



## Guidelines for Proposal Review of Scientific and Technical Merit

### 2012 Life Sciences Discovery Fund PreCede Grant Competition

#### A. Introduction and Background

**Introduction.** These guidelines apply to the Life Sciences Discovery Fund (LSDF) 2012 PreCede grant competition and are for scientific/technical expert proposal reviewers engaged by the American Association for the Advancement of Science (AAAS). Before starting your reviews, read the Request for Proposals (RFP) for this grant competition, which can be found at:

[http://lsdfa.org/documents/LSDF\\_2012\\_PreCede\\_Grant\\_Competition\\_RFP.pdf](http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_RFP.pdf)

These guidelines will also be posted on the LSDF website. Although this document highlights the competition's purposes and requirements, it is not a substitute for the RFP.

**Contact Information.** If you have questions at any point during the review, contact:

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**Background of the Life Sciences Discovery Fund.** LSDF was created by the Washington State Legislature to receive payments from the master tobacco settlement to invest in life sciences research and development. LSDF carries out its mission by making grants to promote life sciences competitiveness, enhance economic vitality, and improve health and health care.

**Board of Trustees.** LSDF is governed by a board of trustees, which has final award-making authority. The board is considerably informed by the expert review process, but uses additional criteria in making award decisions.

**Expectations of Reviewers.** LSDF achieves its mission by funding proposals through a competitive granting process, the success of which depends upon superb expert review. **The AAAS review covered by this guide is restricted to the scientific and technical merit of the proposals. Commercial/business and financial reviews of these proposals will be performed by other experts recruited by LSDF.**

As a reviewer, you are expected to protect the confidentiality of the applicants' proposals and of the review process itself and to abide by a strict standard in avoiding any conflict of interest. Any concerns you may have about a proposal or your ability to review it impartially should be communicated in confidence to AAAS.

*Confidentiality.* The proposals and the review process are confidential. If you believe that additional expertise is needed to review a proposal, you should not solicit it yourself, but instead notify AAAS to make arrangements for outside assistance. You must not contact applicants or the LSDF Board of Trustees regarding a proposal. You will be asked to sign a Confidentiality Certification prior to reviewing LSDF proposals.

*Conflict of Interest.* A perceived or actual conflict of interest exists when a reviewer has an interest associated with a grant proposal that may bias his or her evaluation of it. There are several bases for a conflict of interest: employment, financial arrangements, personal or professional relationships, or other personal interests. Any one condition may disqualify you from participating in the review of a proposal. If you feel that there may be a conflict or a perception of conflict, notify AAAS, who will make the determination about your ability to review a proposal. As part of your duties as an LSDF expert reviewer, you will be expected to sign a declaration that you have disclosed all conflicts of interest that you may have with the proposals.

**Revisions to these Guidelines.** If revisions or additions to these guidelines are necessary, LSDF will post them on its website and send them to you through AAAS.

## **B. Competition Goals and General Proposal Review Considerations**

Commercialization of new health- and health care-related products and services (together generically referred to in this document as “products”) is a key component of LSDF’s mission. PreCede grants will focus on validation of the commercial merit of new technologies, work that is often referred to as “proof of concept” or “prototype development.” The immediate goal of PreCede grants is to lower commercialization risk, thereby making early-stage companies more attractive for near-term equity investment. Such equity investment will strengthen Washington’s early-stage companies and enhance the probability that new technologies and concepts will be developed into marketable products.

Proposals with the potential to have near-term impact on improving health and health care, while also reducing the associated costs, are especially desirable. However, work funded under this competition does not have to result in a market-ready commercial product by the end of the grant term.

LSDF intends to award up to \$300,000 in grants in the 2012 PreCede grant competition, enough to fund two grants. To be competitive for funding, applicants must convincingly demonstrate that LSDF support is uniquely appropriate and necessary to procure equity investment funding to help commercialize the proposed product.

**What is Fundable under a PreCede Grant?** PreCede grants support applied research and development, not basic or discovery research. All funded activities must be scientifically and technically rigorous and enhance the ability of the applicant to procure investment capital.

Applicants must provide a clear description of the product under development. Products must address both a market need and a health or health-care need relevant to Washington. Funded work must have the potential to be beneficial to the Washington economy and to health and

health care—that is, not merely continuing the current state of care or practice, but changing it demonstrably for the better. PreCede grants will fund research and development leading to new commercial products, including, but not limited to, new approaches to:

- provide tools that have the potential to lead to breakthroughs in health-related research;
- diagnose, treat, prevent, or manage disease;
- manage health-care delivery environments and systems;
- promote healthy patient behaviors and patient compliance with care-providers' recommendations;
- better integrate care providers, patients, and health-care systems; or
- accomplish any of the above in a manner that reduces health-care costs.

Types of projects envisioned for PreCede grants include:

- Experiments to validate a technology's use for a generic purpose: that a novel method can be used to deliver a chemical substance; that a new assay reporter system has an acceptable sensitivity range; or that inhibition of a specific enzyme has a desired cellular effect.
- Experiments to validate a technology's use for a specific purpose: an animal study to show that inhibition of an enzyme has a desired clinical effect; confirmation that a specific biomarker correlates with disease; or measurement of a physiological parameter in an animal model in response to treatment with a therapeutic device.
- Construction of a prototype product: assembly of an integrated research instrument to facilitate use with human subjects; chemical modification of a promising compound to generate a more suitable candidate drug; or development of a graphical user interface for a piece of software.
- Testing of a prototype: use of an instrument to image a specific anatomical region; pharmacokinetic studies on a possible drug lead; testing that a software tutorial can improve clinical practice; or safety or efficacy trials of a new drug or device in human subjects.

These examples are for illustration only and are not the only types of projects supportable or solicited in this competition.

PreCede grants will **not** support:

- Activities focused primarily on marketing research/studies; or
- Activities related to intellectual property protection, including but not limited to patent filings, freedom to operate analyses, or other legal expenses.

LSDF recognizes that the research and development activities and the commercial opportunities proposed by applicants are inherently risky. In moving technology from promising companies along the commercialization pathway to facilitate equity investment, LSDF is willing to accept scientific, technical and business risk.

**Proposal Evaluation and Rating Process.** The proposal consists of two main sections (technical narrative and business plan) plus supporting documents (budget, biosketches, letters of support, etc.). Evaluation of the proposal's scientific and technical merit, including the appropriateness of the budget, will be undertaken by two separate reviewers (you and one other), through your engagement by AAAS. **Separate expert evaluations of the applicant's financial documents and of the health, health-care, commercial (e.g., market size, competition,**

intellectual property position) and economic merit of the proposal will be performed by financial experts and by a panel recruited by LSDF respectively. Even though your evaluation focuses on scientific, technical, and budget issues, you are strongly encouraged to read the full proposal, particularly the business plan, for context.

Your evaluation of the proposal will be provided to commercial reviewers in advance of their panel meeting. The commercialization panel will incorporate your comments into its own evaluation and make the final funding recommendations to the LSDF Board of Trustees. Your identity will remain confidential and will not be shared with commercial reviewers or applicants.

You will write a review of each proposal, supporting your recommendation regarding its scientific and technical merit. You will rate the proposal's scientific and technical merit as "excellent," "good," or "poor."

Principal investigators will receive the reviews of their proposals, so these reviews must be constructive and written with care, accuracy, and respect.

The overall review should consider all scientific and technical aspects of the proposal, and, to be of most help to LSDF and to proposal submitters, it must be thorough. Do not describe the investigator's plans in detail, but briefly describe the overall goals of the proposal. Then summarize the scientific and technical strengths and weaknesses of the proposal. Put strengths and weaknesses in perspective by indicating their relative magnitude. Evaluate and comment on the appropriateness of the budget. The budget justification is in a freestanding document to encourage applicants to provide sufficient detail for evaluation. If any changes in the budget are recommended, explain what changes should be made and why. In a very strong proposal, the technology will be innovative, the scientific and technical plan and the budget will be appropriate for the work to be performed, the team will be complete and highly qualified to accomplish the work, and the project outcomes will be feasible and well defined.

Because the impact of a technology on health and health care can often be intertwined with scientific and technical aspects of a proposal, an **optional** comment field for health and health-care impact is provided.

**Pre-proposal.** The proposals you will review were preceded by pre-proposals. Principal investigators received written feedback on their pre-proposals from a commercialization expert panel convened by LSDF. Consequently, you may see references in proposals to the pre-proposal review.

### C. Detailed Proposal Review Criteria

**Collaborators.** LSDF understands that early-stage companies often do not have the depth of scientific and technical expertise on staff or the necessary equipment or facilities to perform the proposed work on their own. Consequently, an application may list a non-technical individual as the principal investigator and include one or more subcontractors (e.g., a university) or service providers (e.g., a contract research organization) that will help execute the scientific/technical program. In this event, reviewers should focus their evaluation on the organizations and individuals proposed to execute the work plan.

**Specific Review Criteria.** (Read Sections 2.1.1 and 2.1.2 in the RFP for further context.) The principal review criteria are derived from LSDF's mission. Proposals are reviewed for their (1) scientific and technical merit, (2) impact on health and health care, and (3) commercial merit and future economic returns, all in the context of stimulating the applicant organization's ability to present a compelling case for equity investment. **AAAS reviewers will comment on (1) and have the option of commenting on (2). The commercial review panel will focus its attention on aspects (2) and (3) after your evaluation.** Your review will describe the proposal's strengths and weaknesses, including the appropriateness of the budget. If you wish, you may comment on (2) inasmuch as it relates to the scientific and technical merit. For example, the scientific merit of the proposal may be high, but you may believe that alternative approaches are more clinically relevant, or that the technology is too complicated for physicians or patients to use, or that the technology has advantages such as low power requirements that are primarily useful in low resource environments.

In addition, you will be asked to note any scientific or technical areas or serious issues that should be addressed if the proposal is not funded and the principal investigator resubmits the proposal for a later competition.

Rate the proposal as it is presented in light of its probability of success, not on its theoretical potential, *i.e.*, do not rate the proposal on what it could become if it were improved or changed.

**AAAS Review Criteria in Detail.** Your review of proposals is based on your judgment of the extent to which a proposal:

- demonstrates that the proposed product is beyond the stage of basic or discovery research;
- provides a promising approach to solving the problem being addressed;
- establishes a framework for the proposed activities with strong potential to achieve novel and important results;
- defines clear and realistic outcomes;
- demonstrates the principal investigator's and any co-investigators' commitment, experience, and ability to execute the proposed work successfully;
- demonstrates, where collaboration is proposed, that investigators have a history of effective collaboration and an appropriate plan to manage the collaborative process;
- demonstrates that subcontractor's and service provider's personnel and facilities are appropriate if the majority of the proposed activities will be performed by such entities; and
- justifies that the budget is appropriate to the scope and goals of the proposed work.

A strong scientific and technical plan will be necessary, but not sufficient, for funding.

## D. Overall Rating

**Indirect costs.** LSDF grants pay the full costs of accomplishing the proposed activities including facilities and administrative costs, with all costs expressed as direct costs. Reviewers are not expected to determine how the principal investigator arrived at any facilities and administrative charges.

**Outliers.** LSDF understands that proposal quality will vary across the core review criteria. For example, a proposal that may be scientifically unexciting may address a major health or health-care need. As you prepare your evaluation, make special note of compelling opportunities within proposals that might otherwise be considered ordinary or overly risky.

**Rating.** Use the following guidelines to rate proposals' scientific and technical merit:

Scientific and technical merit is excellent

Scientific and technical merit is good

Scientific and technical merit is poor and lacking in one or more critical areas

## AAAS Evaluation Comment Form

### Proposal Review of Scientific and Technical Merit for 2012 PreCede Grant Competition

Request ID:  
Proposal Title:  
Principal Investigator:  
Applicant Organization:  
Request Amount:

**Note: this form is a sample and will not be provided to reviewers in the Guide. The actual form and mechanism are provided through AAAS' online proposal evaluation system.**

#### Overall scientific and technical merit:

- Scientific and technical merit is excellent
- Scientific and technical merit is good
- Scientific and technical merit is poor and lacking in one or more critical areas

Analyze the proposal's scientific and technical merit and provide constructive comments. Indicate the relative magnitude of both strengths and weaknesses.

Overall comments:
Strengths:
Weaknesses:

Comment on the appropriateness of the budget and explain any recommendations for changes.

Comments:
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**Scientific or technical areas or serious issues to be addressed.** Note any scientific or technical areas or serious issues that should be addressed if the proposal is not funded and the applicant resubmits the proposal for a later competition.

Comments:
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**Optional:** You may comment on the proposal's health and health-care merit, as it relates to the scientific and technical merit.

Overall comments:
Strengths:
Weaknesses: