

Commercial Reviewer Guidelines

Proposals for 2011 Commercialization Grant Competition – Round 2

New for Round 2:

- The American Association for the Advancement of Science (AAAS) scientific and technical reviews will no longer be the result of a panel, but rather two individual expert reviews.
- AAAS reviewers will have a formal, but optional, opportunity to comment on the health and health-care impact of the proposal.

A. Introduction and Background

Introduction. These guidelines apply to the Life Sciences Discovery Fund (LSDF) 2011 Commercialization Grant Competition – Round 2 and are for commercial expert proposal reviewers. Although this document highlights the competition’s purpose and requirements, it is not a substitute for the Request for Proposals (RFP). Before starting your reviews, read the RFP for this grant competition, at:

<http://lsdfa.org/documents/LSDF%202011%20Commercialization%20Grant%20Competition%20Round%20%20RFP%2011-17-11.pdf>

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 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 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. Except as authorized by LSDF during the review process, you must not contact research team members or the LSDF Board of Trustees regarding a proposal. You will be asked to sign a Confidentiality Certification prior to reviewing 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 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. You will be expected to review the LSDF conflict of interest policy and to sign declarations that you have disclosed all conflicts of interest that you may have with the proposals both before and after the panel review meeting.

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 e-mail.

B. Competition Goals and Overview of the Review Process

Commercialization Grants. Advancing commercialization of ideas and research discoveries is a key component of LSDF's mission. LSDF commercialization grants 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.”

The primary goal of commercialization grants is to markedly enhance the probability that new technologies and concepts will be developed into marketable products, services, or practices (together generically referred to in this document as “products”). 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.

LSDF intends to award up to \$750,000 in grants in the second round of the 2011 Commercialization Grant Competition. Individual awards will be up to \$150,000 with work to be completed within one year.

What is Fundable under a Commercialization Grant? Commercialization grants support applied research and development, not basic or discovery research. Principal investigators must provide a clear description of the product under development. Ordinarily, intellectual property protection will already have been filed for prior to submission of a proposal to LSDF.

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. 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.

Types of projects envisioned for commercialization 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 under commercialization grants.

LSDF recognizes that the research and commercial opportunities proposed for this competition are inherently risky. In moving promising projects along the commercialization pathway, LSDF is willing to accept scientific and technical risk. However, if a market is not foreseen at the time of the review, LSDF cannot accept the risk that a future market will fail to develop.

Proposal Review and Rating Process. You will be a member of a group of commercialization experts (the “panel”) who will assist LSDF in assessing the suitability of the proposed research and development activities for funding. The review process initially follows two 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). 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 review into your review.

The expert review process consists of three stages:

- First, using a form in LSDF's web-based commercial reviewer system, you will 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 reviews provided by AAAS.
- Second, you will meet with the other members of the panel to evaluate all of the proposals. The panel 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. Prior to the panel meeting, principal investigators will have received their AAAS reviews but not your individual comments. To enhance the discussion, principal investigators will be encouraged to have available an additional person, a "commercialization partner" (see Section C below), to speak for the business case associated with 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 panel meeting, a summary review of each proposal 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, as well as to principal investigators, so all comments provided by reviewers 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 proposed new product will address an important market(s), be superior to existing practices and products, and be protectable as intellectual property;
 - there will be close coordination between the scientific and technical program and the developing business case; and
 - the anticipated outcome of the work will significantly advance the technology along the commercialization pathway.

Pre-proposal and Resubmission. 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. If a proposal you are reviewing is a resubmission of a previously unfunded proposal, the application will include both a copy of and a response to the previous full proposal review.

C. Detailed Proposal Review Criteria

Commercialization Partners. LSDF strongly encourages principal investigators to engage the assistance of a “commercialization partner” in preparing a grant application and executing a funded grant. The principal investigator is responsible for specifying and executing the scientific and technical plan, with the commercialization partner being responsible for articulating and developing the business case. A commercialization partner is an organization or individual having a direct business interest in commercializing the proposed technology or concept—generally the applicant organization’s technology commercialization office (or equivalent) for earlier stage projects or a licensee of the underlying intellectual property.

Corporate Involvement. (Read Section 1.6 in the RFP for further context.) For-profit entities are not eligible to apply directly to LSDF for funding in this competition, 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.

You are not expected to determine whether or not a proposal complies with LSDF’s policies regarding corporate financial involvement. However, if you believe that a proposal is inconsistent with LSDF policies, you 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.

Coordinating Science and Technology with Business Development. While the centerpiece of commercialization 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, or developing a regulatory strategy). Compelling proposals will show coordination between execution of the scientific/technical agenda and development of the business case, with each track informed and enhanced by the other. Proposals must designate the individual who will be responsible for coordinating the scientific and technical aspects of the proposed work with business planning activities (the “commercialization coordinator”). The coordinator must be conversant in the languages of both science and business, facilitate information flow, and ensure that the efforts are proceeding synchronously. The

commercialization coordinator represents the interests of the commercialization partner, and it is possible that a single individual could play both the partner and coordinator roles.

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 efforts. Organizational commitment may be in the form of either cash or in-kind contributions (e.g., equipment, research tools, software, supplies, or expenditures for intellectual property protection or market research). Please refer to Section 3.3.5.C of the RFP for further information. If you question the commitment of an applicant organization to a proposal, you 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 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. **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 reviews.

Rate the proposal as presented by the principal investigator and not on the basis of its theoretical potential, *i.e.*, don't 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. 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 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 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 caregivers' 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. 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. However, 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 the potential for LSDF support to enhance commercialization. The proposal must:

- provide a clear and understandable description of the product that the proposed work ultimately aims to develop;
- 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 existing products;
- 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;
- include a reasonable plan to advance the business case for the proposed product during the grant period;
- include a "commercialization coordinator" who adds significant value to the project and the commercialization effort;
- present a strong plan for how development of the business case will be coordinated with the proposed scientific and technical work;
- demonstrate a commitment on the part of the applicant organization toward commercialization of the proposed technology; and
- demonstrate that LSDF support will markedly enhance the probability that the technology or product concept will be developed into a marketable product and reduce the risk associated with downstream commercial development.

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. 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 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 them into account in making award decisions. LSDF staff may request that the commercial 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 address a major commercial opportunity. 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

Life Sciences

DISCOVERY FUND

Individual Reviewer Comment Form

2011 Commercialization Grant Competition - Round 2 Proposals

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

Note: Reviewers use a web-based proposal review system to complete this form.

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. **Health-care applications.** 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 in Washington? Include whether near-term benefits are likely.

Comments:

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

Comments:

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

Comments:

D. Competition. Is the proposed product superior to existing products that serve the target market? If so, in what ways is it superior? If not, what are its shortcomings?

Comments:

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

Strengths:

Weaknesses:

F. Impact of LSDF funds. Where is the proposed work in the commercialization pathway? Would LSDF support have a catalytic effect in enabling further work along the commercialization pathway? If so, how?

Comments:

G. **Development of business case.** Is the plan for advancing the business case for the proposed product during the grant period, including coordination with the scientific/technical work, reasonable? If not, what other steps should be taken?

Comments:

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

Strengths:

Weaknesses:

I. **Commitments.** What commitments have the applicant organization and commercialization partner made toward commercialization of the technology? How will these commitments promote commercialization?

Comments:

J. **Scientific/technical review.** Commercial review panelist comments on AAAS scientific and technical reviews:

- The panelist accepts the AAAS reviews without comment.
- The panelist accepts the AAAS reviews but wishes to add the following:

- The panelist disagrees with the AAAS reviews on the following grounds: