

Washington State Life Sciences Discovery Fund Authority Request for Proposals LSDF 08-01

Innovative research projects
to improve health and health care

January 23, 2008

Executive Summary

Applicants are invited to propose research projects to improve health and health care in Washington State. Proposals are invited from Washington public and nonprofit organizations, singly or in collaboration with other public and nonprofit organizations or with for-profit companies.

The Life Sciences Discovery Fund expects to distribute \$6-8 million in grants in this competition. There is no cap on grant amount or duration.

Applications are made through LSDF's on-line application system. Letters of intent are due February 20, 2008, with proposals due April 16, 2008. Award announcements are expected on August 6, 2008.

Proposals will be evaluated according to scientific and technical merit and the potential to benefit health and health care and the economy in Washington State. All funded proposals must have the potential to contribute to the achievement of LSDF's primary strategic goals—promoting life sciences competitiveness, improving health and health care for Washington's citizens, and fostering economic growth.

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1. Introduction

LSDF 08-01: Innovative research projects to improve health and health care.

1.1. Background

The Life Sciences Discovery Fund Authority (LSDF) was created in 2005 by the governor and legislature of the State of Washington. LSDF is funded by tobacco settlement bonus payments of approximately \$35 million per year over a ten year period to invest in the state's life sciences sector. Its mission is to support innovative research to promote life sciences competitiveness, enhance economic vitality, and improve health and health care in Washington.

1.2. The Niche for LSDF Funding in Washington State

Annual life sciences research expenditures within Washington State are in excess of a billion dollars. In light of this fact, LSDF seeks to make grants where they can have the greatest impact. This often means providing grants that enable organizations to be more competitive for future funding or that help translate discoveries into widespread use. LSDF does not believe that replicating funding programs offered by other granting sources, particularly the National Institutes of Health (NIH), will help it achieve its mission. Consequently, applicants are discouraged from submitting applications to LSDF that they would normally send to NIH. In their proposals, applicants will be expected to make a compelling argument for why LSDF dollars are necessary to accomplish their research.

1.3. Applicant Organizations and Eligibility

Applications for LSDF 08-01 funding are invited from Washington public and nonprofit organizations, singly or in collaboration with other public and nonprofit organizations or with for-profit companies.

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

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

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

Eligible applicant organizations are those that have recently engaged in competitively funded, sponsored research, or similar activities, and have the personnel, resources, and experience necessary to accomplish research projects of the sort contemplated by this RFP. Eligible applicants include, but are not limited to, the following:

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

For-profit entities are not eligible to apply individually for funding under LSDF 08-01, but are encouraged to join an eligible applicant as a co-applicant or collaborating organization.

Organizations from outside of Washington State are not eligible to apply individually for funding, but they may join an eligible applicant as a co-applicant or collaborating organization. In order to be funded, the necessity for the participation of an out-of-state entity will need to be justified.

1.4. Principal Investigators and Co-investigators

LSDF grant applications are submitted by a single principal investigator, regardless of how many researchers or organizations will be involved in the project. LSDF does not recognize the title of “co-principal investigator”. A principal investigator may submit only one application for this competition, but may serve as a co-investigator on other applications.

An application may include one or more co-investigators. A co-investigator is an individual other than the principal investigator who plays a leading role in the design, conduct and reporting of the research. A co-investigator can be from the applicant organization, or from a co-applicant or collaborating organization.

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

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

1.5. RFP Updates

LSDF reserves the right to amend this RFP after its release. Any clarifications or changes in guidelines or requirements will be posted on the 08-01 page of the LSDF website:

www.lsdfa.org/grants/current/08-01/LSDF_08-01.html .

Applicants are responsible for consulting amendments to be sure they have the latest information regarding this competition.

1.6. Frequently Asked Questions

For brief answers to the most common questions about this LSDF grant opportunity, visit the 08-01 page of the LSDF website:

www.lsdfa.org/grants/current/08-01/LSDF_08-01.html .

2. Funding Opportunity Description

This section is crucial for the formulation of a successful application. It describes the scope and essential requirements for a grant award.

2.1. Scope

The LSDF 08-01 grant competition will support innovative research projects aimed at improving health and health care. In addition, funded projects will be expected to advance the other core goals of the Fund—to promote life sciences competitiveness in Washington and foster growth of the state’s economy.

LSDF expects to distribute \$6-8 million in grants in this competition. There are no restrictions on the dollar amounts or duration of funded grants.

2.2. LSDF 08-01 Grant Opportunity

Projects funded under LSDF 08-01 must have the potential to be beneficial to health and health care in Washington State—that is, not merely continuing the current state of care or practice, but changing it demonstrably for the better.

LSDF expects to fund research leading to a variety of 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-givers' recommendations;
- better integrate care-givers, patients and health-care systems; or
- accomplish any of the above in a more cost-effective manner.

2.3. Requirements for Research Proposals

All proposed research must be scientifically rigorous. Proposals will be evaluated according to scientific and technical merit and the potential to benefit health and health care and the economy in Washington State. [Further discussion of anticipated returns on the state's investment in life sciences research is included in the [2006 LSDF Report to the Washington State Legislature](http://www.lsdfa.org/about/files/12-01-06_Report_to_the_Legislature.pdf) found on the LSDF website (www.lsdfa.org/about/files/12-01-06_Report_to_the_Legislature.pdf)].

LSDF desires to fund teams that show a commitment to translating the results of their research into widespread use. 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 are especially desirable. Such additional resources may include follow-on research funding and/or investor funding; 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 other interested parties to adopt a successfully demonstrated strategy or technology.

2.4. Questions to Consider Before Applying for LSDF 08-01 Funds

Due to the breadth of research projects that will address LSDF's goals in 08-01, competition in this grant cycle is expected to be rigorous. Because preparation of a proposal can involve considerable time and effort, applicants are strongly advised to read this RFP carefully and review the questions below before deciding to apply. If an applicant cannot make a strong case with regard to each of the following questions, it is unlikely that his or her application will be successful.

- What are the compelling reasons why this project won't be accomplished without LSDF's investment?
- What will be the pay-off to the State of Washington from LSDF's investment in this research:
 - in terms of improving health or health care?
 - in terms of contributing to the growth of the economy?

Applicants' answers to these questions will be evaluated as part of the proposal review process.

Applicants are strongly encouraged to confer with LSDF programs staff (programs@lsdfa.org) regarding the appropriateness of their project for LSDF funding in advance of making application.

3. Application Process

Compliance with this RFP and assurance that application materials are accurate, complete, and timely is the sole responsibility of the applicant. Applications that do not adhere to content requirements, are incomplete or incorrect, or are late will not be reviewed.

Applicants must complete two steps: a letter of intent (LOI) followed by a proposal. LOIs and proposals are submitted electronically via an on-line application system available on the LSDF website:

www.lsdfa.org/grants/apply.html .

Detailed instructions for submitting the LOIs and proposals are provided in the on-line application system. LOIs or proposals do not need to be completed in one session. They can be saved and returned to later for additional work. Once submitted to LSDF, however, they are no longer available for revision.

Applicants who discover an error or omission after submitting an LOI or proposal, but before the deadline for submission, may notify LSDF at programs@lsdfa.org and seek authorization to submit a corrected version. Only complete and fully compliant LOIs and proposals received by the deadline will be accepted and reviewed. Applications found to be incomplete during or after their evaluation may be disqualified for funding.

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

3.1. Key Dates

Letter of intent due	Wednesday, February 20, 2008, 5:00PM PST
Proposal due	Wednesday, April 16, 2008, 5:00PM, PDT
Expert review of proposals	April-June 2008
Awards announcement	August 6, 2008
Funding start date	Upon completion of the grant agreement

3.2. Resubmissions

Applicants who were not funded in a previous LSDF competition may resubmit an application to this competition. Details regarding resubmissions are provided in Sections 3.3, 3.4.3 and 3.4.4.

3.3. Letter of Intent

All applicants must submit an LOI stating their intent to submit a proposal. Submitting an LOI does not require the prospective applicant to submit a proposal. However, no proposal will be reviewed unless an LOI has been received.

The LOI is not a pre-proposal. The LOI helps LSDF prepare for expert review of the proposals. If an LOI describes a project that is clearly not suited for LSDF 08-01 funding, the applicant will be notified of that determination.

In addition to other information, LOIs include the following:

- a descriptive, non-confidential title for the project;
- a list of co-applicant organizations;
- an abstract of 500 words or less, stating the objectives of the project, its distinctive methods, and its most important scientific, economic and health benefits; and
- up to five keywords descriptive of the project. A single 'keyword' may be a short phrase.

If the LOI is a resubmission of a previously unfunded application to LSDF, the applicant must indicate this in the space provided within the on-line system.

Upon receipt of the LOI by LSDF, an e-mail acknowledgement will be sent to the principal investigator along with an invitation code to be used when logging in to the on-line system to work on the proposal.

3.4. Proposal Requirements

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

The on-line application system requires the applicant to input information under the following headings:

- Face Page
- Applicant Organization Information
- Co-applicant Organization Information
- Co-investigator Information

- Proposal Details
- Proposal Narrative
- Required Attachments

3.4.1. Face Page

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

The face page includes the following elements:

- the name and Entity Identification Number (EIN) of the applicant organization;
- the project title;
- the principal investigator name and contact information;
- the names of co-applicant organizations;
- the dates of requested project support;
- the budget amount being requested;
- answers to questions regarding the applicant organization's financial conflict of interest policy and whether the research will include human or animal subjects;
- the name and contact information of the authorizing individual; and
- the authorizing signature.

After the data are entered into the on-line system under the "face page" heading, the applicant generates the face page by selecting the "print" button. After the authorizing individual has signed the form, the page must be scanned to a Portable Document Format (PDF) file and uploaded to the proposal. The signature of the authorizing individual on the face page is a requirement. If this signature is missing the proposal will be considered incomplete.

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

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

3.4.3. Proposal Details

Instructions for providing the required information under the Proposal Details heading are in the on-line system. The following additional information is to be provided.

Resubmissions. If the proposal is a resubmission of a previously unfunded proposal to LSDF, the applicant must indicate this in the space provided within the on-line system and identify the competition in which the proposal was last considered.

Abstract. Applicants must provide an abstract of 500 words or less, in prose understandable to a lay audience, stating the objectives of the proposed project, its distinctive methods, and its most important scientific, economic and health benefits. The text of the proposal abstract may be different than the text of the LOI abstract

Keywords. Applicants must provide up to five keywords that are descriptive of the project. A single 'keyword' may be a short phrase.

Proposal evaluators. Applicants may indicate the names of reviewers whom they would prefer not review their application in the space provided within the on-line application system.

Patents and Inventions. Applicants must describe any invention disclosures they have made and any patent applications filed or license agreements executed or pending related to the subject matter of their proposal.

New Company Formation. Applicants must describe any plans and activities to date related to starting a new company based upon the subject matter of their proposal. If a new company has been formed, provide a summary of its business plan in two pages or less and upload it in PDF form through the on-line system.

3.4.4. Proposal Narrative

The proposal narrative is to be uploaded in PDF form to the proposal in the on-line application system. An e-mail acknowledgement will be sent to the principal investigator when LSDF receives the proposal.

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

- 8½" by 11" portrait-oriented page dimensions;
- Single spaced with all margins measuring at least 1";
- At least 12 point font in Times New Roman or Arial (not proportionally reduced); and
- In the upper right-hand corner of each page, inclusion of a header with the name of the principal investigator, the grant competition number (*i.e.*, LSDF 08-01), and the page number, using the form: "Page x of xx."

All tables, charts, or graphs must be contained within the 20-page limit. Consult the on-line application instructions for specific information about the format of tables, charts, or graphs. When contemplating the submission of information in color, applicants 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 do not figure in the 20-page limit. A maximum of five pages of references will be accepted. Website addresses (URLs) or attachments should not be used to provide additional information necessary to the narrative.

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

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

Resubmitted proposals must be accompanied by the following documents:

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

These documents must be uploaded in PDF form according to instructions provided in the on-line application system.

A. Specific Aims

List the objectives of the specific research project being proposed, *e.g.*, to test a stated hypothesis, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new procedure or treatment to improve health or health care.

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

Briefly sketch the background leading to the present research, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. Ensure that all the following questions are answered:

- What health or health-care problem does this project address?
- What is the significance of this problem in Washington State?
- How is this problem addressed currently?
- What approaches other than that being proposed are under development to alleviate the problem?
- How does your research lead to a solution for the problem?

- Why is LSDF funding essential to accomplish the work being proposed?

C. Preliminary Studies

Provide an account of the principal investigator's preliminary studies pertinent to this proposal, including relevant data.

D. Research Design and Methods

Describe the conceptual framework, research design, procedures, and analyses to be used to accomplish the project. Include how the data will be collected, analyzed, and interpreted. Describe any novel concepts, approaches, tools, or technologies deployed for the proposed studies.

E. Challenges

Discuss the potential difficulties and limitations of the proposed project and alternative approaches to achieving the project's aims.

F. Timeline and Milestones

Provide a timeline for the research keyed to the project's objectives. Identify major milestones, propose target dates for their accomplishment, and define the criteria by which achievement of each of the milestones will be assessed.

G. Personnel

Identify key project personnel: principal investigator, co-investigators, and other individuals who will be responsible for key aspects of the project. Define their roles, and explain how their work will be coordinated.

H. Budget Justification

Describe the complete funding plan, detailing any support from other sources. Highlight and explain the need for any extraordinary expenditures. Describe any other research support received or applied for that is related to the subject matter of the project being proposed to LSDF.

Detailed budget figures are to be provided elsewhere. (See Section 3.4.5.)

I. Facilities and Equipment

Describe the facilities, equipment, and resources available for the project. If new equipment is part of the proposal request and will be available to support other efforts outside the scope of the LSDF-funded proposal, explain how time will be allocated to it.

J. Outcomes and Future Plans

Describe how the project will contribute to the broad, long-term strategic goals of LSDF—scientific competitiveness, improved health and health care, and

economic benefit for Washington. Ensure that the following questions are answered:

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

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

- the potential for follow-on research funding;
- clinical or organizational implementation of project-developed scientific findings; and
- commitments from the research team, applicant, co-applicant and collaborating organizations or other interested parties to translate the project's results into practical application.

3.4.5. Required Attachments

The following information is to be provided using the on-line application system under the Required Attachments heading.

Budget. Budget forms are to be completed using the on-line application system and uploaded in PDF form.

The budget must be appropriate for the scope and goals of the proposed project. Costs must be reasonably associated with the conduct and completion of the proposed project. All should be listed as direct costs, including costs typically associated with general facilities and administration.

The following budget categories are provided:

- salaries;

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

- equipment;

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

- administrative costs;

Include administrative salaries and other associated administrative costs that support the project, including clerical and fiscal support. If it is impossible to break down administrative costs that are charged on an institution-wide or central basis, you may apply that portion of the indirect cost rate to the total project budget (after subtracting equipment to be purchased) and include its value in administrative costs. Departmental or other "local" administrative costs

must be calculated as direct costs before inclusion. At the time of award, the applicant organization will be expected to provide the details of the components that comprise administrative costs. A one-time fee of up to \$15,000 may be charged by the applicant organization for administration of a subcontract.

- facilities costs;

Include the cost of using existing facilities for the program. Do not apply an existing indirect cost rate to the total project budget to calculate facilities costs. At the time of award, the applicant organization will be expected to provide the details of the components that comprise facilities costs.

- supplies;

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

- services;

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

- subcontracts;

Include the expenses of project research performed by co-applicants. For proposals listing for-profit collaborating companies as co-applicants, the companies will be expected to pay for their own internal costs associated with research and development activities performed on a best-effort basis. Monies may be subcontracted from the applicant organization to a company for products and services provided as deliverables to the project.

- travel;

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

- other.

Itemize costs falling outside of the typical budget categories above, including education fees for trainees.

Neither costs associated with facilities construction and remodeling, nor for patient care beyond what are required for project research, are allowed by LSDF.

Biographical Sketches. Applicants must provide biographical information on key research and personnel using biosketch forms according to instructions provided. The biosketch form used for National Institutes of Health grant applications (form 398/2590) may be substituted for the LSDF form, but the length of the submission must not exceed LSDF's four-page limit.

Key Personnel Roster. Applicants must supply a roster of the research and administrative personnel involved in the project using the form and instructions provided.

Letters of Support. Letters of support are required to confirm the commitment of time and resources to the project from key personnel and organizations. The letters should be converted to PDF documents and uploaded to the proposal.

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

Proposals must clarify whether applicant organizations have policies regarding ownership and management of IP developed by their employees. If a party other than the applicant, co-applicant or collaborating organization(s) will own or have rights to IP developed under an LSDF-funded grant, the applicant must provide an explanation of and justification for such provision.

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

4. Evaluation

Following the proposal deadline, all proposals will be screened for compliance with this RFP. Those 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.

In the case of resubmissions, it is unlikely that a resubmitted proposal will be evaluated by the same expert panel.

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

Names of reviewers will not be made available to applicants. Applicants and their representatives may not contact reviewers or members of the LSDF Board of Trustees regarding submitted applications. Any such contact or attempt to contact may result in the disqualification of that applicant's proposal from the competition.

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

4.2. Evaluation Criteria

All funded proposals will be expected to have the potential to contribute to LSDF's primary strategic goals: to promote life sciences competitiveness, improve health and health care for Washington's citizens, and to foster economic growth. Within this general framework, reviewers will use the following criteria to evaluate proposals for LSDF 08-01.

4.2.1. Scientific and Technical Merit

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

- the proposed project is innovative, with scientific and technical originality;
- it provides promising new approaches or ways of thinking;
- it establishes a research framework with strong potential to achieve novel and important results;
- its proposed research outcomes are clearly defined and realistic;
- 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 experience and ability to execute the proposed project successfully;
- where collaboration is proposed, 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 project.

4.2.2. Importance to Health and Health Care

The proposed project must have the potential to benefit health and health care within Washington State. The project's importance to health and health care will be judged by how well the proposal demonstrates the following qualities:

- it addresses a significant issue in health or health care in Washington State;
- it has the potential to make a substantial, beneficial and measurable contribution to improving health and health care in Washington;
- it will achieve benefits such as the following:
 - improved diagnosis, treatment, prevention or management of disease;
 - better management of health-care delivery environments and systems;
 - promotion of healthy patient behaviors and patient compliance with care-givers' recommendations;
 - better integration of care-givers, patients and health-care systems; or
 - accomplishing any of the above in a more cost-effective manner.

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

4.2.3. Future Economic Returns

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

- direct economic activity entailed in the conduct of project research;
- measurable gains in cost-effective health care due to the application of research results;
- future economic consequences of project-induced improvements in health or health care;
- new training and employment opportunities fostered by project research;
- attracting life sciences researchers, companies, and jobs to Washington;

- creating new companies and jobs and attracting investment capital to Washington;
- creating intellectual property that presents attractive licensing opportunities;
- starting new Washington companies based on project research; and
- future life sciences research funding enabled by the LSDF grant.

5. Selection of Awards

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 grant competition. Consistent with these and with its enabling legislation, the board may also consider the following in making award decisions:

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

The board will select proposals which in its judgment are the most meritorious. All award decisions are final and cannot be appealed.

6. Grant Agreement

Awards are subject to grant agreements that will be negotiated between the grant recipient organizations and LSDF. Research funding will be disbursed to applicant organizations on a cost-reimbursement basis subject to the achievement of mutually agreed upon milestones and timelines. The grant agreement will include the right of LSDF to withhold research payments if progress reports have not been provided or milestones have not been met in a timely fashion.

The LSDF grant agreement template can be found on the LSDF website at:

www.lsdfa.org/grantees/grantee_info_docs/Grant_agreement_state_Final.pdf .

7. Additional Information

7.1. Confidentiality and Public Disclosure

Information in grant applications is received by LSDF with the understanding that it shall be used or disclosed solely for evaluation of applications or as required by law. LSDF holds all applications confidential in accordance with its confidentiality policy [www.lsdfa.org/grants/Conf_Policy.pdf] and subject to the public disclosure laws of the State of Washington. (For more information about Washington public disclosure law, applicants are referred to RCW 42.56 and to the amendments to the exemption provisions in RCW 42.56.270(14).)

Typically, when it receives LOIs and proposals, LSDF releases to the public the name of the principal investigator, the applicant organization, the title of the project, the dates of the proposed grant period, the funding amount requested, and miscellaneous contact and demographic data. For unfunded applications, 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 release to the public certain additional information from the application, including an abstract 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 application under Washington State law, LSDF may provide further information from the application 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 funded or unfunded application, it will notify the applicant organization of such a 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 organizations have a financial conflict of interest policy in place and

that all proposals submitted to LSDF have been vetted according to that policy. In accepting an award, the applicant organization will certify to LSDF in the grant agreement that potential financial conflicts of personnel participating in the funded research have been disclosed and that all conflicts have been eliminated or mitigated. Applicant organizations that do not have a financial conflict of interest policy should consult with LSDF (programs@lsdfa.org) early in the application process to discuss how the financial conflict of interest review will be performed.

7.3. Human Subjects and Vertebrate Animal Research Requirements

If a project 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. Its procedures must also comply with all Department of Health and Human Services (DHHS) 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 has been reviewed and approved by the applicable human subjects oversight bodies.

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

Any LSDF-funded research involving human subjects or vertebrate animals will need to have been reviewed and approved prior to execution of the grant agreement.

7.4. Intellectual Property

Projects involving multiple collaborating organizations must be supported by an agreement that makes explicit provision for the disposition of IP rights among the organizations. Such an agreement must clearly allocate the rights that the organizations will have in any IP developed during LSDF-funded research and identify which of the organizations will be responsible for commercialization. The IP rights disposition agreement does not need to be submitted with the proposal but must be in place before the grant agreement is signed. One

example of an appropriate agreement for this purpose can be found in the Federal Small Business Technology Transfer Research Program—“*The Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization*”:

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

7.5. Reporting Requirements

LSDF grants are an investment by the State of Washington in the future of its citizens. Full and timely reporting of the progress and results of funded research by principal investigators has great 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 project and financial reports, and post-project annual reports for a period of five years. Site visits to and in-person briefings from principal investigators may be used by LSDF as tools to track the progress of funded projects.

7.6. Publicity

LSDF reserves the right to publicly disseminate information about its granting activities. LSDF communications to the public may include lists of LOIs and proposals received, the names of principal investigators and applicant organizations, project titles, the field(s) in which the research will be conducted, descriptions of proposals funded, and reports about project progress and outcomes. Recipient organizations and principal investigators will be expected to provide LSDF with reasonable assistance in communicating funded research and its 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 September, 2008.

7.8. Contact Information

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