



Life Sciences Discovery Fund Request for Proposals

May 12, 2009

2009 Summer Commercialization Grants Competition

Executive Summary

The Life Sciences Discovery Fund (LSDF), a Washington State grant-making authority, will launch a new grant mechanism in 2009 to support research and development that enhances commercialization of technologies having the capacity to improve health and health care. 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 entities.

LSDF intends to award up to \$750,000 in grants in the 2009 Summer Commercialization Grants Competition. Individual awards will be up to \$150,000 in total costs, with work expected to be completed within one year. Principal investigators must apply online at <http://www.lsdfa.org/grants/apply.html>. LSDF requires a pre-proposal for this competition.

Key dates include:

Pre-proposal due	July 15, 2009
Pre-proposal comments provided	August 15, 2009
Proposal due	September 9, 2009
Award announcement	December 15, 2009

Proposals will be evaluated according to their scientific merit, commercial potential, and their ability to advance LSDF's primary strategic goals for Washington State—

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improving health and health care, stimulating economic activity, and promoting life sciences competitiveness.



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1. Introduction

LSDF 2009 Summer Commercialization Grants Competition

1.1. Background

The Life Sciences Discovery Fund Authority (LSDF) was established in 2005 by the governor and legislature of the State of Washington. LSDF is funded by bonus monies from the Master Tobacco Settlement Agreement of 1998 of approximately \$33 million per year for a ten-year period 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.

The funding for the commercialization grants will be drawn from philanthropic funds originally donated to initiate LSDF grant-making activities and from tobacco settlement funds.

1.2. The Niche for LSDF Funding in Washington State

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

1.3. LSDF Funding Categories

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

- **Commercialization grants** support small-scale, highly targeted studies that move technologies along the commercialization pathway. Awards of up to \$150,000 are intended to advance research with commercial potential to a stage appropriate for licensing, start-up company formation, or private investment.
- **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.



- **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.

This RFP invites proposals for commercialization grants. Please consult the applicable Request for Proposals (RFP) for more information on project grants at: www.lsdfa.org/grants/current/2009/Projects_Grants/RFP.pdf; and program grants at: www.lsdfa.org/grants/current/2009/Programs_Grants/RFP.pdf.

1.4. Applicant Organizations and Eligibility

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

The applicant organization is responsible for submitting the proposal, leading the research and development work, administering the grant, and disbursing LSDF funding. 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 work and receives a portion of the grant award under a subcontract. Throughout this 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 activities, but will not share in LSDF grant funds.

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

Eligible applicant organizations are Washington State entities that have recently engaged in competitively funded, sponsored research, or similar activities, and have the personnel, resources, and experience necessary to accomplish research and development work of the type described within this RFP. Eligible applicants include, but are not limited to, the following:

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



- health-care systems.

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

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

1.5. Principal Investigators and Co-investigators

A single principal investigator submits the pre-proposal and proposal for an LSDF grant, regardless of how many researchers or organizations will be involved in the work. LSDF does not recognize the title of "co-principal investigator." A principal investigator may submit only one pre-proposal and proposal for this competition, but may serve as a co-investigator on other pre-proposals and 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 and development activities. 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 work, managing the budget, and reporting progress and results. Principal investigators must meet their employer's requirements for such status.

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

1.6. Resubmissions

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

1.7. RFP Updates

LSDF may amend this RFP after its release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF 2009 Commercialization Grants Competition webpage:

http://www.lsdfa.org/grants/current/2009/Commercialization_Grants/.



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

1.8. Frequently Asked Questions

Brief answers to the most common questions may be found on the LSDF 2009 Commercialization Grants Competition webpage at: www.lsdfa.org/grants/current/2009/Commercialization_Grants.

2. Funding Opportunity Description

2.1. LSDF 2009 Summer Commercialization Grants Opportunity

Commercialization of ideas and research discoveries is a key component of LSDF's mission. During the commercialization process, the practical ideas or technologies of researchers and inventors are translated into marketable products, services, and practices. The 2009 Summer Commercialization Grants Competition will support Washington's public and non-profit research institutions in this process. Work funded under these grant competitions 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 activities 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.

LSDF commercialization grants support highly targeted research and development activities from a segment of the commercialization pathway - the so-called "valley of death" - which is considered to be too applied for federal grant support and yet too risky for private investment.¹ Work within this segment centers on validating the commercial merit of new technologies. This type of work is often referred to as "proof of principle" or "reduction to practice," (e.g., the first demonstration of a new therapeutic approach in an animal model) or "prototype development" (e.g., the creation of an integrated instrument for further testing).

1. For further information about the "valley of death", please consult the following URL: <http://www.reuters.com/article/pressRelease/idUS235179+12-Feb-2008+PRN20080212>

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Commercialization grants fund scientifically rigorous research and development leading to health and health-care innovations in the form of new commercial goods, services, and practices, 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.

LSDF intends to distribute up to \$750,000 in grants in this competition. Individual awards will be up to \$150,000 with work to be completed within one year. Collaborations with for-profit entities are encouraged.

All proposals must demonstrate a commitment on the part of the applicant organization to commercialization of the technology under development. Such commitment may include, but is not limited to, institutional support of the research leading up to or cost sharing in the current proposal, expenditures for intellectual property protection or market analyses, and assignment of technology transfer personnel to manage the technology under development.

Proposals with the potential to have near-term impact on improving health and health care are especially desirable. However, successful LSDF-funded research and development does not have to result in a market-ready commercial product or service (*i.e.*, one that is ready for commercial sale). Successfully completed activities are expected to lower the risk associated with further commercial development by increasing the probability of follow-on research and development (*e.g.*, Small Business Innovation Research) and/or investor funding, generation of significant intellectual property, formation of a new company, or licensing to an existing company. LSDF strongly encourages company formation and licensing within Washington State to promote the growth of the life sciences industry and maximize the returns to the state.

2.2. Key Dates

Pre-proposal due	Wednesday, July 15, 2009, 5:00PM PDT
Pre-proposal comments provided	August 15, 2009
Proposal due	Wednesday, September 9, 2009, 5:00PM PDT
Awards announcement	December 15, 2009
Funding start date	Upon execution of the grant agreement



2.3. Questions to Consider Before Applying for a Commercialization Grant

Since pre-proposal and 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 pre-proposal or proposal will be successful.

- Is there a clear description of the eventual product or service the work is aimed toward?
- Why does the market need this product or service?
- What are the compelling reasons why this work is appropriate for this competition and can't be accomplished without LSDF's investment?
- How will Washington State benefit from LSDF's investment in this work:
 - in terms of improving health or health care?
 - in terms of contributing to economic growth?
- Has the applicant organization demonstrated a commitment to commercialization of the technology under development?

Principal investigators are strongly encouraged to confer with LSDF programs staff (programs@lsdfa.org) regarding the appropriateness of their work 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 pre-proposal and proposal (collectively, "application") materials are accurate, complete, and submitted on time. Applications that do not adhere to content requirements, are incomplete or incorrect, or are late will not be reviewed.

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

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



Pre-proposals or proposals do not need to be completed in one session. They can be saved and returned to later for additional work. Once submitted to LSDF, however, they are no longer available for revision.

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

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

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

3.2. Pre-proposal

3.2.1. Submission

Principal investigators must submit a pre-proposal. Submitting a pre-proposal does not require submission of a full proposal. However, the pre-proposal is required for proposal submission.

Detailed instructions for submitting pre-proposals are provided in the online application system. The following information is required:

- a description of the product or service that the proposed work eventually aims to develop;
- a description of how the proposed product or service would improve health and health care in Washington State;
- an estimate of the market size for the proposed product or service;
- a description of how existing products or services address the market and how the proposed product or service is better;
- a description of the specific aims and the design and methods of the proposed work, including the anticipated outcomes and next steps in the commercialization pathway;
- a description of the intellectual property protection plan for the subject matter of the proposed work; and
- the role of any "commercialization partners" (e.g., licensees or other companies, investors) associated with the technology and the proposed work.

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In addition, pre-proposals include the following:

- a descriptive, non-confidential title for the proposed research and development activities;
- an estimated budget total;
- a list of co-applicant organizations;
- resubmission information, if applicable;
- up to five keywords descriptive of the proposed activities.

3.2.2. Evaluation

The pre-proposal will be used by LSDF to assess the suitability of the proposed research and development activities for LSDF funding. All pre-proposals will be evaluated by an LSDF-convened panel of external experts having direct experience in the commercialization of technologies within the health care sector. The panel may also include LSDF trustees. Brief written reviews of pre-proposals will be provided to principal investigators in advance of the full proposal submission deadline. Pre-proposals deemed promising will be encouraged to submit a full proposal and those deemed unsuitable will be discouraged. A full proposal may be submitted by the principal investigator regardless of the outcome of the pre-proposal review.

Following are criteria that may be used to evaluate pre-proposals:

- there should be a clear and understandable description of the product or service that the proposed work eventually aims to develop;
- the proposed product or service should have the potential to improve health or health-care in Washington State;
- the potential market size, in Washington and beyond, for the proposed product or service must be commercially viable;
- there must be a compelling argument for the superiority of the proposed product or service over existing products and services;
- the intellectual property protection plan for the subject matter of the proposed work must be clear and appropriate for the product or service and the target market; and
- LSDF support should have the potential to advance the technology and lower the risk associated with further work along the commercialization pathway.

It is unlikely that a resubmitted pre-proposal will be evaluated by the same expert panel that reviewed the previous submission.

Names of reviewers assigned to the pre-proposal review panel 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 pre-proposals. Any such contact or attempt to contact may result in the disqualification of the pre-proposal from the competition.

Brief written reviews of their pre-proposals will be provided to all principal investigators by e-mail according to the schedule shown in Section 2.2 above.

3.3. Proposal Requirements

The proposal must consist of the same subject matter as the pre-proposal.

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

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

3.3.1. Face Page

The face page contains essential information for identifying, processing, and tracking the proposal. The face page also contains the signature of the authorizing individual (the person with authority to commit the applicant organization to the implementation of the proposed activities). 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 title of the proposed research and development activities;
- the principal investigator name and contact information;
- the names of co-applicant organizations;
- the dates of requested support;
- the budget amount being requested;
- whether the work will include human or vertebrate animal subjects;
- the name and contact information of the authorizing individual; and
- the authorizing signature.

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

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

3.3.3. Proposal Details

The following additional information is required.

Abstract. Provide an abstract of 500 words or less describing the proposed work and its importance to health, health care and economic growth.

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

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

Intellectual Property and Technology Transfer. Describe any invention disclosures made, intellectual property applications filed or issued, or option or license agreements executed or pending related to the subject matter of the proposal.

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

3.3.4. Proposal Narrative

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

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



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

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

A. Specific Aims

List the objectives of the work being proposed, e.g., to build a prototype instrument, to perform a proof of principle experiment, to build a user interface, or to scale up a production methodology. Describe the product or service that the proposed work ultimately aims to develop and the problem it addresses.

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

Briefly describe the background leading to the proposed activities and specifically identify the key steps in the commercialization pathway that the work is intended to address. Ensure that all the following questions are answered:

Commercial Significance

B.1. Target market. What market does the proposed product or service address (*i.e.*, who would buy the product or service and why)?

B.2. Market size and trends. What is the size of the market targeted by the proposed product or service? If the product or service directly targets a disease or condition, what are the incidence, prevalence, mortality, and/or significance of the disease or condition in Washington State? In the U.S.? Are these parameters increasing or declining? What specific market needs are not currently being met?

B.3. Competition. Describe other products or services that currently address the target market. What are the strengths and weaknesses of existing approaches?

B.4. Pipeline. What products or services other than that which you are proposing are under development by others to address the target market?

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B.5. Intellectual property. Describe the intellectual property protection plan for the proposed technology. Are third-party intellectual property positions likely to present a barrier to market entry?

B.6. Potential commercialization partners. Have any potential investors or corporate partners demonstrated an interest in the technology under development? If so, describe briefly. (Refer to Section 3.3.3 regarding new company formation and Section 3.3.5 for information on submitting letters of support.)

Technical Significance

B.7. How does the technology under development lead to a solution for the problem addressed by the proposed product or service? Why is this solution better than both current solutions and those under development?

Relevance to LSDF Program Goals

B.8. How does this work advance the mission of LSDF of improving health and health care, stimulating economic activity, and promoting life sciences competitiveness in Washington? What is the estimated timeline for translating the results of the work for the benefit of health and health care?

B.9. Why is LSDF funding particularly appropriate and necessary to enhance commercialization of the technology?

C. Preliminary Studies

Provide a short summary of the principal investigator's preliminary studies pertinent to this proposal, including relevant data and funding sources.

D. Work Design and Methods

Describe the conceptual framework, design, procedures, and analyses to be used to accomplish the proposed work. Include how the data will be collected, analyzed, and interpreted. Describe the anticipated outcomes of the proposed work.

E. Challenges

Discuss the potential difficulties and limitations of the proposed work and alternative approaches to achieving the aims. Include any anticipated challenges in downstream funding and competitive efforts by other entities.

F. Timeline and Milestones

Provide a timeline for the objectives of the work. Identify four to six measurable milestones, propose target dates for their accomplishment, and define the criteria 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:

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

G. Personnel

Identify key personnel: principal investigator, co-investigators, and other individuals who will be responsible for the activities. Briefly define their roles and explain how their work will be coordinated.

H. Facilities and Equipment

Provide a short description of any unique facilities, equipment, or resources available for the work.

I. Outcomes and Future Plans

Describe the commercialization plan for the technology under development. How does the successful LSDF-funded work enhance commercialization? Describe the next steps in the commercialization pathway and the plan for relevant funding.

J. Organizational Commitment

Describe the commitment(s) either already made or to be made by the applicant organization regarding commercialization of the technology under development. Such commitments may include, but are not limited to, institutional support of the research leading up to or cost sharing in the current proposal, expenditures for intellectual property protection or market analyses, and assignment of technology transfer personnel to manage the technology under development.

3.3.5. Attachments

The following information is to be provided using either relevant forms provided in the online application system or as an uploaded PDF file under the Attachments heading.

Budget. Detailed budgets are to be completed using the form from the online application system.

The budget must be appropriate for the scope and goals of the proposed work. Costs must be reasonably associated with the conduct of the proposed work and must be in accordance with the applicant organization's fiscal policies. All should be listed as direct costs, including costs typically associated with facilities and administration.

The following budget categories are provided:

- salaries;

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

- equipment;

Include equipment with a unit cost greater than \$5,000 that is specifically required for the work. 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 work, including clerical and fiscal support. If it is impossible to break down administrative costs that are charged on an institution-wide or central basis, apply that portion of the organization's indirect cost rate attributed to institution-wide or central costs to the total budget (after subtracting equipment to be purchased) and include the resulting value within administrative costs. Departmental or other "local" administrative costs must be calculated as direct costs before inclusion. A one-time fee of up to \$15,000 may be charged by the applicant organization for administration of each subcontract.

- facilities costs;

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

- supplies;

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

- services;

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

- subcontracts;

Include the expenses of work performed by co-applicants. Co-applicant companies will be expected to pay for their own internal costs associated with research and development activities performed on a best-effort basis. Companies that provide products and/or services as deliverables can be reimbursed for associated expenses. Facilities and administration costs incurred by a for-profit company collaborating with Grantee in the Project are not eligible for payment by Grantor.

- travel;

Include expenses required for travel directly required for the proposed work, 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.



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

Budget Justification. The budget justification should provide enough detail to allow reviewers to determine that the budget is appropriate for accomplishing the proposed work. Describe the complete funding plan, detailing any support from other sources. Include any instances in which other resources complement LSDF funding, including matching funds or cost sharing provided by the applicant organization, significant resources paid for by other sources, or other ongoing related support. Highlight and explain the need for any extraordinary expenditures. Describe any other support received or applied for that is related to the subject matter of the proposed work. Describe how any funding overlap issues will be handled should an LSDF award be made. Detailed budget figures must be included on the relevant form provided in the online application system. The budget justification must not be longer than three pages.

Biographical Sketches. Biographical sketches are limited to four pages. Provide biographical information on key personnel using biosketch forms provided. The biosketch form used for National Institutes of Health grant applications (Form 398/2590) may be substituted for the LSDF form. Each biosketch must be uploaded as an individual PDF document. Do not combine biosketches into one PDF file.

Key Personnel Roster. Supply a roster of the technical and administrative personnel involved in the proposed work using the form and instructions provided.

Letters of Support. Letters of support are required to confirm the commitment of time and resources from key personnel and organizations. A letter of support, from an individual having authority over technology transfer matters, that delineates the resources committed to date and/or to be committed by the applicant organization to commercialize the technology under development must also be submitted. Principal investigators may also submit letters of interest in the technology under development from potential investors, corporate partners, or customers. Letters of support must be submitted by the principal investigator as individual PDF files through the online application system and not sent directly to LSDF by the individuals writing them.

Intellectual Property Certification. The intellectual property certification is required for LSDF to assess how intellectual property developed under the proposed activities will be owned and managed. Principal investigators must complete the form according to the instructions provided. (See Section 7.4 for related information.)



The intellectual property certification must clarify whether the applicant organization has policies regarding ownership and management of intellectual property developed by its employees. If a party other than the applicant, co-applicant or collaborating organization(s) will own or have rights to intellectual property developed under LSDF-funded activities, the principal investigator must provide an explanation of and justification for such provision.

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

Executive Summary. Submit a one page executive summary of the proposed work and its market significance according to the form and instructions provided.

Resubmissions. Resubmitted proposals must be accompanied by:

- a complete copy of the expert reviewers' comments from the most recent commercialization grant competition (if resubmitting a proposal from an LSDF "projects" or "programs" competition, please contact LSDF staff at programs@lsdfa.org for directions about submission of prior reviews);
- a written response, not to exceed three pages, to the previous reviewers' comments, and a summary of where, and how, those comments have been addressed in the current proposal.

4. Evaluation

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

4.1. Expert Review

Proposals will be evaluated by two separate panels of experts. The scientific and technical review panel will be convened by the American Association for the Advancement of Science. The commercial review panel, consisting of external experts with direct experience in the commercialization of technologies within the health-care sector, will be convened by LSDF. The commercial review panel will be informed by the scientific and technical reviews. Expert reviewers will be required to sign nondisclosure agreements.



It is unlikely that a resubmitted proposal will be evaluated by the same expert panel(s) that reviewed the previous proposal.

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

Principal investigators will receive copies of both panels' evaluations of their proposals.

4.2. Evaluation Criteria

All proposals will be expected to enhance commercialization of a technology that addresses a market need in the State of Washington. Successful proposals will also have the potential to contribute to LSDF's primary strategic goals: to improve health and health care, stimulate economic activity, and promote life sciences competitiveness in Washington. Within this general framework, reviewers will use the following criteria to evaluate proposals.

4.2.1. Scientific and Technical Merit

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

- provides promising new approaches to solving problems in health and health care;
- establishes a framework for the proposed activities with strong potential to achieve novel and important results;
- defines clear and realistic outcomes;
- demonstrates the principal investigator's and any co-investigators' commitment, experience, and ability to execute the proposed work successfully;
- demonstrates, where collaboration is proposed, that investigators have a history of effective collaboration and an appropriate plan to manage the collaborative process; and
- justifies that the budget is appropriate to the scope and goals of the proposed work.



4.2.2. *Importance to Health and Health Care*

The importance of the proposed activities to health and health care within Washington State will be judged by how well the proposal demonstrates the following qualities:

- addresses a significant problem in health or health care in Washington State;
- has excellent potential to make a substantial, beneficial, and measurable contribution to improving health and health care in areas such as the following:
 - 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.

Principal investigators may propose a broad range of improvements in health or health care, and the impact of the proposed work 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. *Commercial Merit and Future Economic Returns*

Principal investigators must clearly state the commercial merit of the technology under development and the potential for LSDF support to enhance commercialization. The technology must:

- address a market need that is amenable to commercial exploitation;
- have the potential to be superior to existing products, services, and practices;
- have a demonstrated commitment on the part of the applicant organization toward its commercialization; and
- offer the opportunity for intellectual property protection or demonstrate features that pose barriers to competition.

The proposed benefits of the work to the state's economic environment must be clear. Benefits may include, but are not limited to, the following:

- measurable gains in cost-effective health care due to the application of the results of the work through commercialization;

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- future economic consequences of improvements in health or health care induced by the proposed work, e.g., through restoring work time that would otherwise be lost;
- new training and employment opportunities fostered by the proposed work;
- 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 research and development and investment funding enabled by the LSDF grant.

5. Selection of Awards

The commercial review panel will incorporate the recommendations of the scientific review panel and recommend proposals to the LSDF Board of Trustees for funding. Work that is scientifically strong, but without a compelling commercial opportunity is unlikely to be funded. Work that is scientifically weak is unlikely to be funded regardless of its commercial merit. The board's award selections will be based on these recommendations, the availability of funds, and the goals of the grant competition. The board may also consider the following in making award decisions:

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

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

6. Grant Agreement

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

The form of LSDF grant agreements that will be used for the commercialization grants can be found on the LSDF website:

- For organizations that are public entities:



www.lsdfa.org/grants/current/08-01/08-01_Grant_Award_Agreement_for_WA_State_Organizations.pdf

- For organizations that are private, non-profit entities:
www.lsdfa.org/grants/current/08-01/08-01_Grant_Award_Agreement.pdf

7. Additional Information

7.1. Confidentiality and Public Disclosure

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

Typically, when it receives pre-proposals and proposals, LSDF publicly releases the name of the principal investigator, the applicant organization, the title of the proposed work, 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 work, 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 activities will include human subjects, the work site must operate under an appropriate Office of Human Research Protections-approved assurance for the protection of human subjects. The work 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 activities involving human subjects will have been approved by the applicable human subjects oversight bodies before the principal investigator initiates the human studies.

For activities 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 activities 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

Research and development activities involving collaborating organizations must be supported by an agreement that 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 work 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 work summary and financial report, and annual reports for a period of five years after completion of the work. 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 pre-proposals and proposals received, the names of principal investigators and applicant organizations, titles of proposed activities, the field(s) in which the work 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 work 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 January, 2010.



7.8. Contact Information

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