

First Phase Expert Reviewer Guidelines

Life Sciences Discovery Fund 2010 Program Grant Competition

The following guidelines apply to the Life Sciences Discovery Fund (LSDF) 2010 Program Grant Competition. American Association for the Advancement of Science (AAAS) expert reviewers will use these guidelines for the **first (mail) phase** of external evaluation.

Please read the Request for Proposals (RFP) (at http://www.lsdfa.org/grants/current/2010/Programs_Grants/) before starting your evaluations. Any revisions or additions to these guidelines will be posted on this website and sent to reviewers through AAAS.

If you have questions at any point during the evaluation, please contact:

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A. Introduction and Background

Overview of the Life Sciences Discovery Fund. LSDF was created by the Washington State Legislature to invest in life sciences research. The mission of LSDF is to support innovative research in Washington to improve health and health care, stimulate economic activity, and promote life sciences competitiveness.

Board of Trustees. LSDF is governed by a board of trustees, which has final funding authority. The board is considerably informed by the expert evaluation process, but uses additional criteria in making award decisions. Your evaluation comments should not assume that a proposal will or will not be funded.

Expectations of Reviewers. LSDF achieves its mission by funding proposals through a competitive granting process, the success of which depends upon superb expert evaluation. As a reviewer evaluating LSDF proposals, you are expected to protect the confidentiality of the proposals and of the evaluation process itself and to abide by a strict standard in avoiding any conflict of interest. Any concerns you may have about a proposal or the ability to evaluate it impartially should be communicated in confidence to AAAS.

1. *Confidentiality.* The proposals and the evaluation process are confidential. You must not contact research team members or the LSDF Board of Trustees under any circumstances. You will be asked to sign a nondisclosure agreement prior to your participation in the evaluation of LSDF proposals.

2. *Conflict of Interest.* A perceived or actual conflict of interest in expert evaluation 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 a reviewer from participating in the evaluation of a proposal. If you believe that there may be a conflict or a perception of conflict, notify AAAS, who will make the determination about your ability to evaluate 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.

Proposals Must Serve the LSDF Mission. The Life Sciences Discovery Fund is an investment made on behalf of the citizens of Washington to improve health and health care, stimulate economic activity, and promote life sciences competitiveness. As a reviewer, you will not be expected to be familiar with the particular environment of Washington. It is the principal investigators' responsibility to articulate that environment clearly and to define convincingly the specific benefits their research is designed to produce.

B. Competition Goals

Overview of the LSDF 2010 Program Grant Competition. This competition will award up to \$10 million for the launch and development of new broad-based research initiatives that will help Washington research organizations advance their strategic priorities and leadership/competitive positions in health and health-care research.

What is a Fundable Program? Programs are collaborative, scientifically rigorous research initiatives that address major problems within a field of study. Program proposals may request support for many kinds of activities, including:

- establishing new centers for research;
- creating new multi-institutional consortia;
- recruiting outstanding scientists to lead new research programs;
- acquiring major equipment to accelerate advances within a new research program;
- training the state's scientific workforce, particularly in emerging industries; and
- establishing research infrastructure to support commercialization of multiple technologies over a sustained period of time.

New for 2010 is eligibility of proposals for programs to help solve problems in health or health care by providing an enabling research resource for Washington investigators. Such a resource must have the power to catalyze numerous research efforts, readily serve a significant number of intrastate users, and have broad applicability.

LSDF also funds two other types of grants through separate RFP processes. Commercialization grants are highly targeted studies that advance technologies with commercial potential to a stage appropriate for licensing, start-up company formation, or private investment. Opportunity

grants support work that is highly leveraged and ineligible for other LSDF competitions due to its urgency or nature.

Programs are evaluated according to their scientific, technical, and organizational merit and their potential to benefit life sciences competitiveness, health and health care, and the economy in Washington. Examples of funded programs and cumulative returns to Washington from LSDF investments are at www.lsdfa.org/about/news/LSDF_InvestingBro_pages.pdf.

- **Proposed programs must be built upon an applicant organization's strengths and have clear strategic importance for the applicant organization.** Principal investigators must describe their plans to launch and build the program, the ways the program will advance the applicant organization's strategic direction, and the resource commitments that will be in place to support and sustain the program's growth and development. LSDF expects that applicant organizations will make significant resource commitments (cash and/or in-kind) to support the proposed programs and help them grow to sustainability. Organizational resource commitments may include but are not limited to:
 - support for key research, technical, or administrative personnel;
 - recruitment of and start-up support for program researchers;
 - absorption of institutional facilities and administration ("indirect") charges;
 - provision of laboratory, clinical, or office space that is newly or specifically designated for program activities;
 - support for renovations of program facilities; and
 - purchase of new equipment or supplies, or dedication of existing equipment or supplies to the program.
- **Proposed programs must have a long-term vision and be designed to endure.** The program must not be structured around research questions that will be answered within a few years, or without long-term plans for expanding program activities or evolving to meet new challenges.
- **Programs will create new synergies among participating researchers and organizations.** This is essential to a program, but sometimes difficult to measure. Synergy results from the interchange among participants with complementary strengths and perspectives who are able to develop new programmatic research directions because of the collaboration. In this context, the opposite of synergy would be an assembly of research projects operating in parallel with no added value to each other.
- **Programs must include a well-detailed plan of research.** The research may be either led by the principal investigator or conducted by other Washington investigators using a research resource provided by the principal investigator through the program. In all cases, principal investigators must describe the program's research activities – including the research focus/agenda and metrics for assessing success – such that reviewers can understand the research priorities and the methodologies to be used.

Proposals that seek only to develop research resources in the absence of clearly articulated research initiatives will not be considered for funding. Similarly, a program to implement an innovation (e.g., an improved clinical method) or to train a cadre of

professionals in the absence of research questions is not fundable. Translation of innovations to broader practice must be accompanied by investigation of research questions.

- **LSDF desires to fund teams that show a commitment to translating the results of their research into widespread use.** “Translation” includes transitions from the laboratory into practice and/or expanding local practice into broad acceptance and use. Translation can involve intra- or inter-organizational adoption of research results into practice, public policy initiatives, and commercialization.

Proposals with the capacity to attract additional resources to enable translation or broader implementation of the research are especially desirable. Such additional resources may include follow-on research and/or investor funding; recruitment of scientific talent or companies to Washington; commitments to commercialization of research discoveries through the formation of a new company or licensing to an existing company; and commitments from research partners or others to adopt a successfully demonstrated strategy or technology.

- **Proposals with the potential to have near-term impact on improving health and health care are of particular interest.** All proposals are expected to provide health-related returns to the state. Such returns may include, but are not limited to, enhancement of disease prevention, diagnosis, treatment, or management; and improved efficiencies in health and health-care systems.

Restructuring of existing resources within an organization without developing new resources or capabilities does not meet LSDF’s definition of a “program.” Rather, LSDF support is meant to assist with the launch of new initiatives that represent innovative thinking within the participating organizations and the field.

C. Proposal Evaluation Process and Criteria

The principal evaluation criteria for this grant competition are derived from the Fund’s mission. You will evaluate proposals with regard to their 1) scientific, technical, and organizational merit, 2) importance to health and health-care, and 3) future economic returns. In addition, you will be asked to specifically address 1) the appropriateness of and necessity for LSDF funding, and 2) whether the proposal meets the LSDF’s definition of a program. Further, you will be asked to list any areas or issues that should be addressed in an interview or a resubmission.

Proposal Rating Process and Evaluation. Expert evaluation of program proposals occurs in two phases:

- In this, the first phase, expert reviewers conduct individual preliminary evaluations of proposals and then develop consensus evaluations during panel discussions. Informed by the first-phase evaluations, the Board of Trustees selects candidates to be interviewed.
- In the second phase, an expert panel evaluates the selected proposals, conducts interviews, and provides consensus evaluations of the proposals. The board selects awardees from among the interviewed candidates.

The objective of this evaluation is to place proposals into one of three rating categories (Highly Recommended, Recommended, or Not Recommended). This rating will reflect the reviewers' collective recommendation for advancing the proposal to the interview phase. If any member of the panel has an opinion that diverges markedly from the consensus, that divergence will be noted and explained.

The Board of Trustees and principal investigators will receive the consensus evaluations, so all comments provided must be constructive, accurate, and respectful. You should provide sufficient feedback and detail to assure principal investigators that their proposals were evaluated thoroughly, to help formulate a resubmission if not funded, and to inform the board in making its decisions. Neither principal investigators nor LSDF will receive individual reviewers' preliminary comments on proposals.

Technical Commentary. If you believe that additional scientific or technical expertise is necessary to evaluate a proposal, you should not solicit it yourself, but instead notify AAAS to make arrangements for outside assistance.

Resubmissions. Proposals may be resubmitted to LSDF, and principal investigators are responsible for including previous evaluation comments and a response. Resubmissions are treated as new proposals, *i.e.*, they are neither penalized nor "fast-tracked" simply because they are a resubmission. If you are assigned to evaluate a resubmitted proposal, consider how the new proposal addresses the comments from the prior evaluation.

Review components. LSDF has provided a form for the reviewers' comments that is divided into the sections listed below. In several sections, reviewers are instructed to list both strengths and weaknesses. When enumerating positive and negative elements, please indicate their relative magnitude (*i.e.*, whether an issue is major or minor):

Overall Comments

The Overall Comments section briefly describes the goals of the proposal and highlights the most significant strengths and weaknesses. This section also discusses issues such as modifications to the budget that are not key evaluation criteria (below).

Scientific and Technical Merit

The proposed program must be of high scientific and technical merit. Merit will be judged by how well the proposed program demonstrates the following qualities:

- it is innovative, possessing or fostering scientific and technical originality;
- it builds upon the established strengths of the applicant organization;
- the applicant organization commits significant resources to enhance the probability of the proposed program's success;
- its proposed research studies, methodologies, and metrics for success are clearly described;
- its proposed research outcomes are clearly defined, significant, and realistic;

- it has the potential to establish the applicant organization and any co-applicants as leaders in the field;
- the principal investigator and any co-investigators demonstrate the commitment, experience, and ability to execute the proposed program successfully;
- for proposals that involve the development of research infrastructure to enhance commercialization, the principal investigator presents a clear description of the commercial opportunities that the program will address, the potential for industrial participation in the program, and the plans for selecting research projects for the program, fostering commercialization of multiple projects on a self-sustaining basis, monitoring progress, and addressing various types of potential delays and difficulties;
- for proposals to provide a research resource, it meets a demonstrated need, has a credible plan for attracting users from across the state, and has a plan for establishing priority of access; and
- the budget is appropriate to the scope and goals of the proposed program.

Please note that if a proposal includes application of a technology platform (e.g., a drug delivery technology or a diagnostic tool), you must evaluate both the application and the platform.

Organizational Merit

The proposed program must be of high organizational merit. "Organization" refers to the structure and governance of the program itself, not the applicant organization. Merit will be judged by how well the proposed program demonstrates the following qualities:

- investigators demonstrate a history of effective collaboration and an appropriate plan to manage the collaborative process;
- it is organized in a clear way that facilitates communication among participants, decision-making, and future growth;
- procedures exist to coordinate and prioritize the work of the program;
- a coherent decision-making structure (governance) exists;
- its objectives are consistent with the strategic priorities of the applicant organization;
- it establishes a research or operational framework with strong potential to achieve novel and important results; and
- for proposals to provide a research resource: it has a plan to sustain itself and to keep user access fees reasonable, and has adequately considered issues such as data sharing, intellectual property rights, human subject protection and confidentiality.

Impact on Health and Health Care

The proposed program must have the potential to benefit health and health care of Washington residents. The program's impact on health and health care will be judged by how well the proposal demonstrates the following qualities:

- it addresses a significant problem in health or health care for Washington residents;
- it has excellent potential to make substantial, beneficial, and measurable contributions to improving health and health care in areas such as:
 - 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.
- it proposes a credible mechanism for how research results will be translated into benefit, e.g., through practice adoption, policy implementation, or commercialization.

Principal investigators may propose a broad range of improvements in health or health care, and the impact of the proposed program 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.

Future Economic Returns

The proposed program must have the potential to benefit Washington's economy. Principal investigators must clearly state the proposed benefits of the program to the state's economic environment. Benefits may include, but are not limited to:

- providing direct economic activity through the conduct of program research;
- producing measurable gains in cost-effective health care due to the application of research results through practice adoption, policy implementation, or commercialization;
- contributing to future economic gains through program-induced improvements in health or health care; e.g., through restoring work time that would otherwise be lost;
- fostering new training and employment opportunities through program research;
- attracting life sciences researchers, companies, and jobs to Washington;
- creating new Washington companies and jobs and attracting investment capital to Washington;
- creating new or enhancing existing intellectual property that presents attractive licensing opportunities;
- obtaining future life sciences research funding enabled by the LSDF grant.

Additional Evaluation Criteria

Your evaluation must also address the following questions directly.

Does the proposal adequately justify the appropriateness of and necessity for LSDF funding?
(See Section 1.2 of the RFP.)

Reviewers should assess how well the principal investigators establish the particular appropriateness and necessity of LSDF funding for their proposals. LSDF support is intended to play a catalytic role in helping investigators and their organizations apply their strengths in various areas of research. Principal investigators should explain how the program's purpose and scope make LSDF a particularly appropriate source of funding.

Does the proposal describe a "program," as defined by LSDF?

Principal investigators should clearly detail how the proposed work meets the LSDF definition of a "program" – a strategic, synergistic research initiative, broad in scope, that is designed to endure over time and address problems within a field of study and to position an organization

for future competitiveness and leadership. One of the characteristics that defines a program is significant institutional commitment. This is not measured by a minimum cost-sharing percentage or other formulaic, quantitative criterion, but rather should be judged as significant in the context of the applicant and co-applicant organizations' resources. **If the answer to this question is "no" then the proposal should be rated Not Recommended overall.**

Please note any areas or issues that should be addressed if the principal investigator is invited to an interview.

Reviewers should list any topics or questions that they recommend the second-phase reviewers consider in their evaluations and interviews with the proposal teams.

If your overall proposal rating is "Not Recommended" please note any areas or issues that should be addressed if the proposal is not funded and the principal investigator resubmits the proposal for a later competition.

These can include issues that simply need clarification as well as recommendations for substantive changes to the proposal.

D. Clarification of Issues That May Arise During Evaluation

Following are issues that you are not required to comment on, but that may arise as you evaluate proposals.

Budget. LSDF requires two budgets: 1) detailed budgets for each year of requested funding, with costs broken down by category; and 2) complete funding plans detailing total income for the first five years of the program and how those revenues will be allocated. If any changes in the budget are recommended, explain what changes should be made and why.

Indirect costs. LSDF grants pay the full costs of doing research (*i.e.*, including what are typically called "indirect" costs, and noted on the LSDF budget forms as "Administrative Costs" and "Facilities Charges") with all costs expressed as direct costs. You are not expected to determine how the principal investigator arrived at the F & A charges.

LSDF participation in consensus evaluation. An LSDF program staff person may listen in during the consensus evaluation phone calls. The program staff person is not acting as a reviewer.

E. Overall Rating

Outliers. LSDF understands that proposal quality will vary across the core evaluation criteria. 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.

Rating. Please use the following general guidelines to rate proposals:

Highly Recommended: outstanding, deserves highest priority for an interview

Recommended: good, worthy of consideration for an interview

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

AAAS Evaluation Comment Form First (Mail) Phase

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

Life Sciences Discovery Fund (LSDF) 2010 Program Grant Competition

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

Rating Scale

Please use the following scale in your ratings.

Highly Recommended: outstanding, deserves highest priority for an interview

Recommended: good, worthy of consideration for an interview

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

Overall proposal rating: Highly Recommended
 Recommended
 Not Recommended

Please briefly describe the goals and the main strengths and weaknesses of the proposal. Include any recommendations for changes to the budget.

Goals of the Proposal:

Strengths:

Weaknesses:

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

Scientific and Technical Merit

Highly Recommended
 Recommended
 Not Recommended

Strengths:

Weaknesses:

Organizational Merit:

Is the program organized and governed in a manner that will allow it to effectively carry out its work and grow?

- Yes
- No

Comments:

Impact on Health and Health Care

- Highly Recommended
- Recommended
- Not Recommended

Strengths:

Weaknesses:

Future Economic Returns

- Highly Recommended
- Recommended
- Not Recommended

Strengths:

Weaknesses:

Does the proposal adequately justify the appropriateness of and necessity for LSDF funding?

- Yes
 No

Comments:

Does the proposal describe a "program," as defined by LSDF?

- Yes
 No

Comments:

Please note any areas or issues that should be addressed if the principal investigator is invited to an interview. If your overall proposal rating is "Not Recommended," please note any 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: