

First Phase Expert Reviewer Guidelines

Life Sciences Discovery Fund (LSDF) 2009 Program Grant Competition

The following guidelines apply to the LSDF 2009 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/2009/Programs_Grants/) before starting your evaluations. These guidelines will be posted there. Any revisions or additions to the guidelines will also 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 in 2005 by the Washington State Legislature to receive approximately \$33 million per year in tobacco settlement bonus payments over a period of 10 years (\$19.5 million per year in 2010 and 2011) to invest in life sciences research. The mission of LSDF is to support innovative research in Washington State 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 decision-making authority, including funding. The board is considerably informed by the expert evaluation 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 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 applicants 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.

B. Competition Goals and General Proposal Evaluation

LSDF 2009 Program Grant Competition Goals. This competition will award up to \$15 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. Programs are expected to demonstrate a dynamism and synergy among participants that would not exist but for the organization of their efforts into the program. Principal investigators may request the budget amount and duration that are appropriate for the work.

Proposals Must Serve the LSDF Mission. The Life Sciences Discovery Fund is an investment made on behalf of the citizens of Washington State 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 State. It is the principal investigators' responsibility to articulate that environment clearly and to define convincingly the specific benefits their research is designed to produce.

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.

LSDF also funds two other approaches in separate RFP processes. Projects are focused, investigator-initiated studies that will be accomplished during the LSDF grant term. 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.

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 State. A fundable proposal will be innovative, address important issues, and generate confidence that the proposed research will make a significant impact. [More information on anticipated returns on the state's investment in life sciences research is included in the 2006 LSDF Report to the Washington State Legislature found on the LSDF website at: [http://www.lsdfa.org/about/files/12-01-06_Report_to_the_Legislature.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. Such resource commitments demonstrate that the proposed program is of strategic importance to the applicant organization and that the organization is invested in helping the program 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 charges;
 - provision of laboratory, clinical, or office space that is newly or specifically designated for program activities;
 - support for renovations of program facilities;
 - purchase of new equipment or supplies, or dedication of existing equipment or supplies to the program; and
 - matching funds from institutional sources.
- **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 a long-term plan 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.
- **Programs must include a well-detailed plan of research.** In addition to detailing the program's structure and operations, 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.

Programs may include establishment of core facilities or infrastructure. However, proposals that seek only to develop such resources in the absence of clearly articulated research objectives are not fundable. 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.

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 the first phase review is to place proposals into one of three rating categories (Highly Recommended, Recommended, or Not Recommended). This placement will reflect the reviewers' collective recommendation for advancing the proposal to the interview stage.

You will first evaluate proposals individually, according to your assessment of their strengths and weaknesses. Once all of the proposal evaluations are complete, you and the other expert reviewers will participate in a phone meeting, and a consensus evaluation will be written. 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, and to inform the board in making its decisions. Neither principal investigators nor LSDF will receive individual reviewers' preliminary comments on proposals or their names.

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.

C. Detailed Proposal Evaluation Criteria

Please read sections 1.2, 3.3.4, 3.3.5, and 4.2 in the RFP for further context.

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 with regard to all of the criteria described below.

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.

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 criteria (below).

Scientific and Technical Merit

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

- it meets LSDF's definition of a "program" and offers the likelihood of synergistic outcomes;
- it is innovative, with scientific and technical originality;
- it focuses on a significant problem or complex set of problems;
- it builds upon the established strengths of the applicant organization;
- its objectives are consistent with the strategic priorities of the applicant organization;
- the applicant organization commits significant resources to enhance the probability of the proposed program's success;
- it establishes a research framework with strong potential to achieve novel and important results;
- 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;
- it has the potential to increase the life sciences competitiveness of the applicant organization and of Washington State;
- 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, sustainably fostering commercialization of multiple projects, monitoring progress, and addressing various types of potential delays and difficulties;
- the budget is appropriate to the scope and goals of the proposed program; and
- the principal investigator makes a clear case for why an investment from LSDF is appropriate and necessary to the success of the program.

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; and
- a coherent decision-making structure (governance) exists.

Importance to Health and Health Care

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

- it addresses a significant issue in health or health care;
- it has the potential to make substantial, beneficial, and measurable contributions to improving health and health care;
- it will achieve benefits 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 State citizens.

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, the following:

- 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 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? (or, "Why is LSDF funding appropriate and necessary for this program?") (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 intends to provide grant support that is not readily available from other sources. Its purpose is to play a catalytic role in helping investigators and their organizations apply their strengths in various areas of research. Proposals should clearly detail why the program is not necessarily appropriate for other funding opportunities and why the program cannot be accomplished without LSDF's investment. They 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 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. Institutional commitment can take forms other than cash, such as commitment of space and faculty hiring.

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 has revised the budget forms to require greater detail than in prior competitions. Specifically, principal investigators must provide - 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 or the LSDF grant period (whichever is longer), and how those revenues will be allocated. LSDF has also moved the budget justification from the proposal narrative to a separate document to encourage greater detail. 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. Principal investigators are not to apply their federally negotiated indirect cost rate to their "direct" costs to derive facilities and administration (F & A) charges. You are not expected to determine how the principal investigator arrived at the F & A charges. Awardees will be required to provide a detailed breakdown of all costs.

Eligibility. You may assume that organization eligibility has been reviewed by LSDF staff, but you may raise concerns with AAAS if you feel strongly that an organization is ineligible.

Innovation. LSDF wishes to support innovative programs, especially within the context of a portfolio of funded programs that spans the spectrum of risk. See also "Outliers," below.

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.

Success of approach vs. importance of problem. Note that you should rate the proposal as presented by the principal investigator and not on the basis of its theoretical potential, *e.g.* in the absence of its 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. In the "Importance to Health and Health Care" criterion, even though this disease is very important and its cure would be extremely valuable, if the proposal's approach is flawed, the rating for this criterion should not be high.

E. Overall Rating

Interviewee Selection. This is a highly competitive fund. Twenty-nine letters of intent were received for the 2009 Program grant competition, and funds available will be sufficient for no more than 3 to 5 awards, depending on the number and quality of submissions received. The Board of Trustees will take the first phase consensus evaluations into account in choosing interviewees, but will have state-specific interests to consider as well.

Outliers. LSDF understands that proposal quality will vary across the core evaluation criteria. For example, a proposal that may not be scientifically innovative may offer a major opportunity to impact health-care cost effectiveness. Similarly, a mid-level proposal in the economic return and health-care categories could have outstanding scientific innovation. 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

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 review system.

AAAS Review Comment Form First (Mail) Phase Evaluation

Life Sciences Discovery Fund (LSDF) 2009 Program Grant Competition

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

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 main strengths and weaknesses of the proposal. Include any recommendations for changes to the budget.

Overall comments:
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

Overall comments (Include your assessment of the competency of the principal investigator and team to carry out their respective roles):

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:

Importance to Health and Health Care

- Highly Recommended
- Recommended
- Not Recommended

Overall comments (Include whether near-term benefits are likely):

Strengths:

Weaknesses:

Future Economic Returns

- Highly Recommended
- Recommended
- Not Recommended

Overall comments:

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: