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Overview Information

<table>
<thead>
<tr>
<th><strong>Number of applications</strong></th>
<th>A faculty member may only submit one application.</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>The purpose of the pilot project grants is to help faculty establish or revive their research program. All topics should be health-related and relevant to the mission of NIH.</td>
</tr>
<tr>
<td><strong>Pre-application Due Date</strong></td>
<td>April 25, 2016. Pre-applications are required. Please complete and submit the pre-application form, available on the ASCEND website. The pre-application will be used to facilitate the selection of internal and external proposal reviewers. A written invitation to submit a full proposal will be sent to Principal Investigators. If the pre-application describes projects that are not health related, do not address the mission of NIH, or do not include the participation of undergraduates, they will be declined.</td>
</tr>
<tr>
<td><strong>Application Due Date</strong></td>
<td>June 15, 2016</td>
</tr>
<tr>
<td><strong>Scientific Merit Review</strong></td>
<td>June 2016 – November 2016</td>
</tr>
<tr>
<td><strong>Earliest Start Date</strong></td>
<td>December 1, 2016</td>
</tr>
<tr>
<td><strong>Project Period</strong></td>
<td>December 1, 2016–November 30, 2016 (can end earlier)</td>
</tr>
<tr>
<td><strong>Funding Instrument</strong></td>
<td>Grant</td>
</tr>
<tr>
<td><strong>Anticipated Number of Awards</strong></td>
<td>Up to 9</td>
</tr>
</tbody>
</table>

**Award Budget:** Applications may request up to $50,000 (total costs) for one year. There are no indirect costs associated with this award.

**Eligibility:** In order to be eligible to apply, the primary researcher must be a tenured or tenure-track faculty member at Morgan State University.

**Funding Opportunity Description:** The purpose of the pilot project grants is to help faculty establish or revive their research program. All research topics should be health-related (broadly defined). In addition to proposals outlining basic science biomedical research, proposals that are interdisciplinary and/or community-based are strongly encouraged.

**Application Submission:** Applications must be prepared using the grant applications forms provided on the ASCEND website (www.morgan.edu/ascend). Email the completed forms and any related attachments to ascend@morgan.edu by June 15, 2016, 11:59 pm.
Questions: If you have any questions, please contact Ms. Gillian Silver, Program Manager, at 443-885-3541, or gillian.silver@morgan.edu.

Formatting specifications: Font and margin specifications must be followed; if not the application may not be reviewed.
- Font size of 11 point or larger.
- NIH requires the use of one of four approved fonts: two serif fonts (Palatino and Georgia) and two sans serif fonts (Arial and Helvetica).
- A symbol font may be used to insert Greek letters or special characters; the font size requirement still applies.
- A smaller font size may be used for figures, graphs, diagrams, charts, tables, figure legends, and footnotes, but this type must follow the font typeface requirement and be readily legible.
- Text should be single-spaced.
- Pages should be single-sided.
- Use ½- to 1-inch margins. No information should appear in the margins, including the PD/PI's name and page numbers.
- Use standard paper size (8 ½" x 11").
- Consecutively number pages throughout the application. Do not use suffixes (e.g., 5a, 5b).

Language Use:
- Use English; avoid jargon.
- If terms are not universally known, spell out the term the and first time it is used and note the appropriate abbreviation in parentheses. The abbreviation may be used thereafter.

Page Limitations: Follow all page limitations instructions provided on the forms, or as follows:
- Specific Aims: 1 page
- Research Strategy: 4 pages
- Inclusion of Undergraduate Students: 1 page
- Budget Narrative: 2 pages
- Biosketch: 5 pages (each)

Cover/Face Page: Most of the items on the face page are self-explanatory.

Description, Project/Performance Sites, Senior/Key Personnel, Other Significant Contributors:

- Project Summary: 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 1) the health-research-relatedness of the project and 2) relevance to ASCEND’s goals. Make a statement as to how MSU undergraduates will participate in the project (a new requirement). 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.
ASCEND Faculty Pilot Research Projects Application Guidance

- **Relevance**: Using no more than two or three sentences, describe the relevance of this research to public health. In this section, be succinct and use plain language that can be understood by a general, lay audience.

- **Project/Performance Site(s)**: Indicate where the work described in the Research Plan will be conducted. Include not only MSU, but any other sites or organizations where the research will be performed.

- **Senior/Key Personnel**: In addition to the PD/PI, Senior/Key Personnel are defined as individuals who contribute to the scientific development or execution of the project in a substantive, measurable way, whether or not salaries are requested. Typically, these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level should be included if their involvement meets the definition of Senior/Key Personnel. Consultants and those with a postdoctoral role should also be included if they meet the same definition.

  Senior/Key Personnel must devote measurable effort (described in person months) to the project, whether or not salaries are requested. "Effort of zero person months" or “as needed” are not acceptable levels of involvement for those designated as Senior/Key Personnel. Start with the PD/PI(s). List the PD/PI’s last name first. When multiple PIs are proposed, list the contact PI first, then all additional PIs in alphabetical order. Then list all other Senior/Key Personnel in alphabetical order, last name first. For each individual provide name, eRA Commons User Name (required), organization name (their institutional affiliation), and role on the project. Under role on the project, indicate how the individual will function on the proposed project.

- **Other Significant Contributors**: This category identifies individuals who have committed to contribute to the scientific development or execution of the project, but are not committing any specified measurable effort (i.e., person months) to the project. These individuals are typically presented at "effort of zero person months" or "as needed." Individuals with measurable effort may not be listed as Other Significant Contributors (OSCs). Consultants should be included if they meet this definition.

  An NIH-formatted biosketch, including Research Support information, will be required for Senior/Key Personnel and OSCs, as this highlights their relevant accomplishments. Reviewers use these pages to address the "investigator(s)" review criterion. Please note that significant changes were made to the biosketch format in May 2015. Workshops and one-on-one sessions will be offered by ASCEND staff and faculty to aid investigators in creating new or revising exiting biosketches to meet the new NIH requirements.

**Research Plan**

- **Specific Aims**: Limited to one 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.

- **Research Strategy**: This section is limited to four pages (separate from the Bibliography and References Cited, and Involvement of Undergraduate Students). Organize the Research Strategy into the following sections: Significance, Innovation, Approach, and Impact. Start each section with the appropriate section heading. Cite published experimental details in the Research Strategy section and provide the full reference in the Bibliography and References Cited section.

For the Impact section, provide a detailed personal development plan, describing how data generated with this funding will allow you to expand your research capacity and ability to publish your findings and will enable you to apply for funding through the NIGMS MOORE division SCORE program funding, NIH, NSF or other government or private agencies. If you previously applied unsuccessfully for such funding, specify how ASCEND funding will help you to address reviewer comments. Describe any existing relevant collaborations with investigators at MSU and majority partner institutions or those you plan to establish. If you are a beginning investigator, describe the scientific or career mentorship you currently have or will be seeking. If you are a seasoned investigator applying for “bridge funding,” describe how your research program has or will impact your department’s overall research infrastructure and training capacity. Include evidence of your previous undergraduate and graduate training record, if applicable. If the proposed research is funded, describe how it will affect the following (please be specific and realistic in your assessment):

Also include in the Impact section:
1) The number of graduate students you will train;
2) The infrastructure capacity of your laboratory/research program for future work;
3) The overall research infrastructure in your department;
4) Your ability to engage in interdisciplinary collaborations on- or off-campus;
5) How you plan to disseminate your research results (e.g., through presentations and publications).

- **Bibliography and References Cited/Progress Report Publication List**: List the titles and complete references to all appropriate publications, manuscripts accepted for publication, patents, and other printed materials that have resulted from the project since it was last reviewed competitively. Each reference must include 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. Follow scholarly practices in providing citations for source materials relied upon in preparing any section of the application. The references should be limited to relevant and current literature. While there is not a page limitation, it is important to be concise and to select only those literature references pertinent to the proposed research.

**Letters of Support**: Provide all appropriate letters of support, including any letters necessary to demonstrate the support of consortium participants and collaborators such as Senior/Key Personnel and Other Significant Contributors included in the grant application. Letters are not required for personnel (such as research assistants) not contributing in a substantive, measurable way to the scientific development or execution of the project. Letters should stipulate expectations for co-authorship, and
whether cell lines, samples or other resources promised in the letter are freely available to other investigators in the scientific community or will be provided to the particular investigators only. For consultants, letters should include rate/charge for consulting services and level of effort/number of hours per year anticipated. In addition, letters ensuring access to core facilities and resources should stipulate whether access will be provided as a fee-for-service. Consultant biographical sketches should be included in the Biographical Sketch section.

**Detailed Budget**: Budgets can include requests for funding for salaries/wages, benefits, supplies, local and domestic travel, and professional development. Proposals must include a line-item budget and an up to 2-page budget narrative.

Each element listed on the Detailed Budget for Initial Budget Period form must be clearly justified. List only the direct costs requested in this application; indirect costs (Facilities and Administrative (F&A) costs) are not permitted.

**Personnel**

- **Name.** Starting with the PD/PI(s), list the names of all applicant organization employees who are involved on the project during the initial budget period, regardless of whether a salary is requested. Include all collaborating investigators, individuals in training, and support staff.

- **Role on Project.** Identify the role of each individual listed on the project. Provide budget narrative for ALL personnel by position, role, and level of effort using person months (calendar, academic and/or summer). This includes any “to-be-appointed” positions.

- **Months Devoted to Project.** Enter the number of months devoted to the project. Three columns are provided depending on the type of appointment being reflected: academic, calendar, and/or summer months. Individuals may have consecutive appointments within a calendar year, for example for an academic period and a summer period. In this case, each appointment should be identified separately using the corresponding column. If effort does not change throughout the year, use only the calendar months column. If effort varies between academic and summer months, leave the calendar months column blank and use only the academic and summer months columns. In cases where no contractual appointment exists with the applicant organization and salary is requested, enter the number of months for the requested period.

- **Salary Requested.** Regardless of the number of months being devoted to the project, indicate only the amount of salary being requested for this budget period for each individual listed. Some PHS grant programs are currently subject to a legislatively imposed salary limitation. Any adjustment for salary limits will be made at the time of award. NIH grants also limit the compensation for graduate students. Compensation includes salary or wages, fringe benefits and tuition remission. While actual institutional-based compensation should be requested and justified, this may be adjusted at the time of the award.

- **Fringe Benefits.** Fringe benefits may be requested in accordance with institutional guidelines for each position, provided the costs are treated consistently by the applicant organization as a direct cost to all sponsors.

- **Totals.** Calculate the totals for each position and enter the subtotals in each column where indicated.

**Consultant Costs.** Whether or not costs are involved, provide the names and organizational affiliations of all consultants, other than those involved in consortium/contractual arrangements. Include persons who are confirmed to serve on external monitoring or advisory committees. Include the number of days
of anticipated consultation, the expected rate of compensation, travel, per diem, and other related costs.

**Equipment.** List each item of equipment with amount requested separately and justify each purchase. Equipment includes individual items costing $5,000 or more.

**Supplies.** Itemize supplies in separate categories, such as glassware, chemicals, radioisotopes, etc. Categories in amounts less than $1,000 do not have to be itemized.

For research involving animals, if animals are to be purchased, state the species and the number to be used. Please note that at this time MSU does not have an approved research animal facility, so live vertebrate animals cannot be purchased for use on the MSU campus. *Investigators will need to make arrangements with research partners at institutions with approved animal facilities.*

**Travel.** Itemize travel requests and justify them. Provide the purpose and destination of each trip and the number of individuals for whom funds are requested.

**Alterations and Renovations.** Not allowed.

**Other Expenses.** Itemize any other expenses by category and unit cost. These might include animal maintenance (unit care costs and number of care days), participation incentives, donor fees, publication costs, computer charges, rentals and leases, equipment maintenance, service contracts, and tuition remission when budgeted separately from salary/fringe benefits.

**Consortium/Contractual Costs.** Each participating consortium/contractual organization must submit a separate detailed budget for the initial budget period. Consortium arrangements may involve personnel costs, supplies, and other allowable costs, including Facilities and Administrative (F&A) costs. Contractual costs for support services, such as the laboratory testing of biological materials, clinical services, or data processing, are occasionally sufficiently high to warrant a similar categorical breakdown of costs. For each budget from a participating consortium/contractual organization, leave the "Consortium/Contractual Direct Costs" category blank and use the "Subtotal Direct Costs" category to total the consortium direct costs. When F&A costs are requested by a consortium organization, enter those costs in the "Consortium/Contractual F&A Costs" category for each supplementary budget. Provide the F&A cost base and rate information in the budget justification section. The "Total Direct Costs for Initial Budget Period" category can be used for the consortium/contractual Total Costs (Direct Costs plus F&A). For the applicant organization budget, list the sum of all consortium/contractual costs (direct and F&A). Insert additional budget page(s) after the overall budget page, numbering them sequentially.

**Budget for Entire Proposed Project Period Direct Costs Only:** Grants that are accepted will be awarded funding for one year (the Initial Budget Period mentioned above). However, applicants may submit requests for up to two or three years of funding (total); continuation years could be funded depending on availability of funds, and only if substantial progress is evident.

**Biographical Sketches:** Follow the instructions on the Biographical Sketch Format Page, and refer to the sample biosketch provided. Each Biographical Sketch may not exceed 5 pages. This section must contain the biographical sketches of all individuals listed as Senior/Key Personnel and Other Significant Contributors, following the order as listed on Form Page 3.
Resources: This information is used to assess the capability of the organizational resources available to perform the effort proposed.

- Identify the facilities to be used (laboratory, ASCEND core laboratory (see website), clinical, animal, computer, office, other). If appropriate, indicate their capacities, pertinent capabilities, relative proximity and extent of availability to the project. Describe only those resources that are directly applicable to the proposed work. Provide any information describing the Other Resources available to the project (e.g., machine shop, electronic shop) and the extent to which they would be available to the project.
- 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.
- If there are multiple performance sites, describe the resources available at each site.
- Describe any special facilities used for working with biohazards or other potentially dangerous substances. Note: Information about Select Agents must be described in the Research Plan, 5.5.11 (Select Agent Research).

Appendices: Graphs, diagrams, tables, and charts should be included in the body of the Research Strategy unless a PDF file is necessary to show detail. Provide a summary listing all of the items included in the appendix. Applicants are prohibited from using the appendix to circumvent page limits in any section of the application for which a page limit applies.

Review Criteria: Reviewers will consider standard review criteria in the determination of scientific merit, based on the requirements for each section as written in this document and in the forms, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact.

Training in the Responsible Conduct of Research: Documentation must be provided to show that each investigator involved in the project has participated in training in the responsible conduct of research, whether through OSPR at Morgan State (e.g., CITI), or otherwise.

Protection for Human Subjects: A completed MSU IRB application specific to the proposed research must be submitted with the proposal by the June 15 deadline; these IRB applications will be submitted for review in August 2016. 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. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.
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. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Planned Enrollment Report: If this application involves the Inclusion of Women and Minorities, complete the Planned Enrollment Report.

Vertebrate Animals: NIH and reviewers 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. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animal Section.

Review and Selection Process: Applications will be evaluated for scientific and technical merit by appropriate external reviewers convened by ASCEND, in accordance with NIH peer review policy and procedures. As part of the scientific peer review, all applications will receive a written critique and a score.

The following will be considered in making funding decisions:
• Scientific and technical merit of the proposed project as determined by scientific peer review.
• Availability of funds.
• Relevance of the proposed project to program priorities.

Appeals of initial peer review will not be accepted for applications submitted in response to this funding opportunity announcement. Following initial peer review, recommended applications will receive a second level of review by NIH officials.

Reporting: Reporting to the ASCEND Center for Biomedical Research is required. The exact reporting requirements will be detailed if the proposal is successful.

Much, but not all, of the text of this guidance come from the PHS 398 guidance provided by US DHHS.