



Commercial Reviewer Guidelines

Proposals for 2012 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 commercial expert 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' 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 LSDF.

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 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 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 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 LSDF, 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 by email.

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.

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 established 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.

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. You will be a member of a group of commercialization experts (the “panel”) convened to assist LSDF in making an assessment of the suitability of the proposed research and development activities for PreCede funding. The review process initially follows three paths, which come together under your panel. Evaluation of the scientific and technical merit of the proposal, including the appropriateness of the budget, will be undertaken by two separate reviewers recruited by the American Association for the Advancement of Science (AAAS). The applicant organization’s financial documents will be evaluated by financial professional(s) engaged by LSDF. Your primary charge is expert evaluation of the health, health-care, commercial (e.g., market size, competition, intellectual property position), and economic merit of the proposal, and you will incorporate the AAAS and financial evaluations into your review.

The commercialization expert review process consists of three stages:

- First, you will review proposals individually and, using an online form provided by LSDF, evaluate them in advance of the panel meeting according to your judgment of their strengths and weaknesses. You will also consider the scientific and technical evaluations provided by AAAS and the financial evaluation.
- Second, you will meet with the other members of the panel to evaluate all of the proposals. (Financial reviewers will participate in this panel as non-voting members.) The evaluation will include an in-person interview with each principal investigator for a period of up to 45 minutes. Prior to the panel meeting, principal investigators will have received their AAAS evaluations. 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. The panel’s ultimate objective is to place proposals into one of three rating categories, “highly recommended,” “recommended,” or “not recommended,” reflecting its collective judgment regarding their suitability for funding.
- Third, after the meeting of the review panel, a summary evaluation of each proposal 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 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. Summarize the strengths and weaknesses of the proposed work and the applicant'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 applicant's competitiveness for procuring near-term investment funding.
- Put strengths and weaknesses in perspective by indicating their relative magnitude. In a very strong proposal:
 - the proposed product will address an important market(s), show superiority over existing practices and products, and be protectable as intellectual property;
 - the scientific/technical and business 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 applicant's ability to obtain near-term investment funding.

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. The written consensus reviews of the pre-proposals will be available to you in the online reviewer system.

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 include one or more sub-contractors (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 (e.g., writing a business plan, performing market research, developing a regulatory strategy, meeting with potential investors). Compelling 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. (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). The commercial panel will incorporate the separately conducted financial review into criterion (3). Cite the proposal's strengths and weaknesses in your reviews.

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.

Review Criteria in Detail. Your review of proposals is based on your judgment of the extent to which a proposal meets each of the criteria listed below.

(1) Scientific and Technical Merit. Review of the scientific and technical merit of the proposal, including the appropriateness of the budget, will be undertaken by independent expert reviewers recruited by AAAS. The AAAS reviews of the proposal will be provided to you in advance of the panel meeting.

In your deliberations as a panel, you will consider the scientific and technical merit as reported by the AAAS reviewers. Overall, the scientific and technical plan must be logical and feasible. A strong scientific and technical plan is necessary, but not sufficient, for funding. Proposals with flawed scientific or technical plans should not be recommended for funding. You should not "re-review" the proposal for scientific and technical merit or the budget, but if in your judgment the AAAS reviews are inaccurate, raise that point in your preliminary review and during the panel discussion. Individual AAAS reviewers will not necessarily agree on the scientific and technical merit.

Principal investigators will also be provided with a copy of the AAAS scientific and technical reviews of their proposals in advance of the panel's meeting. The panel may query the principal investigator about the scientific and technical reviews during the interview at the panel meeting.

(2) Impact on Health and Health Care. The impact of the proposed activities on health and health care within Washington will be judged by how well the proposal demonstrates the following qualities:

- it addresses a significant problem in health or health care in Washington;
- it has excellent potential to make a substantial, beneficial, and measurable contribution to improving health and health care in areas such as:
 - improved tools that have the potential to lead to breakthroughs in health-related research;
 - improved diagnosis, treatment, prevention or management of disease;
 - better management of health-care delivery environments and systems;
 - promotion of healthy patient behaviors and patient compliance with care-givers' recommendations; or
 - accomplishing any of the above in a more cost-effective manner.

Principal investigators may propose a broad range of improvements in health or health care, and the impact of the proposed work may be near- or long-term, with near-term benefit being especially desirable. LSDF will give priority to proposals that address widespread health and health-care problems and that provide compelling evidence that they have the potential to yield benefits for the greatest number of Washington residents.

Even though AAAS reviewers will have had the opportunity to comment on the health and health-care impact of the proposed activities (to the extent that the impact of a technology on health and health care can often be intertwined with scientific and technical aspects of a proposal), the commercial panel will be the formal reviewer for this criterion.

(3) *Commercial Merit and Future Economic Returns*. Principal investigators must make a compelling argument for the commercial merit of the technology under development and present a strong case that LSDF support will enhance the applicant organization's ability to raise investment funding. You will incorporate the review conducted by the financial reviewer(s) into your evaluation of this criterion. Financial reviewers will be available during the panel meeting to provide input and may ask questions of the applicants. The proposal must:

- provide a clear and understandable description of the proposed product and the problem it addresses;
- provide a clear description of who would buy the product and why;
- show that the potential market size for the proposed product is commercially viable;
- present a compelling argument for the superiority of the proposed product over both existing products and those in development;
- demonstrate that the applicant organization has clear title or access to key intellectual property;
- present an intellectual property protection plan (or other features that pose barriers to competition) for the subject matter of the proposed work that is clear and appropriate for the product and the target market;
- address any key barriers to market entry or penetration;
- include a reasonable plan to advance the business case for the proposed product during the grant period;
- provide evidence that the applicant organization has financial acumen consistent with its being able to successfully execute its business plan and procure equity funding in the near term;
- provide evidence that applicant's principals (management, board, key advisors) have the experience and knowledge needed to commercialize the proposed product;
- make a reasonable case that LSDF support will promote job creation and retention in Washington;
- present, as appropriate, reasonable plans for obtaining regulatory approval and reimbursement from third-party payers;
- demonstrate a commitment on the part of the applicant organization toward commercialization of the proposed technology; and
- present a compelling case for how LSDF funding will help position the applicant for near-term equity investment.

The proposed benefits of the work to the state's economic environment must be clear. Benefits may include, but are not limited to, the following:

- measurable gains in cost-effective health care due to the application of the results of the work through commercialization;
- future economic gains due to improvements in health or health care induced by the proposed work, e.g., through restoring work time that would otherwise be lost;

- new training and employment opportunities fostered by the proposed work; and
- future research and development funding enabled by the LSDF grant.

D. Overall Rating

Funding. Funds available are sufficient for only two awards. It is acceptable if the panel finds fewer proposals to be meritorious, as it is LSDF's desire that only the best proposals be recommended for funding. The panel's summary reviews, including the AAAS scientific and technical evaluations, will be presented to the Board of Trustees, which will take them into account in making award decisions. LSDF staff may request that the commercial panel rank proposals in order of their priority for funding. Such rankings may be shared with the board, but not with the principal investigators.

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 commercial opportunity or health or health-care need. As reviewers discuss proposals, LSDF asks them to 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 as a panel:

Highly Recommended: outstanding, deserves highest priority for funding

Recommended: good, worthy of consideration for funding

Not Recommended: poor, lacking in one or more critical areas; funding not recommended

Individual Reviewer Comment Form

Proposals for 2012 PreCede Grant Competition

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

Note: the actual form and mechanism are provided through LSDF's web-based proposal review system.

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

- Has the applicant organization already received substantial equity investment?
- Does the applicant organization have a substantial presence in Washington?
- Does the 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?
- 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?
- Do the applicant's financials indicate sound financial practice and a realistic approach to moving forward?
- 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?

A. Briefly provide an overall review of the proposal and indicate the relative magnitude of both its main strengths and weaknesses. Include any recommendations for changes to the budget.

Overall comments:
Strengths:
Weaknesses:

Review the proposal's responsiveness to the following key criteria and provide constructive comments:

B. Health and health-care impact. What is the potential for the proposed product to significantly improve health or health care in Washington? Include whether near-term benefits are likely.

Comments:

C. Economic impact. Describe the main strengths and weaknesses of the proposal relative to its future economic impact on Washington.

Strengths:
Weaknesses:

D. Impact of LSDF funds. Would LSDF support have a catalytic effect in helping the applicant procure near-term investment funding? If so, how?

Comments:

E. (Optional) Scientific/technical and financial reviews. Commercial review panelist comments on AAAS scientific/technical and/or financial reviews of the proposal:

The panelist offers the following comments:

Comments: