

PROCEDURES FOR THE SOLICITATION, APPLICATION AND REVIEW OF THE LILLY SEED GRANTS

Objective

The objective of the Lilly Seed Grant Program is to provide seed money to support innovative research in one of the following target areas:

1. *Medication Safety*: a focus on applying systems approaches to improving the safety of current drug distribution and administration systems.
2. *Counterfeit Medications*: an emphasis on applying modern technological approaches (chemical or electronic signatures) for assuring the integrity of drug products from the point of manufacture to patient administration.
3. *Optimization of Drug Manufacturing*: an emphasis on methods to develop integrated, predictive models for pharmaceutical processing – particularly the production of drug combination products; all with the aim of reducing the time to introduce innovative and generic drug products to the market.
4. *Application of Nanotechnology to Cancer Therapeutics*: a focus on the application of nanotechnology to reduce the toxicity of cancer therapeutics agents.

Scope of the Application

Applications must address one of the four target areas given above. The Principal Investigator (PI) must be a faculty member in one of the three departments within the School of Pharmacy and Pharmaceutical Sciences: Industrial and Physical Pharmacy, Medicinal Chemistry and Molecular Pharmacology, and Pharmacy Practice. The proposal may include other co-Principal Investigators (co-PIs). *Strong preference will be given to interdisciplinary proposals.* Full applications will be accepted for two deadlines each year, October 1 and March 1 starting October, 2007 and ending March 2009. Funding decisions will generally be made by November 15 and April 15 respectively. It is expected that projects would be initiated within 3 months of the funding decision.

The maximum total budget for a proposal will be \$100,000 with project periods not to exceed 2 years. Projects with budgets \$50,000 or less with project periods 1 year or less are encouraged. Applications will not be renewable. Faculty may submit one proposal as PI for each deadline.

Letters of Intent

The letter of intent must include the following information.

1. Cover page (1 page; use the form provided)
 - a. Title of the proposal
 - b. Applicable initiative(s)
 - c. Names and addresses of all faculty investigators
 - d. Signature of PI
2. Abstract of proposed project, including a paragraph describing how the research addresses the initiative specified on the cover page, and a separate paragraph describing how the PI is uniquely qualified to conduct the proposed research. (1 page)
3. A list of five suggested reviewers who are experts in the field. These suggested reviewers should include faculty members from Purdue where possible. The list may include colleagues with whom the PI or co-PIs have published or with whom they have collaborated provided the last joint publication occurred more than three years ago. Please provide contact information (email and phone) for these reviewers.

All letters of intent must be submitted electronically as PDF files, by noon of the due date.

Structure of the Application

The applications shall take the following form.

1. Cover page (1 page; use the form provided)
 - a. Title of the proposal
 - b. Applicable initiative(s)
 - c. Names and addresses of faculty investigators
 - d. Signatures of PI, co-PIs, and department heads
2. Abstract of proposed project, including a paragraph describing how the research addresses the initiative specified on the cover page, and a separate paragraph describing how the PI is uniquely qualified to conduct the proposed research. (1 page)
3. Summary of the work proposed containing the following sections. (maximum length 6 pages single-spaced; Arial or Helvetica font; font size 11; 0.5 in margins)
 - a. Specific aims (0.5 pages)
 - b. Background and significance (0.5 to 1.5 pages)
 - c. Plan of Research (3 to 4 pages)
 - i. Description of prior work if applicable
 - ii. Description of proposed work with an emphasis on how the project addresses the initiative(s) in a new and creative way
 - iii. Description of collaborative aspects of the project including details of integration and potential for synergistic interaction
 - iv. Timeline for accomplishing the specific aims and a list of milestones
 - d. Cited Literature (0.5 to 1.5 pages)
 - e. Letter(s) of support from *consultants* and *unsupported collaborators*. *Unsupported collaborators* are investigators participating in the project whose contributions are independently supported by other means. They are to be distinguished from co-PIs and collaborators who are to receive support from the grant. The roles of the co-PIs and collaborators must be explicitly specified in the proposal. The support letters provide the *consultants* and *unsupported collaborators* with an opportunity to delineate value-added contributions to the project beyond the tasks described in the proposal.
4. A plan for using the results from this seed project to write and submit proposals to obtain support from outside granting agencies must be provided (0.5 page). If the PI has been successful in the past at leveraging seed funds (from any source) to obtain extramural funding, these efforts should be described briefly (0.5 p.).
5. Additional materials
 - a. NIH style 2-page biographical sketch for each PI and co-PI; for any personnel listed in the budget other than graduate students; and for any consultants and unsupported collaborators.
 - b. A complete list of all existing and pending grant support for each PI. This list should include any additional sources of support applied for or planned for this project. Each source of support should list the following:
 - i. Project title
 - ii. Agency and Grant Number (if applicable)
 - iii. Total project period
 - iv. Direct costs awarded or requested for current period
 - c. Budget on the form provided. (See the RFP for details of budget preparation.) If two years of support are requested, please provide a separate budget page for each year. Requests for permanent equipment and travel are generally discouraged and will be considered only when exceptionally well justified.

- d. A list of five suggested reviewers who are experts in the field. These suggested reviewers should include faculty members from Purdue where possible. The list may include colleagues with whom the PI or co-PIs have published or with whom they have collaborated provided the last joint publication occurred more than three years ago. Please provide contact information (email and phone) for these reviewers.

All proposals must be submitted electronically as PDF files, by noon of the due date. In addition, each proposal must include an SPS submission form (transmittal check sheet).

Progress Reports

There will be a mandatory investigators' meeting once per year for each initiative area and an annual workshop in which investigators from all initiative areas report the results of their research through oral presentations. Acceptance of seed grant awards will indicate the willingness of the PI. to attend Progress Report Meetings and the annual workshop. In addition, grant recipients will be expected to be available to serve on the *ad hoc* review panel for the subsequent round of submissions.

At the completion of the grant period the PI will be required to submit a ***final report*** to the Associate Dean for Research. The report should summarize the goals and accomplishments of the project. A list of (1) publications, (2) abstracts, and (3) proposals submitted stemming from this grant should be attached. Final reports will be presented to and reviewed by the Pharmacy Executive Committee.

Review Process

All proposals will be submitted to a two-stage review. In the first stage, applications will be assessed solely based upon scientific merit, while the second stage will include assessment based on programmatic priorities.

For the first stage review, proposals will be reviewed by an *ad hoc* panel consisting of three members appointed by the Associate Dean for Research, with a panel selected for each initiative area. Each panel, whose chair will be appointed by the Associate Dean for Research, will consist of a combination of School and non-School reviewers (and may include non-Purdue members). Each *ad hoc* panel will identify a maximum of three proposals for consideration of funding. These proposals, along with a summary of the panel's review, will be submitted to the Associate Dean for Research for the second stage review. If a panel is unable to identify three proposals it deems merit funding, it may submit fewer than three proposals for the second stage review. The proposals selected will be forwarded unranked for second stage review.

The second stage review will be conducted by the Pharmacy Executive Committee (PEC). The PEC will evaluate the proposals submitted by each panel.

Criteria for the First-Stage Review

All reviews will be confidential. Reviewers will be provided with the following guidelines for reviewing grant proposals

The reviews should contain the following sections, but given the length and scope of the proposals the comments should be concise (a few sentences in each of the following sections).

Significance: Does this study adequately address the stated goals of the initiative? If the aims of the application are achieved, how will scientific knowledge towards these goals be advanced? What will be the effect of these studies on the concepts or methods that drive this field?

Approach: Are the conceptual framework, design, methods, and analyses adequately developed, well-integrated, and appropriate to the aims of the project? Does the applicant acknowledge potential problem areas and consider alternative tactics?

Innovation: Does the project employ novel concepts, approaches or method? Are the aims original and innovative? Does the project challenge existing paradigms or develop new methodologies or technologies?

Investigator: Is the investigator appropriately trained and well suited to carry out this work? Is the work proposed appropriate to the experience level of the principal investigator and other researchers (if any)?

Resources and Environment: Does the scientific environment in which the work will be done contribute to the probability of success? Do the proposed experiments take advantage of unique features of the scientific environment or employ useful collaborative arrangements?

Potential to attract extramural funding: Do you think that the proposed work, if accomplished, will allow the investigators to prepare a proposal that would be competitive for extramural funding.

Summary: Briefly summarize the strengths and weaknesses of the application.

Criteria for the Second-Stage Review

Scientific Merit: Judgment of scientific merit will be based on the review provided by the *ad hoc* panels.

Balance among Initiatives: Where possible, the PEC will attempt to provide at least \$100,000 of funded projects in each of the initiative areas for each funding cycle.

Interdisciplinary Strength of the Project: Projects that leverage existing campus resources and expertise are especially encouraged.

Success in Leveraging Previous Seed Funding for Extramural Awards: As the goal of this program is to stimulate new areas of research that can be sustained, previous success in accomplishing this goal will strengthen an application.