

Reviewer Guidelines

Proposals for 2009 Summer Commercialization Grants Competition

A. Introduction and Background

Introduction. The following guidelines apply to the Life Sciences Discovery Fund (LSDF) 2009 Summer Commercialization Grants Competition and are for commercial expert proposal reviewers to follow in reviewing full proposals. Before starting your reviews, read the request for proposals (RFP) for this grant competition, which can be found at: ([http://www.lsdfa.org/grants/current/2009/Commercialization Grants/RFP.pdf](http://www.lsdfa.org/grants/current/2009/Commercialization%20Grants/RFP.pdf)), as well as within the on-line reviewer system. These Reviewer Guidelines will also be posted in both places.

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 approximately \$33 million per year (\$19.5 million per year in 2010 and 2011) in tobacco settlement bonus payments over a period of 10 years to invest in life sciences research. The mission of LSDF is to support innovative research in Washington State 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.

Commercialization Grants. Advancing commercialization of ideas and research discoveries is a key component of LSDF's mission. LSDF commercialization grants will support research and development to enhance the flow of technologies from the research lab to the marketplace. These grants support highly targeted research and development activities in a segment of the commercialization pathway—the so-called “valley of death”—which is considered to be too applied for federal grant support and yet too risky for private investment. Work within this segment centers on validating the commercial merit of new technologies. This type of work is often referred to as “proof of principle” or “reduction to practice,” (e.g., the first

demonstration of a new therapeutic approach in an animal model) or “prototype development” (e.g., the creation of an integrated instrument for further testing).

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 considering LSDF proposals, you are expected to protect the confidentiality of the 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.

1. *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. You must not contact applicants or the LSDF Board of Trustees under any circumstances. You will be asked to sign a Confidentiality Certification prior to your engagement to review LSDF proposals.

2. *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 serve to 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 without conflict. 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 under review.

Revisions to These Guidelines. If revisions or additions to these guidelines are necessary, we will post them on our web site and the on-line reviewer system and send them to you by e-mail.

Pre-proposal and Resubmission. The proposals you are reviewing were preceded by a pre-proposal. Principal investigators received written feedback on their pre-proposal from a previous commercialization expert panel. Consequently, you may see references in the proposal to that pre-proposal review. Neither pre-proposals nor reviewers’ comments on the pre-proposals will be available for the current review. If a proposal you are reviewing is a resubmission of a previously unfunded proposal, you will see a response to the previous full proposal review.

B. Competition Goals and General Proposal Review

Commercialization Grant Goals. LSDF intends to award up to \$750,000 in grants in the 2009 Summer Commercialization Grants Competition. As many as five to six grants could be funded.

The work of successfully completed grants is expected to lower the risk associated with further commercial technology and product development by increasing the probability of follow-on research and development funding (e.g., Small Business Innovation Research and/or private investment), generation of significant intellectual property, formation of a new company, or licensing to an existing company. LSDF strongly encourages company formation and licensing within Washington to promote the growth of the life sciences industry and maximize the returns to the state. Proposals with the potential to have near-term impact on improving health and health care are especially desirable. However, successful LSDF-funded research and development does not have to result in a market-ready commercial product or service (*i.e.*, one that is ready for commercial sale).

What is Fundable under a Commercialization Grant? All funded activities will be expected to enhance commercialization of a technology that addresses both a market need and a health or health-care need relevant to Washington State. Proposed research and development must be scientifically rigorous and have commercial merit. Funded work must have the potential to be beneficial to health and health care—that is, not merely continuing the current state of care or practice, but changing it demonstrably for the better. Commercialization grants fund research and development leading to new commercial goods, services, and practices, including, but not limited to, new approaches to:

- 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 more cost-effective manner.

Proposal Rating Process and Evaluations. The expert review process consists of individual preliminary evaluations of proposals and a summary evaluation developed during a review panel discussion. The panel discussion will be conducted by LSDF staff. Your objective, in the summary evaluation, is to place proposals into one of three rating categories, reflecting your collective recommendation regarding their suitability for funding.

First, using an on-line form provided by LSDF, you will review and evaluate assigned proposals individually, according to your judgment of their strengths and weaknesses. Then, following a meeting of the review panel, a summary evaluation will be written by LSDF staff based upon the written comments and group discussion of the reviewers. The summary evaluations will be presented to the LSDF Board of Trustees, who will select the awardees, as well as to principal investigators, so all comments provided must be constructive, accurate, and respectful. Principal investigators will not receive individual reviewers' preliminary evaluations of proposals, nor will they learn the identity of the reviewers who constitute the panel.

In preparing your preliminary evaluation and during the panel review meeting, follow these guidelines:

- The overall evaluation should be thorough. Summarize the strengths and weaknesses of the proposed work according to the following aspects of LSDF's goals and mission:
 - its potential for improving health and health-care in Washington State, and
 - its commercial merit and potential for future economic impact in Washington State.
- Weigh each of these criteria equally. Put strengths and weaknesses in perspective by indicating their relative magnitude.
- In a very strong proposal, the technology will be innovative, address an important market(s), show superiority over existing practices and products, and the suggested outcome of the work will significantly advance the technology along the commercialization pathway.

C. Detailed Proposal Review Criteria

In particular, read sections 3.3.4, 3.3.5, and 4.2 in the RFP for further context.

Proposals Must Serve the LSDF Mission. The Life Sciences Discovery Fund is an investment on behalf of the citizens of Washington State. All proposals will be expected to enhance commercialization of a technology that addresses a market need in the State of Washington. Successful proposals will also have the potential to contribute to LSDF's primary strategic goals: to improve health and health care, stimulate economic activity, and promote life sciences competitiveness in Washington.

Specific Review Criteria. The principal review criteria for this grant competition are derived from the Fund's mission. Proposals are evaluated with regard to their (1) scientific and technical merit, (2) impact on health and health care, and (3) commercial merit and future economic returns. **The commercial review panel will focus its attention on aspects (2) and (3).** Where possible and appropriate, construct your discussion of the principal review criteria with sections describing the proposal's strengths and weaknesses.

Review Criteria in Detail. Your evaluation of proposals is expected to be 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 a separate expert review panel convened by the American Association for the Advancement of Science (AAAS). This panel's evaluation of the proposal will be provided to commercial reviewers in advance of the panel meeting. The commercial review panel should not "re-review" the proposal for scientific and technical merit or the budget, but

if in a commercial reviewer's judgment the AAAS panel's evaluation is inaccurate, it is the responsibility of the reviewer to raise that point in his/her preliminary evaluations and during the panel discussion.

In its summary evaluation of proposals, the commercial review panel should consider the scientific and technical merit as reported by the AAAS panel. A strong scientific and technical plan is necessary, but not sufficient, for funding by LSDF. Proposals with flawed scientific or technical plans should not be recommended for funding.

(2) Importance to Health and Health Care

The importance of the proposed activities to health and health care within Washington State will be judged by how well the proposal demonstrates the following qualities:

- addresses a significant problem in health or health care in Washington State;
- has excellent potential to make a substantial, beneficial, and measurable contribution to improving health and health care in areas such as the following:
 - 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;
 - better integration of care-givers, patients, and health-care systems; 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.

(3) Commercial Merit and Future Economic Returns

Principal investigators must clearly state the commercial merit of the technology under development and the potential for LSDF support to enhance commercialization. The proposal must:

- provide a clear and understandable description of the product or service that the proposed work eventually aims to develop;
- show the potential for the new product or service to improve health or health care in Washington State;
- demonstrate that the potential market size, in Washington and beyond, for the proposed product or service is commercially viable;

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- provide a compelling argument for the superiority of the proposed product or service over existing products and services;
- present an intellectual property protection plan for the subject matter of the proposed work that is clear and appropriate for the product or service and the target market;
- demonstrate the applicant organization's commitment to commercialization of the technology under development; and
- show how LSDF support advances the technology and lowers the risk associated with further work along the commercialization pathway.

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 through commercialization of the proposed technology;
- future economic consequences of 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;
- attracting life sciences researchers, companies, and jobs to Washington;
- creating new companies and jobs and attracting investment capital to Washington;
- creating new or enhancing existing IP that presents attractive licensing opportunities; or
- future research and development and investment funding enabled by the LSDF grant.

D. Overall Rating

Funding. LSDF grants are highly competitive. Funds available are sufficient for only five to six awards. It is acceptable if the panel finds fewer proposals to be highly meritorious, as it is LSDF's desire that only the best proposals be recommended for funding. The commercial panel's summary evaluations, including the comments from the AAAS scientific and technical reviews, will be presented to the board of trustees which will take the evaluations into account in making award decisions. During the commercialization panel meeting, LSDF staff may request that the panel rank proposals in order of their priority for funding. Such rankings may be shared with the board, but not with the applicants.

Outliers. LSDF understands that proposal quality will vary across the core review criteria. For example, a proposal that may be scientifically unexciting but may offer a major opportunity to impact health-care cost effectiveness. 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 general guidelines to rate proposals:

Highly Recommended: outstanding, deserves highest priority for funding

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Recommended: good, worthy of consideration for funding

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

Proposal Commercialization Panel: Review Comment Form

2009 Summer Commercialization Grants Competition Proposals

Request ID:
Pre-proposal Title:
Principal Investigator:
Applicant Organization:
Co-Applicants:
Request Amount:

Rating Scale

Use the following scale to rate the proposal:

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

Overall proposal rating: Highly Recommended
 Recommended
 Not Recommended

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

Strengths:

Weaknesses:

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

A. Does the proposed work address an important health or health-care need in Washington State? What are the most compelling health or health-care applications of the proposed work? What is the potential of the proposed work to significantly improve health or health care? Include whether near-term benefits are likely.

Comments:

B. Is there a clear, comprehensible description of a new commercial product or service that could eventually result from the proposed work? If not, what is lacking?

Comments:

C. Is the market size for the proposed new product or service commercially viable? Why or why not?

Comments:

D. Does the proposed product or service appear to be superior to existing products or services that serve the target market? If so, in what ways is it superior? If not, what are its shortcomings?

Comments:

E. What are the strengths and weaknesses of the intellectual property protection plan?

Strengths:

Weaknesses:

F. Where is the proposed work in the commercialization pathway? Is it likely that LSDF support will help advance the technology and lower the risk associated with further work along the commercialization pathway?

Comments:

G. Describe the main strengths and weaknesses of the proposal relative to its potential for future economic impact in Washington.

Strengths:

Weaknesses:

H. What commitments has the applicant organization made toward commercialization of the technology? How will these commitments promote commercialization of the technology?

Comments:

I. Commercial review panelist comments on AAAS scientific and technical review:

- The panelist accepts the AAAS rating and review without comment.
- The panelist accepts the AAAS rating and review but wishes to add the following:

- The panelist disagrees with the AAAS rating and/or review on the following grounds: