



Life Sciences Discovery Fund

2012 PreCede Grant Competition Request for Proposals (RFP)

January 10, 2012

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.

New for 2012, the PreCede grant competition funds research and development activities to help position early-stage Washington life sciences companies with commercially promising health-related technologies for their first significant round of equity investment funding.

LSDF invites submissions from **eligible Washington for-profit entities**. **Non-profit organizations and educational institutions may not apply directly for funding.**

LSDF has allocated up to \$300,000 for the 2012 PreCede grant competition. 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>. All applicants must submit a pre-proposal to be considered for a PreCede grant. Only a subset of pre-proposals will be invited to submit a full proposal.

Key dates:

Event	
Pre-proposal due by 5:00 PM Pacific Time	March 7, 2012
Pre-proposal review meeting and principal investigator interview	Week of April 2, 2012
Pre-proposal written comments provided	Week of April 9, 2012
Proposal due by 5:00 PM Pacific Time	May 9, 2012
Commercial review meeting and principal investigator interview	June 29, 2012
Board of Trustees proposal evaluation	July 31, 2012
Earliest funding start date	September, 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 this competition—improving health and health care, stimulating economic activity, promoting life sciences competitiveness, and appropriately positioning applicant organizations for near-term equity investment funding.

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

Grant funds will be disbursed to recipient organizations on a cost-reimbursement basis subject to progress towards mutually agreed upon milestones and timelines.

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1. Introduction

LSDF 2012 PreCede Grant Competition

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 health and health care, stimulate economic activity, and promote life sciences competitiveness in Washington.

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.

1.2. Applicant Organizations and Eligibility

The applicant organization is legally responsible for authorizing pre-proposals and proposals (collectively, "applications"), submitting applications, administering the grant, and disbursing LSDF funding. Throughout this RFP, the terms "applicant" or "applicant organization" refer to the organization employing the principal investigator.

LSDF invites applications for 2012 PreCede grants from eligible Washington **for-profit entities. Non-profit organizations and educational institutions may not apply directly for funding.**

To be considered an eligible Washington for-profit entity for this competition, the applicant organization must:

- Have a substantial presence in Washington, as determined by LSDF based on factors including, but not limited to: number of full-time equivalent employees who are residents of Washington and their relative levels of compensation compared to other sites of corporate activity; having research and development, administrative, or manufacturing facilities located in Washington; payment of Washington Business and Occupation or other taxes; or any combination of such factors. Applicant organizations will be required to provide a certificate of existence/authorization from the state of incorporation with their proposals;
- Be pursuing development-stage health or health-care related products or services (together generically referred to in this RFP as "products");
- Not have received substantial equity investment;
- Have or have engaged the personnel, resources, and experience necessary to accomplish research and development work of the type described within this RFP; and

- Certify that it has read, understood, and is willing to accept the terms of the LSDF grant agreement in substantially the form provided on the LSDF website dated January 10, 2012 (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Grant_Agreement.pdf).

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

1.3. Co-applicant Organizations, Service Providers, and Collaborators

An application may include one or more co-applicant organizations, service providers, or collaborators.

A co-applicant organization employs personnel who are key to the design, conduct, and reporting of the proposed research and development activities and receives a portion of the grant award under a subcontract.

A service provider is an entity that will conduct a portion of the proposed research and development activities and receive LSDF grant funds on a fee-for-service basis. Such entities include but are not limited to contract research organizations (CROs).

A collaborator (also referred to as a collaborating organization) is an entity that will contribute to the design, conduct, and reporting of the proposed research and development activities, but will not receive LSDF grant funds.

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.

All subcontracts, service provider relationships, 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.

1.4. Principal Investigator and Co-investigators

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.

A single principal investigator submits the application for an LSDF grant, regardless of how many individuals 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 application for the current competition, but may be listed as a co-investigator (as defined below) on other applications.

The principal investigator and/or the applicant organization cannot be changed between the pre-proposal and proposal submissions.

A proposal may include co-investigators, defined as individuals who play leading roles in the design, conduct, and reporting of the proposed research and development activities.

1.5. Resubmissions

LSDF permits resubmission of unfunded applications.

1.6. Frequently Asked Questions

Brief answers to the most common questions may be found at http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_FAQ.pdf.

1.7. Updates to RFP and Application Instructions

LSDF may amend this RFP, the Pre-Proposal Application Instructions, or the Proposal Application Instructions after release. Any clarifications or changes in guidelines or requirements will be posted on the LSDF 2012 PreCede grant competition webpage at <http://www.lsdfa.org/apply/competitions/2012-precede-grant>.

Principal investigators are responsible for consulting amendments to the RFP and Application Instructions 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.

2. Funding Opportunity Description

2.1. LSDF 2012 PreCede Grant Competition

2.1.1. Overview

Commercialization of new health- and health-care related products is a key component of LSDF’s mission. The 2012 PreCede grant competition is intended to help position eligible early-stage Washington life sciences companies with commercially promising health-related technologies for near-term equity investment.

To be competitive for funding, principal investigators must convincingly demonstrate that LSDF support is uniquely appropriate and necessary to enable the applicant organization to successfully procure equity investment funding to commercialize the proposed product.

Submissions to this competition may focus either on technologies that were developed entirely at the applicant organization or those that were licensed from another entity. In either case, the applicant organization must have clear title or access to key intellectual property.

Further, technologies must be beyond the stage of basic or discovery research, and applicants must clearly describe a commercial product that has the potential to improve health and health care in Washington—that is, not merely continuing current practice, but changing it demonstrably for the better. 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; or
- better integrate care providers, patients, and health-care systems.

Applications with the potential to have near-term impact on improving health and health care, while also reducing the associated costs, are especially desirable. However, work funded under this competition does not have to result in a market-ready commercial product by the end of the grant term.

Funded activities will also 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. In particular, proposals must demonstrate potential for creating and retaining jobs in Washington.

LSDF has allocated up to \$300,000 for the 2012 PreCede grant competition. Individual requests are not to exceed \$150,000, with work expected to be completed within one year.

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). For further information, see the 2012 PreCede Grant Competition Proposal Application Instructions, which will be posted at

http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Proposal_Application_Instructions.pdf no later than January 31, 2012.

2.1.2. Types of Activities Supported

PreCede grants are meant to help reduce risk associated with the development of promising technologies, thereby helping to position early-stage companies for equity investment. Grants support research and development activities focused on demonstrating proof of concept or constructing prototypes.

Types of projects envisioned for PreCede 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.

PreCede grants will **not** support:

- Activities focused primarily on marketing research/studies; or
- Activities related to intellectual property protection, including but not limited to patent filings, freedom to operate analyses, or other legal expenses.

2.2. Key Dates

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2.3. 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.

The Washington Biotechnology & Biomedical Association (WBBA), a trade association serving the life sciences industry in Washington, offers free commercialization consulting services (<http://www.washbio.org/displaycommon.cfm?an=1&subarticlenbr=18>).

The Institute of Translational Health Sciences (ITHS, www.iths.org) provides “mentoring” assistance to principal investigators in applying for PreCede 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 application submission 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, and assistance in identifying research and clinical collaborators. ITHS does not help write applications or perform market research.

3. Application Process

All applicants must submit a pre-proposal to be considered for a PreCede grant. Only a subset of the pre-proposals will be invited to submit a full proposal.

Consult the 2012 PreCede Grant Competition Pre-Proposal Application Instructions (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Pre-Proposal_Application_Instructions.pdf) for detailed directions for pre-proposal submission.

Consult the 2012 PreCede Grant Competition Proposal Application Instructions for detailed directions for proposal submission. These instructions will be posted at http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Proposal_Application_Instructions.pdf no later than January 31, 2012.

4. Evaluation

Applicants, principal investigators, and their representatives may not contact reviewers outside of the pre-proposal or proposal review meetings or members of the LSDF Board of Trustees regarding their applications. Any such contact or attempt to contact may result in the disqualification of the application from the competition.

All expert reviewers will be required to sign nondisclosure agreements.

4.1. Pre-proposal

4.1.1. Expert Review

LSDF will assess the pre-proposal to determine its compatibility with the goals of the PreCede 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 participate in an interview with the commercialization panel, either in person or by telephone, on the date shown in Section 2.2 to answer questions about the commercial and scientific/ technical aspects of the proposed work. During the exchange, the panel may offer constructive criticism regarding the strengths and weaknesses of the pre-proposal. To enhance the discussion, principal investigators will be encouraged to have available an additional person so that both the scientific/technical and the business cases associated with the proposed work can be addressed.

LSDF will send further details regarding the interview format and times to principal investigators following pre-proposal receipt. LSDF will provide written evaluations of pre-proposals to principal investigators by email according to the schedule shown in Section 2.2.

Pre-proposals deemed promising will be invited to submit a full proposal and those deemed unsuitable will not be invited. **An invitation is mandatory for full proposal submission. There is no appeal process.**

4.1.2. Evaluation Criteria

Consult the 2012 PreCede Grant Competition Pre-Proposal Reviewer Guidelines (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Pre-Proposal_Reviewer_Guidelines.pdf) for detailed descriptions of the review process and evaluation criteria.

4.2. Proposals

4.2.1. Expert Review

Each proposal presents a scientific and technical, as well as a business case for funding. Proposals will be evaluated by three separate sets of external experts:

- Scientific and technical experts, recruited by the American Association for the Advancement of Science (AAAS).
- Financial experts with direct experience in the fiscal management of early-stage life sciences companies, recruited by LSDF.
- Experts in the commercialization of technologies within health-related sectors, recruited by LSDF. The commercial review panel will be informed by the scientific and technical and financial reviews.

Principal investigators will be required to meet with the commercial review panel on the date shown in Section 2.2 to answer questions about their proposals. To enhance the discussion, principal investigators may bring along one additional person so that both the scientific/technical and the business cases associated with the proposed work can be addressed. LSDF will send further details regarding the meeting format and interview times to principal investigators following proposal receipt.

LSDF reserves the right to require a site visit as part of the expert review process. LSDF will be responsible for any reasonable costs incurred by the applicant organization for these visits.

LSDF further reserves the right to conduct credit checks on key individuals associated with the applicant organization and to use the information contained in such credit reports in the evaluation process.

LSDF may order reports on the applicant organization from Dun & Bradstreet (<http://www.dnb.com/>) or any other applicable public source and use the information contained in such reports in the evaluation process.

Principal investigators will receive written evaluations of their proposals.

4.2.2. Evaluation Criteria

Consult the 2012 PreCede Grant Competition AAAS, Financial, and Commercial Reviewer Guidelines documents for detailed descriptions of evaluation criteria. These guidelines will be posted at <http://www.lsdfa.org/apply/competitions/2012-precede-grant> no later than January 31, 2012.

5. Selection of Awards

The commercial review panel will recommend proposals to the LSDF Board of Trustees for funding based on the strengths of both the scientific/technical and business cases. The board's award selections will be based on these recommendations, the availability of funds, and the goals of the grant competition. The board may also consider the following in making award decisions:

- the diversity of subject matter;
- the variety of health, health-care and economic benefits anticipated; and
- the geographic impact of the work in Washington.

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 recipient organizations on a cost-reimbursement basis subject to progress towards mutually agreed upon milestones and timelines. LSDF may withhold reimbursement payments if the recipient organization is not in compliance with the terms of the grant agreement; e.g., if progress reports have not been provided or milestones have not been met in a timely fashion.

In submitting applications to the 2012 PreCede grant competition, the applicant organization must affirm that it has read, understood, and is willing to accept the terms of the LSDF grant agreement in substantially the form provided on the LSDF website dated January 10, 2012

(http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Grant_Agreement.pdf). Any modifications to this grant agreement will be at the sole discretion of LSDF, and receipt of any award is contingent upon prompt execution of such agreement. 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 September, 2012.

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, administration of grant awards, 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, 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:

Soon after the submission closing date for an application, 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 principal investigator 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, research and development 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 research and development team members do not impede their judgment or compromise the execution of the LSDF-funded activities. Even the perception of a conflict of interest has the potential to erode the public's confidence in the research and development process. Regarding financial conflict of interest, LSDF has adopted the 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 (http://grants.nih.gov/grants/policy/coi/fcoi_final_rule.pdf). In addition, principal investigators invited to submit full proposals will be required to answer questions in the LSDF online application system regarding the potential for financial conflict of interest in certain aspects of the proposed work. Consult the 2012 PreCede Grant Competition Proposal Application Instructions for additional information.

7.3. Human Subjects and Vertebrate Animal Use Requirements

For activities involving the use of human subjects, the applicant organization must ensure that the research site operates under an appropriate Office of Human Research Protections (OHRP)-approved assurance for the protection of human subjects and complies with all Department of Health and Human Services human subjects-related policies and any other applicable laws or regulations. In accepting a grant award from LSDF that involves human subjects activities, the recipient organization must warrant that such activities have been reviewed and approved, or will be reviewed and approved as specified within the grant milestones and timeline, by the appropriate human subjects oversight bodies as compliant with federal, state, and local government regulations to protect the rights, well-being, and personal privacy of human subjects in research. The recipient organization shall provide documentation of review and approval by the applicable oversight bodies of all human subjects activities set forth in the milestones and timeline prior to commencing such activities.

For activities involving vertebrate animals, the applicant organization must ensure that all performance sites hold Office of Laboratory Animal Welfare (OLAW)-approved assurances. In accepting a grant award from LSDF involving vertebrate animal activities, the recipient organization must warrant that such activities have been reviewed and approved, or will be reviewed and approved as specified within the grant milestones and timeline, by the appropriate animal use and care oversight bodies as compliant with federal, state, and local government regulations to humanely, efficiently, effectively and legally use live vertebrate animals in research. The recipient organization shall provide documentation of review and approval by the applicable oversight bodies of all vertebrate animal activities set forth in the milestones and timeline prior to commencing such activities.

7.4. Intellectual Property

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

Research and development 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 during LSDF-funded work and identify which of the organizations will be responsible for commercialization of such intellectual property. The intellectual property rights disposition agreements do not need to be submitted with the proposal; the timing of their 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 is essential for calculating the returns on that investment.

Reporting requirements will be finalized in the grant agreement. LSDF requires the following reports for PreCede grants: regular oral progress updates, semi-annual written progress reports, annual financial reports, and periodic reports 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. 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) 456-9577.