

Life Sciences

DISCOVERY FUND

AAAS Guidelines for Review of Research Proposals

Proposal Review of Scientific and Technical Merit for 2010 Commercialization Grant Competition – Round 2

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 AAAS expert proposal reviewers to follow. Before starting your reviews, read the Request for Proposals (RFP) for this grant competition at: (http://www.lsdfa.org/grants/current/2010/Commercialization_Grants/). These Reviewer Guidelines will also be posted there.

Contact Information. If you have questions at any point during 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 the 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.

The AAAS review covered by this guide is restricted to the scientific and technical merit of the proposals. Commercial/business reviews of these proposals will be performed by a separate panel convened by LSDF.

As a reviewer, 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 AAAS.

(1) *Confidentiality*. The proposals and the review process are confidential. If you believe that additional scientific expertise is needed to review a proposal, you should not solicit it yourself, but instead notify AAAS to make arrangements for outside assistance. You must not contact principal investigators, members of research teams, 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 a reviewer from participating in the review of a proposal. If you feel that there may be a conflict or a perception of conflict, notify AAAS, who will make the determination about your ability to review a proposal without conflict. You will be expected to sign declarations 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, LSDF will post them on its web site and send them to reviewers through AAAS.

B. Competition Goals and General Proposal Evaluation

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.

Proposal Review and Rating Process. Evaluation of the scientific and technical merit of the proposal, including the appropriateness of the budget, will be undertaken by your AAAS-organized panel. **A separate expert evaluation of the health, health-care, commercial and economic merit of the proposal will be performed by a panel convened by LSDF.** Your panel's evaluation of the proposal will be provided to commercial reviewers in advance of their panel meeting. The commercial evaluation panel will incorporate your panel's comments into its own evaluation and make the final funding recommendations to the LSDF Board of Trustees.

First, you will review proposals individually, according to your judgment of their strengths and weaknesses. Then, following a meeting of the review panel, a consensus review of each proposal will be written, reflecting your collective recommendation regarding its suitability for funding.

Principal investigators will receive the consensus reviews of their proposals, so these reviews must be constructive and written with care, accuracy, and respect. Neither principal investigators nor LSDF will receive individual reviewers' preliminary comments on proposals.

In preparing both preliminary and consensus reviews, follow these guidelines. The overall review should consider all scientific and technical aspects of the proposal, and, to be of most help to the LSDF and to proposal submitters, it must be thorough. Do not describe the investigator's plans in detail, but briefly describe the overall goals of the proposal. Then summarize the scientific and technical strengths and weaknesses of the proposal. Put strengths and weaknesses in perspective by indicating their relative magnitude. Evaluate and comment on the appropriateness of the budget. The budget justification is in a freestanding document to encourage PIs to provide greater detail and to facilitate your evaluation. If any changes in the budget are recommended, explain what changes should be made and why. In a very strong proposal, the technology will be innovative, the scientific and technical plan and the budget will be appropriate for the work to be performed, the team will be complete and highly qualified to accomplish the work, and the project outcomes will be feasible and well defined.

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 panel of commercialization experts. 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, the application will include a response to the previous full proposal review.

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. LSDF is an investment on behalf of the citizens of Washington state. Successful proposals will 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. As a reviewer, you will not be expected to be familiar with the particular environment of Washington state.

Specific Review Criteria. The principal review criteria for this grant competition are derived from the Fund's mission. Proposals are ultimately 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 AAAS scientific and technical review panel will address aspect (1) only.** Construct your review with sections describing the proposal's strengths and weaknesses, including the appropriateness of the budget.

In addition, you will be asked to identify any scientific or technical areas or issues that should be addressed as the proposal is considered for funding. If your overall proposal rating is "Not Recommended," note any scientific or technical areas or issues that should be addressed if the proposal is not funded and the principal investigator resubmits the proposal for a later competition.

AAAS Review Criteria in Detail. Your review of proposals is expected to be based on your judgment of the extent to which a proposal meets the scientific and technical merit criteria listed below. The merit of the proposal will be judged by how well it demonstrates the following qualities:

- provides promising new approaches to solving problems in health and health care;
- establishes a framework for the proposed activities with strong potential to achieve novel and important results;
- defines clear and realistic outcomes;
- demonstrates the principal investigator's and any co-investigators' commitment, experience, and ability to execute the proposed work successfully;
- demonstrates, where collaboration is proposed, that investigators have a history of effective collaboration and an appropriate plan to manage the collaborative process; and
- justifies that the budget is appropriate to the scope and goals of the proposed work.

A strong scientific and technical plan will be necessary, but not sufficient, for funding by LSDF.

Principal investigators will be provided with a copy of the AAAS-convened scientific and technical review of their proposals in advance of the commercialization panel's meeting. The panel may query the principal investigator about aspects of the scientific and technical review during a telephone interview at its meeting.

Rating. Use the following general guidelines to rate proposals:

Highly Recommended: scientific and technical merit is excellent

Recommended: scientific and technical merit is good

Not Recommended: scientific and technical merit is poor and lacking in one or more critical areas

D. Clarification of Issues That May Arise During Review

These are not issues that you are required to comment on, but they may arise as you review proposals.

Indirect costs. LSDF grants pay the full costs of accomplishing the proposed activities (*i.e.*, including what are typically called “indirect” costs, and noted on the LSDF budget as “Organizational Administrative Expenses” and “Research Space Costs”), with all costs expressed as direct costs. Principal investigators are not to apply their organization’s federally negotiated indirect cost rate to their “direct” costs to derive facilities and administration (F & A) charges. Reviewers are not expected to determine how the principal investigator arrived at the F & A charges.

Outliers. As reviewers prepare consensus evaluations, LSDF asks them to make special note of compelling opportunities within proposals that might otherwise be considered ordinary or overly risky.

LSDF participation in consensus review. An LSDF program staff person may listen in during the panel’s proposal review meeting. The program staff person is not acting as a reviewer.

AAAS Evaluation Comment Form

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

Rating Scale

Use the following scale in your ratings.

Highly Recommended: scientific and technical merit is excellent

Recommended: scientific and technical merit is good

Not Recommended: scientific and technical merit is poor and lacking in one or more critical areas

Overall scientific and technical merit:

- Highly Recommended
 Recommended
 Not Recommended

Analyze the proposal's scientific and technical merit and provide constructive comments. Indicate the relative magnitude of both strengths and weaknesses. Comment on the appropriateness of the budget and explain any recommendations for changes.

Overall comments:

Strengths:

Weaknesses:

Note: this form is a sample and will not be provided to reviewers in the Guide. The actual form and mechanism is provided through AAAS' online proposal evaluation system.

Note any scientific or technical areas or issues that should be addressed as the proposal is considered for funding. If your overall proposal rating is "Not Recommended," note any scientific or technical areas or issues that should be addressed if the proposal is not funded and the principal investigator resubmits the proposal for a later competition.

Comments: