



Life Sciences Discovery Fund Request for Proposals

2010 Program Grant Competition

January 6, 2010

New for 2010:

- The Letter of Intent (LOI) is no longer required.
- Proposals for state-wide research resources are now eligible (see Section 2.1).
- All proposal forms have been revised; do not use forms from previous competitions (see Section 3.2.5).
- Corporate financial involvement in grants has been more explicitly described (see Section 1.7).

Executive Summary

The Life Sciences Discovery Fund (LSDF), a Washington State grant-making authority, supports research programs to improve health and health care and foster economic growth in Washington State.

LSDF invites proposals from eligible Washington public and non-profit organizations, singularly or collaboratively with other public and non-profit organizations, or with for-profit companies.

LSDF intends to award up to \$13 million in grants in the 2010 Program Grant Competition. Proposals should request the budget amount and duration that are appropriate for the work. LSDF expects to fund three to five 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:

February 1, 2010	Online grant application system available
July 14, 2010 by 5:00pm PDT	Proposals due
November 16, 2010	Interviewees announced
Week of January 10, 2011	Interviews conducted
March 1, 2011	Award announcement
As early as April 2011	Funding start date

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

2010 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 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 intend to replicate funding programs offered by other granting sources. Consequently, principal investigators are discouraged from submitting proposals to LSDF that would normally be more appropriate for other granting sources. 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 offer four different granting mechanisms in 2010, each of which is covered in a separate Request for Proposals (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.
- Opportunity grants support compelling proposals having (1) an urgency or nature that cannot be aligned with LSDF's annual competition cycles; (2) the ability for LSDF to immediately and significantly leverage its investment against funding from other sources, including investment by the applicant organization;



(3) a high probability that the LSDF investment will attract future financial resources, lead to commercialization of research results, or improve the quality and cost effectiveness of health care; and (4) a clear demonstration of statewide benefit.

- 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 program grants. Please consult the applicable RFP for:

Project grants at:

http://www.lsdfa.org/grants/current/2010/Projects_Grants/

Commercialization grants at:

http://www.lsdfa.org/grants/current/2010/Commercialization_Grants/

The RFP for opportunity grants

http://www.lsdfa.org/grants/current/2010/Opportunity_Grants/ is expected to be released on May 3, 2010.

1.4. Applicant Organizations and Eligibility

LSDF invites proposals for 2010 program grants from eligible Washington public and non-profit organizations, singularly or collaboratively with other public and non-profit organizations, or with for-profit companies.

The applicant organization is legally responsible for submitting the proposal, administering the research grant, and disbursing LSDF funding. Throughout this RFP, the terms "applicant" or "applicant organization" refer to the organization employing the principal investigator.

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

Eligible applicant organizations are Washington State governmental or non-profit entities that have recently engaged in competitively funded, sponsored research, or similar activities, and have the personnel, resources, and experience necessary to design and carry out programs. Eligible applicants include, but are not limited to, the following:

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

1.5. Co-applicant and Collaborating Organizations

A proposal may include one or more co-applicant organizations. A co-applicant organization employs personnel who are key to the design, conduct, and reporting of the research and receives a portion of the grant award under a subcontract.

Within this RFP, the terms “collaborating organization” or “collaborator” refer to an entity that will contribute to the design, conduct, and reporting of the proposed research, but will not receive LSDF grant funds.

Organizations from outside of Washington State may receive funding as a co-applicant. However, the proposal must justify the necessity for the participation of an out-of-state entity and preference will be given to work that is partnered with an in-state organization.

All subcontracts and collaborations must be supported by written agreements (see Section 7.4). The timing for completion of such agreements may be subject to the terms and conditions of the grant agreement between LSDF and the grant recipient organization.

1.6. Principal Investigators and Co-investigators

A single principal investigator submits the 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.

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.

1.7. Corporate Involvement

For-profit entities are not eligible to apply directly to LSDF for funding, but are encouraged to join an eligible organization as a co-applicant or collaborator. Under certain circumstances, LSDF funds may be subcontracted to a for-profit entity. Companies requesting subcontract funds must make either financial or significant in-kind commitments to the proposed work. For a subcontract to be acceptable, the expenditure of LSDF funds by the for-profit entity must:

- enhance the grantee's ability to meet the stated goals of the proposed work;
- bring clear benefit to the grantee organization; and
- bring clear benefit to the state of Washington.

Possible benefits that could accrue to a grantee organization from a corporate subcontract include, but are not limited to, the following:

- The proposed work has the potential to enhance an existing license from the grantee to the for-profit entity.
- The for-profit entity has unique expertise or technology or is providing deliverable goods or services that enable the research to be accomplished.
- Access to the for-profit entity's unique expertise or technology will help the grantee gain a competitive future advantage.
- There is a high probability that jointly-owned intellectual property will result from the proposed work.
- There is a provision in the subcontract agreement for the grantee to receive financial returns from the for-profit partner from future sales of a product or service based upon the results from the proposed work.

The following non-exhaustive list of possibilities would not be consistent with LSDF's expectations for the primary types of benefit it expects to see accrue to a grantee organization under a subcontract to a for-profit entity:

- educational or employment benefit to an individual from the grantee organization participating in the proposed activities;
- a generalized claim that the proposed work will lead to future regional economic development;
- LSDF funding will be a substitute for venture capital and enhance the probability of success of a company spun out of the grantee organization; or



- the grantee has unique expertise or resources to help better position a company's existing product in the marketplace.

Preference will be given to work that is partnered with an in-state entity.

1.8. Resubmissions

LSDF permits resubmission of unfunded proposals. Details regarding resubmissions are provided in Section 3.2.5. LSDF has developed new proposal forms for 2010; do not use older forms in resubmissions.

1.9. RFP Updates

LSDF may amend this RFP after its release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF 2010 program competition webpage at: http://www.lsdfa.org/grants/current/2010/Programs_Grants/

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

1.10. Frequently Asked Questions

Brief answers to the most common questions may be found at: http://www.lsdfa.org/grants/current/2010/2010_LSDF_FAQ_122909.pdf

2. Funding Opportunity Description

2.1. LSDF 2010 Program Grant Opportunity

Programs funded under the LSDF 2010 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 2010 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;
- 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.

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

An example of this is a program led by a principal investigator with expertise in a specific area of study related to health or health care and who can provide both that expertise and related materials in support of other investigators' work. High-quality research occurs as a result of such a program, but it is not necessarily led by the principal investigator. Principal investigators considering this type of program proposal are strongly encouraged to confer with LSDF program staff well in advance of preparing their proposals to ensure that their ideas are consistent with this solicitation.

To be competitive for funding, programs must:

- be of strategic priority to applicant organizations;
- be innovative within their fields;

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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- create new synergies among participating researchers that would not exist but for the organization or support of their efforts through 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 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. Please refer to Section 3.2.5.C of this RFP for further information.

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.

Where infrastructure in support of commercialization or a research resource program is proposed, principal investigators must give detailed examples of the research that would be enabled by the infrastructure or resource (e.g., likely users, likely research aims and outcomes, and any evolution of the infrastructure or resource over time). The examples must be reinforced by letters of support. Plans for attracting a broad cross-section of users and establishing priority of access must be provided.



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 \$13 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 three to five program proposals, depending on the number and quality of submissions received. Collaborations with for-profit entities to achieve commercialization-related objectives are encouraged.

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 or their users’ 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

February 1, 2010	Online grant application system available
July 14, 2010 by 5:00pm PDT	Proposals due
November 16, 2010	Interviewees announced
Week of January 10, 2011	Interviews conducted
March 1, 2011	Award announcement
As early as April 2011	Funding start date

2.3. Questions to Consider Before Applying for an LSDF 2010 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 is appropriate for this competition and can't be accomplished without LSDF's investment?
- What tangible resources are being committed by the applicant organization to facilitate the success of the proposed research?
- 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 program staff at programs@lsdfa.org regarding the appropriateness of their program 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 proposal materials are accurate, complete, and submitted on time. Proposals that do not adhere to content requirements, are incomplete or incorrect, or are late will not be reviewed.

To apply for an LSDF program grant, principal investigators must complete two steps: (1) create an account via the LSDF online application system at <http://www.lsdfa.org/grants/apply.html> and (2) submit the proposal via the same system no later than 5:00PM Pacific Time on the deadline date. The online account needs to be set up only once, but should be reviewed in advance of submitting a proposal to ensure that the information entered is correct.

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

Proposals do not need to be completed in one online session; they can be saved and returned to later for additional work. Once submitted they are no longer available for revision without prior approval from LSDF.

Proposal submission requires documents to be uploaded to the LSDF online application system. Documents must be uploaded in PDF (portable document format) form.



Principal investigators who discover an error or omission after submitting a proposal, but before the submission deadline, may notify LSDF at grantsadmin@lsdfa.org and seek authorization to submit a corrected version, which must be submitted no later than 5:00 PM Pacific Time on the deadline date. Proposals found to be incomplete during or after their evaluation may be disqualified for funding.

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

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

3.2. Proposal Requirements

The proposal is prepared by the principal investigator who enters information directly into the LSDF online application system and completes and uploads required forms and documents.

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

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

3.2.1. Face Page

The face page section requires input of information pertaining to the applicant organization (including the name, title and e-mail address of the authorizing individual), as well as completion of a form that contains essential information for identifying, processing, and tracking the proposal (including the proposal title, principal investigator name and contact information, dates for requested support, budget amount being requested, animal welfare and federal-wide assurance numbers, names of co-applicant organizations, and financial conflict of interest and intellectual property policy information). The LSDF face page form requires 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. Complete and upload the signed, completed face page PDF form.

3.2.2. 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.

3.2.3. Proposal Details

The proposal details section collects essential information regarding the proposal, such as principal investigator contact, title of the proposal, start and end dates, funding request, whether the proposal is a resubmission, new company formation, conflict of interest policies, use of human subjects or animal subjects, as well as the following:

Abstract. An abstract of 500 words or less describing the proposed work and its impact on health, health care and economic development.

Keywords. Up to five keywords that are descriptive of the proposed work.

Proposal Reviewers. The names of reviewers whom the principal investigator would prefer not review the proposal.

Intellectual Property. If commercialization is the ultimate pathway through which health benefits will be realized from the proposed work, the principal investigator must describe in detail the intellectual property protection plan for the proposed work. For patents, describe what types of applications have been filed and where. Give examples of the type and breadth of claims being pursued (e.g., composition of matter, method of use). Describe any freedom to practice analyses that have been performed.

If a party other than the applicant organization will own or have other rights to intellectual property developed under the proposed LSDF-funded work, the principal investigator must provide an explanation of and justification for such provision.

Organizations without an intellectual property policy or an established infrastructure to manage intellectual property must contact LSDF at programs@lsdfa.org before submitting their proposal to discuss how they plan to manage and commercialize intellectual property associated with the proposed work.



3.2.4. Proposal Narrative

Please review the following requirements before uploading and submitting your proposal narrative as a single PDF document. The narrative must be no longer than 25 pages (not to exceed 10MB) and must conform to the following format requirements:

- 8½-by-11-inch portrait-oriented page dimensions;
- Single spaced with all margins measuring at least one 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 2010 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. Website addresses (URLs) or attachments must not be used to provide additional information necessary to the narrative. 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. The proposal narrative must include sufficient information needed to evaluate the scientific and technical merit and beneficial returns of the program, independent of any other document. The narrative must include all of the following sections described below.

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 (and those of its users, if a research resource is proposed).

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 of 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?

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- 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, research resource, or infrastructure to support commercialization lead to an improved solution for the problem?
- How does the proposal 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. For proposals that involve the development of a research resource, describe the principal investigator's and applicant organization's experience in: creating and administering a broad access resource; ensuring equitable user access (such as cost, institutional affiliation, and geography); and if applicable, establishing equitable policies for data sharing, intellectual property rights, protection of human subjects information, and navigating IRB approval processes.

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. This is required even for programs that propose a research resource—describe likely users and what research would be enabled by the research resource.

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 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. For proposals for research infrastructure to enhance commercialization or for resources to enable research, please describe:

- How projects will be selected for the program;
- How issues of data ownership, protection of participant data, and intellectual property will be addressed;
- How a diverse group of users will be attracted;
- How the progress of each project will be monitored and assessed;
- What actions will be taken to assist investigators and projects that are stalled or behind schedule; and
- The ways in which the infrastructure to support commercialization or research resource will be attractive to industry and how industrial participants will be recruited.

E. Challenges

Describe the challenges the proposed program may face in achieving its objectives and the plans to overcome them.

F. Timeline and Milestones

Provide a timeline for a) developing, funding, launching, and conducting the program, and b) completing or enabling the completion of research objectives. Identify measurable major milestones, propose target dates for their accomplishment, and define the criteria or metrics by which achievement of organizational and research milestones will be assessed. For information regarding writing milestones see:

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

G. Key Personnel

Key personnel are individuals who contribute substantively and commit a specified fraction of their time to the work. Key personnel include the principal investigator, all co-investigators, and any other individuals who have a substantive contribution. 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. List names of all key personnel and briefly describe their roles in the proposed work.

H. Facilities and Equipment

Provide a short description of any unique facilities or equipment available for the proposed work. If new equipment is requested and 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- 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 to further develop the program or scale-up the research resource; 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.

3.2.5. Attachments

Forms for the following proposal attachments are provided on the LSDF website. After their completion, the attachments must be uploaded as PDF files under the Attachments section in the online application system.

Budget. The proposal budget includes multiple components, which when combined, comprise a complete description of the proposed expenditures and organizational resource commitments.



A. Detailed Budget

Provide a detailed budget for each year of requested funding using the forms provided on the LSDF website http://www.lsdfa.org/grants/current/2010/Programs_Grants/. The budget must be appropriate for the scope and goals of the proposed research 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 detailed budget information is required for work to be performed by any co-applicant organization(s) utilizing a subcontract mechanism.

The detailed budget is comprised of two sections: Part 1: Research Detailed Budget, and Part 2: Administrative Detailed Budget (further comprised of two separate sections: 2A Administrative Detail, and 2B Facilities Detail). Complete detailed budgets are uploaded as a single PDF.

Part 1: Research Detailed Budget. All proposed expenditures must be placed into one of the following budget categories; do not create additional categories.

- Salaries - Include wages, benefits and stipends. Provide the compensation requested for research and operational staff associated with the program. Salaries should be calculated on the basis of the individual's percent effort on the program. Do not list personnel who will not receive salary support, e.g., someone whose salary is being paid by another source or who is listed at a 0% effort.
- Equipment - Include equipment with a unit cost greater than \$5,000 that is specifically required for program research or operation. 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 at or under \$5,000. Expenses for personal computers are not allowable unless the computers are used primarily for the proposed work.
- Travel - 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.
- Other - Itemize costs falling outside of the typical budget categories above, including education fees for trainees (e.g., graduate student tuition), fees for services performed, consultants, manuscript publication fees, and any other miscellaneous expenses.



- Subcontracts - Include the expenses associated with the activities performed by co-applicants using the same categories described immediately above.

Part 2A: Administrative Detailed Budget. The following budget categories are provided:

- Research-associated Administrative Expenses:
 - Salaries - Include wages and benefits for administrative personnel, including clerical and fiscal support, and any other associated administrative costs. Salaries should be calculated on the basis of the individual's percent effort associated with the proposed research.
 - Supplies - Include consumable materials and supplies required for the administrative management of the proposed research.
- Organizational Administrative Expenses:
 - IRB expenses - A one-time fee of up to \$1,500 may be charged for each IRB protocol required for the proposed work.
 - Subcontract administration expenses - A one-time fee of up to \$15,000 may be charged by the applicant organization for administration of each subcontract.
 - General organizational expenses - If it is impossible to break down administrative expenses 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 research budget (after subtracting equipment and tuition) and show the resulting value.

Part 2B: Facilities Detailed Budget. The following budget categories are provided:

- Research space costs - Include the cost of actual allocated space associated with the proposed research. This category is often calculated utilizing an assignable square footage value or assigned a lump sum value.
- Facility lease/rental expenses
- Any additional costs associated with lease or rental of research facilities

Do not apply the organization's Federal indirect cost rate to the total program budget to calculate facilities costs.

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

Administrative and facilities expenses incurred by for-profit subcontractors are not reimbursable by LSDF.



B. Budget Justification

Provide justification for expenses within each category requested within the budget, in sufficient detail to allow reviewers to determine that the budget is appropriate for accomplishing the proposed work. Highlight and explain the need for any extraordinary expenditures. Salary expenses should include a short narrative for all personnel (research, operational, and administrative) by position, role description, and requested level of effort. If consultants are requested in the detailed budget, provide a description of the services to be performed, including length of anticipated consultation, expected rate of compensation, and any other relevant information. The budget justification should also include a detailed description regarding calculation of facilities costs associated with the proposed budget.

Describe any plans for using LSDF funds for efforts whose costs or nature cannot yet be accurately determined (including but not limited to re-granting or recruitment start-up 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.

For subcontracts to for-profit entities, provide justification for expenses incurred by for-profit subcontractors. Review Section 1.7 before completing this part of the budget justification.

- Describe how the for-profit subcontracted work:
 - enhances the grantee's ability to meet the stated goals of the proposed work;
 - brings clear benefit to the grantee organization; and
 - brings clear benefit to the state of Washington.
- Describe the financial or significant in-kind commitments being provided by the for-profit subcontractor to accomplish the proposed work.

Provide justification for the participation of any non-Washington subcontractors or collaborators.

The budget justification must not exceed five pages, and is uploaded as a single PDF.

C. Organizational Commitments

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. Principal



investigators must provide a written description of the resource commitments made to this proposal, as well as a completed resource/expenditure summary form that quantifies the monetary value of the committed resources. In the written description, list the tangible commitments of resources provided by the applicant organization to the proposed research. Organizational resource commitments may include, but are not limited to, the following:

- partial to full salary support for key personnel;
- recent recruitment of and start-up support for program researchers;
- recent purchase of new equipment or supplies, or dedication of existing equipment or supplies to the proposed work;
- allocation of laboratory, clinical, or office space that is newly or specifically designated for the proposed activities;
- recent support for renovations of program facilities;
- absorption of institutional facilities and administration charges;
- tangible items and services, resulting from contemporaneous work supported by other entities, that are critical for the success of the proposed research;
- expenditures for intellectual property protection or market analyses, and assignment of an entrepreneur-in-residence or a technology transfer professional to guide or manage a technology under development; and
- matching/committed 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.

The organizational commitment written description must not exceed one page, and is uploaded as a single PDF.

Using the resource/expenditure summary form and accompanying instructions, quantify monetarily any tangible commitments of resources provided in support of the proposal. These amounts must match what is described in the budget justification and letters of support. The resource/expenditure summary is a one-page form, and is uploaded as an individual PDF.

Biographical Sketches. Provide biographical information on key personnel using the LSDF biographical sketch form. The LSDF form is very similar to the current NIH biographical sketch version (Rev 06/09).



In Section D (Research Support) of the LSDF biosketch form, principal investigators must include information on active and pending scientific research support for themselves, as well as for co-investigators and key personnel. Include completed scientific research support as part of the biosketch only if it is directly relevant to the proposed work. For individuals with no active or pending support, indicate "none." Do not include this LSDF proposal in the support listing. If the listed support is provided under a consortium/subcontract arrangement or is part of a multi-project award, also indicate the project number, principal investigator/program director, and sponsor of the overall project. Summarize for each individual any potential overlap with the active or pending projects and this specific proposal in terms of the research, budget or an individual's committed effort.

Biographical sketches are limited to four pages, and are uploaded as individual PDFs for each designated member of the key personnel. Do not combine multiple biosketch forms into one PDF.

Personnel Roster. Using the form provided by LSDF, provide for all personnel involved in the proposed program the name, role, organization, and total proposed level of effort. For each individual, indicate if any salary is being contributed from non-LSDF sources. Complete and upload the form as a single PDF.

Letters of Support. Letters of support are required to confirm the commitment of time and resources to the program from key personnel and co-applicant and collaborating organizations. Letters should clearly detail the type and magnitude of the resources being committed to the program and should be signed by the individuals having the authority to make said commitments. If a research resource is proposed, letters of support must come from a cross-section of the state, to document the statewide need and usage of the resource. Letters of support must be uploaded by the principal investigator as individual PDF files through the online application system and not sent directly to LSDF by the individuals writing them. Do not combine letters of support into one PDF file.

New Company Formation/Commercialization Partners. List any "commercialization partners" (*i.e.*, parties working with the principal investigator and having a focus on the business aspects of commercializing the proposed research output, including, but not limited to, an existing or a start-up company, entrepreneur, or investor) associated with the proposed work. Describe any option or license agreements, executed or pending, related to the subject matter of the proposal. Describe any plans and activities to date related to starting a company based upon the subject matter of the proposal. If either a start-up company or an existing company is engaged as a commercialization partner,



provide, in two pages or less, a description of that company's market focus and a summary of its business plan related to the proposed work. The principal investigator must complete and upload the summary as a single PDF.

Resubmissions. Resubmitted proposals must be accompanied by:

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

Respond to the comments provided for the first stage of review, i.e., if your previous proposal resulted in an interview, do not use those reviewers' comments.

LSDF has developed new proposal forms for 2010; do not use older forms in resubmissions.

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 on LSDF's website. Principal investigators will receive copies of the expert reviewers' consensus evaluations of their proposals.

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.

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 framework, reviewers will use the criteria below to evaluate proposals, placing them in one of three categories based on their recommendation for interview (first-phase review) or for funding (second-phase review): Not Recommended, Recommended, and Highly Recommended.

Reviewers will rate the proposal as presented by the principal investigator and not on the basis of its theoretical potential, e.g., without considering the proposal's likelihood of success. For example, a principal investigator may propose to cure a devastating disease affecting many Washingtonians but have a poor approach to doing so. Even though this disease is very important and its cure would be extremely valuable, if the proposal's approach is flawed, its rating on this criterion would not be high.

4.2.1. *Scientific, Technical, and Organizational Merit*

The scientific and technical 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, possessing or fostering scientific and technical originality;
- it establishes a research or operational framework with strong potential to achieve novel and important results;
- its proposed research outcomes are clearly defined, significant, and realistic;
- 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;

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- it builds upon the established strengths of the applicant organization;
- it has the potential to establish the applicant organization and any co-applicants as leaders in the field;
- its 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;
- for proposals to provide a research resource, it meets a demonstrated need, has a credible plan for attracting users from across the state, has a plan for establishing priority of access, has a plan to sustain itself to keep user access fees reasonable, and has adequately considered issues such as data sharing, intellectual property rights, human subject protection and confidentiality;
- 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;
- the principal investigator makes a clear case for why an investment from LSDF is appropriate and necessary to the success of the program;
- investigators demonstrate a history of effective collaboration and an appropriate plan to manage the collaborative process; and
- the budget is appropriate to the scope and goals of the proposed program.

4.2.2. Impact on Health and Health Care

The program's impact on health and health care in Washington State will be judged by how well the proposal demonstrates the following qualities:

- It addresses a significant problem in health or health care for residents of Washington State.
- It has excellent potential to make a substantial, beneficial and measurable contribution to improving health and health care in areas such as:
 - improved diagnosis, treatment, prevention or management of disease;

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- better management of health-care delivery environments and systems;
- promotion of healthy patient behaviors and patient compliance with care-givers' recommendations;
- better integration of care-givers, patients and health-care systems; or
- accomplishing any of the above in a more cost-effective manner.
- It proposes a credible mechanism for how research results will be translated into benefit, e.g., through practice adoption, policy implementation or commercialization.

Principal investigators may propose a broad range of improvements in health or health care, and the impact of the proposed program may be near- or long-term, with near-term benefit being especially desirable. LSDF will give priority to proposals that address widespread health and health-care problems and that provide compelling evidence that they have the potential to yield benefits for the greatest number of Washington residents.

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 gains due to 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 new or enhancing existing intellectual property 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. When a corporate subcontract is proposed, the board will consider the benefit accruing to the grant recipient organization from the subcontract. The board may also consider the following in making award decisions:

- the diversity of research topics within the portfolio of LSDF-funded grants and the applicant pool;
- the variety of health, health-care and economic benefits accruing from the portfolio of LSDF-funded grants and the applicant pool; and
- the geographic impact of the work in Washington State.

The board will select proposals which in its judgment are the most meritorious. 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. For organizations that are public entities (e.g. public universities) see:

http://www.lsdfa.org/about/background/2008_Grant_Agreement_state-final.pdf

For organizations that are private, non-profit entities see:

http://www.lsdfa.org/about/background/2008_Grant_Agreement_non-state_final.pdf

7. Additional Information

7.1. Confidentiality and Public Disclosure

Information in grant proposals is received by LSDF with the understanding that it shall be used or disclosed solely for evaluation of proposals or as required by law. LSDF holds all proposals confidential in accordance with its confidentiality policy at http://www.lsdfa.org/about/background/LSDF_Confidentiality_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 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 at 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 the applicant organization and either subcontracting or collaborating organizations must be supported by an agreement that, at a minimum, makes explicit provision for the disposition of intellectual property rights among the organizations. Such an agreement must clearly allocate the rights that the organizations will have in any intellectual property developed during LSDF-funded research and identify which of the organizations will be responsible for commercialization. The intellectual property 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 can be found on the LSDF website at <http://www.lsdfa.org/grantees/information.html>.

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 after termination of the grant agreement. 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 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 April 2011.

7.8. Contact Information

For further information about LSDF or grant administration, visit the LSDF website at <http://www.lifesciencesdiscoveryfund.org> or contact programs@lsdfa.org or telephone (206) 732-6788.