

Washington State Life Sciences Discovery Fund Authority Request for Proposals LSDF 07-02

Innovative Programs to Advance Health Research

June 27, 2007

Executive Summary

Applicants are invited to propose innovative programs to advance health research. Proposals are invited from Washington nonprofit organizations, singly or in collaboration either with other nonprofits or with for-profit companies.

This funding opportunity of the Life Sciences Discovery Fund will distribute approximately \$20 million dollars in grants for new strategic initiatives designed to accelerate the development of answers to important health questions and to make life sciences inquiry more productive.

Letters of intent are due August 8, 2007, with proposals due October 24, 2007, and award announcements expected April 9, 2008.

There is no cap on grant amount or duration. A typical award is expected to be between \$2 and \$4 million and to range over three years.

In order to provide the most robust grant support for applicants in this competition, all the actual costs of research will be allowable for LSDF funding as direct costs.

Proposals will be evaluated according to scientific, technical, and organizational merit, benefits to health and health care, and future economic outcomes. All awardees will demonstrate the potential to contribute to LSDF's primary strategic goals—promoting life sciences competitiveness, improving health and health care for Washington's citizens, and fostering economic growth.

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1. Introduction

1.1. Title

Innovative Programs to Advance Health Research

1.2. Objective

This funding opportunity—LSDF 07-02—has been designed to support new programs of research with the potential to achieve significant scientific, competitive, health, and economic benefits for Washington State. Proposals are invited from Washington nonprofit organizations, singly or in collaboration either with other nonprofits or with for-profit companies.

1.3. Background

The Life Sciences Discovery Fund Authority (LSDF) was created in 2005 by the governor and legislature of the State of Washington. LSDF is authorized to invest \$350 million of tobacco settlement bonus payments in the state's life sciences sector over ten years beginning in 2008. In fulfilling this legislative mandate, LSDF seeks to enable innovation by providing the sort of catalytic resources traditionally not available from other granting sources. Its mission is to support innovative research in Washington State to promote life sciences competitiveness, enhance economic vitality, and improve health and health care.

Examples of areas of research expected to improve health and health care include the following:

- new approaches to diagnosis, treatment, prevention, and management of disease;
- translation of basic science discoveries to health-care practice;
- implementation of predictive and preventive health-care strategies
- advances in human nutrition;
- scale-up of effective health-care practices from individuals to populations;
- demonstrations of improved efficiencies and outcomes in health-care delivery; and
- innovations in health-care cost effectiveness.

Research dedicated to achieving these beneficial health and health-care results is also expected to foster substantial economic returns by creating new jobs, attracting additional non-state dollars in research funding and investment to the economy, and enhancing commercialization of scientific innovations. Further discussion of 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.

1.4. Frequently Asked Questions (FAQ)

For brief answers to the most common questions asked by potential applicants about LSDF and its opportunities, see the Appendix or visit the [Grants](#) section of the LSDF website.

1.5. Eligibility

Applications for LSDF funds are submitted by a principal investigator, acting on behalf of the organization where he or she is employed and only with that organization's authorized approval. Throughout this request for proposals (RFP), the terms "applicant" or "applicant organization" refer to the organization employing the principal investigator.

An application may include one or more co-applicants. A co-applicant is an organization other than the applicant organization that employs personnel key to the implementation of the program or the design, conduct, and reporting of the program research. Only one of the collaborating organizations will assume the role of applicant. The applicant organization will take responsibility for submitting the application and for managing administration and disbursement of LSDF funding for program activities. Except for these unique responsibilities, which belong to the single organization submitting the grant application, the use of the word "applicant" in this RFP also refers to any co-applicant organizations participating in the proposed program.

An application may also include one or more co-investigators. A co-investigator is an individual other than the principal investigator who plays a leading role in the design, conduct, and reporting of the program research. Though a principal investigator may submit only one application for this competition, he or she may serve as a co-investigator on other proposals.

Eligibility for LSDF 07-02 grants is restricted to nonprofit institutions, state and local government agencies, and educational institutions in Washington. Eligible applicants will have been recently engaged in competitively funded, sponsored research, or similar activities, and will have the capacity, resources, and experience necessary to launch, grow, and maintain a program of the sort contemplated by this RFP. Applicants will include, but not be limited to, the following:

- public and private universities,
- nonprofit research institutions,
- public health departments,
- public and private hospitals, and
- health-care systems and clinics.

For-profit entities are not eligible to apply individually for funding under LSDF 07-02, but are encouraged to join an eligible applicant in a collaborative proposal.

Organizations from outside of Washington State are not eligible to apply individually for funding, but they may join an eligible applicant in a collaborative proposal. In order to be funded, the necessity for the collaboration will need to be justified. Further, the

proposed results of the program will need to be demonstrably beneficial to the citizens of Washington.

1.6. Request for Proposal Updates

The information applicants need to apply for LSDF 07-02 is included in this RFP. LSDF reserves the right to amend the RFP after its release. Any additional information—any amendments, clarifications or changes in guidelines or requirements—will be posted on the LSDF website, www.lsdfa.org. Applicants are responsible for consulting those addenda to be sure they have the latest information regarding this competition.

2. Funding Opportunity Description

This section describes the scope, purpose, and essential requirements for an LSDF 07-02 grant proposal.

2.1. Overview

LSDF invites proposals having the potential to advance life sciences research competitiveness, benefit the Washington economy, and improve human health and health care in the state.

LSDF 07-02 is intended to support the development of new, innovative, strategic research initiatives. Proposed programs will have clear strategic importance for the applicant organization. Each funded proposal will address how the applicant organization plans to build and launch the program it describes, how the program advances the strategic direction of the applicant organization, and what resource commitments are in place or will be in place to support and sustain the program's growth and development.

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 new areas of research. Proposals should clearly detail why the program is not necessarily eligible for other funding opportunities. They should explain how their program's purpose and scope make the LSDF a particularly appropriate source of funding.

Approximately \$20 million will be available for awards in this competition. There are no restrictions on the dollar amounts or duration of funded grants, but a typical award is expected to be between \$2 million and \$4 million and to range over three years.

2.2. Nature of the Grant Opportunity

This RFP invites proposals for programs that will be innovative within their fields, build upon established strengths within the participating organization(s), have the potential

for growth and sustainability over time, and benefit their organizations, their communities, and the state.

Innovation in funded programs may take many forms. Programs may formulate research problems in original ways, reframe issues in a field, and advance new experimental approaches. They may accelerate the development of answers to important questions—creating new collaborations within and outside the applicant organization, creating cross-disciplinary perspectives that have the potential to make life sciences inquiry more productive. Restructuring of existing resources within an organization does not constitute a new program, as the term “program” is envisioned within this RFP. Nor is an applicant’s need for infrastructure development a sufficient basis for a program proposal. Rather, LSDF support is meant to aid organizations in launching new initiatives that represent innovative thinking within the organization and the field.

Program proposals eligible for LSDF 07-02 funding may request support for many kinds of activities. A few examples are included here to suggest the range of possibilities:

- establishing new centers for research,
- creating new multi-institutional consortia,
- recruiting outstanding scientists to lead new research programs, and
- acquiring major equipment to accelerate advances within a new research program.

The benefits derived from programs in this competition are also varied. Examples of benefits include the following:

- enhancing the ability of the state’s life sciences sector to solve important problems in health and health care;
- attracting additional financial resources to life sciences research;
- advancing the scientific leadership position of Washington research organizations;
- promoting the training of the state’s workforce, particularly in an emerging industry;
- drawing new scientific talent to Washington in the form of students, post-doctoral fellows, researchers, and companies; and
- developing opportunities for new intellectual property creation and commercialization.

2.3. Requirements for Program Proposals

Programs proposed for LSDF 07-02 funding must be based on a rigorous scientific and organizational rationale. In establishing that rationale, all proposals will be expected to describe the following:

- the proposed program and the types of innovations it brings to the field;
- the problem or area of study to be addressed and its importance;
- the strategic importance of the program to the applicant organization;
- the roles of the participating organizations and how their activities will be coordinated;

- how the proposed program builds upon the organizations’ and investigators’ prior research and experience, and capitalizes on their established strengths and excellence;
- the facilities in which the program will be housed and the major equipment and other tangible resources that will be made available to the program;
- the scientific personnel who will be involved in the program, their roles and any plans for expansion of personnel;
- the support personnel and their roles;
- how the program will be structured, managed, funded, and developed during its first five years, including milestones, budgets and sources of funding;
- expected outcomes, clearly articulated and capable of being documented;
- how and at what intervals the program will be evaluated; and
- tangible commitments from the participating organizations to support the proposed program.

Proposals must detail how the program will increase the future competitiveness of the Washington life sciences sector. They must also describe the potential for the program’s research to benefit the health of the state’s citizens or to beneficially impact the state’s health-care systems, as well as the time frame for doing so.

Proposals for this competition must also describe the economic benefits that have the potential to flow from the new program. Proposals must detail the program’s potential to secure other sources of financial support, follow-on research funding, or commercialization investment in the future. Innovative programs with the potential to leverage near-term economic and health benefits for the state are particularly desirable.

At the time of application, it is not necessary for the applicant to have secured all of the funding and resource commitments upon which the program proposal is predicated. LSDF may make an award contingent upon the applicant’s ability to secure the additional resources necessary to launch the initiative. The period reserved to satisfy any contingencies shall be specified by the LSDF. In order to be selected for a contingent award, the proposal must detail convincingly how, from whom, and by when the remaining commitments will come. Programs in which LSDF dollars can be used to leverage those from other entities in building a new initiative will be regarded as especially strong.

Programs funded by LSDF 07-02 grants will be expected to demonstrate sustained institutional commitment to long-term results. Therefore, although the duration of grants is not limited, the RFP asks applicants to describe program operations, growth projections, and funding plans for five years or the grant period, whichever is longer.

3. Application Process

Compliance with this RFP and assurance that application materials are accurate, complete, and timely is the sole responsibility of the applicant. Application materials

that do not adhere to content requirements, are incomplete or incorrect, or are late will not be reviewed.

The application process consists of two steps: a letter of intent (LOI) followed by a proposal. LOIs and proposals will be submitted electronically via an on-line application system available on the LSDF website, www.lsdfa.org. Instructions for submitting LOIs and proposals are provided in the application system. LOIs and proposals do not need to be completed in one session. They can be saved and returned to later for additional work. Once submitted to LSDF, however, they are no longer available for revision.

Note: Each LOI and proposal must contain the approval signature of an authorizing individual within the applicant organization. Because of the strategic nature of this grant opportunity, LSDF expects that approval signatures will come from persons with the authority to make strategic commitments of applicant organization resources. The instructions for authorized signature submission are found in the on-line application system.

Applicants who discover an error or omission after submitting an LOI or proposal, but before the final deadline for submissions, may notify LSDF at programs@lsdfa.org and seek authorization to submit a corrected document. Only complete and fully compliant proposals received by the deadline will be accepted and reviewed.

3.1. Key Dates

Letter of intent due	Wednesday, August 8, 2007, 5:00PM PDT
Proposal due	Wednesday, October 24, 2007, 5:00PM PDT
Review of proposals	October 2007—March 2008
LSDF Trustees award selection	April 8, 2008
Awards announcement	April 9, 2008
Funding start date	Upon completion of the grant agreement between LSDF and the applicant organization

3.2. Letter of Intent

All applicants must submit an LOI stating their intent to submit a proposal. The LOI does not bind the prospective applicant to submit a proposal. However, no proposal will be reviewed unless an LOI has been received by the deadline of 5:00PM PDT, Wednesday, August 8, 2007.

The LOI is not a pre-proposal. It is not intended to be a screening mechanism. The LOI helps LSDF prepare for peer review of the proposals. In the rare circumstance that an LOI describes a program that is clearly not suited for LSDF 07-02 funding, the sender will be notified of that determination.

The LOI is to be submitted by the principal investigator, with the written approval of the applicant organization that employs him or her and that will be legally and financially responsible for the activities supported by the award.

Detailed instructions for LOI submission are found in the on-line application system. In order to access the on-line system, the principal investigator will need to know the Entity Identification Number (EIN) or Tax-ID number of the applicant organization.

In addition to other information, LOIs include the following:

- a descriptive, non-confidential name for the program;
- a list of co-applicants;
- an abstract of 500 words or less, stating the objectives of the proposed program, the strengths and resources the program will build upon, and its most important scientific, economic, and health benefits; and
- the name and contact information of the individual from the applicant organization whose signature provides institutional authorization for the letter of intent.

The LOI and ensuing proposal are expected to consist of the same subject matter. Although the text of the LOI abstract may be different than the text of the abstract within the proposal, the overall content of the proposal must be the same as that of the LOI.

Upon receipt of the LOI by LSDF, an e-mail acknowledgement will be sent to the principal investigator. Acknowledgment from LSDF will reiterate the invitation to submit a proposal for LSDF 07-02.

3.3. Proposal Requirements

The proposal is to be submitted electronically following instructions within the on-line application system. The final deadline for proposals is 5:00PM PDT, Wednesday, October 24, 2007.

Upon receipt of the proposal by LSDF, an e-mail acknowledgement will be sent to the principal investigator.

The proposal consists of several sections:

- face page,
- narrative,
- budget,
- biographical information,
- letters of support, and
- intellectual property certification.

3.3.1. Face Page

The face page section contains essential information for identifying, processing, and tracking the proposal. The information includes, but is not limited to, the following elements:

- the program name (which should be both descriptive and non-confidential);
- the name of, and contact information for, the principal investigator;
- the names of co-applicants;

- the name, address, type, and Entity Identification Number (EIN) of the applicant organization;
- the dates of requested program support;
- the budget amount being requested;
- key words related to the proposed program;
- an abstract, not to exceed 500 words and written in prose understandable to a lay audience;
- notification of whether the proposed research involves the use of human subjects or vertebrate animals (and the Federal Assurance Numbers, as appropriate);
- the name and contact information of the individual from the applicant organization whose signature provides institutional authorization for the proposal; and
- the authorizing signature.

3.3.2. Proposal Narrative

The proposal narrative is to be uploaded in Portable Document Format (PDF) to the on-line application system.

Length and Format. The narrative must be no longer than 20 pages and conform to the following format requirements:

- 8½" by 11" portrait-oriented page dimensions
- Single spaced with all margins measuring at least 1"
- At least 12 point font in Times New Roman or Arial (not proportionally reduced)
- Type density of no more than 15 characters per inch
- No more than six lines of type within a vertical space of 1"
- In the upper right-hand corner of each page, inclusion of a header with the name of the principal investigator, the grant competition number (*i.e.*, LSDF 07-02), and the page number, using the form: "Page x of xx."

The narrative must be self-contained. All tables, charts, or graphs must be contained within the 20-page limit. Consult the on-line application instructions for specific information about the format of tables, charts, or graphs. References are to be included within the narrative, but do not figure in the 20-page limit. Website addresses (URLs) or attachments should not be used to provide additional information necessary to the program description.

Instructions for submitting the narrative are provided in the electronic application system.

Proposals that do not comply with these length and format requirements will not be reviewed.

Content. (*See also Section 2.*) The proposal narrative must include sufficient information needed to evaluate the scientific rationale and beneficial returns of the program, independent of any other document. Where content requirements make reference to the "applicant," they refer also to any co-applicants who may be participating in the

proposed program. The narrative should make clear how each of the co-applicants meets the requirements. The narrative must include all the following sections.

A. Program Objectives and Relevance to LSDF Goals

List the immediate and long-term objectives of the proposed program. Explain its importance to the strategic direction of the applicant organization and how it will advance the organization's research strengths. Relate the objectives of the proposal to the broad, long-term goals of LSDF—scientific competitiveness, improved health and health care, and economic benefit for Washington.

B. Background and Significance

Describe the background planning and preparation leading to the proposed program and the important scientific and health needs it is designed to address. Do not include detailed background on prior research and data. Instead, focus on the background of the program and point to the planning and research efforts that give it compelling purpose.

C. Established Organizational Experience

Describe the principal investigator's and applicant organization's experience in launching, growing, and conducting comparable initiatives or programs. Include relevant experience with strategic planning, organizational leadership, collaborative structures, personnel and budget management, the coordination of multi-faceted research activities, success in attracting and retaining talent, management of sustained institutional buy-in and support, and effective use of major facilities, equipment, and instrumentation.

D. Program Description

Provide a detailed account of the proposed program's structure, operation, research agenda, and anticipated results. Explain the research focus of the program and the anticipated sources of its funding.

If the proposal involves the acquisition of a major piece of equipment, explain in detail the role the equipment will have in achieving the program's objectives. Indicate also the provisions that have been made for its use and maintenance.

Summarize how the program will advance and grow for the first five years, during the grant period and beyond. Describe its future directions and the applicant's resource commitments to its long-term sustainability. Describe also the schedule and methods of evaluation by which the program and its research will be assessed.

E. Challenges

Discuss the difficulties the proposed program may face in achieving its objectives and the plans being developed to overcome these challenges.

F. Timeline and Milestones

Provide a timeline for developing, funding, launching, and conducting the program. Identify major milestones of progress, target dates for accomplishment, and criteria by which achievement of each of the milestones

will be assessed. LSDF expects to make phased funding disbursements contingent upon grantees achieving the milestones to which they and LSDF have agreed.

G. Personnel

Identify the person(s) who will lead and manage the program's operations, describing their various roles. If researchers from multiple organizations will participate in the proposed program, explain how decision-making authority will be distributed among them. Identify all the key personnel responsible for conducting the program's research. Provide a brief summary of their background and research expertise, and explain how their work will be coordinated to fit the program.

If the proposal involves the recruitment of a leading researcher, explain the role and responsibilities he or she will assume in the program, and describe how his or her ongoing research will catalyze or complement the program's scientific mission.

H. Budget Justification

Describe the complete funding plan for the first five years of the program, during the grant period and beyond. Provide the rationale for both the costs and revenue itemized in the proposal budget. Identify those categories of expense that require the kind of support traditionally incorporated in an indirect cost allowance, and justify the need for such support in the operation of the program. Explain the program's appropriateness for LSDF support, the resource commitments of the applicant organization, the amounts and sources of other program support, and projections for follow-on funding from other sources. The budget description should also explain the need for any extraordinary expenditures or for a special disbursement schedule.

I. Facilities and Equipment

Describe the facilities, equipment, and other laboratory, clinical, and office resources available for program activities. Summarize the arrangements and agreements that have been made to ensure that these facilities will continue to be available and maintained in support of the program.

If new equipment is part of the proposal request, describe available equipment and explain why it cannot be used. If the new equipment will be available to support efforts outside the scope of the program, explain how time and LSDF funding support will be allocated to it. Describe plans for facilities and equipment maintenance necessary for the sustained success of the program.

J. Outcomes

Describe both the near-term and long-term outcomes the program is designed to achieve. Explain the near-term health benefits and economic consequences of the program. Describe also the following:

- the potential for follow-on research funding;
- clinical application of program-developed scientific findings;
- commitments from the applicant organization, collaborating organizations, research partners, or other interested parties to maintain and grow the program;

- commercial development of program technology;
- formation of new companies or licensing of program discoveries; and
- investor funding associated with commercialization activities.

Explain in detail the program’s potential to increase the life sciences competitiveness of the applicant organization and of Washington State.

3.3.3. Budget

The budget must be appropriate for the scope and goals of the proposed program, and its rationale must be justified in the proposal narrative.

Programmatic initiatives such as those envisioned by LSDF 07-02 are characteristically expensive and complex. They often consist of a blend of elements ranging from capacity-building to the actual conduct of research. Budgeting for these initiatives, therefore, often requires a combination of types of categories and sources of funding.

The budget for proposed programs in this competition must itemize all of these categories of cost and revenue, and all costs should be listed as direct costs.

A. Resource commitments from sources other than LSDF

LSDF expects that applicant organizations will make tangible resource commitments to support the proposed programs. Such resource commitments demonstrate to LSDF 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. Resource commitments may include, but are not limited to, the following:

- creation and support of positions for key programmatic researchers,
- support of technical and administrative personnel,
- provision and improvement of facilities,
- absorption of indirect costs, and
- matching funds from institutional sources.

In proposals including for-profit collaborating companies, the companies will be expected to pay for their own internal costs associated with program development and for research and development activities performed on a best-effort basis. Monies may be subcontracted from the applicant organization to a company for products and services provided as deliverables to the program.

Funds acquired from or committed by sources other than LSDF—*e.g.*, the applicant organization, collaborating organizations, other granting agencies or foundations, donors, companies, and investors—should be listed in the budget and certified with letters of support. Opportunities for LSDF to leverage its support with that of other contributors are particularly desirable.

LSDF may make an award contingent upon the applicant’s ability to secure the additional resources necessary to launch the initiative. Refer to Section 2.3 for further detail about contingent awards.

B. Budget Preparation

In order to provide the most robust grant support for applicants in this competition, all costs reasonably associated with the development and operation of the proposed program should be included in the proposal budget. All should be listed as direct costs, including costs typically associated with general facilities and administration expenses.

Instructions for uploading the budget are provided in the on-line application system. Applicants are to provide a total program budget for the first five years of the program or for the grant period, whichever is longer.

The following budget categories should be included:

- salaries (including wages, benefits, stipends, and education fees for trainees);
- equipment specifically required for program research;
- administrative costs;
- facilities costs;
- supplies;
- services;
- grant-related travel; and
- other.

In the “other” category, applicants should itemize costs falling outside of the typical budget categories above.

Costs associated with patient care beyond what is required for program research are not allowed by LSDF.

Indicate each of the sources of revenue intended to support the budget, including the total amount being requested from LSDF. Where non-LSDF sources of revenue can be allocated across the budget categories, please do so; otherwise list them as total contributions to the program.

In order to allow applicant organizations maximum flexibility in cost allocation, LSDF funds do not need to be allocated to specific costs in the proposal budget. Detailed budget allocations describing the specific uses of LSDF funding will be requested at the time of the grant agreement. A mutually agreed upon detailed budget will become part of the grant agreement between LSDF and the applicant organization. Re-allocation of LSDF monies will be permissible after the award, subject to LSDF approval.

3.3.4. Additional Required Information

Proposals must include biographical information on key research and administrative personnel using biosketch forms provided within the on-line application system.

Letters of support are required to confirm the commitment of time and resources from key personnel and organizations.

Applicants must also include an intellectual property ownership and management certification, a detailed description of how intellectual property will be owned and managed. (See Section 6.7 for further information.)

Instructions for uploading this information are included in the on-line application system.

4. Evaluation

Following the proposal deadline, all proposals will be screened for compliance with this RFP. Those that are judged to be compliant will be submitted for confidential expert review. Reviewers will evaluate the proposals according to the criteria described below.

4.1. Key dates

October 2007—March 2008 Expert review of proposals

4.2. Expert Evaluation

Proposal evaluation will be conducted by expert reviewers from outside Washington State. Evaluations will be submitted to the [LSDF Board of Trustees](#) to facilitate selection of award recipients (see Section 5: Selection below).

LSDF reserves the right to invite applicants for a personal interview or to require a site visit as part of the expert review process. LSDF will be responsible for travel costs incurred by applicants invited for these visits.

Except in cases where there are site visits or personal interviews, the names of reviewers will not be made available to applicants. Applicants and their representatives are not permitted to contact reviewers or members of the LSDF Board of Trustees regarding submitted applications. Any such contact or attempt to contact reviewers or LSDF board members concerning pending applications may result in the disqualification of that applicant's proposal from the LSDF 07-02 grant competition.

4.3. Evaluation Criteria

All funded proposals will be expected to have the potential to contribute to LSDF's primary strategic goals: to improve health and health care for Washington's citizens, to increase the competitiveness of the state's life sciences sector, and to strengthen its economy. Within this general framework, reviewers will use the following criteria to evaluate proposals for LSDF 07-02.

4.3.1. Scientific, Technical, and Organizational Merit

The scientific, technical and organizational merit of the proposal will be judged by how well it demonstrates the following qualities of the proposed program:

- the proposed program is innovative, with scientific and technical originality;
- it focuses on a significant problem or complex set of problems and provides promising new approaches or ways of thinking;
- it proposes innovative hypotheses or addresses critical barriers to research progress in the field;
- it establishes a research framework with strong potential to achieve novel and important results;
- it has the potential to make a substantial contribution to the program’s field of research;
- it has the potential to establish the applicant organization and any co-applicants as leaders in the field;
- it will measurably increase the life sciences competitiveness of the applicant and of Washington State;
- its proposed research outcomes are clearly defined;
- the significance of the program’s outcomes is clearly established, and the importance of the program in achieving them is demonstrated;
- the program is demonstrably superior to alternate approaches in achieving its scientific outcomes;
- the principal investigator and any co-investigators demonstrate the experience and ability to execute the proposed program successfully;
- where collaboration is required, investigators demonstrate a history of effectively working together and an appropriate plan to manage the collaborative process;
- the proposed program builds upon the already established strengths of the applicant organization;
- the objectives of the program are consistent with the strategic priorities of the applicant and co-applicant organizations;
- the applicant and co-applicant organizations demonstrate this alignment by committing resources to enhance the probability of the proposed program’s success; and
- the budget is appropriate to the scope and goals of the proposed program.

4.3.2. Importance to Health and Health Care

The program’s importance to health and health care will be judged by how well the proposal demonstrates that it possesses the following qualities:

- the program has the potential to make a substantial and measurable contribution to improving health and health care in Washington
- it will move the current state of knowledge in health or health care forward
- it will achieve one or more of the following benefits: improved diagnosis, treatment, prevention, and management of disease and improved delivery of health-care services.

The range of possible proposed improvements is understood to be broad, and the intended health results of the proposed program may be near- or long-term. Priority will be given to proposals that address widespread health and health-care problems and that provide compelling evidence that they have the potential to yield the greatest benefits for Washington citizens.

4.3.3. Future Economic Returns

The proposed program must have the potential to benefit Washington's economy. Applicants must clearly state the proposed economic benefits of the program and how those benefits improve the state's economic environment. Benefits may include, but are not limited to, the following:

- direct economic activity entailed in the operations of the program and the conduct of its research;
- measurable savings in the cost of health care due to the application of program research results;
- future economic consequences of program-induced improvements in health;
- new training and employment opportunities fostered by the program's research enterprises;
- success in attracting life sciences researchers, companies, and jobs to Washington;
- success in creating new companies and jobs and attracting investment capital to Washington;
- creation of intellectual property, presenting attractive licensing opportunities for start-up and existing companies; and
- future life sciences research funding.

5. Selection

5.1. Key date

April 8, 2008 LSDF Board of Trustees selects awardees

5.2. Selection process

Expert reviewers will recommend proposals to the LSDF Board of Trustees for funding. The board's selections will be based on these recommendations, the availability of funds, and the goals of the LSDF program. Consistent with these and with its enabling legislation, the board also will consider factors such as the following in making awards:

- diversity of research,
- variety of health benefits,
- breadth of economic opportunity, and
- geographic impact.

Based on its consideration of all of these factors, the board will select proposals which in its judgment are the most meritorious.

Final awards are subject to negotiation between the applicant organization and LSDF regarding the cost, scope, and milestones associated with the proposed program.

All award decisions are final and cannot be appealed.

Successful and unsuccessful applicants will receive copies of the expert reviewers' evaluations.

6. Additional Information

6.1. Application submission limits

Each application submitted to the LSDF must have a single principal investigator. Principal investigators may submit only one application for this competition. However, they may also serve as co-investigators on other proposals. There is no limit to the number of applications that may be submitted from an applicant organization.

6.2. Principal investigator requirements

LSDF grant proposals must have a single principal investigator, regardless of how many investigators or organizations will be involved in the program. The principal investigator must be employed by the applicant organization. He or she will be responsible for leading the proposed program, ensuring that the scientific and technical requirements of the grant agreement are met, and reporting the progress and results of the program as required by LSDF. To be a principal investigator on an LSDF grant, individuals must meet the requirements set by their employer for such status.

Awards cannot be reassigned or transferred without written authorization from LSDF. If the principal investigator of a funded program changes his or her employment status with the recipient organization or otherwise becomes unable to continue in the role of principal investigator, the recipient organization must, within 30 days, notify LSDF and identify an alternate principal investigator, acceptable to LSDF, to assume leadership of the program. If such an arrangement is not feasible, the portion of the award remaining after payment of documentable recipient organization expenditures will be rescinded.

6.3. Confidentiality

Information in grant applications is received by LSDF with the understanding that it shall be used or disclosed only for evaluation of applications or as required by law. LSDF holds all applications confidential in accordance with its [confidentiality policy](#) and subject to the public disclosure laws of the State of Washington (for more information,

applicants are referred to RCW 42.56 and to the amendments to the exemption provisions in RCW 42.56.270(14)).

Typically, when it receives LOIs and proposals, LSDF expects to release to the public the name of the principal investigator, the applicant organization, the non-confidential name of the program, the dates of the proposed grant period, the funding amount requested, and miscellaneous contact and demographic data. For unfunded proposals, LSDF will not release the abstract or narrative of the proposed work, the budget, or the names and contact information of any co-investigators or co-applicants, as disclosure of these items might be expected to result in private loss to the applicants or investigators. Once a proposal has been funded, LSDF will make the non-confidential sections of the proposal public.

LSDF requires expert reviewers to sign confidentiality and conflict of interest agreements.

No proposal should include information that might compromise the applicant's subsequent ability to secure patent or other intellectual property protection.

If LSDF receives a public records request for disclosure of applicant information, it will notify the applicant organization of such a request in a timely manner in order to allow the applicant organization to assert objections to disclosure in any applicable proceeding.

6.4. Conflict of interest

Financial conflict of interest has become an increasingly important issue in research. When performing research, it is essential that the personal interests of investigators do not impede their judgment or compromise their objectivity. Even the perception of conflict has the potential to erode the public's confidence in the research process. It is essential that applicant organizations have a financial conflict of interest policy in place and that all proposals submitted to LSDF will have been vetted according to that policy. In accepting an LSDF award, the applicant organization will certify to LSDF in the grant agreement that potential financial conflicts of personnel participating in the funded program have been disclosed and that all conflicts have been eliminated or mitigated. Applicant organizations that do not have a financial conflict of interest policy should consult with LSDF (programs@lsdfa.org) early in the application process to discuss how the financial conflict of interest review will be performed.

6.5. Grant agreement

LSDF awards are subject to grant agreements which will be negotiated between the grant recipient organizations and LSDF. The agreements will include the following:

- specification of the principal investigator responsible for launching and conducting the program,
- the funding amount and duration of the grant,
- milestones for the program's development and research activities and timelines for their achievement,

- the criteria to be used for assessment of milestone completion,
- the financial and other resource contributions of the recipient organization and any other participating organizations,
- auditing and reporting requirements,
- a detailed budget showing how LSDF grant funds are to be allocated, and
- other standard terms and conditions.

Research funding will be disbursed to applicant organizations in increments based upon mutually agreed upon milestones and timelines. As part of the grant agreement, LSDF will reserve the right to withhold future payments if timely progress reports have not been provided or agreed upon milestones have not been met.

6.6. Human subjects and vertebrate animal research requirements

If a proposed program will be conducting research involving human subjects, the applicant organization is responsible for ensuring that the research site operates under an appropriate Office of Human Research Protections-approved assurance for the protection of human subjects and complies with all National Institutes of Health (NIH) human-subjects-related policies. In accepting an award from LSDF, an organization certifies that it has a system that complies with federal, state and local government regulations to protect the rights, well-being and personal privacy of human subjects in research and that any LSDF-funded program research involving human subjects will be reviewed and approved by the applicable human subjects oversight bodies.

For research involving vertebrate animals, the applicant organization must ensure that all performance sites hold Office of Laboratory Animal Welfare-approved assurances. In accepting an award from LSDF, an organization certifies that it has a system that complies with federal, state and local government regulations to humanely, efficiently, effectively and legally use live vertebrate animals in research. Further, it certifies that any LSDF-funded program research involving vertebrate animals will be reviewed and approved by the applicable animal use and care oversight bodies.

Any research involving human subjects or vertebrate animals identifiable at the time of negotiation of the grant agreement will need to have been reviewed and approved prior to execution of the grant agreement.

6.7. Intellectual property

LSDF grants are intended to support research that may lead to discoveries having commercial potential. LSDF will not assert an ownership interest in intellectual property (IP) resulting from the research conducted by an LSDF-funded program. Proposals are expected to clarify ownership of IP resulting from program research. If a party other than the applicant or co-applicant organization(s) will own or have rights to IP developed under an LSDF-funded program, the applicant must provide an explanation of and justification for such provisions.

Applicants must describe how IP developed in the course of program activities will be managed. Applicant organizations with established IP management infrastructures can meet this requirement by referencing the policies, practices, and structures they already

have in place for IP management. Organizations without such established infrastructures should explain in detail how they plan to manage and commercialize the IP associated with the proposed program. Applicant organizations that do not have an IP policy or mechanism to manage and commercialize IP should consult with LSDF (programs@lsdfa.org) early in the application process to discuss how IP will be managed.

Collaborative proposals must make explicit provision for an IP rights disposition agreement among the collaborators. Such an agreement must clearly allocate the rights that the collaborators will have in any IP developed within the program and identify which of the parties will be responsible for commercialization of that IP. The IP rights disposition agreement does not need to be submitted with the proposal but must be in place before the grant agreement is signed. One example of an appropriate agreement for this purpose can be found in the Federal Small Business Technology Transfer Research Program—[*"The Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization."*](#)

Electronic forms and directions for describing the IP management plans of the applicant are available in the LSDF on-line application system.

6.8. Reporting requirements

LSDF is an investment by the State of Washington in the future of its citizens. Therefore, full and timely reporting of the progress and results of funded programs by principal investigators has great importance for calculating the returns on investment.

Reporting requirements, specific for each funded proposal, will be finalized in the grant agreement. LSDF requires, at a minimum, the following reports: semi-annual progress reports, final reports, and post-project annual reports for a period of five years. Site visits and in-person briefings by principal investigators may be used by LSDF as tools to track the progress of funded projects. Noncompliance with this reporting requirement may jeopardize the continuation of funding to a recipient organization or eligibility for future LSDF funding.

6.9. Publicity

LSDF reserves the right to publicly disseminate information about its granting activities through a variety of means. Such communications may include lists of LOIs and proposals received, the names of PIs and applicant organizations, the field(s) in which the research will be conducted, descriptions of proposals funded, and reports about program progress and outcomes.

6.10. Funding amounts and award length

The number of awards will generally depend upon the availability of funds and the number of meritorious proposals. The expected total amount of funds available in the 07-02 competition will be approximately \$20 million. LSDF has not established limits for the amount or length of grants, but a typical award is expected to be between \$2 million and \$4 million and to range over three years. Funding will be distributed to

grantees in increments, according to a schedule specified within the grant agreement and based upon timely reporting and the achievement of milestones during the grant period.

6.11. Funding start date

The funding start date in this grant competition may be as early as May, 2008. In no case will funds be released by LSDF to the recipient organization until the grant agreement between LSDF and the grantee institution is completed.

6.12. Contact information

For information about LSDF, procedures and requirements of this competition, or grant administration of LSDF 07-02, visit the LSDF website at www.lsdfa.org, or contact programs@lsdfa.org.

Appendix

Frequently Asked Questions

The following questions and answers are meant to provide a convenient summary of the issues of most frequent interest to potential LSDF applicants. This FAQ may be amended from time-to-time in response to questions received from the community. The most current version of the FAQ is available on the LSDF website at www.lsdfa.org.

A. What is the Life Sciences Discovery Fund?

A.1 What is LSDF and what are its goals?

The Life Sciences Discovery Fund (LSDF) Authority is a Washington State agency, established in 2005 and authorized to distribute up to \$350M over 10 years to life sciences research--to promote life sciences competitiveness, to improve health and health care for the state's citizens, and to foster economic growth.

A.2 What is the source of LSDF funds?

Generous private donors contributed an initial \$3 million to launch LSDF's grant-making in 2007. However, the bulk of LSDF's resources come from the tobacco settlement bonus payments being received by the State of Washington in annual increments of \$35 million from 2008 to 2017.

Funds for LSDF 07-02 grants will come from the first tobacco settlement bonus payment, scheduled to be received in April, 2008.

A.3 What does “life sciences research” mean?

As defined within the Fund’s enabling legislation, life sciences research is “advanced and applied research and development intended to improve human health.”

A.4 What does it mean when I hear that LSDF awards are considered to be “investments”?

The governor and legislature created the LSDF expressly to leverage its tobacco settlement bonus payments for the benefit of the citizens of Washington State. The LSDF is expected to use these public dollars in its grant programs to catalyze tangible public gains. Proposals for funding therefore are expected to demonstrate the potential to earn returns on the state’s investment.

A.5 What types of returns on investment is LSDF seeking?

Knowledge gains will enhance the reputation of Washington as a global center of life sciences research and provide a source of leverage for follow-on research and investment funding. Scientific discovery will contribute to robust industry development and economic growth. Research will lead to innovations that will improve health-care outcomes, efficiencies in delivery, and cost effectiveness.

A more extended discussion of 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.

A.6 Where can I read the legislation that created the Life Sciences Discovery Fund?

LSDF’s enabling legislation, passed on April 23, 2005—[Engrossed Second Substitute Senate Bill 5581](#)—can be read on the LSDF website.

B. What kinds of grants does LSDF make?

B.1 Where can I find information about grant programs or proposal guidelines?

General inquiries about grant programs and questions about proposal guidelines may be addressed to LSDF by e-mail —programs@lsdfa.org.

B.2 What are the size and duration of LSDF grants?

LSDF grants vary in size and duration depending on the competition focus, the needs of the proposals being offered, and the availability of funds. In LSDF 07-02, there are no restrictions on grant size or duration, but a typical award is expected to be between \$2 million and \$4 million and to range over three years.

B.3 LSDF 07-02 invites proposals for innovative “programs.” What are “programs,” and how do they differ from “projects”?

“Projects” are individual scientific studies, relatively limited in scope, with a sharply defined research focus. “Programs” are strategic research initiatives, broader in scope, designed to address problems within a field of study and to position an organization or organizations for future competitiveness and leadership.

LSDF 07-02 invites proposals for programs. Proposals for “projects” will not be eligible for this competition.

B.4 My organization needs infrastructure expansion for programs that are already underway. Is this need eligible for LSDF 07-02 support?

No. LSDF 07-02 is designed to support new programs, not to provide additional infrastructure for existing programs.

B.5 Does the LSDF make equity investments in companies?

No. The LSDF makes grants to nonprofit entities for the purposes of research.

C. Who may apply for an LSDF grant?

C.1 Who may apply for LSDF funding under LSDF-07-02?

Applicants must be nonprofit Washington State institutions or organizations, including public and private universities, nonprofit research institutions, public health departments, and nonprofit hospitals and clinics.

C.2 How can I receive grant funding from LSDF?

You can receive funding by submitting an application—on behalf of an eligible organization—in response to a request for proposals (RFP) announced by LSDF. Notices of RFPs are published on the LSDF website (www.lsdfa.org).

C.3 Can for-profit or out-of-state entities apply?

No, but they may join Washington nonprofit applicants in collaborative proposals.

C.4 Is collaboration required for LSDF proposals?

No, but it is encouraged, to foster an even more vibrant and competitive life sciences sector for Washington State.

C.5 Who within eligible organizations may apply?

To be a principal investigator on an LSDF grant, individuals must meet the requirements of their employer regarding such status. Though prepared and submitted by the principal investigator, proposals officially come from the applicant organization, not the principal investigator. Both the letter of intent and the proposal must be signed by an individual with the authority to commit applicant organization resources to support the proposed program.

C.6 Can a principal investigator submit more than one proposal in a single grant competition?

No, but he or she may serve as a co-investigator on other proposals.

C.8 Will the LSDF cap the number of proposals it is willing to review from a single organization?

No.

D. What are the requirements for submitting an LSDF application?

D.1 How are application materials submitted?

Application materials are submitted electronically via an on-line application system accessed through the LSDF website, www.lsdfa.org.

D.2 Do applicants need a special code to access the electronic application system?

No. Applicants can access the system directly via the LSDF website. Instructions for submitting letters of intent (LOIs) and proposals are provided in the system.

D.3 Is there a pre-proposal process for applying for LSDF grants?

No. A letter of intent is required to be able to submit a proposal. The letter of intent is not a pre-proposal and is not used as a screening mechanism for applications.

D.4 What information is required in an LSDF application?

Specific requirements for LSDF grants are included in the RFP, but applications generally consist of two elements: (1) a letter of intent and (2) a proposal, which includes a face page, project narrative, budget, and supplementary materials.

D.5 What is a letter of intent?

The letter of intent (LOI) is the first part of the application process. It is an electronically submitted notification to LSDF of an applicant's intention to

submit a proposal. The LOI does not bind the prospective applicant to submit a proposal. It is not a pre-proposal. Its purpose is to assist LSDF in planning the review process.

D.6 Does the letter of intent require institutional approval or signature?

Yes. The letter of intent must be signed by the person with institutional authority to commit the applicant organization's resources to supporting the proposed program.

D.7 Can I go beyond the 500 word limit for the LOI abstract in order to include a list of references?

No. Limit the abstract to 500 words and save the references for the proposal.

D.8 Can I submit a proposal if I do not submit an LOI?

No. The LOI is an essential requirement of an LSDF application.

D.9 When is the LOI due?

Key dates for all parts of the application process are included in the RFP for each LSDF funding program. For LSDF 07-02, the deadline for the LOI is Wednesday, August 8, 2007, 5:00PM PDT.

D.10 What is the page limit on the narrative portion of the proposal?

The proposal narrative should be no longer than 20 pages, though shorter narratives are strongly encouraged. Up to five additional pages of references may be appended to the narrative.

D.11 What is the deadline for submitting an LSDF 07-02 proposal?

The proposal deadline for LSDF 07-02 is Wednesday, October 24, 2007, 5:00PM PDT.

D.12 How may I obtain more information if I have questions?

General information about LSDF funding programs can be sought at

programs@lsdfa.org
206-732-6770.

E. Important Questions about LSDF Grant Policy

E.1 Which costs are allowable for funding by LSDF?

All costs reasonably associated with the development and operation of the proposed program are eligible to be included in the proposal budget. Such costs include salaries, equipment and facilities, administrative costs, supplies, services, and grant-related travel.

Costs associated with patient care beyond what is required for program research are not allowed by LSDF.

E.2 Is there a cap on allowable salaries in an LSDF proposal budget?

No, but salaries must be consistent with applicant organization policies.

E.3 Is cost-sharing required?

No specific formula for cost-sharing is required. However, it is expected that applicant organizations will make tangible resource commitments to support programs proposed for LSDF 07-02 funding.

In proposals including for-profit collaborating companies, the companies will be expected to pay for their own internal costs associated with program development and for exploratory research and development activities performed on a best-effort basis. Monies may be subcontracted from the applicant organization to a company for products and services provided as deliverables to the program.

E.4 Are the LSDF granting programs carried out in a confidential manner?

Yes. LSDF holds all applications confidential, subject to the public disclosure laws of the State of Washington. For more information, see RCW 42.56 and the amendments to the exemption provisions in RCW 42.56.270(14). LSDF will require grant reviewers to sign confidentiality agreements.

LSDF reserves the right to publicly disseminate information about its granting activities through a variety of means. Such communications may include lists of LOIs and proposals received, the names of PIs and applicant organizations, the field(s) in which the research will be conducted, descriptions of proposals funded, and reports about program progress and outcomes.

E.5 Who owns the intellectual property developed under the research of an LSDF-funded program?

Normally, the intellectual property (IP) resulting from research in a funded program will be owned by the applicant organization, not by the LSDF. However, proposals are expected to make clear specifically who will own the IP, who will be responsible for managing it, and in the case of a collaborative program how rights to the IP will be shared by collaborators.

E.6 Will LSDF fund programs involving human subjects research?

Yes. If a proposed program will involve human subjects research, the applicant organization is responsible for ensuring that program research sites and projects operate under an appropriate Office of Human Research Protections (OHRP)-approved assurance for the protection of human subjects and comply with all NIH human-subjects-related policies.

E.7 Will LSDF fund programs involving animal subjects research?

Yes. For programs involving vertebrate animal research, the applicant organization must ensure that all program research sites and projects hold Office of Laboratory Animal Welfare (OLAW)-approved assurances and approvals.

E.8 Must I already have human subjects approval or animal use approval at the time I submit my application?

No, but the necessary approvals for human subjects or vertebrate animal research will need to have been received prior to execution of the grant agreement.

F. How are LSDF proposals evaluated and selected for funding?

F.1 What evaluation criteria are used to evaluate LSDF proposals for funding?

Specific evaluation criteria are described in the RFP for each funding competition. The general criteria for LSDF awards, however, are consistent with the Fund's goals: to promote scientific competitiveness, improve health and health care, and foster economic growth.

F.2 How are proposals selected for awards?

Expert reviewers recommend proposals to the LSDF Board of Trustees for funding. The board's selections are based on these recommendations, the availability of funds, and the goals of the LSDF program. Consistent with these and with its enabling legislation, the board also considers factors such as the following in making awards:

- diversity of research,
- variety of health benefits,
- breadth of economic opportunity, and
- geographic impact.

Based on its consideration of all these factors, the board selects proposals which in its judgment are the most meritorious.

F.3 Can LSDF funding decisions be appealed?

No. All funding decisions are final and cannot be appealed.

F.4 What are some ways LSDF grants differ from federal grants in their expectations and requirements?

LSDF grants are investments with expected returns. They require the establishment of specific milestones and timelines. Their fund-disbursement schedule is phased and contingent upon milestone achievement. Also, they require frequent reporting.

F.5 Do LSDF grants have standard terms and conditions?

Yes. These are the guiding principles which establish the legal procedures and responsibilities for LSDF and its grantees. Specific terms and conditions are established in the grant agreement for individual grant awards.

F.6 When will a recipient organization receive funds once a proposal is selected for funding?

The disbursement schedule will be established as part of the grant agreement. Funding will be distributed to recipient organizations in increments, based upon timely reporting and the achievement of milestones during the grant period. Disbursements will be authorized by LSDF when recipient organizations have achieved the specific milestones delineated in the grant agreement.

F.7 If I receive an LSDF award, will I have to submit progress reports? If so, how often?

Yes. Reporting by principal investigators is the primary way that LSDF is able to track program progress and return on investment. Reporting requirements, specific for each funded proposal, will be finalized in the grant contract. But LSDF requires, at minimum, semi-annual financial and technical progress reports and post-award annual reports for a period of five years. Site visits and in-person briefings by principal investigators may be used by LSDF as tools to track the progress of funded programs.