

Commercial Reviewer Guidelines

Proposals for 2010 Commercialization Grant Competition – Round 2

New for 2010:

- Corporate financial involvement in grants has been more explicitly described (see Section 1.7 of the RFP).
- Principal investigators will be required to be available by telephone during the commercialization panel's review of their proposals to answer questions (see Section 4.1 of the RFP).
- Additional detail is required regarding organizational resource commitments to the proposed work (see Section 3.3.5.C of the RFP).

A. Introduction and Background

Introduction. The following guidelines apply to the Life Sciences Discovery Fund (LSDF) 2010 Commercialization Grant Competition– Round 2 and are for commercial expert proposal reviewers to follow. 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/2010/Commercialization_Grants/), as well as within the online reviewer system. These Reviewer Guidelines will also be posted in both places.

Contact Information. If you have questions about any aspect of the review process, 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 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”, “reduction to practice”, or “prototype development”.

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 pre-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. Except as authorized by LSDF during the review process, you must not contact principal investigators, research team members, or the LSDF Board of Trustees regarding a proposal. 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 review 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.

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

B. Competition Goals and General Proposal Review

Commercialization Grant Goals. LSDF intends to award up to \$750,000 in grants in the second round of the 2010 Commercialization Grant Competition. Individual awards will be up to \$150,000 with work to be completed within one year.

The primary goal of commercialization grants is to markedly enhance the probability that new technologies and concepts will be developed into products and services. While many types of projects are fundable, the most important aspect of a successful commercialization grant is its catalytic effect in enabling further work along the commercialization pathway. Optimally, the data set from a successful project should have the power to attract: additional financial resources (e.g., Small Business Innovation Research grants and/or investor funding);

commercialization expertise (e.g., a CEO to start a new company); licensing interest; or other resources that enhance commercialization. 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.

What is Fundable under a Commercialization Grant? Commercialization grants support applied research and development leading to new commercial goods, services, and practices, and not basic or discovery research. Principal investigators must provide a clear description of the product or service toward which their project is ultimately aimed. Ordinarily, intellectual property protection will already have been filed for prior to submission of a commercialization grant proposal.

Types of projects envisioned for commercialization grants include the following:

- Experiments to validate a technology's (e.g., a platform technology) 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 given for illustration purposes only and should not be deemed as an exact specification of the types of projects supportable or solicited under commercialization grants.

All funded activities must be scientifically rigorous and enhance commercialization of technologies that address both a market need and a health or health-care need relevant to Washington state. Such technologies may include, but are 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 more cost-effective manner.

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.

LSDF recognizes that the research and commercial opportunities contemplated by the proposals within this competition are inherently risky. In moving promising projects along the commercialization pathway, LSDF is willing to accept scientific and technical risk. However, LSDF cannot accept the risk that a future market will develop if none is foreseen at the time of the review.

Proposal Review and Rating Process. The proposal review will be performed by a group of commercialization experts (the “panel”) to assist LSDF in assessing the suitability of the proposed research and development activities for funding.

The expert review process consists of three stages:

- First, using an online form provided by LSDF, you will individually review proposals assigned to you, according to your judgment of their strengths and weaknesses, in advance of the panel meeting. You will also consider the scientific and technical merit review provided by AAAS.
- Second, you will meet with the other members of the panel to review all of the proposals. Panel discussions will be chaired by LSDF staff. Principal investigators will be requested to be available by telephone during a specified period on the day of the panel meeting to answer questions, should the panel have any that cannot be answered by the proposal. To enhance the discussion, principal investigators will be encouraged to have available an additional person to speak for the commercial aspects of the proposed work. 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 panel, a summary review will be written by LSDF staff based upon the reviewers’ written comments and group discussion. The summary reviews 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’ advance comments on proposals.

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

- The overall review 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, and
 - its commercial merit and potential for future economic impact.
 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 address an important market(s), show superiority over existing practices and products, and be protectable as intellectual property; and

- o the anticipated outcome of the work will significantly advance the technology along the commercialization pathway.

Pre-proposal and Resubmission. The proposals you are reviewing were preceded by pre-proposals. Principal investigators received written feedback on their pre-proposals from a previous commercialization expert panel. Consequently, you may see references in proposals to the pre-proposal review. The written reviews of the pre-proposals will be available in the online reviewer system for the current review. If a proposal you are reviewing is a resubmission of a previously unfunded proposal, the application will include a response to the previous full proposal review.

C. Detailed Proposal Review Criteria

Proposals Must Serve the LSDF Mission. LSDF 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 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.

Corporate Involvement. (Read Section 1.7 in the RFP for further context.) For-profit entities are not eligible to apply directly to LSDF for funding, but are encouraged to join an eligible organization as a co-applicant or collaborator. Under certain circumstances, LSDF funds may be subcontracted to a for-profit entity. Companies requesting subcontract funds must make either financial or significant in-kind commitments to the proposed work. For a subcontract to be acceptable, the expenditure of LSDF funds by the for-profit entity must:

- enhance the grantee's ability to meet the stated goals of the proposed work;
- bring clear benefit to the grantee organization; and
- bring clear benefit to the state of Washington.

Commercial reviewers are not expected to determine whether or not a proposal complies with LSDF's policies regarding corporate financial involvement. However, if a reviewer believes that a proposal is inconsistent with LSDF policies, he/she should note that in the preliminary review and during the panel discussion.

Preference will be given to work that is partnered with an in-state entity.

Organizational Commitment. To be competitive for funding, applicant organizations must make a tangible commitment of resources that directly support and sustain the proposed research and commercialization. Organizational commitment may be in the form of either cash or in-kind contributions (e.g., equipment, research tools, software, supplies, or services). Please refer to Section 3.3.5.C of the RFP for further information. If a reviewer questions the commitment of an applicant organization to a proposal, he/she should note that in the preliminary review and during the panel discussion.

Specific Review Criteria. (Read Sections 3.3.4, 3.3.5, and 4.2 in the RFP for further context.) The principal review criteria for this grant competition are derived from the Fund's mission. Proposals are reviewed 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.

Rate the proposal as presented by the principal investigator and not on the basis of its theoretical potential, e.g., without considering the proposal's likelihood of success. For example, a principal investigator may propose to cure a devastating disease affecting many Washingtonians but have a poor approach to doing so. Even though this disease is very important and its cure would be extremely valuable, if the proposal's approach is flawed, its rating on this criterion would not be high.

Review Criteria in Detail. Your review 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 review 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 review is inaccurate, it is the responsibility of the reviewer to raise that point in his/her preliminary reviews and during the panel discussion.

In its summary review 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.

Principal investigators will also be provided with a copy of the AAAS-convened scientific and technical review of their proposals in advance of the panel's meeting. It is acceptable for the panel to query the principal investigator about aspects of the scientific and technical review during a telephone 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 state will be judged by how well the proposal demonstrates the following qualities:

- it addresses a significant problem in health or health care in Washington state;
- 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;
- 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 make a compelling argument for 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 ultimately aims to develop;
- demonstrate that the technology or product concept is in an appropriate stage of development for this competition, *i.e.*, not basic or discovery research;
- provide a compelling argument for how LSDF funding can markedly enhance the probability that the technology or product concept will be developed into a product or service and reduce the risk associated with downstream commercial development;
- demonstrate that the proposed product or service has the potential to improve health or health care in Washington state;
- provide a clear description of who would buy the product or service and why;
- show that the potential market size for the proposed product or service is commercially viable;
- present a compelling argument for the superiority of the proposed product or service over existing products and services;
- 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 or service and the target market; and
- have a demonstrated commitment on the part of the applicant organization toward commercialization of the proposed technology.

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;

- 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 intellectual property that presents attractive licensing opportunities; and
- 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 meritorious, as it is LSDF's desire that only the best proposals be recommended for funding. The commercial panel's summary reviews, including the comments from the AAAS scientific and technical reviews, will be presented to the Board of Trustees, which will take the reviews into account in making award decisions. During the commercialization panel meeting, LSDF staff may request that the panel rank proposals in the 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 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

Recommended: good, worthy of consideration for funding

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

Life Sciences

DISCOVERY FUND

Individual Reviewer Comment Form

2010 Commercialization Grant Competition - Round 2 Proposals

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 LSDF's web-based proposal review system.

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:

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 have a catalytic effect in enabling further work along the commercialization pathway?

Comments:

G. If there is a company planning to participate in the proposed work, will that participation benefit the project and/or applicant organization? If so, how?

Comments:

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

Strengths:

Weaknesses:

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

Comments:

J. 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: