Executive Summary

Commercialization of new health- and health-care-related products and services (collectively, “products”) is the Life Sciences Discovery Fund’s (LSDF) mission. Life Sciences Ecosystem grant(s) will seed programs that sustain that mission.

Recognizing that commercialization best occurs within a supportive ecosystem, LSDF invites applicants to identify gaps in that ecosystem and create a sustainable and, ideally, statewide program that assists entrepreneurial teams attempting to commercialize products that improve health and health care.

Proposals will be accepted from non-profit and for-profit entities. Applicants must be based in Washington state.

LSDF expects to award up to $2,000,000 in this competition.

Pre-proposals and proposals must be submitted online and will be reviewed by expert reviewers. Pre-proposals are due September 21, 2015. Consultation with LSDF program staff - programs@lsdfa.org or (206) 456-9582 - prior to pre-proposal submission is highly recommended. Additional key dates can be found in Section 1.5.

Award announcement is expected February 8, 2016.
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1. Introduction

1.1. Introduction

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 human health and health care, stimulate economic activity, and promote life sciences competitiveness in Washington. Most LSDF grants to date have been aimed at commercialization of promising technologies through start-up companies.

1.2. Applicant Organizations and Eligibility

This RFP invites pre-proposals and proposals (collectively, “applications”) from eligible Washington non-profit and for-profit organizations for the type of grant described in Section 2.

Eligible organizations must have access to the personnel, resources, experience, and community connections necessary to accomplish activities of the type described within this RFP.

The applicant organization is legally responsible for authorizing and submitting proposals, administering the grant, and disbursing LSDF funding. Throughout this RFP, the terms “applicant” or “applicant organization” refer to the organization employing the program director.

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

To be competitive for funding, applicant organizations must make a commitment of tangible resources that directly support and sustain the proposed activities. Organizational commitment may be in the form of either cash or in-kind contributions.

Proposals will be accepted from Washington state-based non-profit and for-profit entities. Applications from collaborating entities are encouraged, but only when the work of the parties is significantly potentiated through working together.

1.3. Subcontractors, Collaborators and Service Providers

A proposal may include one or more subcontractors, collaborators or service providers.

A subcontractor is an individual or organization that will conduct a portion of the activities set forth in the milestones and timeline and will be paid by the grantee from the grant on a cost reimbursement basis.

A collaborator is an individual or organization that is key to the design, conduct, and reporting of the activities set forth in the milestones and timeline and will not be paid by grantee from the grant.
A service provider is an individual or organization, including but not limited to, contract research organizations (“CROs”), that will conduct a portion of the activities set forth in the milestones and timeline and will be paid by grantee from the grant on a fee-for-service basis.

With compelling justification, organizations from outside of Washington may receive funding as a co-applicant or service provider. Preference will be given to work that is partnered with in-state organizations.

For a subcontract to be acceptable, the expenditure of LSDF funds by the 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.

All subcontracts, service provider relationships, and collaborations must be supported by written agreements (see Section 7.3). The deadline for completion of such agreements will be determined during award negotiations between LSDF and the grant recipient organization.

1.4. Program Director

The program director 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. Program directors must meet their employer’s requirements for such status.

A single program director submits the application for an LSDF grant, regardless of how many individuals or organizations will be involved in the work. A program director may have only one active LSDF application pending. A program director may be listed as a participant in other applications without limit, e.g., playing a role in the design or conduct of the proposed activities. Co-investigators may be employed at the applicant, subcontractor, or collaborating organizations.

1.5 Timelines and Calendar

Pre-proposal application instructions will be posted on August 5, 2015. A webinar will be presented on August 13; see the LSDF Life Sciences Ecosystem grant webpage for more information. Significant dates for the competition are as follows:

<table>
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<tr>
<th>Event</th>
<th>Date</th>
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<tr>
<td>Pre-proposal Submission Deadline</td>
<td>September 21, 2015</td>
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<tr>
<td>Review Panel Issues Proposal Invitations to Applicants</td>
<td>October 15, 2015</td>
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<tr>
<td>Proposal Submission Deadline</td>
<td>January 6, 2016</td>
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<td>Board of Trustees Award Decision Meeting</td>
<td>February 8, 2016</td>
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1.6. Updates to RFP and Application Instructions

LSDF may amend this RFP or other application-related materials after release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF Life Sciences Ecosystem grant webpage.

Program directors are responsible for consulting amendments to the RFP and application-related materials 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.

1.7. Funding

LSDF expects to award up to $2,000,000 in total costs in this competition. Grant funding will be provided during the project period on a cost-reimbursement basis and subject to progress towards the accomplishment of milestones.

2. Funding Opportunity Description

Underlying this RFP is the belief that successful commercialization of promising new technologies in the life sciences is dependent on a robust and supportive ecosystem. While scientific discovery may provide the raw material for new product development, effective commercialization also requires experienced entrepreneurs, sophisticated facilities and equipment, and risk capital within an environment that promotes an active exchange of ideas and perspectives among stakeholders. The grant(s) contemplated under this RFP are aimed at enhancing the life sciences commercialization infrastructure within Washington by addressing key gaps within the ecosystem to achieve measurable and sustainable results.

Commercialization is greatly enhanced when entrepreneurial teams have a balanced view of needs within their cognate markets and the pathways that exist to capitalize on those needs. In many instances, entrepreneurs with promising ideas do not have previous experience in protecting intellectual property, assessing markets, raising non-dilutive and equity capital, negotiating strategic partnerships, appropriately sequencing research and development activities, and writing compelling business plans. Expertise may exist to assist entrepreneurs, but all too often that expertise is geographically concentrated or fragmented and entrepreneurs do not know how to access it, nor do they have the resources to pay for specialized consultation.

LSDF invites applicants to identify gaps within the life sciences commercialization ecosystem in Washington and create a program to bridge those gaps for commercialization of products and services (hereafter jointly referred to as “products”) that improve human health and health care. Those products may 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 at a lower cost with equal or better patient outcomes.

A successful program will have the power to demonstrably enhance life sciences commercialization efforts within Washington. Activities could range from providing assistance to technologists and entrepreneurs to help them improve their business plans, attract non-dilutive and equity capital, establish strategic partnerships, create jobs, identify supportive resources within their industries, and launch products, to addressing issues associated with intellectual property protection, market identification, product differentiation, regulatory approval, reimbursement, and research and development study design.

To be competitive for funding, a program must:
• provide evidence for the existence of the ecosystem gaps it intends to address;
• be of strategic priority to applicant organization(s);
• use innovative or proven strategies;
• create new synergies among participating entities that would not exist but for the organization or support of their efforts through the program;
• build upon established strengths within the participating organization(s);
• have the potential for growth and sustainability over time; and
• show significant commitment of resources from applicant organizations to support and sustain the program’s growth and development. Organizational commitment may be in the form of either cash or in-kind contributions (e.g., equipment, research tools, software, supplies, or services). Matching funds provided by applicants may enhance the competitiveness of an application, but are not required.

Programs may include re-granting e.g., funding pilot projects.

Methods must be in place at the outset of the program to objectively measure outcomes and impact. Consistent with LSDF’s mission to promote the growth of the life sciences industry and maximize the returns to Washington, entities and individuals served by a program under this RFP must be located in Washington. Applicants will describe their plan to make their program known to potential clients in Washington and the criteria, if any, to be used in client screening.

Applicants must demonstrate prior expertise, either directly or indirectly, related to commercialization of health-related life sciences technologies and their ability to sustain a program with maximum reach.

LSDF views the grant(s) provided under this RFP as seed funding for a program to be sustained in the future by the grantee. Applicants must describe the metrics they will use to assess the impact of their program and their plans for sustaining it beyond the period of the grant. While matching funds are not required to receive the LSDF grant, tangible forms of support from other entities for the proposed program will be considered positive evidence for the prospects of future sustainability.
To be competitive for funding, all applicants must convincingly demonstrate that LSDF funding is uniquely appropriate and necessary to achieve the desired outcome.

3. Proposal Process

A pre-proposal is required. Pre-proposals deemed competitive through expert review will be invited to submit a full proposal. An invitation is mandatory for full proposal submission. Program directors are encouraged to confer with LSDF program staff in preparing pre-proposals to ensure that their contemplated program is consistent with the goals of this RFP. Program directors for invited pre-proposals will be required to confer with LSDF prior to proposal submission.

All applications are submitted through the LSDF online application system.

Consult the Pre-Proposal Application Instructions for detailed directions for pre-proposal submission.

Consult the Proposal Application Instructions for detailed directions for proposal submission.

4. Evaluation

Funded proposals will be expected to advance the core goals of LSDF—to improve human health and health care, to foster the growth of the Washington economy, and to promote the competitiveness of the state’s life sciences sector.

Submitted pre-proposals that are judged to be compliant will proceed to review by an LSDF-convened panel of internal and external experts having direct experience in entrepreneurship in health-care-related companies or related activities. Internal experts will be members of LSDF’s Board of Trustees; the Washington life sciences community will be represented within the external experts. All expert reviewers are required to sign nondisclosure agreements.

Based upon their initial pre-proposal review, the expert panel will invite those deemed meritorious to submit proposals. Invited program directors will be required to meet with the expert review panel on January 29, 2016, at a time assigned by LSDF (see Section 1.5) to pitch their program and to answer questions about their proposals. To enhance the discussion, program directors should include up to four additional individuals so that multiple facets of the proposed work can be addressed. LSDF will consider paying reasonable travel costs to attend the interview in person, for the program director only, if the program director’s place of business is at least 100 miles from Seattle. Please inquire for details and approval.

Consult the Reviewer Guidelines for detailed descriptions of application evaluation criteria.

Applicants, program directors, and their representatives may not contact reviewers outside of the proposal review meetings or members of the LSDF Board of Trustees regarding their pre-proposals or proposals. Any such contact or attempt to contact may result in disqualification.
Program directors will receive written evaluations of their pre-proposals and proposals.

5. Selection of Awards

The expert review process is advisory to the LSDF Board of Trustees, which will determine whether any proposal(s) will be funded. The board’s award selection will be based on expert reviews, the availability of funds, and the goals of the granting program.

Upon recommendation of the reviewers or staff, the board may specify that certain activities, not covered within the proposal, be performed 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 a grant agreement between the grant recipient organization and LSDF. Funds will be disbursed to recipient organizations on a cost-reimbursement basis subject to progress towards mutually agreed upon milestones and timelines.

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.

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 one month after notification of award.

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 for funding, administration of grant awards, or as required by law. LSDF holds all applications confidential in accordance with its confidentiality policy and subject to the public disclosure laws of the state of Washington. For more information about Washington public disclosure law, refer to Washington State Public Records Act RCW 42.56 and the amendments to the exemption provisions in RCW 42.56.270 (14).

In compliance with the Washington State Public Records Act, LSDF withholds information covered by its exemption. Accordingly, in consultation with the Office of the Attorney General, LSDF has implemented the following disclosure practices:
For unfunded applications:
LSDF may publish on its website a tabular summary of the applications it has received. LSDF may also publish a list of all the parts of the application and its judgment about whether each part is exempt or non-exempt from disclosure under state public disclosure law, as well as the non-exempt parts of the application.

LSDF considers application information such as program director and applicant organization identities and contact data, application titles, and funding request amounts to be non-exempt from disclosure and may make such information publicly available on its website or disclose it in response to public records requests.

Information deemed to be exempt from disclosure and withheld in response to public records requests related to unfunded applications includes abstracts, identities of collaborating individuals and organizations, personnel biographical sketches, work plans and budgets, business plans, market analyses, intellectual property strategies, corporate financial data, and other proprietary business information.

For funded applications:
After announcement of grant awards, LSDF publishes synopses of the funded applications on its website, including the identities of collaborating individuals and organizations and summaries of work and commercialization plans. In response to public records requests, additional information, including a roster of grant personnel and their biographical sketches and portions of the application’s abstract and narrative sections, may be provided, to the extent that release of this information is not reasonably expected to result in private loss to its provider(s).

If LSDF receives a public disclosure request for a grant application, it will notify the named grant applicant or recipient organization in a timely manner in order to allow that organization the opportunity to assert objections to disclosures in any applicable proceeding.

7.2. Conflict of Interest

It is essential that the personal financial interests of individuals organizing and performing activities under LSDF grants do not impede their judgment or compromise the execution of the funded activities. Even the perception of a conflict of interest has the potential to erode the public’s confidence in the research and development and entrepreneurial processes.

Non-profit applicant and co-applicant organizations must either have a financial conflict of interest policy in place governing the LSDF-funded activities at the time of award or develop such a policy before expenditure of any LSDF funds. In accepting an award, non-profit applicant and co-applicant organizations must 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.

With respect to for-profit applicants, LSDF has adopted the conflict of interest standard set by the U.S. Department of Health and Human Services governing Small Business Innovation Research (SBIR)/Small Business Technology Transfer (STTR) Phase I program grant applications.
7.3. Intellectual Property

LSDF does not take an ownership stake or any other rights in intellectual property developed under LSDF grants.

All grants have a grant payback provision. Details regarding grant payback may be found in the grant agreement.

Grant activities involving the applicant organization and subcontracting, collaborating, or service provider organizations must be supported by written agreements that, at a minimum, make explicit provision for the disposition of intellectual property rights among the organizations. Such agreements must clearly allocate the rights that the organizations will have in any intellectual property developed under the LSDF-funded work and identify which of the organizations will be responsible for managing such intellectual property. The intellectual property rights disposition agreements do not need to be submitted with the application; the timing of their completion will be determined during award negotiations between LSDF and the grant recipient organization. See an example of an appropriate agreement for this purpose.

7.4. 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 program directors is essential for calculating the returns on that investment.

Reporting requirements will be finalized in the grant agreement. LSDF may require the following reports: regular oral progress updates, semi-annual written progress reports, invention reports, revenue reports, annual financial reports, and periodic reports after completion of the work. Site visits to and in-person briefings from program directors may be used by LSDF as tools to track the progress of funded activities.

7.5. Publicity

LSDF reserves the right to publicly disseminate information about its granting activities. LSDF communications to the public may include lists of applications received, the names of program directors 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 program directors will be expected to provide LSDF with reasonable assistance in communicating funded work and its related impacts to the public.

7.6. Contact Information

For further information about LSDF or grant administration, visit the LSDF website at or contact LSDF staff at programs@lsdfa.org or (206) 456-9577.
7.7. List of URLs referenced

LSDF homepage:
http://lsdfa.org/

2016 Life Sciences Ecosystem Grant webpage:
http://www.lsdfa.org/apply/competitions/2016-LifeSciences-Ecosystem

Register for program updates by email:
programs@lsdfa.org

Confer with LSDF program staff:
programs@lsdfa.org

Online application site for pre-proposals:
http://www.lsdfa.org/apply/online

Online application site for proposals:
http://www.lsdfa.org/apply/online

Pre-proposal Application Instructions:

Proposal Application Instructions:

Reviewer Guidelines for detailed descriptions of evaluation process and criteria:

LSDF grant agreement templates:
Awards to Non-Profit Entities
http://www.lsdfa.org/documents/pdfs/LSDF_Non-Profit_Grant_Agreement.pdf
Awards to For-Profit Entities
http://www.lsdfa.org/documents/pdfs/LSDF_For-Profit_Grant_Agreement.pdf

LSDF Confidentiality Policy:

Washington public disclosure law:
http://apps.leg.wa.gov/RCW/default.aspx?cite=42.56

LSDF-relevant amendments to the exemption provisions:
http://apps.leg.wa.gov/RCW/default.aspx?cite=42.56.270

LSDF example template for intellectual property rights disposition among collaborators:
http://lsdfa.org/documents/CRA%20IP%2007.06.11.pdf