



Life Sciences Discovery Fund Request for Proposals (RFP) – REVISED

2009 Program Grant Competition

June 3, 2009

Revisions:

This revised RFP includes the following modifications from the 2009 Program Grant Competition RFP that was issued on January 6, 2009. The relevant sections of this RFP are listed in parentheses after each modification:

- Reductions in total LSDF funding for 2010-2011, the allocation for this competition, and the expected number of awards for this competition (Executive Summary, 1.1, 2.1).
- Adjustment of key competition dates (Executive Summary, 2.2).
- Movement of the budget justification from the proposal narrative to a separate document to permit greater detail (3.3.4, 3.3.5).
- Revision of the resource/expenditure summary form to require the principal investigator to list all of the applicant organization's cash and in-kind commitments to the proposed program. Additional details about organizational resource commitments also are provided (2.1, 3.3.5).

The above-listed modifications are highlighted in **yellow** within this RFP.

Further, note that LSDF has revised the guidelines for first-phase expert reviewers consistent with the RFP modifications

(http://www.lsdfa.org/grants/current/2009/Programs_Grants/).



New:

LSDF has revised the budget forms to require greater detail than in prior competitions. Refer to Section 3.3.5 of this RFP for additional information.

Executive Summary

The Life Sciences Discovery Fund (LSDF), a Washington State grantmaking authority, supports the launch and development of **new** research programs to improve health and health care in Washington State. A program is a strategic research initiative, broad in scope, which addresses problems within a field of study and positions institutions for future competitiveness and leadership. All proposals must include a detailed and clearly articulated plan of research.

LSDF invites proposals from Washington public and nonprofit organizations, singularly or collaboratively with other public and nonprofit organizations, or with for-profit entities.

LSDF intends to award up to **\$15** million in grants in the 2009 Program grant competition. Proposals should request the budget amount and duration that are appropriate for the work. **LSDF expects to fund 3 to 5 Program proposals, depending on the number and quality of submissions received.** Principal investigators must apply online at <http://www.lsdfa.org/grants/apply.html>.

Key dates include:

- | | |
|-----------------------------------|---|
| • March 4, 2009 | Letters of Intent due |
| • July 22, 2009 | Proposals due |
| • Week of January 11, 2010 | Interviews conducted for selected proposals |
| • February 16, 2010 | Award announcement |

Proposals will be evaluated according to their potential to advance LSDF's primary strategic goals for Washington State—improving health and health care, stimulating economic activity, and promoting life sciences competitiveness.



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1. Introduction

2009 LSDF Program Grant Competition

1.1. Background

The Life Sciences Discovery Fund Authority (LSDF) was established in 2005 by the governor and legislature of the State of Washington. LSDF is funded by bonus monies from the Master Tobacco Settlement Agreement of 1998 of approximately \$33 million per year for a ten-year period (\$19.5 million per year in 2010 and 2011) to invest in the state's life sciences sector. Its mission is to improve health and health care, stimulate economic activity, and promote life sciences competitiveness in Washington.

1.2. The Niche for LSDF Funding in Washington State

LSDF leverages its grant monies to enable organizations to be more competitive for future funding or to help translate high-impact discoveries into widespread use. LSDF does not replicate funding programs offered by other granting sources, such as the National Institutes of Health (NIH). Consequently, principal investigators are discouraged from submitting proposals to LSDF that they would normally send to NIH. In their proposals, principal investigators must make a compelling argument for why an LSDF grant is uniquely appropriate and necessary to accomplish their research.

1.3. LSDF Funding Categories

LSDF will fund three types of research in 2009, each of which is covered in a separate RFP:

- **Program grants** support new collaborative research initiatives that address major problems within a field of study and position organizations for future competitiveness and leadership. Programs must demonstrate significant organizational commitment and potential for long-term growth and sustainability.
- **Project grants** support investigator-initiated studies that will be accomplished during the LSDF award term. Projects typically focus on research topics or concepts that require significant work before commercialization or widespread implementation or adoption.
- **Commercialization grants** support small-scale, highly targeted studies that move technologies along the commercialization pathway. Awards of up to \$150,000 are



expected to advance research with commercial potential to a stage appropriate for licensing, start-up company formation, or private investment.

This RFP invites proposals for programs. Please consult the RFPs for more information on Project grants at: (www.lsdfa.org/grants/current/2009/Projects_Grants/RFP.pdf) and Commercialization grants at: (www.lsdfa.org/grants/current/2009/Commercialization_Grants/RFP.pdf).

1.4. Applicant Organizations and Eligibility

LSDF invites proposals for 2009 Program grants from Washington public and nonprofit organizations, singularly or collaboratively with other public and nonprofit organizations, or with for-profit entities.

The applicant organization is responsible for submitting the proposal, leading the research program, administering the research grant, and disbursing LSDF funding. A proposal may include one or more co-applicant organizations. A co-applicant organization employs personnel key to the design, conduct, and reporting of the research and receives a portion of the grant award under a subcontract. Throughout this Request for Proposals (RFP), the terms “applicant” or “applicant organization” refer to the organization employing the principal investigator.

Within this RFP, the terms “collaborating organization” or “collaborator” refer to an entity that will contribute to the proposed research, but will not share in LSDF grant funds.

There is no limit to the number of proposals that may be submitted from an applicant organization.

Eligible applicant organizations are those that have recently engaged in competitively funded, sponsored research, or similar activities, and have the personnel, resources, and experience necessary to launch, execute, and grow complex research programs. Eligible applicants include, but are not limited to, the following:

- public and private universities and colleges;
- nonprofit research organizations;
- public health departments;
- public and private hospitals and clinics; and
- health-care systems.



For-profit entities are not eligible to apply individually for funding, but are encouraged to join an eligible applicant as a co-applicant or collaborating organization.

Organizations from outside of Washington State may receive funding as a co-applicant. The proposal must justify the necessity for the participation of an out-of-state entity.

1.5. Principal Investigators and Co-investigators

A single principal investigator submits the letter of intent (LOI) and proposal for an LSDF grant, regardless of how many researchers or organizations will be involved in the program. LSDF does not recognize the title of "co-principal investigator." A principal investigator may submit only one proposal for this competition, but may serve as a co-investigator on other proposals.

A proposal may include 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 research. A co-investigator can be from the applicant organization, or from a co-applicant or collaborating organization.

The principal investigator must be employed by the applicant organization. He or she will be responsible for leading the proposed program, managing the budget, and reporting progress and results. Principal investigators must meet their employer's requirements for such status.

The principal investigator and/or the applicant organization may be changed between the LOI and proposal submissions upon prior approval of LSDF.

1.6. Resubmissions

LSDF permits resubmission of unfunded proposals. Details regarding resubmissions are provided in Section 3.3.5.

1.7. RFP Updates

LSDF may amend this RFP after its release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF 2009 Program grant competition webpage at:

www.lsdfa.org/grants/current/2009/Programs_Grants



Principal investigators are responsible for consulting LSDF amendments to be sure they have the latest information regarding this grant competition.

1.8. Frequently Asked Questions

Brief answers to the most common questions may be found on the LSDF 2009 Program grant competition webpage at:

www.lsdfa.org/grants/current/2009/Programs_Grants

2. Funding Opportunity Description

2.1. LSDF 2009 Program Grant Opportunity

Programs funded under the LSDF Program grant competition must have the potential to improve health and health care in Washington State—that is, not merely continuing current practice, but changing it demonstrably for the better. Additionally, funded programs will be expected to advance the other core goals of LSDF—to promote life sciences competitiveness in Washington and foster growth of the state’s economy. Review Section 1.3 for the definition of a program.

LSDF’s 2009 Program grant competition supports the launch and development of new, scientifically rigorous research initiatives that will help Washington research organizations advance their strategic priorities and leadership positions in health and health-care research. Programs are expected to result in health and health-care innovations, including, but not limited to, new approaches to:

- diagnose, treat, prevent or manage disease;
- manage health-care delivery environments and systems;
- promote healthy patient behaviors and patient compliance with care-providers’ recommendations;
- better integrate care providers, patients and health-care systems; or
- accomplish any of the above in a more cost-effective manner.

Proposals may request support for a variety of activities, including, but not limited to:

- 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;

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- training the state's scientific workforce, particularly in emerging industries; and
- establishing research infrastructure to support commercialization¹ of multiple technologies over a sustained period of time.

Collaborations with for-profit entities to achieve commercialization-related objectives are encouraged.

To be competitive for funding, programs must:

- be of strategic priority to applicant organizations;
- be innovative within their fields;
- create new synergies among participating researchers that would not exist but for the organization of their efforts into the program;
- build upon established strengths within the participating organization(s);
- have the potential for growth and sustainability over time; and
- show significant commitment of resources from applicant organizations to support and sustain the program's growth and development. Organizational commitment may be in the form of either cash or in-kind contributions (e.g., equipment, research tools, software, supplies, or services).

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.

Principal investigators must list all organizational cash and in-kind resource commitments on the resource/expenditure summary form and in the budget justification. Significant organizational resource commitments should also be described in the appropriate letters of support (see Section 3.3.5).

¹ LSDF defines commercialization as the "effective flow of new ideas from Washington's researchers and inventors into our companies' products and services." (Adapted from the Washington Economic Development Commission)

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All programs must include a well-detailed plan of research. Principal investigators must describe the research activities to be conducted as part of the program in sufficient detail to allow external reviewers to understand the initial priorities of the components of the program. Provide timelines for completion of research objectives and outline metrics for measuring success. Although programs may include establishment of core facilities or infrastructure, proposals that seek only to develop such resources in the absence of clearly articulated research initiatives will not be considered for funding. Note that the restructuring of existing resources within an organization without developing new resources or capabilities does not meet LSDF's definition of a "program," and such proposals will not be supported.

LSDF intends to distribute up to **\$15** million in grants in this competition. Principal investigators may request the budget amount and duration that are appropriate for their work. **LSDF expects to fund 3 to 5 Program proposals, depending on the number and quality of submissions received.**

Programs will be evaluated according to their scientific, technical, and organizational merit and their potential to benefit health and health care and the economy in Washington State. LSDF desires to fund research teams that show a commitment to translating the results of their research into widespread use, e.g. through commercialization, practice adoption, or policy implementation. Proposals with the potential to have near-term impact on improving health and health care and/or the capacity to attract additional resources to enable broader implementation of the research results 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.

2.2. Key Dates

Letter of Intent due	Wednesday, March 4, 2009, 5:00PM PST
Proposal due	Wednesday, July 22, 2009, 5:00PM PDT
Phase 1 expert review of proposals	August-October 2009
Interviewee selection	November 10, 2009
Phase 2 expert review of proposals	November 2009-January 2010
Interviews (in Seattle)	Week of January 11, 2010
Awards announcement	February 16, 2010
Funding start date	Upon execution of the grant agreement, but no sooner than mid-April, 2010



2.3. Questions to Consider Before Applying for an LSDF 2009 Program Grant

Since proposal preparation involves considerable time and effort, principal investigators are strongly advised to carefully read this RFP. If a principal investigator cannot make a strong case regarding each of the following questions, it is unlikely that his or her proposal will be successful.

- What are the compelling reasons why this program can't be accomplished without LSDF's investment?
- What are the features of this program that distinguish it from a research project or a series of projects performed in parallel?
- What significant resources are being provided by the applicant organization to help launch and sustain this program?
- How will Washington State benefit from LSDF's investment in this research:
 - in terms of improving health or health care?
 - in terms of contributing to economic growth?

Principal investigators are strongly encouraged to confer with LSDF programs staff (programs@lsdfa.org) regarding the appropriateness of their research for LSDF funding.

3. Application Process

3.1. General Information

It is the sole responsibility of the principal investigator to comply with this RFP and the instructions in the online application system, and ensure that the letter of intent and proposal (collectively, "application") materials are accurate, complete, and submitted on time. Applications that do not adhere to content requirements, are incomplete or incorrect, or are late will not be reviewed.

Principal investigators must complete two steps: (1) an LOI followed by (2) a proposal. Both the LOI and proposal must be submitted via the LSDF website, www.lsdfa.org/grants/apply.html, by 5:00PM Pacific Time on the respective deadline date.

In addition to the specific instructions below, principal investigators must refer to the online application instructions for the detailed requirements of each application component.



LOIs or 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.

Principal investigators who discover an error or omission after submitting an LOI or proposal, but before the submission deadline, may notify LSDF at programs@lsdfa.org and seek authorization to submit a corrected version. Applications found to be incomplete during or after their evaluation may be disqualified for funding.

Individuals having difficulties submitting applications should contact the LSDF grants administrator (grantsadmin@lsdfa.org or 206-732-6788) immediately for assistance.

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

3.2. Letter of Intent

Principal investigators must submit an LOI stating their intent to submit a proposal. Submitting an LOI does not require submission of a proposal. However, the LOI is required for a proposal to be reviewed.

The LOI is not a pre-proposal. The LOI helps LSDF prepare for expert review of the proposals. If an LOI describes a program that is clearly not suited for LSDF funding, the principal investigator will be notified of that determination.

LOIs include the following:

- a descriptive, non-confidential title for the program;
- an estimated budget total;
- a list of co-applicant organizations;
- resubmission information, if applicable;
- an abstract of 500 words or less; and
- up to five keywords descriptive of the program.

3.3. Proposal Requirements

The proposal is expected to consist of the same subject matter as the LOI.

The online application system requires the principal investigator to input information under the following headings:



- Face Page
- Applicant Organization Information
- Co-applicant Organization Information
- Co-investigator Information
- Proposal Details
- Proposal Narrative
- Attachments

3.3.1. Face Page

The face page contains essential information for identifying, processing, and tracking the proposal. The face page also contains the signature of the authorizing individual (the person with authority to commit the applicant organization to the implementation of the proposed program). Principal investigators may not authorize proposals from their own organizations.

The face page includes the following elements:

- the name and Entity Identification Number (EIN) of the applicant organization;
- the program title;
- the principal investigator name and contact information;
- the names of co-applicant organizations;
- the dates of requested support;
- the budget amount being requested;
- whether the research will include human or vertebrate animal subjects;
- the name and contact information of the authorizing individual; and
- the authorizing signature.

3.3.2. Applicant Organization Information, Co-applicant Organization Information and Co-investigator Information

Principal investigators are required to input basic information about the applicant organization and their co-applicants and co-investigators.

3.3.3. Proposal Details

The following additional information is required.



Abstract. Provide an abstract of 500 words or less. The text of the proposal abstract may be different than the text of the LOI abstract.

Keywords. Provide up to five keywords that are descriptive of the program.

Proposal Reviewers. Principal investigators may indicate the names of reviewers whom they would prefer not review their proposal.

Patents and Inventions. Describe any invention disclosures made, patent applications filed, or option or license agreements executed or pending related to the subject matter of the proposal.

New Company Formation. Describe any plans and activities to date related to starting a company based upon the subject matter of the proposal. If a company has been formed within the last two years, provide a summary of its business plan in two pages or less.

3.3.4. Proposal Narrative

The narrative must be no longer than 25 pages and conform to the following format requirements:

- 8½-by-11-inch portrait-oriented page dimensions;
- Single spaced with all margins measuring at least 1 inch;
- At least 12-point font in Times, New Roman, or Arial (not proportionally reduced); and
- In the upper right-hand corner of each page, inclusion of a header with the name of the principal investigator, the grant competition name (*i.e.*, LSDF 2009 Program Grant Competition), and the page number, using the format: "Page x of xx."

All tables, charts, or graphs must be contained within the 25-page limit. Consult the online proposal instructions for specific information about the format of tables, charts, or graphs. If considering the submission of information in color, principal investigators should be aware that proposal reviewers may be performing their reviews using black and white hard copies. References are to be included at the end of the narrative, but are not counted in the 25-page limit. A maximum of five pages of references will be accepted. Website addresses (URLs) or attachments must not be used to provide additional information necessary to the narrative.

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The proposal narrative must include sufficient information needed to evaluate the scientific, technical, and organizational merit and beneficial returns of the program, independent of any other document. The narrative must include all the following sections.

A. Program Objectives

List the immediate and long-term research and organizational 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.

B. Background, Significance, and Relevance to LSDF Program Goals

Describe the background planning and preparation leading to the proposed program and the important scientific and health needs it is designed to address. Ensure that all the following questions are answered:

- What health or health-care related problem does this program address?
- What is the significance of this problem in Washington State?
- How is this problem addressed currently?
- What approaches other than that being proposed are under development to alleviate the problem?
- How does the proposed research lead to an improved solution for the problem?
- How does this research advance the mission of LSDF of improving health and health care, stimulating economic activity, and promoting life sciences competitiveness in Washington?
- Why is LSDF funding particularly appropriate and necessary to accomplish the work being proposed?

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 in areas such as strategic planning; organizational leadership; collaborative structures; personnel and budget management; coordination of multi-faceted research activities; attraction and retention of talent; management of sustained institutional buy-in and support; and effective use of major facilities, equipment, and instrumentation.

For proposals that involve the development of research infrastructure to enhance commercialization, describe the principal investigator's and applicant organization's experience in fostering collaboration with industry and the commercial development of academic research from initial results to first sale.



D. Program Research, Structure, and Operations

Describe the program's research focus or agenda and the anticipated results. Discuss the research studies that will be performed in sufficient detail to allow external reviewers to understand the initial priorities of the components of the program and the methodologies to be used.

Provide a detailed account of the program's structure and operations. If the proposal involves the acquisition of a major piece of equipment, explain the role the equipment will have in achieving the program's objectives. Summarize how the program will advance and grow for the first five years and the possibilities for growth beyond that time. Describe its future directions and the applicant organization's resource commitments to its long-term sustainability. Describe also the schedule and methods of evaluation by which the program will be assessed.

For proposals that involve the development of research infrastructure to enhance commercialization, describe the commercial opportunities the program will address and the plans for commercializing multiple research projects in a sustainable manner. Explain how projects will be selected for the program, how the progress of each project will be monitored and assessed, and what actions will be taken to assist investigators and projects that are stalled or behind schedule. Describe the ways in which the infrastructure will be attractive to industry and how industrial participants will be recruited.

E. Challenges

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

F. Timeline and Milestones

Provide a timeline for – 1. developing, funding, launching, and conducting the program; and 2. completing research objectives. Identify major milestones of progress, target dates for accomplishment, and criteria or metrics by which achievement of each of the organizational and research milestones will be assessed. More information about how to write milestones can be found on the LSDF website:

http://www.lsdfa.org/grantees/grantee_info_docs/current_milestones.pdf.

G. Personnel

Identify and define the roles of the person(s) who will lead and manage the program's operations. Identify all key personnel responsible for conducting the program's research. Provide a brief summary of their background and research expertise. If the proposal involves the recruitment of a leading researcher, explain the role and

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responsibilities he or she will assume in the program, and describe how his or her ongoing research will complement the program's scientific mission. If individuals from multiple organizations or multiple units within an organization will participate in the proposed program, explain how decision-making authority will be distributed. Describe how the program will be organized, how key decisions will be made, and how work will be coordinated.

H. Facilities and Equipment

Describe the facilities, equipment, and laboratory, clinical, and office resources available for the program. Summarize the arrangements and agreements that have been made to ensure availability and maintenance of the facilities and equipment for the program. If new equipment is requested, describe available equipment and explain why it cannot be used. If the new equipment will be available to support other efforts outside the scope of the program, explain how time will be allocated to it.

I. Outcomes and Future Plans

Describe how the program will contribute to the broad, long-term strategic goals of LSDF—improving health and health care, stimulating economic activity, and promoting life sciences competitiveness in Washington. Ensure that the following questions are answered:

- What is the estimated timeline for translating the results of the program for the benefit of health and health care?
- What is the potential for this program to foster economic gains?

Describe the next steps in capitalizing on the program's success, including both the near-term and long-term outcomes the program is designed to achieve. Describe the following:

- the potential for follow-on research funding;
- clinical or organizational implementation of program-developed scientific findings, e.g. changing ways that practitioners work or how organizations and governments deploy their resources;
- plans for the research team, applicant, co-applicant and collaborating organizations or others to further develop and grow the program; and
- plans for the research team, applicant, co-applicant and collaborating organizations or others to translate the program's results into practical application through commercialization.

3.3.5. Attachments

The following information is to be provided using relevant forms provided in the online application system under the Attachments heading.



Budget

1. **General Requirements.** LSDF requires three budget components:

A. *Resource/expenditure summary* – a total program budget for the first five years of the program or the LSDF grant period, whichever is longer, using the form from the online application system. The budget must illustrate both total income (i.e., resources) and respective total expenditures by income source. Opportunities for LSDF to leverage its support with that of other contributors are particularly desirable.

LSDF expects that applicant organizations will make tangible resource commitments 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. 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 of facilities that are newly or specifically designated for program activities;
- improvement of facilities;
- dedication of equipment or supplies for the program;
- absorption of facilities and administrative costs; and
- matching funds from institutional sources.

It is not necessary for the applicant to have secured all of the resource commitments upon which the program's 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 time period reserved to satisfy any contingencies will be specified by LSDF. To be selected for a contingent award, the proposal must detail how, from whom, and by when the remaining commitments will be made.

B. A *detailed program budget* for each year of requested funding, using the form from the online application system. The budget must be appropriate for the scope and goals of the proposed program and should include all costs reasonably associated with the development and operation of the proposed program. These costs must be listed as direct costs, including costs typically associated with general facilities and administration expenses. All costs must be in accordance with the applicant organization's fiscal policies. The same budget

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information is required from any research collaboration that will result in a subcontract agreement.

C. A budget justification that provides enough detail to allow reviewers to determine that the budget is appropriate for accomplishing the proposed work.

2. Resource/Expenditure Summary. Complete the following fields. Do not mix multiple resource status categories within the same column of the spreadsheet or add columns; use a second page if necessary. **Use the first two columns for the applicant organization's in-kind and cash resource commitments, respectively.** If more than five years of funding are requested, use additional pages:

- Resource organizations. List the types of resource providers.
- Names of resource organizations (e.g. NIH). List each unique organization in a separate column.
- Type of resource. List each type in a separate column:
 - cash – e.g. grants or internal funds from the applicant organization; or
 - in-kind – elements of value contributed to the program by the applicant or other organizations, including waiver of fees or costs or equipment that is less than one year old.
- Status of resource contributions:
 - funded – monies are in-hand and committed to the program;
 - applied – applicant organization has applied for the funds; and
 - contingent – applicant organization is only able to utilize the funds if other conditions are met.

3. Detailed Budget Pages. The following budget categories are provided:

- personnel

Salaries include wages, benefits and stipends. Provide the compensation requested for research staff associated with the program. Salaries should be calculated on the basis of the individual's percent effort on the program.

- equipment costs

Include equipment with a unit cost greater than \$5,000 that is specifically required for program research. Include only items of property with an expected service life of more than one year.

- supplies

Include consumable materials and supplies required for the program, including equipment having a unit price of \$5,000 or less. Expenses for personal computers are not allowable unless primarily used for the program.

- travel

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Include expenses required for field work, attendance at meetings and conferences, and other travel required for the proposed program, including per diem allowance, subject to the applicant organization's usual accounting practices.

- services

Include work performed by entities other than the applicant or co-applicant organizations in support of the program, including program consultants. Services are provided as a regular part of such entities' normal business operations.

- subcontracts

Include the expenses of program research performed by co-applicants. Co-applicant companies will be expected to pay for their own internal costs associated with research and development activities performed on a best-effort basis. Companies that provide products and/or services as deliverables to the program can be reimbursed for associated expenses.

- administrative costs

Include administrative salaries and other associated administrative costs that support the program, such as clerical and fiscal support. If it is impossible to break down administrative costs that are charged on an institution-wide or central basis, apply that portion of the organization's indirect cost rate attributed to institution-wide or central costs to the total program budget (after subtracting equipment to be purchased) and include the resulting value within administrative costs. Departmental or other "local" administrative costs must be calculated as direct costs before inclusion. A one-time fee of up to \$15,000 may be charged by the applicant organization for administration of each subcontract.

- facilities costs

Include the cost of using existing facilities for the program. Do not apply the organization's Federal indirect cost rate to the total program budget to calculate facilities costs.

- other

Itemize costs falling outside of the typical budget categories above, including education fees for trainees, facilities construction and remodeling, and recruitment.

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

4. Budget Justification. Describe the complete funding plan (both costs and resources) for the first five years of the program or the LSDF grant period, whichever is longer. Detail any support or projections for follow-on funding from other sources. Include any instances in which other resources complement LSDF funding, including matching funds or cost sharing provided by the applicant organization, co-applicant, or collaborating organizations; significant resources paid for by other sources; or other ongoing related support. Describe the conditions that allow any contingent resources

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to become “funded” resources. Highlight and explain the need for any extraordinary expenditures. Describe any plans for using LSDF funds for efforts whose costs or nature cannot yet be accurately determined (including but not limited to regranting or recruitment startup packages). If the LSDF award is made, and the details of such proposed expenditures are not available by the time of award execution, the principal investigator must obtain written permission from LSDF before committing funds for such efforts. Describe any other research support received or applied for that is related to the subject matter of the program. If an LSDF award is made, describe how any funding overlap issues will be handled. Detailed budget figures must be included on the relevant form provided in the online application system. **The budget justification must not be longer than five pages.**

Biographical Sketches. Biographical sketches are limited to four pages. Provide biographical information on key research personnel using biosketch forms provided. The biosketch form used for National Institutes of Health grant applications (Form 398/2590) may be substituted for the LSDF form. For each non-technical key person (e.g. the executive director of a program), a *curriculum vitae* or resume may be substituted for the biosketch form but must not exceed LSDF’s four-page limit. Each biosketch must be uploaded as an individual PDF document. Do not combine biosketches into one PDF file.

Key Personnel Roster. Supply a roster of the research and administrative personnel involved in the program using the form and instructions provided.

Letters of Support. Letters of support are required to confirm the commitment of time and resources to the program from key personnel and organizations **(including both cash and in-kind commitments)**. Letters of support must be submitted by the principal investigator as individual PDF files through the online application system and not sent directly to LSDF by the individuals writing them. Each letter of support must be uploaded as an individual PDF document. Do not combine letters of support into one PDF file.

Intellectual Property Certification. LSDF supports research that may lead to discoveries having commercial potential. The intellectual property (IP) certification is required for LSDF to assess how IP developed under the program will be owned and managed. Principal investigators must complete the form according to the instructions provided. (See Section 7.4 for related information.)

The IP certification must clarify whether the applicant organization has policies regarding ownership and management of IP developed by its employees. If a party other than the applicant, co-applicant or collaborating organization(s) will own or have



rights to IP developed under an LSDF-funded program, the principal investigator must provide an explanation of and justification for such provision.

Principal investigators must describe how IP developed under an LSDF grant will be managed for commercialization. Applicant organizations with established IP management infrastructures can meet this requirement by referencing the policies, practices, and structures they already have in place. Organizations without an IP policy or an established infrastructure to manage IP should contact LSDF (programs@lsdfa.org) before submitting their proposal to discuss how they plan to manage and commercialize IP associated with the proposed program.

Resubmissions. Resubmitted proposals must be accompanied by:

- a complete copy of the expert reviewers' comments from the most recent competition;
- a written response, not to exceed five pages, to the previous reviewers' comments, and a summary of where, and how, those comments have been addressed in the current proposal.

4. Evaluation

Submitted proposals that are judged to be compliant will proceed to expert review.

4.1. Expert Review

Proposal evaluation will be conducted by expert reviewers from outside of Washington State, convened by the American Association for the Advancement of Science. Expert reviewers will be required to sign nondisclosure agreements.

It is unlikely that a resubmitted proposal will be evaluated by the same expert panel.

Expert review will occur in two phases. The first phase will be conducted by panels that will provide consensus reviews of all proposals. In the second phase, another panel will interview a subset of principal investigators and provide consensus reviews of the proposals selected for interview. LSDF's Board of Trustees will choose interviewees based upon the first-phase consensus reviews, the availability of funds, and the goals of the LSDF. The board will make awards from among the selected proposals.

Principal investigators chosen for interviews will be notified of the time and place of their interview and will be provided a copy of the first-phase expert reviewers' comments. (Dates for the interviews are found in Section 2.2.) Interviewees will be able



to submit supplementary information before the interview. The names and institutional affiliations of interviewees will be posted online at LSDF's public Web site.

Names of first-phase reviewers will not be made available. Applicants, principal investigators and their representatives may not contact reviewers or members of the LSDF Board of Trustees regarding submitted proposals. Any such contact or attempt to contact may result in the disqualification of the proposal from the competition.

Principal investigators will receive copies of the expert reviewers' consensus evaluations of their proposals.

4.2. Evaluation Criteria

All proposals will be expected to have the potential to contribute to LSDF's primary strategic goals: to improve health and health care, stimulate economic activity, and promote life sciences competitiveness in Washington. Within this general framework, both first-phase and second-phase reviewers will use the following criteria to evaluate proposals. Reviewers will place proposals into one of three categories based on their recommendation for interview (first-phase review) or funding (second-phase review): Not Recommended, Recommended, or Highly Recommended.

4.2.1. *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:

- it meets LSDF's definition of a "program" and offers the likelihood of synergistic outcomes;
- the proposed program 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;

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- 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;
- 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;
- 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 this program.

4.2.2. Importance to Health and Health Care

The program's importance to health and health care within Washington State will be judged by how well the proposal demonstrates the following qualities:

- it addresses a significant issue in health or health care;
- it has the potential to make a substantial, beneficial and measurable contribution to improving health and health care;
- it will achieve benefits such as the following:
 - 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;

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- 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 citizens.

4.2.3. Future Economic Returns

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:

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

5. Selection of Awards

Expert reviewers will recommend proposals from among those selected for interviews to the LSDF Board of Trustees for funding. The board's award selections will be based on these recommendations, the availability of funds, and the goals of the grant competition. The board may also consider the following in making award decisions:



- diversity of research topics;
- variety of health, health-care and economic benefits; and
- geographic impact.

Award decisions cannot be appealed. No award is final until a grant agreement has been executed.

6. Grant Agreement

Awards are subject to grant agreements that will be negotiated between the grant recipient organizations and LSDf. Funds will be disbursed to applicant organizations on a cost-reimbursement basis subject to progress towards mutually agreed upon milestones and timelines. LSDf may withhold reimbursement payments if progress reports have not been provided or milestones have not been met in a timely fashion.

The LSDf grant agreements used for the most recent program competition can be found on the LSDf website at:

For organizations that are public entities (e.g., public universities):

www.lifesciencesdiscoveryfund.org/grants/current/08-02/08-02_Grant_Award_Agreement_for_WA_State_Organizations.pdf

For organizations that are private entities:

www.lifesciencesdiscoveryfund.org/grants/current/08-02/08-02_Grant_Award_Agreement.pdf

7. Additional Information

7.1. Confidentiality and Public Disclosure

Information in grant applications is received by LSDf with the understanding that it shall be used or disclosed solely for evaluation of applications or as required by law. LSDf holds all applications confidential in accordance with its confidentiality policy [www.lsdfa.org/grants/Conf_Policy.pdf] and subject to the public disclosure laws of the State of Washington. For more information about Washington public disclosure law, 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 publicly releases the name of the principal investigator, the applicant organization, the proposal title, 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 any identifiers regarding co-investigators or co-applicant organizations, as disclosure of these items might be reasonably expected to result in private loss to the applicant organizations or investigators.

Once a proposal has been funded, LSDF will publicly release certain additional information from the proposal, including a summary of the work and the names and contact information of any co-investigators or co-applicant organizations.

In response to a public records request for a funded proposal under Washington State law, LSDF may provide further information from the proposal to the requestor, but only to the extent that provision of such information would not reasonably be expected to result in private loss to the providers of such information.

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

7.2. Conflict of Interest

When performing LSDF-funded research, it is essential that the personal interests of investigators do not impede their judgment or compromise their objectivity. Even the perception of a conflict of interest has the potential to erode the public's confidence in the research process. It is essential that applicant and co-applicant organizations have a financial conflict of interest policy in place. In accepting an award, the applicant organization will certify to LSDF that potential financial conflicts of personnel participating in the funded research, including those identified by LSDF, 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.

7.3. Human Subjects and Vertebrate Animal Research Requirements

If a program will include research involving human subjects, the research site must operate under an appropriate Office of Human Research Protections-approved assurance for the protection of human subjects. The research site's procedures must also comply with all U. S. Department of Health and Human Services 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 research involving human subjects will have been approved by the applicable human subjects oversight bodies before the principal investigator initiates the human studies.

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 research involving vertebrate animals will have been approved by the applicable animal use and care oversight bodies before the principal investigator initiates the animal studies.

7.4. Intellectual Property

Programs involving collaborating organizations must be supported by an agreement that makes explicit provision for the disposition of IP rights among the organizations. Such an agreement must clearly allocate the rights that the organizations will have in any IP developed during LSDF-funded research and identify which of the organizations will be responsible for commercialization. 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, unless otherwise stated by LSDF. One example of an appropriate agreement for this purpose is 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,"* which can be found online at:

www.dodsbir.net/solicitation/pdf/AllocationofRights.pdf

7.5. Reporting Requirements

LSDF grants are an investment by the State of Washington in the future of its citizens. Full and timely reporting of the progress and results of funded research by principal investigators has considerable importance for calculating the returns on that investment.

Reporting requirements, specific for each funded proposal, will be finalized in the grant agreement. LSDF requires the following reports: semi-annual progress reports, annual



financial reports, final program and financial reports, and post-program annual reports for a period of five years. Site visits to and in-person briefings from principal investigators may be used by LSDF as tools to track the progress of funded programs.

7.6. Publicity

LSDF reserves the right to publicly disseminate information about its granting activities. LSDF communications to the public may include lists of LOIs and proposals received, the names of principal investigators and applicant organizations, program titles, the field(s) in which the research will be conducted, descriptions of proposals funded, and reports about program progress and outcomes. Recipient organizations and principal investigators will be expected to provide LSDF with reasonable assistance in communicating funded research and its related impacts to the public.

7.7. Funding Start Date

Funds will not be authorized for expenditure by LSDF until the grant agreement between LSDF and the recipient organization is completed. The funding start date may be as early as mid-April, 2010.

7.8. Contact Information

For further information about LSDF or grant administration, visit the LSDF website at lifesciencesdiscoveryfund.org or contact programs@lsdfa.org.