

Commercial Reviewer Guidelines

Pre-proposals for 2012 PreCede Grant Competition

New for 2012:

- This inaugural PreCede grant competition funds research and development activities to help position early-stage Washington life sciences companies with commercially promising health-related technologies for their first significant round of equity investment funding.
- Non-profit entities and educational institutions may not apply for PreCede grants.
- Reviewers will recommend a subset of the pre-proposals for invitation to submit full proposals. Without an invitation, a full proposal will not be accepted by LSDF.

A. Introduction and Background

Introduction. These guidelines apply to the Life Sciences Discovery Fund (LSDF) 2012 PreCede grant competition and are for commercial expert pre-proposal reviewers. 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

as well as within the online reviewer system. These Reviewer Guidelines will also be posted in both places. 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. As a reviewer, you are expected to protect the confidentiality of the applicants' pre-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 pre-proposal or your ability to review it impartially should be communicated in confidence to LSDF.

Confidentiality. The pre-proposals and the review process are confidential. If you believe that additional expertise is needed to review a pre-proposal, you should not solicit it yourself, but instead notify LSDF to make arrangements for outside assistance. Except as authorized by LSDF, you must not contact applicants or the LSDF Board of Trustees regarding a pre-proposal. Should an applicant contact you about his/her application, please refer the applicant to LSDF without discussing the application or its review. You will be asked to sign a Confidentiality Certification prior to reviewing LSDF pre-proposals.

Conflict of Interest. A perceived or actual conflict of interest exists when a reviewer has an interest associated with a grant pre-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 pre-proposal. If you feel that there may be a conflict or a perception of conflict, notify LSDF, who will make the determination about your ability to review a pre-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 pre-proposals.

Revisions to these Guidelines. If revisions or additions to these guidelines are necessary, LSDF will post them on its web site and send them to you by email.

B. Competition Goals and General Pre-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.

Eligibility Criteria. Two of the eligibility criteria for a PreCede grant require an exercise of judgment.

- Applicant organizations must have a substantial presence in Washington, where presence is based on factors including, but not limited to: number of full-time equivalent employees who are residents of Washington and their relative levels of compensation compared to the applicant's other sites of activity; having research and development, administrative, or manufacturing facilities located in Washington; payment of Washington Business and Occupation or other taxes; or any combination of such factors.
- Applicant organizations must not have received substantial equity investment prior to PreCede grant funding.

In both cases, LSDF has not indicated a clear quantitative criterion for what constitutes "substantial" to permit flexibility during the application evaluation process.

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. Applications may focus either on technologies that were developed entirely at the applicant organization or those that were licensed from another entity. In either case, the applicant organization must have clear title or access to key intellectual property.

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.

Pre-proposal Evaluation and Rating Process. The pre-proposal is an opportunity for the applicant to provide LSDF with an overview of its technology and business plan without having to take the time to make a full proposal submission. Pre-proposal evaluations will be performed by small groups of commercialization experts like yourself (each constituting a "panel") to assist LSDF in making an assessment of the suitability of the proposed research and development activities for PreCede funding. Applicants whose pre-proposals are deemed promising will be invited to submit a full proposal. Only invited applicants may submit full proposals.

The expert review process consists of three stages:

- First, using an online form provided by LSDF, you will review and evaluate pre-proposals individually, according to your judgment of their strengths and weaknesses, in advance of the panel meeting.
- Second, you will meet with the other members of your panel to evaluate the pre-proposals. Principal investigators will be interviewed by your panel, either in person or

by telephone, to answer questions about the commercial and scientific/technical aspects of the proposed work. During the exchange, the panel may offer constructive criticism regarding the strengths and weaknesses of the pre-proposal. To enhance the discussion, applicants will be encouraged to make available an additional person so that both the scientific/technical and the business cases associated with the proposed work can be addressed. Depending upon pre-proposal volume, 30-60 minutes will be allotted to each pre-proposal (15-30 minutes for the interview and 15-30 minutes for panel evaluation). The panel's ultimate objective is to place pre-proposals into one of two rating categories ("invited" or "not invited"), reflecting its collective recommendation for advancing the pre-proposal to a full proposal submission.

- Third, after the meeting of the review panel, a summary evaluation will be written by LSDF staff based upon the reviewers' written comments and panel discussion. The summary reviews will be shared with principal investigators, so all comments provided must be constructive, accurate, and respectful. Principal investigators will not receive individual reviewers' advance comments on pre-proposals.

Panel discussions will be conducted by LSDF staff.

In preparing your pre-meeting written evaluation and during the panel meeting, follow these guidelines:

- The overall evaluation should be thorough. Indicate whether you believe the applicant organization meets the eligibility criteria for this competition. Summarize the strengths and weaknesses of the proposed work and the company's business plan according to the following aspects of LSDF's goals and mission:
 - the potential for improving health and health care;
 - the commercial merit and potential for future economic impact; and
 - the potential to enhance the company's competitiveness for procuring near-term investment funding.

Put strengths and weaknesses in perspective by indicating their relative magnitude.

- In a very strong pre-proposal:
 - the proposed product will address an important market(s), show superiority over existing practices and products, and be protectable as intellectual property;
 - the team will be experienced and have a good grasp of what it will take to commercialize the proposed product; and
 - the anticipated outcome of the work will significantly enhance the company's ability to obtain near-term investment funding.

C. Detailed Pre-proposal Review Criteria

In particular, read sections 1.2, 1.3 and 2 in the RFP for further context.

Collaborators. LSDF understands that early-stage companies often do not have the depth of expertise on staff or the necessary equipment or facilities to perform the proposed work on

their own. Consequently, an application may 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. Preference will be given to work that is partnered with an in-state entity.

Coordinating Science and Technology with Business Development. While the centerpiece of PreCede grants is research and development, commensurate progress must be made on refining the business case during the grant period. Compelling pre-proposals will demonstrate coordination between execution of the scientific/technical agenda and development of the business case, with each track informed and enhanced by the other.

Specific Review Criteria. Applicants have been asked to provide brief descriptions of several key aspects of their proposed work. These aspects constitute the following primary criteria that commercial reviewers use to evaluate pre-proposals:

- the applicant organization must have a substantial presence in Washington and it must not have already received substantial equity funding;
- company principals (management, board, key advisors) must have the experience needed to commercialize the proposed product;
- there must be a clear and understandable description of the proposed product;
- the proposed product must have the potential to improve health or health care and benefit the economy in Washington;
- the proposed product must be beyond the stage of basic or discovery research;
- there must be a clear description of who would buy the product and why;
- the potential market size, in Washington and beyond, for the proposed product must be commercially viable, and there must be reasonable plans for addressing any key barriers to market entry or penetration;
- there must be a compelling argument for the superiority of the proposed product over existing products and those under development;
- the scientific and technical plan must be logical and feasible;
- the steps to be taken to advance the business case during the grant period are reasonable and well aligned with the proposed scientific and technical activities;
- the applicant organization must have clear title or access to key intellectual property (or reasonable plans to procure such rights in a timely manner), and the intellectual property protection plan (or other features that pose barriers to competition) for the product must be clear and appropriate for the target market;
- as appropriate, there are reasonable plans for obtaining regulatory approval and reimbursement from third-party payers; and
- the applicant organization makes a compelling case for how LSDF funding will help position the company for near-term equity investment.

Construct your evaluation of the pre-proposal with descriptions of its strengths and weaknesses.

D. Overall Rating

At the pre-proposal review meeting the panel will place each pre-proposal into one of the following two categories:

Invited: good to excellent; submission of a full proposal is invited. Proposals will need to address items identified as needing clarity or improvement to be competitive for funding.

Not Invited: poor, lacking in one or more critical areas; submission of a full proposal is not invited.

Individual Reviewer Comment Form

2012 PreCede Grant Competition Pre-proposals

Request ID:
Pre-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 LSDF's Web-based proposal review system.

A. PreCede grants are made to companies having a "substantial presence" in Washington and having not received "substantial equity investment." Under these criteria, is the applicant organization eligible for a PreCede grant?

Yes___

No___

Comments:

B. Consider the following questions before providing a written evaluation of the pre-proposal below. Feel free to supplement this list with additional considerations you deem to be significant.

- Does the applicant company/product have the potential to contribute to the growth of Washington's economy?
- Is the product well defined?
- Does the product have the potential to improve health or health care in Washington?
- Is the target market for the product well defined and realistic?
- Is the product superior to the competition?
- Is the market commercially viable?
- What barriers to market does the applicant face? Can the applicant realistically address/overcome these barriers?
- Is the applicant on the right track in its business planning?

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- Does the intellectual property plan look sound? Does the applicant have access to the intellectual property it needs to enter the market?
- Is the regulatory/reimbursement plan sound?
- Is the proposed project at the right stage for a PreCede grant (*i.e.*, not basic or discovery research)?
- Are the scientific/technical plan and expected outcomes realistic and well thought out?
- Is this the right team for the project and product development? What expertise is lacking?
- Can a successful grant outcome help the applicant raise investment money in the near term?

Using the questions above as a guide, briefly describe the main strengths and weaknesses of the pre-proposal.

Strengths:

Weaknesses:

Comments: