

Life Sciences Discovery Fund 2012 PreCede Grant Competition Frequently Asked Questions

These Frequently Asked Questions (FAQ) address key issues for the Life Sciences Discovery Fund (LSDF) 2012 PreCede grant competition and may be amended in response to questions received from the applicant community. In the event of a discrepancy between this FAQ and the Request for Proposals (RFP)

(http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_RFP.pdf),

the Pre-Proposal Application Instructions

(http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Pre-Proposal_Application_Instructions.pdf),

or the Proposal Application Instructions (to be posted at

<http://www.lsdfa.org/apply/competitions/2012-precede-grant> no later than January 31, 2012)

the RFP and the Application Instructions shall take precedence. Questions about specific competitions may be addressed to LSDF by e-mail (programs@lsdfa.org) or telephone (206-456-9577).

Table of Contents

KEY FEATURES OF PreCede GRANTS	2
APPLICANT ELIGIBILITY	3
SUBMISSION REQUIREMENTS.....	4
BUDGET REQUIREMENTS.....	5
OTHER APPLICATION REQUIREMENTS	6
HUMAN AND ANIMAL SUBJECTS RESEARCH	6
INTELLECTUAL PROPERTY.....	7
APPLICATION REVIEW AND FUNDING SELECTION.....	7
RESOURCES	8

KEY FEATURES OF PreCede GRANTS

Q: What are the most important features of PreCede grants?

A: Key features of PreCede grants are summarized below (consult the RFP for more information):

Award intent	Fund small-scale, highly targeted studies to help position early-stage Washington life sciences companies with commercially promising health-related technologies for their first significant round of equity investment funding
Scope of work	Key research and development activities to reduce the risk of commercialization
Award amount and duration	Up to \$150,000; one year
Funds allocated for 2012	Up to \$300,000

Q: Are submitted applications confidential?

A: Yes. LSDF holds all applications confidential, subject to the public disclosure laws of the state of Washington (see RCW 42.56 and the amendments to the exemption provisions in RCW 42.56.270(14)). LSDF requires grant reviewers to sign confidentiality agreements.

Q: What types of activities are funded by PreCede grants?

A: PreCede grants support research and development activities focused on lowering the risk of product commercialization. This usually involves demonstrating proof of concept or constructing prototypes.

Q: What types of activities are not eligible for PreCede grant funding?

A: PreCede grants do not support:

- basic or discovery research;
- non-research and development activities, such as those 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); or
- indirect or overhead costs.

Q: On what sorts of terms are PreCede grants made?

A: PreCede grants are made subject to the terms of the LSDF grant agreement which is published on the LSDF website (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Grant_Agreement.pdf).

Q: What deliverables are required under PreCede grants?

A: PreCede grants are subject to the achievement of mutually agreed upon technical milestones according to a specified timeline. Progress, financial, and

business/commercialization reports are required during the grant period and at specified times thereafter.

Q: How does LSDF pay out PreCede grants?

A: Funds are 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 milestones have not been met in a timely fashion or if the terms and conditions of the grant agreement have not been complied with (e.g., a progress report is due at the time of submission of an invoice for reimbursement). Upfront or other pre-expenditure payments are ordinarily not possible.

Q: What is the payback provision associated with PreCede grants?

A: LSDF requires payback of a PreCede grant subject to occurrence of certain triggering events. Details of the payback are found in the PreCede grant agreement (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_Grant_Agreement.pdf).

APPLICANT ELIGIBILITY

Q: Who may apply for PreCede grants?

A: Applicants must be Washington state for-profit entities that have not received substantial equity investment. Applicants must have a certificate of existence/authorization from the state of incorporation. Refer to the RFP for more information (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_RFP.pdf).

Q: What criteria are used to determine whether an applicant is a "Washington company?"

A: Applicants 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 compensation, each relative to the applicant's other sites; 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.

Q: If an applicant has already received equity investment funding, is it still eligible for a PreCede grant?

A: LSDF has not set an absolute dollar figure for what constitutes "significant" prior investment funding, but applicants would be expected to not have raised Series A or other preferred stock funding.

Q: Who within eligible organizations may apply?

A: Applications are initiated by the principal investigator for the proposed activities. The principal investigator must be employed by the applicant organization. A completed face page must be submitted with every LSDF pre-proposal and full proposal; the face page requires the signature of the authorized official (the person with authority to commit the applicant organization to the implementation of the proposed work).

SUBMISSION REQUIREMENTS

Q: How do I apply for a PreCede grant?

A: Pre-proposals and proposals are submitted by principal investigators through LSDF's online application system (<http://www.lsdfa.org/apply/online>). Principal investigators must create an account within the system before starting the application process.

Q: What is the deadline for submissions?

A: Deadlines and other key dates are summarized in the table below. All submissions are due no later than 5:00 PM Pacific Time on the deadline date. Late pre-proposals and proposals will not be accepted.

	PreCede Grants
RFP Release	January 10, 2012
Pre-proposals due by 5 PM Pacific Time	March 7, 2012
Pre-proposal review meeting/principal investigator (PI) interviews	Week of April 2, 2012
Proposals due by 5 PM Pacific Time	May 9, 2012
Commercial review meeting/PI interview	June 29, 2012
Board of Trustees proposal evaluation	July 31, 2012

Q: Is a pre-proposal required for the 2012 commercialization grant competitions?

A: Yes.

Q: Are resubmissions of pre-proposals or proposals allowed?

A: Yes. There is no limit on the number of times a pre-proposal or proposal may be resubmitted. However, a principal investigator may submit or resubmit only one pre-proposal and proposal in the current competition.

Q: Can I respond to the expert reviewers' comments in my resubmission?

A: Yes; at the proposal stage, principal investigators must respond to the expert reviewer critiques of the previously submitted proposal.

Q: Can the same individual appear on more than one pre-proposal or proposal?

A: Individuals may not submit multiple pre-proposals or proposals as principal investigator to the current competition. A principal investigator may serve in an alternate role (e.g., as a co-investigator) on other pre-proposals or proposals submitted to the current competition.

Q: Does submission of a pre-proposal entitle an applicant to submit a full proposal?

A: No. A panel of commercialization experts will evaluate pre-proposals and determine which should be invited to submit a full proposal. Only a subset of the pre-proposals will be invited to submit a full proposal.

Q: What pre-proposal elements are required?

A: Pre-proposals consist of basic information about the applicant organization, co-applicants and service providers, in addition to information about the commercial opportunity and the proposed activities.

Q. Can pictures or diagrams be submitted with the pre-proposal?

A: Yes. 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 to provide reviewers with a more comprehensive understanding of the proposed work through visual representation.

Q: Do pre-proposals require a signed face page for submission?

A: Yes.

Q: What proposal elements are required?

A: Proposals consist of a technical narrative, business plan, budget, and related attachments. Financial information such as sources and amounts of the applicant organization's funding to date, capitalization table, 12-month retrospective financials, and 36-month financial forecast of revenues and expenditures are also required.

BUDGET REQUIREMENTS

Q: What are the components of the proposal detailed budget?

A: Budgets are submitted with proposals only and must be submitted on LSDF forms which list proposed expenditures by category. The personnel category must include the name, role, effort commitment in calendar person months (CPM), and associated salary and benefit information for each person requesting salary support. For the other budget categories, an itemized listing of proposed expenditures by general subcategory is required.

A budget justification must also accompany the detailed budget. The justification should provide sufficient information to allow expert reviewers to determine that the budget is appropriate for the proposed work.

Q: May grant funds be paid to another entity?

A: Yes, funds may be paid to:

- a co-applicant organization employing personnel who are key to the design, conduct, and reporting of the proposed research and development activities and receiving a portion of the grant award under a subcontract; or
- a service provider 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).

Q: Are co-applicants' activities subject to detailed budgets as well? How about service providers?

A: Detailed budgets are required for all co-applicants. Service providers (entities performing activities on a fee for service basis) do not have to submit a detailed budget, but their proposed activities should be detailed in the justification.

OTHER APPLICATION REQUIREMENTS

Q: LSDF requires "a commitment of tangible resources that directly support and sustain the proposed research and development and commercialization." What are examples of such commitments?

A: Organizational commitment may be in the form of either cash or in-kind contributions (e.g., equipment, research tools, software, supplies, services, or unbudgeted time and effort).

Q: What is the purpose of the "resource/expenditure summary" form?

A: LSDF is committed to leveraging its support against that from other sources. The form allows principal investigators to quantify the value of tangible resources provided by entities facilitating the accomplishment of the proposed activities.

Q: Can I substitute an NIH biographical sketch for the LSDF biographical sketch form?

A: No. The forms look very similar, but LSDF requires additional information on its biographical sketch.

Q: Does LSDF collect information from applicants regarding financial conflicts of interest?

A: Yes. Applicants invited to submit full proposals must answer questions regarding the potential for financial conflict of interest in conducting the proposed work.

Q: Can an organization be involved simultaneously in two LSDF grant competitions?

A: Yes, if it is eligible. For example, a for-profit organization could be an applicant to the PreCede competition as well as a co-applicant to the LSDF Commercialization grant competition. Each application would be evaluated on its own merits.

HUMAN AND ANIMAL SUBJECTS RESEARCH

Q: Will LSDF fund proposals involving human subjects?

A: Yes. The applicant organization must ensure that all research sites and studies operate under an appropriate Office of Human Research Protections-approved assurance (i.e., Federal Wide Assurance number) for the protection of human subjects and comply with all Department of Health and Human Services human-subjects-related policies.

Q: Will LSDF fund proposals involving vertebrate animals?

A: Yes. The applicant organization must ensure that all research sites and studies operate under an appropriate Office of Laboratory Animal Welfare-approved assurance

for the protection of animal subjects and comply with all Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC)-related policies.

Q: Must I have human subjects or vertebrate animal use approval at the time I submit my application?

A: No, but the necessary approvals must be in place prior to initiation of any LSDF-funded human or vertebrate animal studies.

Q: Can a proposal include the use of human stem cells?

A: LSDF has no restrictions on the source or use of stem cells, subject to standard institutional/organizational or other regulatory approvals.

INTELLECTUAL PROPERTY

Q: Does LSDF take ownership of intellectual property developed under PreCede grants?

A: No; normally, intellectual property resulting from funded activities will be owned by the parties that developed it.

Q: Does the applicant organization need to own background intellectual property that underlies the grant application?

A: No. However, the applicant organization must have clear title or access to key background intellectual property required for commercialization of the proposed product.

APPLICATION REVIEW AND FUNDING SELECTION

Q: How will PreCede proposals be evaluated and selected for funding?

A: Proposals undergo external expert review leading to placement into one of three categories based on their recommendation for funding: Not Recommended, Recommended, and Highly Recommended. Final selection of awards is made by the LSDF Board of Trustees. Scientific and technical reviews are organized by the American Association for the Advancement of Science (AAAS). In addition, LSDF commissions an external review of applicant organizations' financial statements and convenes commercial review panels to evaluate the commercial potential of pre-proposals and proposals.

Q: Will there be an interview with the applicants?

A: Yes. An interview of the principal investigator by the LSDF commercial review panel is required at both the pre-proposal and proposal stages.

Q: Does LSDF conduct credit checks?

A: Yes. At the proposal stage, 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. LSDF also 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.

Q: Can LSDF proposal invitation or proposal funding decisions be appealed?

A: No.

RESOURCES

Q: What resources exist to help companies apply for PreCede grants?

A: LSDF offers the following resources to applicants:

- public information sessions presented around Washington and by webcast; for a schedule go to <http://lsdfa.org/2012PreCedeInfoSessions>;
- the RFP that outlines the goals and key requirements of the competition (http://lsdfa.org/documents/LSDF_2012_PreCede_Grant_Competition_RFP.pdf);
- detailed application instructions about how to complete the pre-proposal and proposal found in the online application system (<http://www.lsdfa.org/apply/competitions/2012-precede-grant>); and
- one-on-one meetings between LSDF staff and potential applicants. Such meetings are associated with public information sessions or by appointment (programs@lsdfa.org or 206-456-9577).

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

The Institute of Translational Health Sciences (ITHS) (www.iths.org) provides feedback on development plans, information on the business case/medical need underlying the application, and assistance in identifying collaborators.