GENERAL ANNOUNCEMENT
REQUEST FOR APPLICATIONS

LSU Biomedical Collaborative Research Program (LBCRP) 2016

I. Funding Opportunity Description
Louisiana State University and Agricultural & Mechanical College (LSU A&M), the Pennington Biomedical Research Center (PBRC), and LSU Health Sciences Center-New Orleans (LSUHSC-NO) School of Medicine are soliciting collaborative applications between LSU A&M, PBRC, and LSUHSC-NO School of Medicine researchers for pilot funding consideration. Applications may be targeted to all aspects of NIH fundable research including bioengineering, comparative medicine, bioinformatics, translational medicine, etc. The goal of this program is to promote interdisciplinary and other team approaches to biomedical research. Following the NIH multi-PI format, applications are required to include two co-Principal Investigators from two different participating campuses. Additionally, applications from research teams that represent new collaborations are strongly encouraged.

II. Award Information
Funding will be awarded as an internal grant by each participating campus. It is anticipated that 10 pilot projects will be awarded. Project budgets should not exceed $50,000 in direct costs over a one-year period. Indirect costs are not allowed. Awarded funds will be distributed equally between the collaborating investigators (i.e. $25,000 to the PI from each campus). The project period is October 1, 2016, through September 30, 2017. (Under exceptional circumstances, renewal funding for a second year may be considered where there is evidence that an additional year of funding will ensure national competitiveness.)

III. Eligibility
Applicants must have a current tenure-track, research, or clinical faculty appointment at LSU A&M, PBRC, or LSUHSC-NO School of Medicine. LSU A&M eligibility is limited to the College of Science, the College of Engineering, College of Human Sciences & Education, and the School of Veterinary Medicine. Proposals must include two Co-PIs, and each Co-PI must hold a primary appointment at a different campus (e.g., 1 PI from LSU A&M and 1 from LSUHSC-NO, 1 from LSU A&M and 1 from PBRC, or 1 from PBRC and 1 from LSUHSC-NO). Research projects in any of the NIH-supported scientific focus areas are eligible.

Renewal applications are not currently being accepted. However, previous recipients of an LBCRP award are eligible to submit applications for new projects.

IV. Application and Submission Information
Applications should be submitted online at: https://lsu.infoready4.com/#competitionDetail/1751879. Applications must be submitted by 5 pm on Monday, August 1, 2016.

Where indicated, elements of the proposal should be uploaded to the online application in PDF format. Applicants must observe the specified page limits. Use standard paper size (8 ½” x 11”) and at least ½” margins (top, bottom, left, and right) for all pages. Use an Arial, Helvetica, Palatino Linotype, or Georgia typeface, a black font color, and a font size of 11 points or larger. Each section of the proposal that is uploaded as a file must be individually paginated prior to being uploaded to the electronic system.

Required and Optional Components:

Coversheet
The coversheet will be generated automatically in the InfoReady online application system. All required fields must be completed.

Project Summary / Abstract
The project summary is meant to 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 health relatedness of the project (i.e., relevance to the mission of NIH). Describe concisely the research design and methods for achieving the stated goals. This section should be informative to other persons working in the same or related fields and insofar as possible understandable to a scientifically or technically literate reader. Avoid describing past accomplishments and the use of the first person. Finally, please make every effort to be succinct. This section must be no longer than 30 lines of text, and follow the required font and margin specifications.

Research Strategy (7 pages)
The research plan should include sufficient information needed for evaluation of the project. Be specific and informative, and avoid redundancies. Applicants must observe the specified page limits and follow the required font and margin specifications. All tables, graphs, figures, diagrams, and charts must be included within the Research Strategy page limit. The Research Strategy (Specific Aims, Research Strategy, and Bibliography & References Cited) must all be uploaded in a single file.

A. Specific Aims (1 page)
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 proposed, e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop new technology.

B. Research Strategy (6 pages)
Organize the Research Strategy in the specified order and using the instructions provided below. Start each section with the appropriate section heading – Significance, Innovation, Approach, Funding Plans. Cite published experimental details in the Research Strategy section and provide the full reference in the References section.

1. Significance
   - Explain the importance of the problem or critical barrier to progress in the field that the proposed project addresses.
   - Explain how the proposed project will improve scientific knowledge, technical capability, and/or clinical practice in one or more broad fields.
   - Describe how the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.
   - Describe the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field will be changed if the proposed aims are achieved.

2. Innovation
   - Explain how the application challenges and seeks to shift current research or clinical practice paradigms.
   - Describe any novel theoretical concepts, approaches or methodologies, instrumentation or interventions to be developed or used, and any advantage over existing methodologies, instrumentation, or interventions.
   - Explain any refinements, improvements, or new applications of theoretical concepts, approaches or methodologies, instrumentation, or interventions.

3. Approach
   - Describe the overall strategy, methodology, and analyses to be used to accomplish the specific aims of the project. Unless addressed separately in the Resource Sharing Plan, include how the data will be collected, analyzed, and interpreted as well as any resource sharing plans as appropriate.
Discuss potential problems, alternative strategies, and benchmarks for success anticipated to achieve the aims.

If the project is in the early stages of development, describe any strategy to establish feasibility, and address the management of any high risk aspects of the proposed work.

Point out any procedures, situations, or materials that may be hazardous to personnel and precautions to be exercised. A full discussion on the use of select agents should appear in the applicable section below.

4. Funding Plans

- Explain how research conducted under LBCRP finding will increase competitiveness for future NIH R21 and/or R01 funding.
- Include a projected timetable for future NIH application submissions. If an applicant has multiple Specific Aims, then the applicant may address Significance, Innovation and Approach for each Specific Aim individually, or may address Significance, Innovation and Approach for all of the Specific Aims collectively.

C. Bibliography & References Cited (No page limit)

Provide a bibliography of any references cited in the Research Plan. Each reference must include the names of all authors (in the same sequence in which they appear in the publication), the article and journal title, book title, volume number, page numbers, and year of publication. Include only bibliographic citations. Applicants should be especially careful to follow scholarly practices in providing citations for source materials relied upon when preparing any section of the application.

Facilities & Other Resources (No page limit)

No special form is required but this section must be completed and attached. Describe how the scientific environment in which the research will be done contributes to the probability of success (e.g., institutional support, physical resources, and intellectual rapport). In describing the scientific environment in which the work will be done, discuss ways in which the proposed studies will benefit from unique features of the scientific environment or subject populations or will employ useful collaborative arrangements.

Human Subjects

If applicable to the proposed research, attach a section entitled “Protection of Human Subjects” to describe and justify the involvement of human subjects, recruitment and inclusion plan, and procedures for protecting against or minimizing risk. Refer to Supplemental Instructions, Part II Section 4.1-4.4 for additional guidance (http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf#4_1_protection_of_human_subject). If necessary Inclusion of Women and Minorities and Inclusion of Children documents must be included in the file upload for Human Subjects.

A. Inclusion of Women and Minorities

This section is required for applicants answering “yes” to the question “Are human subjects involved?” and the research does not fall under Exemption 4. Refer to Supplemental Instructions, Part II Section 4.2 for additional guidance (http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf#4_2_inclusion_of_women_and_minorities).

B. Inclusion of Children

This section is required for applicants answering “yes” to the question “Are human subjects involved?” and the research does not fall under Exemption 4. Refer to Supplemental Instructions, Part II Section 4.3 for additional guidance (http://grants.nih.gov/grants/how-to-apply-application-guide/forms-d/supplemental-instructions-forms-d.pdf#4_4_inclusion_of_children).

Vertebrate Animals

Complete this section if you answered “yes” to the question “Are Vertebrate Animals Used?” If Vertebrate Animals are involved in the project, address each of the following criteria listed below.
1. Description of Procedures. Provide a concise description of the proposed procedures to be used that involve vertebrate animals in the work outlined in the “Research Strategy” section. Identify the species, strains, ages, sex, and total numbers of animals by species, to be used in the proposed work. If dogs or cats are proposed provide the source of the animals.

2. Justifications: Provide justification that the species are appropriate for the proposed research. Explain why the research goals cannot be accomplished using an alternative model (e.g., computational, human, invertebrate, in vitro).

3. Minimization of Pain and Distress: Describe the interventions including analgesia, anesthesia, sedation, palliative care and humane endpoints to minimize discomfort, distress, pain, and injury.

For additional information, see http://grants.nih.gov/grants/olaw/VASchecklist.pdf. Do not use the Vertebrate Animals section to circumvent the page limits of the Research Strategy. Provide a concise, complete description of the animals and proposed procedures.

- The responses to the criteria below must be well-integrated with the other sections. There should be sufficient detail in the responses for peer reviewers and NIH staff to evaluate. Additional details, if any, may be included in the Research Strategy.
- Identify all project/performance or collaborating site(s) and describe activities of proposed research with vertebrate animals in those sites.
- An incomplete application will not be considered for review. It will be considered incomplete if the above criteria are not addressed.
- If plans for the use of animals have not been finalized, explain when and how animals are expected to be used.
- If an award is made, the grantee must provide detailed information on the criteria above, and verification of IACUC approval. These must be submitted to the NIH awarding office prior to the involvement of animals.

Select Agents

Select agents are hazardous biological agents and toxins that have been identified by HHS or USDA as having the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products. CDC and the Animal APHIS Select Agent Programs jointly maintain a list of these agents. See http://www.selectagents.gov/.

If the activities proposed in the application involve only the use of a strain(s) of select agents which has been excluded from the list of select agents and toxins as per 42 CFR 73.3, the select agent requirements do not apply. Use this section to identify the strain(s) of the select agent that will be used and note that it has been excluded from this list. The CDC maintains a list of exclusions, which is available at http://www.selectagents.gov/SelectAgentsandToxinsExclusions.html.

If any of the activities proposed in your application involve the use of select agents at any time during the proposed project period, either at the applicant organization or at any other performance site, address the following three points for each site at which select agent research will take place. Although no specific page limitation applies to this section, be succinct.

1. Identify the select agent(s) to be used in the proposed research.
2. Provide the registration status of all entities* where select agent(s) will be used.
   - If the performance site(s) is a foreign institution, provide the name(s) of the country or countries where select agent research will be performed.
   - "An "entity" is defined in 42 CFR 73.1 as "any government agency (Federal, State, or local), academic institution, corporation, company, partnership, society, association, firm, sole proprietorship, or other legal entity."
3. Provide a description of all facilities where the select agent(s) will be used.
   - Describe the procedures that will be used to monitor possession, use and transfer of select agent(s).
   - Describe plans for appropriate biosafety, biocontainment, and security of the select agent(s).
• Describe the biocontainment resources available at all performance sites.

 Note: If a proposal is funded, any required special authorizations (IRB, IACUC, etc.) must be approved prior to the commencement of work.

**Multiple PI Leadership Plan**
LBCRP projects use the multi-PI model adopted by NIH and must include two Co-PIs from two different campuses. Both PIs will share the responsibility and authority for leading and directing the project. Applications must include a Multiple PI Leadership Plan that describes the roles, the administrative, technical, and scientific responsibilities, and the working relationship of the identified PIs, including communication plans, process for making decisions on scientific direction, and procedures for resolving conflicts.

**Biosketches**
Applicants must include a Biographical Sketch for each PI using the new NIH 5-page format. All biographical sketches must be uploaded as a single PDF. A template is available for download at: http://grants.nih.gov/grants/forms/biosketch-blankformat-Forms-D.docx.

**Resource Sharing Plan**
NIH considers the sharing of unique research resources developed through NIH-sponsored research an important means to enhance the value and further the advancement of the research. When resources have been developed with NIH funds and the associated research findings published or provided to NIH, it is important that they be made readily available for research purposes to qualified individuals within the scientific community. See Supplemental Instructions, Part III 1.5.

**Budget and Budget Justification**
A detailed budget and budget justification must be submitted for each PI using the budget template available for download here.

The total budget requested for each project is not to exceed $50,000-direct costs per year for one year ($25,000 per PI). No indirect costs are allowed. Personnel costs should be limited to technical staff and students. Equipment requests should not constitute a significant portion of the pilot grant budget. All items requested as part of the proposal budget must relate directly to that research project. General purpose supplies and equipment are not allowed. The amounts for each budget line item requested should be documented and justified in the budget justification.

**Submission Date and Time**
The deadline for submission of proposals is 5:00pm CST on Monday, August 1, 2016.

V. **Application Presentation**
All those who submit an application will be invited to present their work during the LBCRP Workshop on Thursday, September 8, in Baton Rouge.

VI. **Award Conditions**
All recipients of LBCRP pilot grants are required to submit an NIH R21 application and/or be able to show that they are making significant progress towards submitting a competitive NIH application by the end of the LBCRP award period.

A progress report (6 months) and final report (12 months) are required and should be submitted on NIH PHS 2590 forms (available here: http://grants.nih.gov/grants/funding/2590/2590.htm).

Reports must be submitted through the InfoReady portal: https://lsu.infoready4.com/#competitionDetail/1751879.

Progress and final reports should state the original objectives of the project and indicate which of the objectives were addressed during the period of funding. Appropriate tables and figures should be included if they help clarify the results.
The final report must also include the title of the resulting grant proposal submitted to external federal agencies and date of submission or the date on which a future submission is planned.

The report should include a list of any resulting articles submitted or published. In addition all recipients of an LBCRP will be required to present their research at the annual LBCRP workshop in fall 2017.

VII. Review and Selection Process

Review Panel and Timeline
A review committee consisting of faculty from both LSU A&M, PBRC, and LSUHSC-NO School of Medicine will review and score all applications. Additional external reviews may be sought, as needed. Individuals submitting applications selected for funding will be notified as soon as possible. It is anticipated that funding will begin around October 1, 2016.

Major Review Criteria
The primary goals of the LBCRP are to (i) encourage biomedical research collaborations between the two LSU campuses and (ii) foster preliminary data leading to additional NIH funding. Particular attention will be paid to how the work augments the capability and subject range of the individual investigators and the likelihood that the work will lead to preliminary data useful to future successful grant applications. A single-digit score and a bulleted list of strengths and weaknesses for each of the six review categories, as well as an overall priority score, using the following NIH-based scoring scale will be used. (Note that an application does not need to be strong in all listed categories to be judged.)

<table>
<thead>
<tr>
<th>Impact</th>
<th>Score</th>
<th>Descriptor</th>
<th>Additional Guidance on Strengths and Weaknesses</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>1</td>
<td>Exceptional</td>
<td>Exceptional strong with essentially no weaknesses</td>
</tr>
<tr>
<td></td>
<td>2</td>
<td>Outstanding</td>
<td>Extremely strong with negligible weaknesses</td>
</tr>
<tr>
<td></td>
<td>3</td>
<td>Excellent</td>
<td>Very strong with only some minor weaknesses</td>
</tr>
<tr>
<td>Medium</td>
<td>4</td>
<td>Very Good</td>
<td>Strong but with numerous minor weaknesses</td>
</tr>
<tr>
<td></td>
<td>5</td>
<td>Good</td>
<td>Strong but with at least one moderate weakness</td>
</tr>
<tr>
<td></td>
<td>6</td>
<td>Satisfactory</td>
<td>Some strengths but also some moderate weaknesses</td>
</tr>
<tr>
<td>Low</td>
<td>7</td>
<td>Fair</td>
<td>Some strengths but with at least one major weakness</td>
</tr>
<tr>
<td></td>
<td>8</td>
<td>Marginal</td>
<td>A few strengths and a few major weaknesses</td>
</tr>
<tr>
<td></td>
<td>9</td>
<td>Poor</td>
<td>Very few strengths and numerous major weaknesses</td>
</tr>
</tbody>
</table>

Collaborations and Utilization of Cores: Applications that demonstrate a trans-disciplinary approach and show convergence of expertise between two or more investigators and/or collaborating institutions will be considered highly responsive to this RFA. A timetable should be provided that outlines plans for seeking subsequent or supplemental extramural support.

Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigators: Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the
investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (exclusion) of children, justified in terms of the scientific goals and research strategy proposed?

Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Leadership and data sharing Plan: How will investigators’ groups communicate data and strategy, and how often? If there are multiple sections or strategies, which investigator will be responsible for each, and why was this investigator chosen to lead this particular set of experiments?

Additional Review Categories: In addition to the above criteria, the following items will be considered in the determination of merit and priority score

Protections for Human Subjects: For research that involves human subjects but does not involve one of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation 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. For research that involves human subjects and meets the criteria for one or more of the six categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials.

Inclusion of Women, Minorities, and Children: When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of children to determine if it is justified in terms of the scientific goals and research strategy proposed.

Vertebrate Animals: The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to the following five points: 1) proposed use of the animals, and species, strains, ages, sex, and numbers to be used; 2) justifications for the use of animals and for the appropriateness of the species and numbers proposed; 3) adequacy of veterinary care; 4) procedures for limiting discomfort, distress, pain and injury to that which is unavoidable in the conduct of scientifically sound research including the use of analgesic, anesthetic, and tranquilizing drugs and/or comfortable restraining devices; and 5) methods of euthanasia and reason for selection if not consistent with the AVMA Guidelines on Euthanasia.
Biohazards: If the proposed research involves the use of materials or procedures, which are potentially hazardous to research personnel and/or the environment, are adequate protections proposed?

Select Agent Research: Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Additional Review Consideration: The following item will be reviewed but not considered in the determination of the impact score.

Budget. Is the proposed budget reasonable and well justified? Is the requested period of support reasonable in relation to the proposed research?

Presentation. Is the presentation well prepared and appropriate for the audience? Does the presentation address a significant biomedical issue?

VIII. Program Contacts
Questions regarding the LBCRP program and/or questions of a scientific nature should be directed to:

K. Gus Kousoulas, PhD  
Associate Vice Chancellor for Research & Economic Development (STEM) Director, LSU-Tulane NIH Center for Biomedical Research Excellence (COBRE) Center for Experimental Infection Disease Research  
Email: vtgusk@lsu.edu  
Phone: 225-578-5833 (ORED)  
Fax: 225-578-5983 (ORED)

Steve Nelson, MD  
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John H. Seabury Professor of Medicine  
Director, Clinical and Translational Research Center  
Email: snelso1@lsuhsc.edu  
Phone: (504) 568-4007  
Fax: (504) 568-2186

Questions regarding proposal preparation and submission should be directed to:

Crissie Molina, MLIS  
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