

# Life Sciences

DISCOVERY FUND

## AAAS Guidelines for Proposal Review of Scientific and Technical Merit 2011 Commercialization Grant Competition – Round 2

### A. Introduction and Background

**Introduction.** These guidelines apply to the Life Sciences Discovery Fund (LSDF) 2011 Commercialization Grant Competition – Round 2 and are for AAAS expert proposal reviewers. Before starting your reviews, read the Request for Proposals (RFP) for this grant competition at:

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

These guidelines will also be posted on the LSDF website.

**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 invest funds from the master tobacco settlement in life sciences research and development. LSDF carries out this 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.

**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 commercialization panel recruited 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 or technical 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 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 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 AAAS, 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.

**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 through AAAS.

## B. Competition Goals and Overview of the Review Process

**Commercialization Grants.** Advancing the 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, and 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 and not basic or discovery research. Principal investigators must provide a clear description of the product toward which their project is ultimately aimed and propose a scientifically rigorous set of activities to advance development of that product. Products 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.

Types of projects envisioned for commercialization grants include the following:

- 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.

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 Process.** Evaluation of the scientific and technical merit of the proposal, including the appropriateness of the budget, will be undertaken by two separate reviewers (you and one other), through your engagement by AAAS. **A separate expert evaluation of the health, health care, commercial (e.g., market size, competition, intellectual property position)**

and economic merit of the proposal will be performed by a panel recruited by LSDF. Your evaluation of the proposal will be provided to commercial reviewers in advance of their panel meeting. The commercialization panel will incorporate your comments into its own evaluation and make the final funding recommendations to the LSDF Board of Trustees. Your identity will remain confidential and will not be shared with LSDF, commercial reviewers, or applicants.

You will write a review of each proposal, supporting your recommendation regarding its scientific and technical merit. You will rate the proposal's scientific and technical merit as "excellent," "good," or "poor."

Principal investigators will receive the reviews of their proposals, so these reviews must be constructive and written with care, accuracy, and respect.

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 principal investigators to provide sufficient detail for 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.

Because the impact of a technology on health and health care can often be intertwined with scientific and technical aspects of a proposal, an **optional** comment field for health and health care impact is provided.

**Pre-proposal and Resubmission.** The proposals you will review were preceded by a pre-proposal. Principal investigators received written feedback on their pre-proposals from a panel of commercialization experts recruited by LSDF. Consequently, you may see references in the proposal to the pre-proposal review. Neither pre-proposals nor reviewers' comments on the pre-proposals will be available for your review. 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

Read sections 3.3.4, 3.3.5 and 4.2.1 in the RFP for further context.

**Specific Review Criteria.** The principal review criteria are derived from LSDF'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 AAAS scientific and technical review will address aspect (1) only; the LSDF-convened commercialization panel will focus on aspects (2) and (3) after you have evaluated the proposals.** Your review will describe the proposal's strengths and weaknesses, including the appropriateness of the budget. If you wish, you may comment on (2) inasmuch as it relates to

the scientific and technical merit. For example, the scientific merit of the proposal may be high, but you may believe that alternative approaches are more clinically relevant, or that the technology is too complicated for physicians or patients to use, or that the technology has advantages such as low power requirements that are primarily useful in the developing world.

In addition, you will be asked to note any scientific or technical areas or serious 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:

- demonstrates that the proposed product is beyond the stage of basic or discovery research;
- provides a promising approach to solving the problem being addressed;
- 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.

#### **D. 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 "Detailed Administrative Budget" and "Facilities Detailed Budget"), 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 you prepare consensus evaluations, make special note of compelling opportunities within proposals that might otherwise be considered ordinary or overly risky.

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## AAAS Evaluation Comment Form

### Proposal Review of Scientific and Technical Merit for 2011 Commercialization Grant Competition – Round 2

Request ID:

Proposal Title:

Principal Investigator:

Applicant Organization:

Request Amount:

#### Overall scientific and technical merit:

- Scientific and technical merit is excellent
- Scientific and technical merit is good
- Scientific and technical merit is poor and lacking in one or more critical areas

Analyze the proposal's scientific and technical merit and provide constructive comments. Indicate the relative magnitude of both strengths and weaknesses.

Overall comments:
Strengths:
Weaknesses:

Comment on the appropriateness of the budget and explain any recommendations for changes.

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**Scientific or technical areas or serious issues to be addressed.** Note any scientific or technical areas or serious issues that should be addressed if the proposal is not funded and the principal investigator resubmits the proposal for a later competition.

Comments:
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**You may comment on the proposal's health and health-care merit,** as it relates to the scientific and technical merit.

Overall comments:
Strengths:
Weaknesses: