



Life Sciences Discovery Fund Request for Proposals

2010 Commercialization Grant Competition Round 2

July 20, 2010

New for 2010:

- Principal investigators are required to meet with the commercialization review panel to discuss the commercial and the scientific/technical background and assumptions underlying their pre-proposals (see Section 3.2.2).
- Principal investigators are required to be available by telephone during the commercialization panel's review of their proposals to answer questions (see Section 4.1).
- Additional detail is required regarding organizational resource commitments to the proposed work (see Section 3.3.5.C).
- All proposal forms have been revised; do not use forms from competitions prior to 2010 (see Section 3.3.5).
- Corporate financial involvement in grants has been more explicitly described (see Section 1.7).
- LSDF has partnered with the Institute of Translational Health Sciences to provide "mentoring" assistance to principal investigators in applying for commercialization grants (see Section 2.4).

Executive Summary

The Life Sciences Discovery Fund (LSDF), a Washington state grant-making authority, supports research and development that enhances commercialization of technologies having the capacity to improve health and health care and foster economic growth in

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

LSDF intends to award up to \$750,000 in commercialization grants in this 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:

August 18, 2010 by 5:00pm Pacific Time	Pre-proposal due
September 16-17, 2010	Pre-proposal review meeting and PI interview
September 21, 2010	Pre-proposal written comments provided
October 27, 2010 by 5:00pm Pacific Time	Proposal due
January 5, 2011	Proposal review meeting and PI teleconference
February 1, 2011	Board of Trustees proposal evaluation
As early as March 2011	Funding start date

Proposals will be evaluated according to their scientific/technical merit, commercial potential, and their ability to advance LSDF's primary strategic goals for Washington state—improving health and health care, stimulating economic activity, and promoting life sciences competitiveness.

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1. Introduction

LSDF 2010 Commercialization Grant Competition – Round 2

1.1. Background

The Life Sciences Discovery Fund Authority (LSDF) was established in 2005 by the governor and legislature of the state of Washington. LSDF is funded by monies from the Master Tobacco Settlement Agreement of 1998 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 intend to replicate funding programs offered by other granting sources. Consequently, principal investigators are discouraged from submitting proposals to LSDF that would normally be more appropriate for other granting sources. In their proposals, principal investigators must make a compelling argument for why an LSDF grant is uniquely appropriate and necessary to accomplish their research.

1.3. LSDF Funding Categories

LSDF offers three different granting mechanisms in 2010, each of which is covered in a separate Request for Proposals (RFP) or on the LSDF website (<http://www.lsdfa.org>):

- Commercialization grants support small-scale, highly-targeted studies that move technologies along the commercialization pathway. Awards of up to \$150,000 are expected to advance research with commercial potential to a stage appropriate for licensing, start-up company formation, or private investment.
- 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.
- Opportunity grants support compelling proposals having, (1) an urgency or nature that cannot be aligned with LSDF's annual competition cycles; (2) the ability for LSDF to significantly leverage its investment against funding from

other sources; (3) a high probability that the LSDF investment will attract future financial resources, lead to commercialization of research discoveries, or improve the quality and cost effectiveness of health care; and (4) strong potential for statewide benefit.

This RFP invites proposals for commercialization grants. Please consult the applicable RFP or Description for more information on:

Program grants http://www.lsdfa.org/grants/current/2010/Programs_Grants/

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

1.4. Applicant Organizations and Eligibility

LSDF invites proposals for the second round of 2010 commercialization grants from eligible Washington public and non-profit organizations, singularly or collaboratively with other public and non-profit organizations, or with for-profit companies.

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

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

Eligible applicant organizations are Washington state governmental or non-profit entities that have recently engaged in competitively funded, sponsored research, or similar activities, and have the personnel, resources, and experience necessary to 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.

1.5. Co-applicant and Collaborating Organizations

A pre-proposal or proposal may include one or more co-applicant organizations. A co-applicant organization employs personnel who are key to the design, conduct, and

reporting of the research and receives a portion of the grant award under a subcontract.

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

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

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

1.6. Principal Investigators and Co-investigators

A single principal investigator submits the 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.

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 with prior approval by LSDF.

1.7. Corporate Involvement

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

kind commitments to the proposed work. For a subcontract to be acceptable, the expenditure of LSDF funds by the for-profit entity must:

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

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

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

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

- educational or employment benefit to an individual from the grantee organization participating in the proposed activities;
- a generalized claim that the proposed work will lead to future regional economic development;
- LSDF funding will be a substitute for venture capital and enhance the probability of success of a company spun out of the grantee organization; or
- the grantee has unique expertise or resources to help better position a company's existing product in the marketplace.

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

1.8. Resubmissions

LSDF permits resubmission of unfunded proposals. Details regarding resubmissions are provided in Section 3.3.5. LSDF has developed new proposal forms for 2010; do not use older forms in resubmissions.

1.9. RFP Updates

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

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

1.10. Frequently Asked Questions

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

2. Funding Opportunity Description

2.1. LSDF 2010 Commercialization Grants Round 2 Opportunity

Commercialization of new 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 second round of 2010 Commercialization Grant Competition will support Washington's public and non-profit research institutions in this process. The commercial products, services, and practices contemplated under this grant competition must have the potential to improve health and health care in Washington state—that is, not merely continuing current practice, but changing it demonstrably for the better. Additionally, funded activities will be expected to advance the other core goals of LSDF—to foster the growth of the Washington economy and to promote the competitiveness of the state's life sciences sector.

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. 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,” “reduction to practice,” or “prototype development”. As such, these grants are meant to help reduce the risk of commercialization of new ideas and technologies.

The primary goal of commercialization grants is to markedly enhance the probability that new technologies and concepts will be developed into products and services. While many types of projects are fundable, the most important aspect of a successful

commercialization grant is its catalytic effect in enabling further work along the commercialization pathway. The data set from a successful project should have the power to attract: additional financial resources (e.g., Small Business Innovation Research grants and/or investor funding); commercialization expertise (e.g., a CEO to start a new company); licensing interest; or other resources that enhance commercialization. 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.

Commercialization grants support applied research and development, not basic or discovery research. Principal investigators must provide a clear description of the product or service toward which the project is ultimately aimed. Ordinarily, intellectual property protection already will have been filed for prior to submission of a proposal to LSDF.

Types of projects envisioned for commercialization grants include the following:

- Experiments to validate a technology's use for a generic purpose: that a novel method can be used to deliver a chemical substance; that a new assay reporter system has an acceptable sensitivity range; or that inhibition of a specific enzyme has a desired cellular effect.
- Experiments to validate a technology's use for a specific purpose: an animal study to show that inhibition of an enzyme has a desired clinical effect; confirmation that a specific biomarker correlates with disease; or measurement of a physiological parameter in an animal model in response to treatment with a therapeutic device.
- Construction of a prototype product: assembly of an integrated research instrument to facilitate use with human subjects; chemical modification of a promising compound to generate a more suitable candidate drug; or development of a graphical user interface for a piece of software.
- Testing of a prototype: use of an instrument to image a specific anatomical region; pharmacokinetic studies on a possible drug lead; testing that a software tutorial can improve clinical practice; or safety or efficacy trials of a new drug or device in human subjects.

These examples are given for illustration purposes only and should not be deemed as an exact specification of the types of projects supportable or solicited under commercialization grants.

The products, services, or practices contemplated by commercialization grants must have the potential to make a positive impact on health or health care. Such impacts include, but are not limited to, new approaches to:

- provide tools that have the potential to lead to breakthroughs in health-related research;
- 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 (See Section 1.7 above for more information about corporate involvement in LSDF grants).

To be competitive for funding, applicant organizations must make a tangible commitment of resources that directly support and sustain the proposed research and commercialization. Organizational commitment may be in the form of either cash or in-kind contributions (e.g., equipment, research tools, software, supplies, or services). Please refer to Section 3.3.5.C of this RFP for further information.

Proposals with the potential to have near-term impact on improving health and health care are especially desirable. However, work funded under commercialization grants does not have to result in a market-ready commercial product or service by the end of the grant term.

2.2. Key Dates

August 18, 2010 by 5:00pm Pacific Time	Pre-proposal due
September 16-17, 2010	Pre-proposal review meeting and PI interview
September 21, 2010	Pre-proposal written comments provided
October 27, 2010 by 5:00pm Pacific Time	Proposal due
January 5, 2011	Proposal review meeting and PI teleconference
February 1, 2011	Board of Trustees proposal evaluation
As early as March 2011	Funding start date

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 competitive.

- Is the technology or product concept in an appropriate stage of development for this competition, *i.e.*, not basic or discovery research?
- How will LSDF funding markedly enhance the probability that the technology or product concept will be developed into a product or service?
- Can a compelling case be made for the commercial potential of the technology or product concept?
 - 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?
 - Is the market size commercially viable?
 - How is the proposed product or service superior to what is currently on the market?
 - How does the intellectual property position for the proposed product or service enhance commercialization?
- 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?
- What tangible resources are being committed by the applicant organization to facilitate the success and commercialization of the proposed research?

2.4. Assistance to Principal Investigators

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

LSDF has partnered with the Institute of Translational Health Sciences (ITHS, www.iths.org) to provide "mentoring" assistance to principal investigators in applying for commercialization grants. ITHS is a regional inter-disciplinary consortium funded through the NIH-NCRR Clinical Translational Science Award (CTSA) to the University of Washington. Principal investigators, regardless of institutional affiliation, are invited to consult with ITHS preclinical development specialists in advance of pre-proposal and proposal submissions ithsprdn@u.washington.edu. ITHS personnel can provide feedback on preclinical and clinical development plans, information on the business case/medical need underlying the LSDF application, identification of research and clinical collaborators, and access to MBA summer fellowship students. ITHS offers independent advice to principal investigators about their applications, but does not help write pre-proposals or proposals or perform market research.

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 three steps: (1) create an account via the LSDF online application system <http://www.lsdfa.org/grants/apply.html>, (2) submit a pre-proposal, and (3) submit a full proposal. Both the pre-proposal and proposal must be submitted via the LSDF website, <http://www.lsdfa.org/grants/apply.html>, by 5:00PM Pacific Time on the respective deadline date. The online account needs to be set up only once, but should be reviewed in advance of submitting a proposal to ensure that the information entered is correct.

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

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

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

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

Individuals having difficulties submitting applications should contact the LSDF grants administrator (grantsadmin@lsdfa.org or 206-732-6777 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;
- a description of who would buy the product or service and why;
- 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” (*i.e.*, parties working with the principal investigator with a business interest in commercializing the proposed technology or concept, including, but not limited to, an existing or a start-up company, entrepreneur, or investor) associated with the technology and the proposed work.

In addition, pre-proposals need to 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; and
- up to five keywords descriptive of the proposed activities.

3.2.2. Evaluation

LSDF will use the pre-proposal information to assess the compatibility of the proposed commercial opportunity and technical plan with the goals of the commercialization grant mechanism.

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. Principal investigators will be required to meet with the commercialization panel on one of the dates shown in Section 2.2 to answer questions about the commercial and the scientific/technical background and assumptions underlying their pre-proposal. During the exchange, the panel will offer constructive criticism regarding the strengths and weaknesses of the assumptions and plans presented in the pre-proposal. To enhance the discussion, principal investigators will be encouraged to bring along an additional person to speak for the commercial aspects of the proposed work.

Further details regarding the interview format and times will be sent to principal investigators when their pre-proposals have been received by LSDF. Brief written summaries of the pre-proposal reviews will be provided to principal investigators by e-mail according to the schedule shown in Section 2.2. 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:

- the technology or product concept must be in an appropriate stage of development for this competition, *i.e.*, not basic or discovery research;
- there must be a clear and understandable description of the product or service that the proposed work ultimately aims to develop;
- the proposed product or service must have the potential to improve health or health care in Washington state;
- there must be a clear description of who would buy the product or service and why;
- 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 (or other features that pose barriers to competition) 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 must have the potential to enhance the probability that the technology or product concept will be developed into a product or service and reduce the risk associated with downstream commercial development.

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

Applicants, principal investigators and their representatives may not contact reviewers outside of the pre-proposal review meeting 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.

3.3. Proposal Requirements

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

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

The online application system requires the principal investigator to input information under the following 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 section requires input of information pertaining to the applicant organization (including the name, title and e-mail address of the authorizing individual), as well as completion of a form that contains essential information for identifying, processing, and tracking the proposal (including the proposal title, principal investigator name and contact information, dates for requested support, budget amount being requested, animal welfare and federal-wide assurance numbers, names of co-applicant organizations, and financial conflict of interest and intellectual property policy information). The LSDF face page form requires the signature of the authorizing individual (the person with authority to commit the applicant organization to the implementation of the proposed work). Principal investigators may not authorize proposals from their own organizations. Complete and upload the signed, completed face page PDF form.

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

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

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

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

New Company Formation/Commercialization Partners. List any option or license agreements, executed or pending, related to the subject matter of the proposal. Describe any plans and activities to date related to starting a company based upon the subject matter of the proposal. If either a start-up company or an existing company is engaged as a partner to commercialize the proposed technology, provide, in two pages or less, a description of that company's market focus and a summary of its business plan for the technology. The principal investigator must complete and upload the summary as a single PDF.

3.3.4. *Proposal Narrative*

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

- 8½-by-11-inch portrait-oriented page dimensions;
- Single spaced with all margins measuring at least one inch;
- At least 12-point font in Times New Roman, or Arial (not proportionally reduced); and
- In the upper right-hand corner of each page, inclusion of a header with the name of the principal investigator, the grant competition name (*i.e.*, LSDF 2010 Commercialization Grant Competition – Round 2), 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. Website addresses (URLs) or attachments must not be used to provide additional information necessary to the narrative. If considering the submission of information in color, principal investigators should be aware that proposal reviewers may be performing their reviews using black and white hard copies.

References are to be included at the end of the narrative, but are not counted in the ten-page limit. A maximum of three pages of references will be accepted.

The proposal narrative must include sufficient information to evaluate the scientific and technical merit, the commercial potential, and the beneficial returns of the work, independent of any other document. When writing the narrative, principal investigators should give careful attention to the commercial review panel's comments on the pre-proposal, but should not explicitly reference those comments. The narrative must include all of the following sections.

A. Specific Objectives

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 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. Regardless of their approach, describe other products or services that currently address the target market. What are the strengths and weaknesses of the existing approaches?

- B.4. Pipeline. Regardless of their approach, describe other products or services that are under development by others to address the target market. What are the strengths and weaknesses of these approaches?
- B.5. Intellectual property. Describe in detail the intellectual property protection plan for the proposed technology. For patents, describe what types of applications have been filed and where. Give examples of the type and breadth of claims being pursued (e.g., composition of matter, method of use). Are third-party intellectual property positions likely to present a barrier to market entry? Describe any freedom to practice analyses that have been performed.

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

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

- B.6. Commercialization partners. Describe the role of any “commercialization partners” (as defined in Section 3.2.1) in the proposed work. Describe how the effort contemplated by the proposal either has the power to add value to existing partnerships (e.g., stimulate investor interest) or to attract a commercialization partner (e.g., engage a CEO or a licensee).

Technical Significance

- B.7. Solution to problem. 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 Goals

- B.8. Advance LSDF mission. How does this work advance LSDF’s mission 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. Funding relevance. Why is LSDF funding particularly appropriate and necessary to enhance commercialization of the technology?
- B.10. Risks and resources. If the proposed study is successful, what commercialization risks are reduced? What types of future resources will the successful study attract?

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

Describe the challenges that may be faced in trying to achieve the objectives of the proposed work and the plans to overcome them. Include any anticipated challenges in downstream funding and competitive efforts by other entities.

F. Timeline and Milestones

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

G. Key Personnel

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

H. Facilities and Equipment

Provide a short description of any unique facilities or equipment available for the proposed research. If new equipment is requested and will be available to support other efforts outside the scope of the project, explain how time will be allocated to it.

I. Outcomes and Future Plans

Describe the overall detailed plan for commercializing the technology and how the proposed work fits into that plan. Describe the next steps in the commercialization pathway and the plan for relevant funding.

3.3.5. Attachments

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

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

A. Detailed Budget

Provide a detailed budget for each year of requested funding using the forms provided at http://www.lsdfa.org/grants/current/2010/Commercialization_Grants/. The budget must be appropriate for the scope and goals of the proposed work and should include all costs reasonably associated with that work. These costs must be listed as direct costs, including costs typically associated with general facilities and administration expenses. All costs must be in accordance with the applicant organization's fiscal policies. The same detailed budget information is required for work to be performed by any co-applicant organization(s) utilizing a subcontract mechanism.

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

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

- Salaries - Include wages, benefits and stipends. Provide the compensation requested for research staff associated with the project. Salaries should be calculated on the basis of the individual's percent effort on the project. Do not list personnel who will not receive salary support, e.g., someone whose salary is being paid by another source or who is listed at a 0% effort.
- Equipment - Include equipment with a unit cost greater than \$5,000 that is specifically required for the proposed work. Include only items of property with an expected service life of more than one year.
- Supplies - Include consumable materials and supplies required for the proposed work, including equipment having a unit price at or under \$5,000. Expenses for personal computers are not allowable unless the computers are used primarily for the proposed work.
- Travel - Include expenses required for travel necessary to perform the proposed work, including per diem allowance, subject to the applicant organization's usual accounting practices.
- Other - Itemize costs falling outside of the typical budget categories above, including education fees for trainees (e.g., graduate student tuition), fees for services performed, consultants, manuscript publication fees, and any other miscellaneous expenses.
- Subcontracts - Include the expenses associated with the activities performed by co-applicants using the same categories described immediately above.

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

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

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

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

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

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

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

B. Budget Justification

Provide justification for expenses within each category requested within the budget in sufficient detail to allow reviewers to determine that the budget is appropriate for

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

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

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

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

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

C. Organizational Commitments

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

- partial to full salary support for key personnel;
- recent recruitment of and start-up support for key personnel;
- recent purchase of new equipment or supplies, or dedication of existing equipment or supplies to the proposed work;
- allocation of laboratory, clinical, or office space that is newly or specifically designated for the proposed activities;
- recent support for renovations of facilities;
- absorption of institutional facilities and administration charges;

- tangible items and services, resulting from contemporaneous work supported by other entities, that are critical for the success of the proposed work;
- expenditures for intellectual property protection or market analyses, and assignment of an entrepreneur-in-residence or a technology transfer professional to guide or manage a technology under development; and
- matching/committed funds from institutional sources.

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

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

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

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

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

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

Letters of Support. Letters of support are required to confirm the commitment of time and resources to the proposed work from key personnel and co-applicant and

collaborating organizations. Letters should clearly detail the type and magnitude of the resources being committed to the work and should be signed by the individuals having the authority to make said commitments. 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, commercialization partners, or customers. Letters of support must be uploaded by the principal investigator as individual PDF files through the online application system and not sent directly to LSDF by the individuals writing them. Do not combine letters of support into one PDF file.

Executive Summary. Provide a single page summary of the proposal according to the following subject headings; use lay/non-specialist terms whenever possible.

- A. *Product/service:* Describe the product or service that the work ultimately seeks to develop and how it would improve health and health care in Washington state.
- B. *Target market:* Describe the market for the new product or service and estimate its size.
- C. *Competitive analysis:* Describe other products or services that currently address the target market and how the proposed product or service is better.
- D. *Work plan:* Describe the work to be performed and its anticipated deliverables or outcomes.

The principal investigator must complete and upload the executive summary as a PDF file.

Resubmissions. Resubmitted proposals must be accompanied by:

- a complete copy of the expert reviewers' comments for the proposal (not the pre-proposal) from the most recent commercialization grant competition in which it was considered, uploaded as a single PDF. 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; and
- a written response, not to exceed three pages, to the expert reviewers' previous comments, and a summary of where, and how, those comments have been addressed in the current proposal, uploaded as a single PDF.

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

4. Evaluation

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

4.1. Expert Review

Each proposal presents a scientific and technical, as well as a business case for funding. 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.

Principal investigators will be requested to be available by telephone during a specified one-hour period on the date shown in Section 2.2 to answer questions from the commercial review panel about their proposals. To enhance the discussion, principal investigators will be encouraged to have available an additional person to speak for the commercial aspects of the proposed work. Further details regarding the question and answer format and times of availability will be sent to principal investigators when their proposals have been received by LSDF.

LSDF also 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.

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' written 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 criteria below to evaluate proposals.

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

4.2.1. Scientific and 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. Impact on Health and Health Care

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

- it addresses a significant problem in health or health care in Washington state;
- it has excellent potential to make a substantial, beneficial, and measurable contribution to improving health and health care in areas such as:
 - improved tools that have the potential to lead to breakthroughs in health-related research;
 - improved diagnosis, treatment, prevention or management of disease;
 - better management of health-care delivery environments and systems;
 - promotion of healthy patient behaviors and patient compliance with care-givers' recommendations;

- better integration of care-givers, patients, and health-care systems; or
- accomplishing any of the above in a more cost-effective manner.

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 residents.

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 proposal must:

- Provide a compelling argument for how LSDF funding can markedly enhance the probability that the technology or product concept will be developed into a product or service and reduce the risk associated with downstream commercial development;
- provide a clear and understandable description of the product or service that the proposed work ultimately aims to develop;
- demonstrate that the technology or product concept is in an appropriate stage of development for this competition, *i.e.*, not basic or discovery research;
- demonstrate that the proposed product or service has the potential to improve health or health care in Washington state;
- provide a clear description of who would buy the product or service and why;
- show that the potential market size for the proposed product or service is commercially viable;
- present a compelling argument for the superiority of the proposed product or service over existing products and services;
- present an intellectual property protection plan (or other features that pose barriers to competition) for the subject matter of the proposed work that is clear and appropriate for the product or service and the target market; and
- have a demonstrated commitment on the part of the applicant organization toward commercialization of the proposed technology.

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;

- future economic gains due to 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 and technical review panel and recommend proposals to the LSDF Board of Trustees for funding. Work that is scientifically strong, but without a compelling commercial case 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. When a corporate subcontract is proposed, the board will consider the benefit accruing to the grant recipient organization from the subcontract. The board may also consider the following in making award decisions:

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

The board will select proposals which in its judgment are the most meritorious. Award decisions cannot be appealed. No award is final until a grant agreement has been executed.

6. Grant Agreement

Awards are subject to grant agreements that will be negotiated between the grant recipient organizations and LSDF. Funds will be disbursed to applicant organizations on a cost-reimbursement basis subject to progress towards mutually agreed upon

milestones and timelines. LSDF may withhold reimbursement payments if progress reports have not been provided or milestones have not been met in a timely fashion.

The 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 see:

http://www.lsdfa.org/about/background/2009_Grant_Agreement_state_final.pdf

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

http://www.lsdfa.org/about/background/2009_Grant_Agreement_non-state_final.pdf

7. Additional Information

7.1. Confidentiality and Public Disclosure

Information in grant 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 http://www.lsdfa.org/about/background/LSDF_Confidentiality_Policy.pdf and subject to the public disclosure laws of the state of Washington. For more information about Washington public disclosure law, applicants are referred to RCW 42.56 and to the amendments to the exemption provisions in RCW 42.56.270(14).

Typically, when it receives 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 at programs@lsdfa.org early in the application process to discuss how the financial conflict of interest review will be performed.

7.3. Human Subjects and Vertebrate Animal Research Requirements

If 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 between the applicant organization and subcontracting or collaborating organizations must be supported by an agreement

that, at a minimum, makes explicit provision for the disposition of intellectual property rights among the organizations. Such an agreement must clearly allocate the rights that the organizations will have in any intellectual property developed during LSDF-funded 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 March 2011.

7.8. Contact Information

For further information about LSDF or grant administration, visit the LSDF website at lifesciencesdiscoveryfund.org or contact programs@lsdfa.org or telephone (206) 732-6777.