Pre-proposal and Proposal Reviewer Guidelines

Revised May 18, 2015

Pre-proposal reviewers should read Sections A and B. Proposal reviewers should read Sections A and C.

A. Introduction and Background

Introduction. These guidelines apply to Life Sciences Discovery Fund (LSDF) 2014-2015 Matching grant pre-proposals and proposals (singularly or collectively, “applications”) only and are for expert application reviewers. Program and Project Matching grants promote commercialization of technologies that improve human health, and require strategic co-investment by external funders. If you are assigned Proof of Concept pre-proposals/proposals to review, you will receive separate guidelines.

This document is not a substitute for the Request for Proposals (RFP). Before starting your reviews, please read the RFP, especially Sections 1 and 2, at: http://www.lsdfa.org/documents/pdfs/LSDF_2014-2015_Matching_Grants_RFP.pdf. These guidelines assume that you have read the RFP and do not fully represent the RFP’s content.

Contact Information. If you have questions at any point during the review, contact:
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Background of the Life Sciences Discovery Fund. LSDF was created by the Washington State Legislature to receive payments from the Master Tobacco Settlement Agreement of 1998 to invest in life sciences research and development. LSDF carries out its mission by making grants to promote life sciences competitiveness, enhance economic vitality, and improve health and health care.
Board of Trustees. LSDF is governed by a board of trustees, which has final award-making authority. The board is considerably informed by the expert review process, but uses additional criteria in making award decisions.

Expectations of Reviewers. LSDF achieves its mission by funding proposals through a competitive granting process, the success of which depends upon superb expert review at both the pre-proposal and proposal stages. As a reviewer, you are expected to protect the confidentiality of the applications and of the review process itself and to abide by a strict standard in avoiding any conflict of interest. Any concerns you may have about an application or your ability to review it impartially should be communicated in confidence to LSDF. Policies and guidance for reviewers are at http://lsdfa.org/apply/application-review.

(1) Confidentiality. The applications and the review process are confidential. If you believe that additional expertise is needed to review an application, you should not solicit it yourself, but instead notify LSDF to make arrangements for outside assistance. Except as authorized by LSDF, you must not contact institutions or individuals associated with an application or the LSDF Board of Trustees regarding an application. Should an applicant contact you about his/her application, please refer the applicant to LSDF without discussing the application or its review. You will be asked to sign a Confidentiality Certification prior to reviewing LSDF applications. http://lsdfa.org/documents/Guidance for LSDF Commercialization Reviewer Interactions with Applicants and Grantees.pdf

(2) Conflict of Interest. A perceived or actual conflict of interest exists when a reviewer has an interest associated with a grant application that may bias his or her review of it. There are several bases for a conflict of interest: employment, financial arrangements, personal or professional relationships, competitive interests, or other personal interests. Any one condition may disqualify you from participating in the review of an application. If you feel that there may be a conflict or a perception of conflict, notify LSDF, who will make the determination about your ability to review an application. You will be expected to review the LSDF conflict of interest policy and to sign declarations that you have disclosed all conflicts of interest that you may have with the applications.

Revisions to these Guidelines. If revisions or additions to these guidelines are necessary, LSDF will post them on its web site and send them to you by email.

B. Pre-proposal Review

Pre-Proposal Review and Rating Process. The pre-proposal is an opportunity for the applicant to provide reviewers with an overview of its technology, business plan, and justification for a Matching grant, and to obtain written feedback without having to take the time to make a full proposal submission. The pre-proposal consists of a two-page executive summary of the proposed work and an optional appendix of figures and tables. Since pre-proposal applicants will not be interviewed, this written document is the basis for the review and rating. Refer to the Pre-Proposal Application Instructions for details on the content of the executive summary.
Pre-proposal submission requires prior determination by LSDF staff that the proposed work appears to meet the intent of the competition, and that the match is of the scale and character that it should qualify. There is no implication that staff supports a pre-proposal for invitation.

You will be a member of a cohort of commercialization experts who will individually review pre-proposal submissions and assess, for each application, whether the commercialization opportunity is sufficiently appropriate for a Matching grant that a full proposal is warranted. You will likely be assigned to review only a portion of the total number of submissions and will likely see pre-proposals from both non- and for-profit applicants, as well as both Program and Project requests. Each pre-proposal will be assigned to approximately four reviewers. LSDF seeks to invite full proposals from the top six pre-proposal applicants (total across all reviewers) for each of Program and Project Matching. A full proposal may only be submitted by the principal investigator if one is invited following the pre-proposal review. Resubmissions are permitted.

The pre-proposal expert review process consists of three stages:

- First, following the **pre-proposal submission deadline**, you will receive confidential pre-proposal data (principal investigators, applicant organizations, and titles). After reviewing this information and the LSDF Conflict of Interest Policy on External Reviews, you will provide LSDF with a list of pre-proposals for which you are in conflict.
- Second, using LSDF’s web-based reviewer system, you will evaluate your assigned pre-proposals (no more than 16, including any Proof of Concept pre-proposals) according to the criteria outlined below and provide the following to LSDF by the specified deadline (approximately two weeks after your receipt of pre-proposals). You will not have access to any pre-proposals for which you have declared a conflict:
  - A numerical rating on a scale of 0-10, in 0.1 increments, where a score of 5.0 or higher signifies that the pre-proposal is of sufficient quality for a full proposal invitation. (However, as described below, a score of 5.0 or higher does not necessarily guarantee that an applicant will receive an invitation.)
  - A written summary of the weaknesses that need to be addressed in a full proposal if invited, or in a resubmission of the pre-proposal if not invited (you will not articulate the strengths).
  - A signed form (to be provided by LSDF staff) affirming that you did not review any pre-proposals for which you have declared a conflict.
- Third, after comments and scores are received from all reviewers, LSDF staff will rank all pre-proposals by average rating (with standard deviation as a secondary criterion) in their respective competitions (Proof of Concept, Program Matching, and Project Matching) and identify a cutoff for full proposal invitations. LSDF aims to invite the six highest-rated pre-proposals for each of Program and Project Matching to submit full proposals. Consequently, depending on the number and quality of pre-proposals reviewed, the cutoff for a full proposal invitation may be higher than 5.0, but under no circumstances will it be below 5.0. LSDF staff will inform each principal investigator whether or not he/she has received a full proposal invitation and also prepare and send a summary review based on the reviewers’ written feedback. Reviewers’ names will not be provided.
If any pre-proposals that you review are invited to submit full proposals, you will also be expected to review those proposals. Refer to Section C of this document for more information on proposal review.

Review Criteria. Evaluate the pre-proposal as presented by the principal investigator and not on the basis of its theoretical potential; i.e., don’t rate the pre-proposal on what it could become if it were improved or changed.

(1) Review criteria that apply to all pre-proposals. Read Section 2 in the RFP for further context:
- the matching funds proposed meet the general requirements outlined in section 2.1 of the RFP;
- if LSDF funds will be matched at a greater ratio than the minimum, the pre-proposal is more compelling (provided the relationship between matching and LSDF funds remains strong);
- the matching funds do not need to be committed unless and until the proposal is funded.

(2) Review criteria that apply to Program Matching pre-proposals:
- the matching funds meet the required threshold of at least 1:3;
- the proposed Program is consistent with section 2.2 of the RFP, including:
  - it is of sufficient scale, including state-wide impact, and philosophy to be a Program;
  - the Program has a clear tie to commercialization of new technologies in health and health care, e.g., the work accelerates commercialization within a field of study or enhances life science commercialization;
  - it is of strategic priority to the applicant organization;
  - it is innovative within its field;
  - if appropriate to the proposed work, the technical plan meets the criteria of a Project Matching pre-proposal, below;
  - it creates new synergies among participating researchers that would not exist but for the organization or support of their efforts through the Program;
  - it builds upon established strengths within the participating organization(s);
  - it has the potential for growth and sustainability over time; and
  - it shows significant commitment of resources from the applicant organization to support and sustain the Program’s growth and development. This is separate from and in addition to matching funds.

(3) Review criteria that apply to Project Matching pre-proposals:
- the matching funds meet the required threshold of at least 1:1;
- the work proposed is consistent with section 2.3 of the RFP, including:
  - the technology or product concept must be in an appropriate stage of development for this competition, i.e., not basic or discovery research;
  - there must be a clear and understandable description of the product that the proposed work ultimately aims to develop;
  - the scientific/technical plan and expected outcomes must be realistic and well thought out;
  - the proposed product must have the potential to improve human health or health care in Washington;
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;
the proposed product is potentially superior to existing practices and products;
the intellectual property protection plan 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 enhance the probability that the technology or product concept will be developed into a product and reduce the risk associated with downstream commercial development.

(4) Review criteria specific to non-profit applicants. Refer to Section 1.2 in the RFP for details:
- Commercialization partner
- Commercialization coordinator
- Intellectual property

(5) Review criteria specific to for-profit applicants. Refer to Section 1.2 in the RFP for details:
- Substantial presence in Washington
- $500,000 or less in equity investment
- Intellectual property access

C. Proposal Review

Proposal Review and Rating Process. You will be on a panel of commercialization experts who will assess the suitability of the proposed research and development activities for funding. Your charge is expert review of the health, health-care, commercial (e.g., market size, competition, intellectual property position) and economic merit of the proposal, along with its scientific and technical merit, including the appropriateness of the budget. You will also review the appropriateness of the proposed work for the Project or Program mechanism, and you will assess the validity of the matching funds. Although this process is described as a single panel per set of proposals for the cycle, there may be additional simultaneous panels, with their own set of reviewers, depending on the total number of proposals. Proposals from both non- and for-profit applicants will be reviewed in the same panel, although the review criteria are somewhat different. You may also be reviewing proposals submitted to the Proof of Concept Grants competition, and you will have separate review instructions for those proposals.

The proposal expert review process consists of three stages:

- First, using LSDF’s web-based reviewer system, you will review proposals assigned to you, according to your judgment of their strengths and weaknesses. You are assigned to each proposal as either a primary or secondary reviewer. If you are the primary reviewer, you will lead the panel discussion, and your review should prepare you for that.
- Second, you will meet with the other members of the panel to evaluate all of the proposals. The panel will be chaired by LSDF staff. Each principal investigator will make a short presentation, followed by approximately 25 minutes of questions and answers. To enhance the discussion, principal investigators will be encouraged to have available additional individuals (up to two for Projects, up to four for Programs) so all aspects of a
proposal can be discussed. The panel’s ultimate objective is to place proposals into one of three rating categories, “highly recommended,” “recommended,” or “not recommended,” reflecting its collective judgment regarding their suitability for funding.

- Third, after the panel meeting, a summary review of each proposal will be written by LSDF staff based upon the reviewers’ panel discussion and sent to principal investigators. Comments will not be individually identified.

Pre-proposal and Resubmission. The proposals you will review were preceded by pre-proposals. Principal investigators received written feedback on their pre-proposals from expert reviewers recruited by LSDF. Consequently, you may see references in proposals to the pre-proposal review. The summary reviews of the pre-proposals will be available to you in the web-based reviewer system. If a proposal you are reviewing is a resubmission of a previously unfunded proposal, the application will include both a copy of and a response to the previous full proposal review.

Review Criteria. Rate the proposal as presented by the principal investigator and not on the basis of its theoretical potential; i.e., don’t rate the proposal on what it could become if it were improved or changed.

(1) Review criteria that apply to all proposals:
- the matching funds proposed meet the general requirements outlined in section 2.1 in the RFP;
- your judgment of the likelihood that the matching funds will be available;
- the match ratio is calculated properly and meets the required minimum. The Resource/Expenditure Summary will assist you in this evaluation. The match is expressed as LSDF funds:Matching funds, e.g., 1:3 means one LSDF dollar is matched by three dollars of non-LSDF funds;
- if LSDF funds will be matched at a greater ratio, i.e., more funds from non-LSDF funders than the required minimum, the proposal is more compelling (provided the relationship between matching and LSDF funds remains strong);
- Organizational Commitment. Refer to Section 1.2 in the RFP for details. The Resource/Expenditure Summary will assist you in this evaluation. If you question the applicant organization’s resource commitment to a proposal, you should note that in your preliminary review and during the panel discussion; and
- Subcontractors and Service Providers. Refer to Section 1.3 in the RFP for details.

(2) Review criteria that apply to Program Matching proposals. Read Section 2.2 in the RFP for a detailed description of Programs. Your review of proposals is based on your judgment of the extent to which a proposal meets each of the criteria listed below.

Matching Funds
LSDF funds must be matched at least 1:3.

Research Activities
If research activities are proposed, for example, a translational research resource, a center for research that features commercialization, a major piece of equipment that will accelerate commercialization, the proposal should meet the review criteria for Projects, above, to the extent applicable. This is in addition to meeting the criteria for a Program.
That it is a Program
Programs as defined by LSDF have a variety of characteristics. A Program is not a single research project with a defined end, although it may have research projects as one of its activities. LSDF is offering larger grants than for a Project, and requiring a higher degree of matching funds, because a Program is typically a large-scale enterprise, with state-wide impact, that significantly accelerates commercialization, either through its own efforts to commercialize health care technology, or by enhancing the ecosystem to facilitate commercialization by others. It will be designed to endure beyond the grant term and will have a credible plan for sustaining its activities and funding. It will have multiple partners whose synergy creates a significantly more effective Program.

(3) Review criteria that apply to Project Matching proposals. Read Section 2.3 in the RFP for further context. Your review of proposals is based on your judgment of the extent to which a proposal meets each of the criteria listed below.

Matching Funds
LSDF funds must be matched at least 1:1.

Scientific and Technical Merit
A strong scientific and technical plan is necessary, but not sufficient, for funding. Although you individually may not have the technical background to fully evaluate the scientific merits and risks of the proposal, you should challenge the principal investigator to justify the choice of problem and approach, including technical risks. In your review, judge to what extent the proposal:

- demonstrates that the proposed product is beyond the stage of basic or discovery research;
- provides a promising approach to solving the problem being addressed;
- establishes a framework for the proposed activities with strong potential to achieve novel and important results;
- defines clear and realistic outcomes;
- demonstrates the principal investigator’s and any co-investigators’ commitment, experience, and ability to execute the proposed work successfully;
- demonstrates, where collaboration is proposed, that investigators have a history of effective collaboration and an appropriate plan to manage the collaborative process;
- demonstrates that subcontractors’ and service providers’ personnel and facilities are appropriate and will enhance the proposed work; and
- justifies that the budget is appropriate to the scope and goals of the proposed work. Refer to Section 2.3.3 in the RFP for details of allowable and unallowable business and regulatory expenditures.

Impact on Human Health and Health Care
The impact of the proposed activities on human health and health care within Washington will be judged by how well the proposal demonstrates the following qualities:
• it addresses a significant problem in health or health care in Washington;
• it has excellent potential to make a substantial, beneficial, and measurable contribution to improving health and health care in areas such as:
  o improved tools that have the potential to lead to breakthroughs in health-related research;
  o improved diagnosis, treatment, prevention or management of disease;
  o better management of health-care delivery environments and systems;
  o promotion of healthy patient behaviors and patient compliance with care-providers’ recommendations; or
  o approaches to accomplishing any of the above at a lower cost with equal or better patient outcomes.

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.

**Commercial Merit and Future Economic Returns**
Principal investigators must make a compelling argument for the commercial merit of the technology under development and the potential for LSDF support to enhance commercialization. In addition, the proposal must:

• 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 and those in development;
• 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;
• address any key barriers to market entry or penetration;
• include a reasonable plan to advance the business case for the proposed product during the grant period;
• make a reasonable case that LSDF support will promote job creation and retention in Washington;
• present, as appropriate, reasonable plans for obtaining regulatory approval and reimbursement from third-party payers; and
• demonstrate that LSDF support will markedly enhance the probability that the technology or product concept will be developed into a marketable product and reduce the risk associated with downstream commercial development.

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.

(3) Review criteria specific to non-profit applicants. Refer to Section 1.2 in the RFP for details:
• Commercialization partner
• Commercialization coordinator
• Intellectual property

(4) Review criteria specific to for-profit applicants. Refer to Section 1.2 in the RFP for details:
• Resources to conduct the work. The management, board, and key advisors must have the experience needed to commercialize the proposed product.
• Substantial presence in Washington
• $500,000 or less in equity investment
• Intellectual property access

Overall Rating

(1) Funding. Up to $4.5 million total is available for Program and Project Matching grants, for award in three granting cycles through September 2015. However, there is no quota or allowance for a given review panel or cycle, and proposals should be recommended for funding based solely on merit. The panel’s summary reviews will be presented to the Board of Trustees, which will take them into account in making award decisions. When a single panel is reviewing all the proposals for a given cycle, LSDF staff may request that the panel rank proposals in the same mechanism (Program or Project) in the order of their priority for funding. Such rankings may be shared with the board, but not with the principal investigators.

(2) Resubmission. Proposals that ultimately are not funded are eligible for resubmission in another competition cycle, although the applicant must return to the pre-proposal submission stage. In your review, consider whether a proposal is “rescuable” and whether a resubmission would be viable.

(3) Outliers. LSDF understands that proposal quality will vary across the core review criteria. For example, a proposal that may be scientifically unexciting may address a major commercial opportunity. As reviewers discuss proposals, LSDF asks them to make special note of compelling opportunities within proposals that might otherwise be considered ordinary or overly risky.

(4) Necessity for LSDF Funding. Matching grants are meant to help applicants advance commercialization of promising technologies, and it is LSDF’s desire that its funding is uniquely
appropriate to achieve this goal. When evaluating an application, consideration of the necessity for LSDF funding for accomplishing the proposed activities is appropriate, especially if the applicant has other financial resources (e.g., sales revenue, other grant support, or investment capital) that might be used toward the same purpose. Reviewers may provide their judgment regarding whether or not the applicant has sufficient resources to accomplish the proposed work without LSDF funding but must not factor this judgment into their pre-proposal or proposal ratings. At the time of evaluation of an application for funding, the LSDF Board of Trustees will weigh the judgment of reviewers as it makes the final determination regarding the necessity for LSDF support.

(4) Rating. Use the following guidelines to rate proposals as a panel:

- **Highly Recommended**: outstanding, deserves highest priority for funding
- **Recommended**: good, worthy of consideration for funding
- **Not Recommended**: poor, lacking in one or more critical areas; funding not recommended