

Life Sciences

DISCOVERY FUND

Opportunity Grants Proposal Submission Requirements

June 23, 2010

Executive Summary

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

Opportunity grants allow the LSDF Board of Trustees to consider extraordinary proposals outside of LSDF's calendar-driven competition cycles that have the potential to advance life sciences research or research infrastructure within Washington's non-profit and public institutions.

Proposals should request the budget amount and duration that are appropriate for the opportunity. Principal investigators from eligible Washington state organizations must apply online at <http://www.lsdfa.org/grants/apply.html>.

Only those principal investigators who have been invited by LSDF to submit a full proposal are eligible to do so. Proposals will be considered on an individual basis as they are received.

Proposals will be evaluated according to their potential to leverage the LSDF investment and 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

LSDF Opportunity Grants

1.1. Background

This document details the requirements for submission of opportunity grant proposals. **Only those principal investigators who have been invited by LSDF to submit a full proposal are eligible to do so.** LSDF will not review uninvited proposals. Refer to the opportunity grants webpage http://www.lsdfa.org/grants/current/2010/Opportunity_Grants/ to review opportunity grant goals.

1.2. Applicant Organizations

The applicant organization is legally responsible for submitting the proposal, administering the grant, and disbursing LSDF funding. Throughout this document, 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.

1.3. 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 proposed activities and receives a portion of the grant award under a subcontract.

Within this document, the terms “collaborating organization” or “collaborator” refer to an entity that will contribute to the design, conduct, and reporting of the proposed activities, 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 activities that are 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.

1.4. Principal Investigators and Co-investigators

A single principal investigator submits the proposal for an opportunity grant, regardless of how many investigators or organizations will be involved in the proposed activities. LSDF does not recognize the title of “co-principal investigator.” A principal investigator may have only one pre-proposal or proposal pending for an opportunity grant at any given time, 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 proposed activities.

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

1.5. Resubmissions

LSDF permits resubmissions of unfunded proposals, but strongly advises applicants to consider LSDF's recommendation regarding the suitability of a resubmission.

1.6. Proposal Submission Requirements Updates

LSDF may amend this Proposal Submission Requirements document after its release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF opportunity grants webpage at:

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

Principal investigators are responsible for consulting amendments to this document to be sure they have the latest information regarding opportunity grants. They may also sign up at programs@lsdfa.org for general LSDF updates, including announcements of changes to grant offerings.

1.7. 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 Opportunity Grants

Refer to the opportunity grants webpage to review the goals of the opportunity grants: http://www.lsdfa.org/grants/current/2010/Opportunity_Grants/.

2.2. Timelines

Proposals will be considered on an individual basis as they are received. LSDF will strive to accomplish its reviews consistent with the time sensitivity of the submission, but cannot be responsive to unreasonable timelines.

Opportunity grants may be made on a contingent basis, e.g., pending the applicant's receipt of matching funds at a future date. In making such an award, LSDF will specify the timeframe in which any contingencies must be removed. Open-ended contingencies will not be permitted.

3. Application Process

3.1. General Information

It is the sole responsibility of the principal investigator to comply with the proposal submission requirements detailed herein and the instructions in the online application system and ensure that the proposal materials are accurate and complete. Proposals that do not adhere to content requirements or are incomplete or incorrect may not be reviewed.

The full proposal must be submitted via the LSDF website, <http://www.lsdfa.org/grants/apply.html>. To create an account in the online application system, see the instructions online. 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.

Individuals having difficulties submitting proposals should contact the LSDF grants administrator (grantsadmin@lsdfa.org or 206-732-6788) 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 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 activities). Principal investigators may not authorize proposals from their own organizations.

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 information, 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 activities and their impact on health, health care, and economic development.

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

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 or economic benefits will be realized from the proposed activities, the principal investigator must describe in detail the intellectual property protection plan related to the activities. 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 activities, 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 activities.

3.2.4. Proposal Narrative

The proposal narrative describes the key features of the proposed opportunity and must be no longer than 10 pages (submitted as a single PDF document not to exceed 10MB). The narrative 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, Calibri, 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, LSDF Opportunity Grants, and the page number, using the format: “Page x of xx.”

All tables, charts, or graphs must be contained within the 10-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 10-page limit. A maximum of three pages of references will be accepted. The proposal narrative must include sufficient information to allow evaluation of the scientific and/or technical merit and beneficial returns of the proposed activities, independent of any other document. The narrative must include all of the sections described below.

A. Objectives

List the immediate and long-term research and organizational objectives related to the LSDF request. Explain the proposal’s importance to the strategic direction of the applicant organization.

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

Describe the background related to the LSDF request and the important health needs it is designed to address. Ensure that all of the following questions are answered:

- What health- or health-care-related problem do the proposed activities address?
- What is the significance of this problem in Washington state?
- How does the proposal advance the LSDF’s mission of improving health and health care, stimulating economic activity, and promoting life sciences competitiveness in Washington?
- Why is an opportunity grant particularly appropriate and necessary to accomplish the activities being proposed?

C. Established Experience

Describe the principal investigator’s and applicant organization’s experience related to the activities associated with the LSDF request. Include, as appropriate, relevant experience in cognate scientific and technical disciplines, in areas such as organizational leadership, collaborative structures, and coordination of multi-faceted research or administrative activities.

D. Proposed Activities

Describe the focus or agenda and the anticipated results. Discuss the activities that will be performed or enabled through the LSDF request in sufficient detail to allow external reviewers to understand the priorities and the methodologies to be used.

E. Timeline and Milestones

Provide a timeline for the proposed activities keyed to the major objectives. Identify measurable major milestones, propose target dates for their accomplishment, and define the criteria or metrics by which achievement of each of the milestones will be assessed. More information about how to write milestones can be found on the LSDF website at: http://www.lsdfa.org/grantees/grantee_info_docs/current_milestones.pdf.

F. Key Personnel

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

G. Outcomes and Future Plans

Describe the expected outcomes of the proposed activities and the plan for translating those outcomes to public benefit. Ensure that the following questions are answered:

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

Describe the next steps in capitalizing on the success of the proposed activities, including both the near- and long-term outcomes. Describe the following:

- the potential for follow-on research or other funding;
- clinical or organizational implementation of scientific findings developed under the grant, e.g., changing ways that practitioners work or how organizations and governments deploy their resources;
- plans of the proposal team for further work; and
- plans for the proposal team, applicant, co-applicant and collaborating organizations or others to translate the results of the proposed activities 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

Use the workbook provided on the LSDF website to develop the budget, see http://www.lsdfa.org/grants/current/2010/Opportunity_Grants/. The workbook directs the development of a detailed budget. **However, upload only the cumulative budget pages for applicants and co-applicants as a single PDF.**

The budget must be appropriate for the scope and goals of the proposal. All costs must be listed as direct costs, including costs typically associated with general facilities and administration expenses, and must be in accordance with the applicant organization's fiscal policies. The same budget development process and information is required for activities to be performed by any co-applicant organization(s) utilizing a subcontract mechanism.

The detailed budget is comprised of two sections: Part 1: Detailed Budget, and Part 2: Administrative Detailed Budget (further comprised of two separate sections: 2A Administrative Detail, and 2B Facilities Detail).

Part 1: 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 proposed activities. Salaries should be calculated on the basis of the individual's percent effort on the activities. 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 the proposed activities. Include only items of property with an expected service life of more than one year.
- Supplies - Include consumable materials and supplies required for the proposed activities, 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 activities.
- Travel - Include expenses required for field work, attendance at meetings and conferences, and other travel required for the proposed activities, including per diem allowance, subject to the applicant organization's usual accounting practices.
- Other - Itemize costs falling outside of the 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:

- 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 activities.
 - Supplies - Include consumable materials and supplies required for the administrative management of the proposed activities.
- 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 activities.
 - 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 budget (after subtracting equipment and tuition) and show the resulting value.

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

- Space costs - Include the cost of actual allocated space associated with the proposed activities. 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 facilities

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

Costs associated with patient care beyond those required for the proposed activities are not allowed by LSDF.

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

Upload only the cumulative budget sheets for the applicant and any co-applicant. Do not upload the detailed budget sheets.

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 activities. 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.

- Describe how the for-profit subcontracted activities:
 - enhances the grantee's ability to meet the stated goals of the proposed activities;
 - 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 activities.

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

The budget justification must not exceed three 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 activities. Such resource commitments demonstrate that the proposal is of strategic importance to the applicant organization and that the organization is invested in its success. Principal investigators must provide a written description of the resource commitments made to this proposal, as well as a completed resource/expenditure summary form (from http://www.lsdfa.org/grants/current/2010/Opportunity_Grants/) 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 activities. 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 researchers;
- recent purchase of new equipment or supplies, or dedication of existing equipment or supplies to the proposed activities;
- allocation of laboratory, clinical, or office space that is newly or specifically designated for the proposed activities;
- recent support for renovations of facilities associated with the proposed activities;
- absorption of institutional facilities and administration charges;
- tangible items and services, resulting from contemporaneous activities supported by other entities, that are critical for the success of the proposed activities;
- 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 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 only using the LSDF biographical sketch form. Although the LSDF form is very similar to the current NIH biographical sketch version (Rev 06/09), the LSDF form must be used.

In Section D (Research Support) of the LSDF biosketch form, principal investigators and other key personnel must include information on active and pending scientific research support. Include completed scientific research support as part of the biosketch only if it is directly relevant to the proposed activities. 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 proposed activities, 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 the name, role, organization, and total proposed level of effort for all personnel involved in the proposal. 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 proposal from key personnel and co-applicant and collaborating organizations. Letters should clearly detail the type and magnitude of the resources being committed to the proposal and should be signed by the individuals having the authority to make said commitments. 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 output of the proposed activities, including, but not limited to, an existing or a start-up company, entrepreneur, or investor) associated with the proposed activities. 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 activities. 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 submission, 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.

Prior Expert Review. If the subject matter of the proposal has undergone expert review, independent of LSDF, within the last six months, provide complete copies of the review comments and the proposal upon which those comments were based. The principal investigator must upload these documents as individual PDF files through the online application system.

4. Evaluation

Proposals will be considered on an individual basis as they are received.

4.1. Expert Review

Submitted proposals that are judged to be compliant will proceed to expert review. Proposal evaluation will ordinarily be conducted by expert reviewers from outside of Washington state. Proposal review panels are typically convened by the American Association for the Advancement of Science (AAAS), but LSDF may in some instances convene a panel on its own. Expert reviewers will be required to sign nondisclosure agreements.

In certain circumstances LSDF may accept a prior expert review of the subject matter of the proposal in lieu of commissioning its own separate review. In determining whether to substitute a prior review for an LSDF-commissioned review, LSDF will consider the following criteria:

- the prior review was based upon a proposal substantially identical to that submitted for the opportunity grant;
- the previously reviewed proposal was submitted to, and reviewed under the auspices of, a grant sponsor having an established track record in funding research or research infrastructure in non-profit and public organizations;
- the prior review was performed by a panel having the appropriate credentials and expertise to be considered experts within the field of the proposed activities;
- the prior review reasonably addresses the same criteria as would a review commissioned by LSDF;
- the prior review was performed within the six month period immediately prior to submission of the LSDF application.

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

Names of 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.

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 framework, LSDF-commissioned reviewers will use the criteria below to evaluate proposals, placing them in one of three categories based on their recommendation for funding: Not Recommended, Recommended, or 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 and/or Technical Merit*

The scientific and/or technical merit of the proposal will be judged by how well it demonstrates the following qualities:

- the proposed activities are innovative, possessing or fostering scientific and/or technical originality;
- it establishes a framework with strong potential to achieve novel and important results;
- its proposed 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 success of the proposed activities;
- 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 activities are organized in a clear way that facilitates communication among participants, decision-making, and future growth (applies when new organizational structures are proposed);
- 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 activities successfully;
- the principal investigator makes a clear case for why an investment from LSDF is appropriate and necessary to the success of the proposed activities;
- 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 proposal.

4.2.2. *Impact on Health and Health Care*

The impact on health and health care of the proposed activities 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 tools that have the potential to lead to breakthroughs in health-related research;
 - 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; and
- it proposes a credible mechanism for how research or other 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 activities 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 benefits of the proposed activities to the state's economic environment. Benefits may include, but are not limited to, the following:

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

5. Selection of Awards

LSDF-commissioned expert reviewers will recommend proposals 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 opportunity grants. 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 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;
- the magnitude of leverage anticipated for the LSDF funds; and
- the geographic impact of the proposed activities 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.

For unfunded proposals, principal investigators will receive written comments about why their proposals were rejected.

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 grant 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/2009_Grant_Agreement_state_final.pdf

For organizations that are private, non-profit entities see: http://www.lsdfa.org/about/background/2009_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 or as required by law. LSDF holds all submissions 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 proposals, LSDF publicly releases the name of the principal investigator, the applicant organization, the 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 activities, 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 activities 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 release 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 activities, 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 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 activities, 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 the proposed research will involve 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

Proposals involving 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 activities 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 activities 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 progress and financial reports, and post-funding 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 activities.

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, proposal titles, the field(s) in which the proposed activities will be conducted, descriptions of proposals funded, and reports about progress and outcomes. Recipient organizations and principal investigators will be expected to provide LSDF with reasonable assistance in communicating funded activities and their 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 October, 2010.

7.8. Contact Information

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