: 1) malignant neoplasms associated with exposure to radiation, or various environmental, industrial and agricultural chemicals; 2) neurological diseases, neuro-behavioral and mental outcomes associated with exposure to lead, methyl mercury or other neurotoxic agents including pesticides; 3) respiratory diseases associated with exposure to air pollutants; 4) reproductive and developmental outcomes associated with exposure to teratogenic and developmental toxicants; and 5) other organ/tissue-specific effects or responses associated with environmental exposures.

This Pilot Project Program FOA is made to encourage grant applications to understand the role played by environmental exposures in the etiology of chronic diseases, and health disparities related to cancer, diabetes/obesity, cardiovascular disease, COPD/asthma and/or mental health. The following topics, while not comprehensive, provide research ideas that align with the RCMI-CEH priorities and fit the funding opportunity announcement.

- To understand the role played by gene-environment interactions in health and disease.

- To understand the mechanisms by which environmental exposures contribute to morbidity and mortality related to cancer and other chronic diseases that disproportionately affect underrepresented communities.
- To examine environmental chemicals which have been shown to increase the risks of chronic diseases in human populations.
- To identify which environmental chemicals that have the capacity to alter homeostatic mechanisms in biologic systems.
- To identify the biomarkers of exposure, susceptibility and effect associated with environmental exposures and chronic diseases.
- To develop and validate specific biomarkers in cell models, animal models or human studies that would indicate increased susceptibility to cancer, metabolic syndrome, and/or other chronic diseases.
- To develop new or improved approaches for detecting or diagnosing the onset or progression, and for treating cancer and other chronic diseases that contribute to health disparities.
- To study the associations between global metabolic changes and perturbations in cellular pathways and disease progression as a result of environmental stress.
- To assess the therapeutic mechanisms and bioactivities of pharmaceutical drugs and natural products that show promise for the control and prevention of cancer and other chronic diseases.
- To develop and validate computational models to predict the molecular targets and bioactivities of pharmaceuticals, environmental toxins, nanomaterials and/or other novel materials.
- To perform basic science, clinical and/or epidemiological studies to evaluate changes in specific gene, protein and/or metabolite profiles associated with environmentally induced diseases.
- To perform functional and comparative studies that use qualitative and quantitative omics approaches to examine perturbations in signaling and regulatory networks in response to environmental stress.
- To develop new technologies and approaches for evaluating health risks and assessing the biologic responses associated with exposure to carcinogens or other toxins.

Funds Available and Anticipated Number of Awards

The RCMI-CEH will commit approximately \$300,000/year for the Pilot Project Program solicitation to fund approximately 6 projects per year. Two types of grant award mechanisms will be considered, including the following:

Career Development Award – This mentored career development mechanism is designed to provide financial support to junior faculty at the early stage of developing a biomedical research program. Hence, the goal of this award is to promote the independent status of promising beginning scientists. Junior faculty at the assistant professor rank and those at the beginning (maximum of 3 years) of their associate professor rank will be eligible to apply. For this “Career Development-CD” award, emphasis will be placed on the quality of the research plan, mentoring plan, and career development plan. Hence, multiple PIs will not be allowed for this award mechanism. A budget of up to \$40,000/year for 2 years will be allowed. A maximum of four awards in the total amount of \$160,000 will be made each year. Each of the four awardees must have a scientific advisor, and an academic mentor. In addition, other mentors may be identified based on the specific aspects of the proposed research.

Creative Partnership Award – This award supports mid-career and senior investigators with an established record of accomplishments and who are interested in transitioning into a new collaborative research area of relevance to RCMI-CEH. Advanced associate professors (more than 3 years at the rank) and full professors are eligible to apply. The goal of this award is to support investigators with different but complementary academic backgrounds and expertise, seeking to build multidisciplinary collaborations to develop innovative and meritorious research projects. For this “Creative Partnership” award, emphasis will be placed on the research plan, quality and strength of partnership plan, and expertise in place for its successful execution. Hence, multiple PIs are allowed for the CP award. A budget of up to \$70,000/year may be allowed for a period of one year with the potential possibility of a competitive renewal for one additional year, contingent on the availability of funds and NIH approval. A maximum of two awards in the total amount of \$140,000 will be made each year.

For both award mechanisms, allowable budget items include personnel, small equipment costing less than \$5,000, supplies, travel, fee-for-service work, shipping, and publication cost. Subcontracts are allowed for the Creative Partnership award. Requested budgets will be subject to a careful review, and applicants should not assume that all requests will be honored. Each applicant must provide a functional description of the specific research activities to be conducted by the PI, mentor, scientific advisor, and collaborators, as well as a rational justification of his/her request for equipment, supplies, travel, and other needs. Although funding can be made for work that is supplemental to an ongoing funded research project, there must be a clear justification and evidence that there is no overlap of supported activities.

Eligibility Requirements

Early stage investigators or junior faculty at the assistant professor rank or beginning associate professor rank (3 years maximum), whose unique skills and innovative ideas could contribute or provide a resource to an on-going and/or new research projects in the targeted areas of environmental health and health disparities, will be eligible to apply for the Career Development award. Similarly, mid-career or experienced researchers (advanced associate professors, and full professors) considering changes in research focus to design multidisciplinary projects that address critical research questions of relevance to the CEH mission will be eligible to apply for the Creative Partnership award. Hence, submissions are strongly encouraged from junior faculty/young investigators (assistant professors) and from mid-level (associate professors) and senior investigators (full professors) exploring innovative avenues of biomedical research.

Applications that demonstrate a strong mentoring arrangement between early stage or mid-career investigators and senior experienced investigators from JSU and other collaborating institutions of higher learning or national laboratories will be considered highly responsive to the PPP Career Development award. Applicants must also demonstrate that their mentors and scientific advisors and collaborators have the appropriate academic qualifications, research experience, and productivity to make contributions to the success of their proposed pilot projects. Applicants should also describe how they will use the existing RCMI core facilities and/or RTRN-DTCC to facilitate the implementation of their collaborative research efforts. In addition, they should develop strategic plans that describe the pathways to independence with reasonable timelines of activities. Hence, each pilot project program investigator will be required to identify both a mentor and a scientific advisor to participate and contribute to the successful development and implementation of his/her biomedical research project. Additional mentors/collaborators may be identified based on the proposed research focus.

As indicated above, mid-career and senior investigators with an established record of accomplishments and who are interested in transitioning into a new collaborative and multidisciplinary research area of relevance to RCMI-CEH are eligible to apply for the Creative Partnership award. Also, early stage investigators with the necessary skills may participate in the creative partnership as collaborators but not as PIs or Co-PIs. It is expected that submitted projects will engage intra-departmental/school and institutional collaborations as well as inter-institutional collaborations (e.g., RCMI-Translational Research Network institutions, University of Mississippi Medical Center/Cancer Institute, UAB-Clinical Center for Translational Science, Tulane University Cancer Center, etc). Partnership arrangements must be mutually beneficial and must be leveraged to promote synergy and increase productivity. Multi/interdisciplinary collaborations, teamwork and intellectual contributions are strongly encouraged.

Application Process

Only complete Pilot Project applications will be accepted for review. A faculty member may not submit more than one project in response to this request for application (RFA), but may serve as collaborator in another project. Applicants are required to include the following sections in their applications:

1. Face Page (Use customized Page 1 – PHS 398);
2. Description, Performance Sites and Key Personnel (Use Page 2 – PHS 398).
3. Table of Content (Use customized Page 3 – PHS 398).
4. Budget and Justification (Use Form Pages 4 and 5 – PHS 398). Detailed justification should be provided for each budget item.
5. Biographical Sketches (Use Form Page 6 – PHS 398). Biographical sketches for the applicant, mentor and scientific advisor and collaborator must be included.
6. Other Support (Use Format Page 7 – PHS 398). All grant support received in the recent 5 years must be listed, and time and effort must be provided. Also, all pending applications must also be listed.
7. Resources (Use Form Page 8 – PHS 398).
8. Research Plan (Use the PHS 398 instructions for Research Plan). The **Research Plan is limited to 6 pages for the Career Development Award and 10 pages for the Creative Partnership award, excluding letters of support and references.** In addition, the significance and relevance of the proposed project to RCMI-CEH mission should be clearly described. Also, the role and contributions of mentors, scientific advisors and collaborators must be clearly described.

The Research Plan must include: 1. Specific Aims; 2. Preliminary Studies (If applicable); 3. Research Design and Methods (study design; implementation plan; data collection and analysis; mentoring plan and/or partnership plan; evaluation and anticipated outcomes; and plan to use results in publications and grant applications for independent funding; 4. References Cited; 5. Human Subjects, if applicable. All projects using human subjects must address the 6 points of Human Subjects as outlined in PHS 398. Also, for each protocol, the investigator must address the inclusion of women, minorities and children. Plans for recruitment and retention of subjects should also be addressed. 6. Inclusion of Women and Minorities; 7. Targeted/Planned Enrollment Table; 8. Inclusion of Children; 9. Vertebrate Animals, if applicable. All projects utilizing vertebrate animals must address the 5 points on the utilization and care of these animals as outlined in the PHS 398 ; 10. Selected Agent Research (Biohazards), if applicable; 11. Letters of Support; 12. Resource Sharing Plan.

All assurance and certification policies must be followed. Hence, IRB and IACUC Approvals or evidences of Pending Submission must be secured, respectively for research involving human subjects and vertebrate animals. It is the responsibility of the applicant to obtain all relevant clearances from the Division of Research and Federal Relations regarding IRB and IACUC. Approvals must be completed before awards are made. Additionally, certifications of education in the areas of Biosafety, Responsible Conduct in Research, and Protection of Human Subject Research Participants must be obtained. Funds **will not** be made available until an applicant of a highly rated pilot project provides evidence of compliance with all assurances and certifications that apply to his/her project.

Submission Rules and Requirements

Complete applications must be submitted electronically to the **RCMI-Program Manager, Carolyn Fletcher (601-979-3448) at: Carolyn.s.fletcher@jsums.edu by 5:00 p.m. on Monday September 23, 2013.** In order to preserve the line spacing, figure location and the overall appearance of applications, all applications must be submitted in one single PDF document. Word files will not be accepted.

Format restrictions: Application text must be in Arial font and can be no smaller than 11-point type. Figures, charts, tables, figure legends, and footnotes must be readily legible. Single-spacing is allowed. Margins, in all directions, must be at least 0.5 inches.

Review Process and Prioritization

The overarching goal of the Pilot Project Program (PPP) is to promote the highest quality pilot project research that will lay the groundwork for external grant submission. PPP is an innovative award program designed to stimulate creativity and enhance the biomedical research agenda of RCMI-Center for Environmental Health. Financial support is provided to facilitate the maturation of these pilot projects into competitive NIH proposals, provide support to access RCMI core facilities, and encourage collaboration and partnership. Hence, funded projects must be timely and innovative.

The review process will follow the NIH-style study section approach using standard merit review criteria including: significance, feasibility of the approach, innovation, the expertise and track record of the investigator and research team, the research environment, and alignment with RCMI-CEH research priorities and its Core Facility capabilities.

Each application will be evaluated by three independent external reviewers who will judge and score its scientific merit. The composite score of the three reviewers of each application will be calculated. Subsequently, the RCMI Pilot Project Program Review Committee will meet as a whole and discuss all proposals weighing scientific merit, potential advancement for the field, relevance, quality of the application, and costs.

Hence, prioritization and selection of proposals to be funded will be made by the RCMI Pilot Project Program Review Committee based on the external reviews, program impact and priorities, potential for leading to a successful independent project, collaborations, and the availability of funds. A rigorous career development plan that describes the potential impact of the award in transitioning the investigators to biomedical research independence will be an integral part of the evaluation and prioritization process. The following review criteria will be considered in determining priority scores:

Significance: Does this study address an important health problem? If the aims of the application are achieved, how will scientific knowledge or clinical practice be advanced? What will be the effect of the study on the concepts, methods, technologies, treatments, services, or preventive interventions that drive this field?

Approach: Are the conceptual or clinical framework, design, methods and analyses adequately developed, well-integrated, well-reasoned and appropriate to the aims of the project? Does the applicant acknowledge potential problems and consider alternative strategies?

Innovation: Is the project original and innovative? For example: Does the project challenge existing paradigms or clinical practice, or address an innovative hypothesis or critical barrier to progress in the field? Does the project develop or employ novel concepts, approaches, methodologies, tools or technologies?

Investigators: Are the investigators appropriately trained and well suited to conduct the proposed collaborative study? Is the proposed research appropriate to the experience level of the principal investigator and collaborators? If the principal investigator is a junior faculty member, has the applicant designated a senior mentor and provided a mentoring plan? If the principal investigator is a senior or mid-career faculty member, has the applicant designated a junior mentee and provided a mentoring plan? Does the investigative team bring complementary expertise and synergy to the project?

Environment: Does the scientific environment in which the study will be performed contribute to the probability of success? Does the proposed study benefit from unique features of the scientific environment, or subject populations, or employ useful collaborative arrangements? Is there evidence of institutional support?

RCMI-CEH Relevance: Will the research make a significant contribution to the development of Environmental health and health disparities research at JSU? Does the project engage collaboration? Does it utilize RCMI-CEH and/or RTRN-DTCC resources? Do the proposed studies have the potential to lead to a successful independent project?

Protections for Human Subjects: Use of human participants for research or certain instructional purposes is subject to prior review and approval of the Institutional Review Board (IRB) for the Protection of Human Subjects. Follow the guidelines for documentation of certification for protection of human subjects in accordance with NIH guidelines

(<http://grants.nih.gov/grants/funding/phs398/phs398.pdf>; Part II). For Non-Exempt Human Subjects Research, be sure to include all required sections beginning on Page II-7 of the NIH document. For research involving human subjects, complete the Targeted/Planned Enrollment Table (<http://grants.nih.gov/grants/funding/phs398/enrollment.doc>). Applications with an incomplete human subjects section may be considered ineligible for review. Release of award funds will be contingent on receipt of IRB approval letter(s) and other regulatory documents. Hence, justification for the involvement of human subjects will be evaluated according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials. If the application involves the use of human subjects, is a Targeted/Planned Enrollment Table format page included?

Inclusion of Women, Minorities, and Children: If the proposed project involves the use of human subjects, are minorities and members of both genders, as well as children, eligible for participation? If not, what are the justifications for their exclusion?

Vertebrate Animals: The JSU Institutional Animal Care and Use Committee (IACUC) in accordance with federal, state and institutional policies, oversees the university's animal programs, facilities and procedures involving the appropriate use, care and humane treatments of animals being used for research, testing and education. Certification for protection for the

care and treatment of laboratory animals should be obtained for all applicable projects in accordance with NIH guidelines. Release of award funds will be contingent on receipt of IACUC approval letter(s) and other regulatory documents.

Biohazards: The JSU Institutional Biosafety Committee (IBC) has the charge of reviewing and approving recombinant DNA research and biohazard projects. All recombinant DNA research at JSU, regardless of funding source, must be conducted in accordance with the NIH Guidelines for Research Involving Recombinant DNA Molecules and the use of infectious micro-organisms in research, teaching and the handling of infectious waste disposal. If the proposed research involves the use of materials or procedures, which are potentially hazardous to research personnel and/or the environment, care must be taken to ensure that adequate protections are provided.

Budget: (will not be considered in the determination of the impact score). Is the proposed budget reasonable and well justified? Is the requested period of support reasonable in relation to the proposed research?

Each of the review criteria will be scored based on the NIH 9-point rating scale according to the following descriptions and additional guidance on strengths and weaknesses:

Impact	Score	Descriptor	Additional Guidance on Strengths/Weaknesses
High	1	Exceptional	Exceptionally strong with essentially no weaknesses
	2	Outstanding	Extremely strong with negligible weaknesses
	3	Excellent	Very strong with only some minor weaknesses
Medium	4	Very Good	Strong but with numerous minor weaknesses
	5	Good	Strong but with at least one moderate weakness
	6	Satisfactory	Some strengths but also some moderate weaknesses
Low	7	Fair	Some strengths but with at least one major weakness
	8	Marginal	A few strengths and a few major weaknesses
	9	Poor	Very few strengths and numerous major weaknesses
<i>Minor Weakness:</i> An easily addressable weakness that does not substantially lessen impact <i>Moderate Weakness:</i> A weakness that lessens impact <i>Major Weakness:</i> A weakness that severely limits impact			

Funding Decision

All applicants will receive summary statements of their proposals. Prior to accepting PPP awards, PIs must agree not to teach an overload or work on a job outside of JSU. Awardees will be required to submit quarterly reports, as well as complete a progress report to be submitted with the RCMI-CEH annual progress report. Awardees will present their projects to EAC members when they visit the program and during one of the CEH monthly distinguished seminars. Applicable IRB and/or IACUC approvals must be obtained prior to the disbursement of funds.