



Financial 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 financial expert proposal reviewers. For your reference, the Request for Proposals (RFP) for this grant competition 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.

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.

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. A proposal is evaluated as it is presented in light of its probability of success, not on its theoretical potential.

Proposal Evaluation and Rating Process. You have been engaged to assist LSDF in assessing corporate financial documents associated with research and development proposals for PreCede funding. Evaluation of the scientific and technical merit of the proposal, including the appropriateness of the budget, will be undertaken by reviewers recruited by the American Association for the Advancement of Science (AAAS). The scientific/technical and financial reviews will be forwarded to an LSDF-convened commercialization panel that will use that information in conjunction with its evaluation of the health, health-care, commercial (e.g., market size, competition, intellectual property position) and economic merit of the proposal. Financial reviewers will be non-voting members of the commercialization panel. The commercialization panel will make final funding recommendations to the Board of Trustees.

The financial expert review process consists of three stages:

- First, you will review the corporate financial documents submitted with the proposals (a table summarizing the sources and amounts of all of the applicant organization's non-equity funding to date, a capitalization table, retrospective financials covering the 12 months prior to proposal submission, and a 36-month financial forecast (by month) of revenues and expenditures) 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 should also review the biographies of the individuals managing the applicant organization to get a sense of their financial management experience. After your review of the financial documents, you will assign a rating of "excellent," "good," or "poor," regarding whether the applicant has exhibited financial acumen consistent with an ability to successfully execute its business plan and procure equity funding in the near term. To gain the best context for your review, you are strongly encouraged to review the proposals in their entirety, especially the applicant's business plan. The substance of your written reviews may be shared with applicants, so all comments provided must be constructive, accurate, and respectful.
- Second, you will attend the commercialization panel meeting where proposals will be evaluated in their entirety. Your evaluation of the proposal will be provided to commercial reviewers in advance of the meeting. 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 scientific/technical and business/financial matters 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. Your role at the meeting will be to comment on the applicant organization's financial documents and to answer questions from the panelists. You may also have the opportunity to ask questions of the applicant team during the interview.
- 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.

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 proposal as informed by your review of the financial documents. Put strengths and weaknesses in perspective by indicating their relative magnitude.
- In a very strong proposal the applicant organization's financial management practices, structure, and projections will indicate financial acumen consistent with its being able to successfully execute its business plan and procure equity funding in the near term.

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; applicant financial documents were not part of the pre-proposal review.

C. Detailed Proposal Review Criteria

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. Your financial review is most closely aligned with aspect (3). 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). Cite the proposal's strengths and weaknesses in your written reviews.

Financial Review Criteria in Detail. A strong financial review will be necessary, but not sufficient, for LSDF funding. The proposal's financial documents should:

- indicate that the applicant has a substantial presence in Washington;
- indicate that the applicant has not already received "substantial" equity investment;
- indicate sound financial practices (including use of Generally Accepted Accounting Principles) in the operations of the applicant;
- be presented in a clear and concise manner, consistent with professional standards;
- not reveal any obligations that might impede future financial health or equity investment;
- indicate a capitalization structure that is conducive to new equity investment;
- project future revenue and expenditures appropriately and realistically for the product being developed and the industry in which that product would compete; and
- indicate a level of financial experience and acumen that would be consistent with the applicant's ability to successfully raise future equity investment.

The commercialization panel will assess the credibility of the applicant's arguments for the commercial merit of the product under development according to the criteria listed below. You are not directly responsible for evaluating how well the applicant meets these criteria, but to the extent that your financial analysis can inform the discussion, you may be asked to participate. Commercial merit is indicated by proposals that:

- 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 company principals (management, board, key advisors) have the experience and acumen 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 company for near-term equity investment.

Finally, 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.

LSDF has reserved the right to do a background personal credit check on key individuals associated with the applicant organization. If you believe that such a credit evaluation is merited, you should indicate so in your written review.

D. Overall Rating

Funding. Funds available are sufficient for only two awards.

Rating. Use the following guidelines to rate proposals:

- The financial documents indicate **excellent** financial acumen in support of executing the applicant's business plan and procuring equity funding in the near term.
- The financial documents indicate **good** financial acumen in support of executing the applicant's business plan and procuring equity funding in the near term.
- The financial documents indicate only **poor** financial acumen in support of executing the applicant's business plan and procuring equity funding in the near term, as they are lacking in one or more critical areas.

Life Sciences

DISCOVERY FUND

Financial 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.

Rating Scale

Use the following scale to rate the proposal:

Overall proposal rating:

- The financial documents indicate **excellent** financial acumen in support of executing the applicant's business plan and procuring equity funding in the near term.
- The financial documents indicate **good** financial acumen in support of executing the applicant's business plan and procuring equity funding in the near term.
- The financial documents indicate only **poor** financial acumen in support of executing the applicant's business plan and procuring equity funding in the near term, as they are lacking in one or more critical areas.

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

- Does the applicant organization have a substantial presence in Washington?
- Has the applicant organization already received substantial equity investment?
- Are the financials presented in a clear and concise manner consistent with professional standards?
- Does the applicant organization have any obligations that might impede future financial health or equity investment?
- Is the capitalization structure conducive to new equity investment?
- Have future revenue and expenditures been projected appropriately and realistically for the product being developed and the industry in which that product would compete?

- Do the financials suggest a level of financial acumen that would be consistent with the applicant's ability to successfully raise future equity investment?

A. Provide an overall review of the proposal's financial documents and indicate the relative magnitude of both their main strengths and weaknesses.

Overall comments:

Strengths:

Weaknesses:

B. Previous funding. Has the applicant organization already received substantial equity funding and is consequently ineligible for a PreCede grant? Explain.

Comments: