

Life Sciences

DISCOVERY FUND

Life Sciences Discovery Fund Request for Proposals (RFP)

2011 Commercialization Grant Competition Round 2

November 17, 2011

New for 2011:

- Principal investigators must present a plan for advancing the business case related to the proposed work during the funding period (e.g., writing a business plan, performing market research, or developing a regulatory strategy; see Sections 2.3 and 3.3.4(l)).
- Principal investigators must indicate how development of the business case will be coordinated with the proposed scientific and technical work and identify the individual (the “commercialization coordinator”) who will play the coordinating role (see Sections 2.3 and 3.3.4(l)).
- If the commercialization partner is not the owner or licensee of the underlying intellectual property (e.g., if the partner is a start-up company, entrepreneur, or investor), their representation of the business side of the application must be endorsed by the owner (see Section 2.2).

New for Round 2:

- Principal investigators may include an appendix of up to two pages of graphs, tables, charts, photos, or illustrations directly pertinent to the proposed work as part of their pre-proposals (see Section 3.2.1).

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. 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 has allocated up to \$750,000 for commercialization grants in the Round 2 competition in 2011. Individual requests are not to exceed \$150,000, with work expected to be completed within one year. Principal investigators must apply online at <http://www.lsdfa.org/apply/online>. A pre-proposal is required for these competitions.

Key dates:

Event	Round 2
Pre-proposal due by 5:00 PM Pacific Time	October 12, 2011
Pre-proposal review meeting and principal investigator interview	November 15-16, 2011
Pre-proposal written comments provided	November 21, 2011
Proposal due by 5:00 PM Pacific Time	January 11, 2012
Proposal review meeting and principal investigator teleconference	March 14, 2012
Board of Trustees proposal evaluation	April 10, 2012
Earliest funding start date	June, 2012

Proposals will be evaluated according to their scientific and 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.

The RFP instructions that follow apply only to Round 2 of the 2011 commercialization grant competition.

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1. Introduction

LSDF 2011 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.

Funding for the 2011 commercialization grant competitions will be drawn from philanthropic monies 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 and 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. Applicant Organizations and Eligibility

LSDF invites proposals for 2011 commercialization grants from eligible Washington public and non-profit organizations, singularly or collaboratively with other public and non-profit organizations, or with for-profit entities.

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.

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.

1.4. 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.

With compelling justification, organizations from outside of Washington state may receive funding as a co-applicant. 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 deadline for completion of such agreements will be determined during award negotiations between LSDF and the grant recipient organization.

1.5. Principal Investigator 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 role of “co-principal investigator” or fund “multiple principal investigator” proposals. A principal investigator may submit only one pre-proposal and proposal for Round 2 of the 2011 commercialization grant competitions, but may be listed 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.

1.6. 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 are expected to 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 between the grantee and the corporate subcontractor.
- The subcontractor has unique expertise or technology or is providing deliverable goods or services that enable the research to be accomplished.
- Access to the subcontractor'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 subcontractor from future sales of a product based upon the results from the proposed work.

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

1.7. Resubmissions

LSDF permits resubmission of unfunded proposals. Details regarding resubmissions are provided in Section 3.3.5. Proposal attachment templates from previous competitions must not be used in resubmissions.

1.8. RFP Updates

LSDF may amend this RFP after its release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF 2011 commercialization grant competitions webpage at:

<http://www.lsdfa.org/apply/competitions/commercialization-grant-2011>

Principal investigators are responsible for consulting amendments to the RFP to be sure they have the latest information. To learn when an amendment has been made, register for programmatic updates by emailing programs@lsdfa.org.

1.9. Frequently Asked Questions

Brief answers to the most common questions may be found at:
<http://www.lsdfa.org/apply/competitions/commercialization-grant-2011>

2. Funding Opportunity Description

2.1. LSDF 2011 Commercialization Grant Opportunity – Round 2

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 (together generically referred to in this RFP as "products"). The commercial products contemplated under the 2011 commercialization 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 foster the growth of the Washington economy and to promote the competitiveness of the state's life sciences sector.

LSDF commercialization grants are meant to help reduce the risk of commercialization of potential new products by supporting 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, often referred to as "proof of principle," "reduction to practice," or "prototype development," centers on validating the commercial merit of potential new products.

The primary goal of commercialization grants is to markedly enhance the probability that promising new technologies and concepts will be developed into products. 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. 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 under development. 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, but are not limited to, 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.

The products contemplated by commercialization grants must have the potential to make a positive impact on health or health care and should also reduce the associated costs. 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; or
- better integrate care providers, patients, and health-care systems.

LSDF has allocated up to \$750,000 for commercialization grants in the Round 2 competition in 2011. Individual requests are not to exceed \$150,000, with work expected to be completed within one year. Collaborations with for-profit entities are encouraged (See Section 1.6).

To be competitive for funding, applicant organizations must make a commitment of tangible resources that directly support and sustain the proposed research and development 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). See Section 3.3.5.(C) 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 by the end of the grant term.

2.2. Commercialization Partners

LSDF strongly encourages principal investigators to engage the assistance of a “commercialization partner” in preparing a grant application and executing a funded grant. A commercialization partner is an organization or individual having a direct business interest in commercializing the proposed product—generally the applicant organization’s technology commercialization office (or equivalent) or a licensee of the underlying intellectual property. While commercialization partners may also include a non-licensee nascent start-up company, entrepreneur, or investor, the owner of the underlying intellectual property must endorse in writing such party’s representation of the business side of the application.

2.3. Coordinating Science and Technology with Business Development

Competitive proposals must be of high scientific and technical merit (*i.e.*, present a strong “scientific/technical case”) and must also present a convincing argument for the commercial opportunity that the project addresses (the “business case”). The principal investigator is responsible for specifying and executing the scientific and technical plan, with the commercialization partner being responsible for articulating and developing the business case. **It is imperative that principal investigators consult early and work closely with their commercialization partner to ensure that their application presents a strong business case.**

While the centerpiece of commercialization grants is research and development, commensurate progress must be made on refining the business case during the grant period. Compelling proposals will show coordination between execution of the scientific/technical agenda and development of the business case, with each track

informed and enhanced by the other. For example, activities performed to advance the business case (e.g., writing a business plan, performing market research, or developing a regulatory strategy) may indicate that a device should have additional technical features to better address a segment of the market, and it may be essential for the technical team to integrate this input into the device design. Conversely, based on unfolding lab work, a previously unrecognized technological feature might prompt the business team to explore new markets. Frequent and explicit communications between the scientific/technical and business efforts are necessary to maximize innovation and efficiently pursue commercialization.

Proposals will designate an individual responsible for coordinating the scientific and technical aspects of the proposed work with business planning (the “commercialization coordinator”). The coordinator must be conversant in the languages of both science and business, facilitate information flow, and ensure that the efforts are proceeding synchronously. The commercialization coordinator represents the interests of the commercialization partner and it is possible that a single individual could play both the partner and coordinator roles. Principal investigators having difficulties identifying a commercialization partner or commercialization coordinator should contact LSDF as early as possible in the application process to discuss their needs.

2.4. Key Dates

Event	Round 2
Pre-proposal due by 5:00 PM Pacific Time	October 12, 2011
Pre-proposal review meeting and principal investigator interview	November 15-16, 2011
Pre-proposal written comments provided	November 21, 2011
Proposal due by 5:00 PM Pacific Time	January 11, 2012
Proposal review meeting and principal investigator teleconference	March 14, 2012
Board of Trustees proposal evaluation	April 10, 2012
Earliest funding start date	June, 2012

2.5. Questions to Consider Before Applying for a Commercialization Grant

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 proposed product beyond the stage of basic or discovery research?
- How will LSDF funding markedly enhance the probability that the proposed product will become commercially available?
- Can a compelling case be made for the commercial potential of the proposed product?

- Is there a clear description of the product?
- Why does the market need this product?
- Is the market size commercially viable?
- How is the proposed product superior to what is currently on the market?
- How does the intellectual property position for the proposed product enhance commercialization?
- Why is this work appropriate for the commercialization grant competition, and why is LSDF investment necessary?
- 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 and development?

2.6. 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 an NIH-NCRR Clinical and Translational Science Award (CTSA). Principal investigators are invited to consult with ITHS preclinical development specialists in advance of pre-proposal and proposal submissions at 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, assistance in identifying research and clinical collaborators, and access to MBA summer fellowship students. ITHS 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.

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

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

If an error or omission is discovered after submitting a pre-proposal or proposal, but before the submission deadline, 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.

Contact the LSDF grants administrator (grantsadmin@lsdfa.org) or 206-732-6788 immediately for assistance regarding any difficulties in submitting applications.

Do not include information in the pre-proposal or proposal that might compromise the applicant's subsequent ability to secure patent or other intellectual property protection. See Section 7.1 for more information regarding confidentiality.

3.2. Pre-proposal

3.2.1. Submission

Principal investigators must submit a pre-proposal to be eligible to submit a full proposal. Submitting a pre-proposal does not necessitate submission of a full proposal.

See the online application system for detailed instructions for submitting pre-proposals. The following information is required:

- a description of the product that the proposed work eventually aims to develop;
- a description of how the proposed product would improve health and health care in Washington state;
- a description of who would buy the product and why;
- an estimate of the market size for the proposed product;
- a description of how existing products address the market and how the proposed product 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 identities and roles of the commercialization partner and commercialization coordinator (see Sections 2.2 and 2.3).

In addition, pre-proposals must include the following:

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

An appendix of up to two pages of graphs, tables, charts, photos, or illustrations directly pertinent to the proposed work may be included in the pre-proposal. The purpose of the appendix is to provide reviewers with a more comprehensive understanding of the proposed work through visual representation. It should not be used to bypass character limitations within the pre-proposal. If considering the submission of appendix information in color, be aware that pre-proposal reviewers may perform their reviews using black and white hard copies.

The appendix must adhere to the following format requirements:

- Page dimensions must be 8½-by-11-inch, either portrait- or landscape-oriented;
- Legends or short explanatory text must be at least 12 point in either Times New Roman or Arial font (not proportionately reduced);
- All margins must be a minimum of one inch;
- Each page must include a header with the name of the principal investigator, the grant competition name (*i.e.*, LSDF 2011 Commercialization Grant Competition – Round 2), and the page number, using the format: "Appendix - Page x of xx."

An appendix that does not conform to these guidelines may be disqualified.

3.2.2. Evaluation

LSDF will assess the pre-proposal information to determine 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 health-related sectors. Principal investigators will be required to meet with the commercialization panel on the date shown in Section 2.4 to answer questions about commercial and scientific and technical aspects of the proposed work. During the exchange, the panel will offer constructive comments regarding the strengths and weaknesses of the pre-proposal. To enhance the discussion, principal investigators will be encouraged to bring along an additional person, preferably the commercialization partner, to speak for the commercial aspects of the proposed work.

LSDF will send further details regarding the interview format and times to principal investigators following pre-proposal receipt. LSDF will provide written summaries of the pre-proposal reviews to principal investigators by e-mail according to the schedule shown in Section 2.4. Pre-proposals deemed promising will be encouraged to submit a full proposal and those deemed unsuitable will be discouraged. The principal investigator may submit a full proposal regardless of the outcome of the pre-proposal review.

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

- the proposed product must be beyond the stage of basic or discovery research;
- there must be a clear and understandable description of the product that the proposed work ultimately aims to develop;
- the proposed product 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 and why;
- the potential market size, in Washington and beyond, for the proposed product must be commercially viable;
- there must be a compelling argument for the superiority of the proposed product over existing products;
- 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 and the target market; and
- LSDF support must have the potential to 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.

Input information under the following headings into the online application system:

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

3.3.1. Face Page

Input information pertaining to the applicant organization into the face page section and complete a form that contains essential information for identifying, processing, and tracking the proposal. The LSDF face page form requires the signature of the authorized official (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. Upload the signed, completed face page in PDF form.

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

Input basic information about the applicant organization and co-applicants and co-investigators.

3.3.3. Proposal Details

The proposal details section collects essential information regarding the proposal and applicant organization, as well as the following:

Abstract. An abstract of 4000 characters 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/Licensees. A description of:

- any option or license agreements, executed or pending, related to the subject matter of the proposal;
- any plans and activities to date related to starting a company based upon the subject matter of the proposal; and
- any start-up company or existing company that is engaged as a partner to commercialize the proposed technology, with a description, in two pages or less, of that company's market focus and a summary of its business plan for the proposed product. Complete and upload the business plan summary as a single PDF file.

3.3.4. *Proposal Narrative*

Review the following requirements before uploading and submitting the proposal narrative as a single PDF file. 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, include a header with the name of the principal investigator, the grant competition name (*i.e.*, LSDF 2011 Commercialization Grant Competition – Round 2), and the page number, using the format: "Page x of xx."

All tables, charts, or graphs submitted with the proposal narrative must be included within the ten-page limit. Consult the online proposal instructions for specific information about the format of tables, charts, or graphs. Do not use website addresses (URLs) or attachments to provide additional information necessary to the narrative. If considering the submission of information in color, be aware that proposal reviewers may perform their reviews using black and white hard copies.

Include a maximum of three pages of references at the end of the narrative; references are not counted in the ten-page limit.

Include sufficient information in the proposal narrative to allow for evaluation of the scientific and technical merit, the commercial potential, and the beneficial returns of the work, independent of any other document. Give careful attention to the commercial review panel's comments on the pre-proposal. 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 or to perform a proof of principle experiment. Describe the product 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 address (*i.e.*, who would buy the product and why)?
- B.2. Market size and trends. What is the size of the market targeted by the proposed product? If the product 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 practices 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 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; provide searchable serial numbers where they exist. Give examples of the type and breadth of claims being pursued (e.g., composition of matter or 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, provide an explanation of and justification for such provision.

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

- B.6. Commercialization partners. Describe the role of the commercialization partner (see Section 2.2) in the proposed work. Describe how the effort contemplated by the proposal has the power to either add value to existing partnerships (e.g., enhance an existing license) or attract a commercialization partner (e.g., stimulate investor interest or 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? 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 launch of the proposed product?
- B.9. Funding relevance. Why is LSDF funding particularly appropriate and necessary to enhance commercialization of the proposed product?
- 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 encountered 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. Milestones and Timeline

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/documents/pdfs/current_milestones.pdf.

G. Key Personnel

Key personnel are individuals who contribute substantively and commit a specified fraction of their time to the work, e.g., the principal investigator and co-investigators. 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. Commercial and Future Plans

Describe the overall detailed plan for commercializing the technology and how the proposed work fits into that plan. Provide a description of what steps will be taken during the grant period to advance the business case related to the proposed work (e.g., writing a business plan, performing market research, or developing a regulatory strategy) and the associated timeline.

Describe how the scientific and technical work under the grant will inform the developing business case for the proposed product and vice versa. Indicate how the two activities will be coordinated and identify the commercialization coordinator; describe his/her previous experience in business/technical coordination. (For further information, see Sections 2.3 and 3.3.5 (*Letters of Support*), regarding specification of and proposal requirements for the commercialization coordinator.)

Describe the next steps in the commercialization pathway and the plan for relevant funding.

3.3.5. Proposal Attachments

Forms for the following proposal attachments are provided on the LSDF website. (Use only these forms and not those from previously submitted proposals.) Upload completed attachments as PDF files under the Attachments section in the online application system.

Budget. The proposal budget includes multiple components—detailed budget, budget justification, and organizational commitments—which, when combined,

constitute a complete description of the proposed expenditures and organizational resource commitments.

A. Detailed Budget

Provide a detailed budget for the requested funding using the instructions and forms provided at <http://www.lsdfa.org/apply/competitions/commercialization-grant-2011>. The budget must be appropriate for the scope and goals of the proposed work and must include only costs that are reasonably associated with that work. List these costs 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. Provide the same detailed budget information 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). Upload completed detailed budgets as a single PDF file.

Part 1: Research Detailed Budget. Place all proposed expenditures into one of the following budget categories; do not create additional categories.

- Salaries - Include wages, benefits and stipends requested for research staff. Calculate salaries on the basis of the individual's commitment of effort as expressed in calendar person months (CPM). 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 0 CPM.
- Equipment - The unit cost of what constitutes an item of equipment is subject to the applicant organization's policies, but shall under no circumstances exceed \$5,000. Include only items of property with an expected service life of more than one year.
- Supplies - Itemize consumable materials and supplies. Expenses for personal computers are not allowable unless the computers are used primarily for the proposed work.
- Travel - Itemize 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 budget categories above, including education for trainees (e.g., graduate student tuition), services, consultants, manuscript publication, 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 - List wages and benefits for administrative personnel, including clerical and fiscal support. Calculate salaries on the basis of the individual's commitment of effort as expressed in CPM.
 - Supplies - Include consumable materials and supplies required for administrative management.
- Organizational Administrative Expenses:
 - IRB expenses - A one-time fee of up to \$1,500 may be charged for each required IRB protocol.
 - 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 – Include general expenses associated with research projects, e.g., libraries or information technology. 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 space actually allocated to the proposed work, calculated on a per square foot or fixed sum basis.
- 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 allowable.

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

B. Budget Justification

Provide justification for expenses within each budget category 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. For

salary expenses, include a short narrative for all personnel (research and administrative) describing position, role, 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 engagement, rate of compensation, and any other relevant information. Include a detailed description of how facilities costs were calculated.

For subcontracts to for-profit entities, provide justification for the proposed expenses. Review Section 1.6 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.

Provide justification for the participation of any non-Washington subcontractors or collaborators. Do not exceed three pages for the budget justification; upload as a single PDF file.

C. Organizational Commitments

Provide a written description of the tangible resource commitments made to the proposal by the applicant organization, as well as a completed resource/expenditure summary form that quantifies the monetary value of the committed resources. 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 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;
- 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 research and assignment of an entrepreneur-in-residence, commercialization coordinator, or a technology transfer professional to guide or manage a technology under development; and

- matching/committed funds from institutional sources.

Do not exceed one page for the organizational commitment written description; upload as a single PDF file.

Using the one-page resource/expenditure summary form, quantify monetarily any commitments of tangible resources provided in support of the proposal. Ensure that these amounts match values presented in the budget justification and letters of support. Upload the completed form as an individual PDF file. Instructions for completing the form can be found at:

http://lsdfa.org/documents/resource_expendsummary_instructions.pdf.

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

List active and pending scientific research support in Section D (Research Support) of the form. 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 the 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, indicate the project number, principal investigator/program director, and sponsor of the overall project. Summarize any potential overlap between the active or pending projects and the LSDF proposal in terms of the research, budget, or committed effort.

Limit biographical sketches to four pages each and upload as individual PDF files. Do not combine multiple biosketch forms into one PDF file.

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 expressed in CPM. For each individual, indicate if any salary for the proposed effort is being contributed from non-LSDF sources. Complete and upload the form as a single PDF file.

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 must be signed by the individuals having the authority to make such commitments.

Submit a letter of support from – (1) an individual representing the organization owning the underlying intellectual property that delineates the resources committed to date

and/or to be committed to commercialize the technology under development, specifies the individual who will serve as the commercialization coordinator, and, if applicable, endorses the commercialization partner's representation of the business side of the proposal; and (2) the commercialization coordinator that outlines the coordination plan and specifies the coordinator's time commitment to the project. Submit letters of interest from potential investors, commercialization partners, or customers, if applicable.

Upload letters of support as individual PDF files; do not send them directly to LSDF. 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. *Project title/principal investigator.*
- B. *Product:* Describe the product that the work ultimately seeks to develop and how it would improve health and health care in Washington state.
- C. *Target market:* Describe the market for the new product and estimate its size.
- D. *Competitive analysis:* Describe other products that currently address the target market and how the proposed product is better.
- E. *Work plan:* Describe the work to be performed and its anticipated deliverables or outcomes.

Upload the executive summary as a PDF file.

Resubmissions. Include the following with resubmitted proposals:

- a complete copy of the expert reviewers' comments (from both the scientific/technical and commercial review panels) for the proposal (not the pre-proposal) from the most recent commercialization grant competition in which it was considered, uploaded as a single PDF file. If resubmitting a proposal from an LSDF "projects" or "programs" competition, 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 file.

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 health-related sectors, 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 2.4 to answer questions from the commercial review panel about their proposals. To enhance the discussion, principal investigators will be encouraged to have available their commercialization partner to speak for the commercial aspects of the proposed work. LSDF will send further details regarding the teleconference format and times of availability to principal investigators following proposal receipt.

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.

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 product 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, *i.e.*, the proposal's likelihood of success will be considered in arriving at a rating. 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:

- demonstrates that the proposed product is beyond the stage of basic or discovery research;
- 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 and experience and their 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 on 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 and reducing associated costs 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; or
- better integration of care-givers, patients, and health-care systems.

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 provide a strong case for the commercial merit of the technology under development, the commercialization plan, and the potential for LSDF support to enhance that plan. The proposal must:

- provide a compelling argument for how LSDF funding can markedly reduce the risk associated with downstream commercial development;
- provide a clear and understandable description of the product that the proposed work ultimately aims to develop;
- provide a clear description of who would buy the product and why;
- show that the potential market size for the proposed product is commercially viable;
- present a compelling argument for the superiority of the proposed product over existing products;
- 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 and the target market;
- present a clear plan for how the business case related to the proposed work will be advanced during the grant period;
- present a strong plan for how development of the business case will be coordinated with the proposed scientific and technical work; 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 evaluate the commercial merit of the proposed work and the report from the scientific and technical review panel and will recommend proposals to the LSDF Board of Trustees for funding. Work that is scientifically strong, but without a compelling business 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. Upon recommendation of the commercialization panel, the board may specify that certain activities, not covered within the proposal, be performed to advance the business case during the grant period.

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 agreement that will be used for commercialization grants can be found on the LSDF website.

For organizations that are public entities see this example:

<http://lsdfa.org/documents/Commercialization%20grant%20agreement%20state%207-8-11.pdf>

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

<http://lsdfa.org/documents/Commercialization%20grant%20agreement%20non-state%207-8-11.pdf>

LSDF reserves the right to retract any award for which a grant agreement has not been completed within 90 days of the notification of award to the applicant organization.

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/documents/pdfs/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 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; the timing of its completion will be determined during award negotiations between LSDF and the grant recipient organization. One example of an appropriate agreement for this purpose can be found on the LSDF website at <http://lsdfa.org/documents/CRA%20IP%2007.06.11.pdf>.

7.5. Reporting Requirements

LSDF grants are an investment by the state of Washington in the future of its citizens. Full and timely reporting of the progress and results of funded 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, invention 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 June 2012.

7.8. Contact Information

For further information about LSDF or grant administration, visit the LSDF website at <http://www.lsdfa.org/> or contact LSDF staff at programs@lsdfa.org or (206) 732-6777.