

# **Washington State Life Sciences Discovery Fund Authority Request for Proposals LSDF 07-01**

## **Beneficial applications of technology in health care: improving health-care quality and cost effectiveness**

**February 28, 2007**

### **Executive Summary**

Applicants are invited to propose projects leading to the beneficial application of existing or emerging technologies for the improvement of health-care quality and/or cost effectiveness. Proposals are invited from Washington nonprofit organizations, singly or in collaboration either with other nonprofits or with for-profit companies.

This inaugural funding opportunity of the Life Sciences Discovery Fund will distribute \$3-\$6 million dollars in grants for innovative health-care and technology research projects. Awards are expected to range between \$250,000 and \$1 million dollars and to extend from one to three years, though there is no fixed cap on amount or length. The facilities and administration allowance for grants in this funding competition is fixed at 15% of direct, allowable costs.

Letters of intent are due March 28, 2007, with proposals due May 23, 2007, and award announcements expected September 19, 2007.

Proposals will be evaluated according to scientific and technical merit, innovative application of technology, and potential to improve health-care quality or cost effectiveness. LSDF-funded research is also intended to leverage benefits beyond the health-care outcomes sought by this RFP. Thus, every proposal will also be evaluated for its potential to attract follow-on resources such as research or commercialization funding or to foster broad implementation within a health-care environment.

All awardees will have demonstrated the potential to contribute to LSDF's primary strategic goal of leveraging the state's investment dollars to promote the health of Washington's citizens, advance its life sciences industry, and strengthen the state's economy.

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# **1. Introduction**

## **1.1. Title**

Beneficial applications of technology in health care: improving health-care quality and cost effectiveness.

## **1.2. Objective**

This funding opportunity (LSDF 07-01) focuses on innovative intersections between health care and technology. (The term “technology” is defined below in 2.2.). Applicants are invited to propose research leading to the beneficial application of existing or emerging technologies for the improvement of either health-care quality or cost effectiveness. However, proposals are especially encouraged for projects leading to both results.

## **1.3. Background**

The Life Sciences Discovery Fund Authority (LSDF) was created in 2005 by the Governor and Legislature of the State of Washington. The LSDF was authorized to invest \$350M of tobacco settlement bonus payments, which will be received by the state in annual increments for ten years beginning in 2008. The LSDF’s goal is to leverage those dollars by investing in life sciences research to promote the health of the state’s citizens, to advance its life sciences industry, and to strengthen its economy.

The LSDF is expected to foster substantial returns by creating new jobs, attracting additional non-state dollars to the economy, commercializing scientific innovation, improving health-care quality, and promoting cost effectiveness. (For further discussion of anticipated returns on the state’s investment of tobacco settlement bonus payments in LSDF grants, see the LSDF Report to the Washington State Legislature, 1 December 2006, at [www.lsdfa.org](http://www.lsdfa.org).)

Examples of areas of research expected to produce such results include the following: new approaches to diagnosis, treatment, prevention, and management of disease; translation of basic science discoveries to health-care practice; implementation of predictive and preventive health-care strategies; advances in human nutrition; scale-up of effective health-care practices from individuals to populations; demonstrations of improved efficiencies and outcomes in health-care delivery; and innovations in cost effectiveness.

LSDF will support innovative research and commercialization projects conducted by Washington nonprofit organizations, singly or in collaboration either with other nonprofits or with for-profit companies.

The current Request for Proposals (RFP), LSDF 07-01, has been designed to address one area in particular: applications of new and existing technologies to improve health-care quality and cost effectiveness.

#### **1.4. Frequently Asked Questions**

For brief answers to the most common questions asked by potential applicants about the LSDF program and its opportunities, see Appendix A.

#### **1.5. Eligibility**

Eligibility for LSDF 07-01 grants is restricted to nonprofit institutions, organizations, and agencies in Washington. Eligible applicants will have been recently engaged in competitively funded, sponsored research, or similar activities. Applicants will include, but not be limited to, the following:

- public and private universities,
- nonprofit research institutions,
- public health departments,
- public and private hospitals, and
- health-care systems and clinics.

For-profit corporations are not eligible to apply individually for funding under LSDF 07-01, but they are welcome to join an eligible applicant in the proposal of a collaborative project. In such a proposed collaboration LSDF grant funds will flow to the nonprofit grantee for disbursement for the research.

Institutions and organizations outside Washington State are not eligible to apply individually for funding, but they may join an eligible in-state applicant in the proposal of a collaborative project. In order to be funded, the necessity for such a proposed collaboration will need to be justified. Further, the proposed results of the project will need to have the potential to be demonstrably beneficial to the citizens of Washington.

#### **1.6. RFP Updates**

The information applicants need to apply for LSDF 07-01 is included in this RFP. LSDF reserves the right to amend the RFP after its release. Any additional information—any clarifications or changes in guidelines or requirements—will be posted on the LSDF website, [www.lsdfa.org](http://www.lsdfa.org). Applicants are responsible for consulting those addenda to be sure they have the latest information regarding this competition.

## 2. Funding Opportunity Description

This section is crucial for the formulation of a successful proposal. It describes the scope, purpose, and essential requirements for a grant award.

### 2.1. Nature of the Grant Opportunity

The LSDF invites proposals for research on the uses of new or existing technology to improve health-care quality and cost effectiveness. It is anticipated that meritorious proposals will focus on one or the other of these results, but proposals with demonstrable benefits for both health-care quality and cost effectiveness are especially encouraged.

Proposals are expected to define the specific improvement in health-care quality or cost effectiveness targeted by the research, describe the technology application to address it, detail the beneficial results that will accrue, and outline the future benefits that successful completion of the project will make possible.

Proposals focused exclusively on medical practices or procedures, in the absence of an innovative application of technology, will not be funded. Similarly, it will not be sufficient for proposed projects to concentrate on the development of technology, in the absence of application. Both the application of the technology and the benefits of its use for health-care quality or cost effectiveness are indispensable to the goals of this program.

The LSDF is intended to provide grant support that is not readily available from other sources. Applicants should therefore make clear how the purpose and scope of the project they are proposing make the LSDF program a particularly appropriate source of funding for the research.

### 2.2. Background

Four fundamental assumptions underlie this RFP:

- (i) that major gains in the quality and cost effectiveness of health care can be achieved through the application of appropriately focused science;
- (ii) that significant beneficial improvements in health care are possible in all stages of patient care—wellness, prevention, diagnosis, treatment, and management;
- (iii) that cost effective measures can be implemented throughout the health-care system—in administration and infrastructure, in front-line service to patients, and in promotion of patient behavior and compliance; and
- (iv) that technologies of various kinds can provide tools and efficiencies that benefit health-care quality and cost effectiveness.

Further, Washington State has considerable resources already in place to enable it to achieve these manifold improvements in health care: a powerful life-sciences research

core, a robust and innovative health-care industry, and one of the most inventive and mature technology environments in the world. The LSDF invites applications that will link these resources in new ways to achieve significant beneficial results.

Viewed broadly for the purposes of this RFP, the term “technology” refers to tools to accomplish a task, including, but not limited to, devices, instruments, tests, computerized systems, software, and drugs and other chemical and biological substances. All proposals in response to this RFP should focus on the application of such a technology to health care.

Similarly, for the purposes of this RFP, technology applications are considered “beneficial” only if they actually change health-care processes for the better. Proposals which merely continue the current state of care—even though they may apply new technological interventions—will not be competitive.

### **2.3. Requirements for Research Proposals**

The goal of this LSDF funding opportunity, LSDF 07-01, is to support the application of technology that will improve health-care quality or cost effectiveness. In order to do so, the LSDF will fund research leading to a variety of innovations, including, but not limited to, new approaches to

- diagnose, treat, prevent or manage disease;
- manage health-care delivery environments and systems;
- promote healthy behaviors and compliance in patients; and
- better integrate practitioners, patients and health-care systems.

Projects that focus on technology development in the absence of application or on modes of practice independent of an innovative application of technology will not be competitive. Supporting the beneficial intersection of practice and technology is the core objective of this funding opportunity.

All proposals will be expected to be scientifically rigorous and to make a substantial contribution to knowledge and understanding of technological applications to health care within the specialty fields they represent. Applicants will be expected to:

- define the technology focus of the proposed project and its potential use in health-care practice;
- detail the specific health-care problem to be addressed by the technology;
- explain how the proposed application of the technology will solve the problem;
- summarize how the proposed project builds upon the investigators’ prior research and experience, providing relevant preliminary data;
- propose a study design of sufficient rigor to substantiate the effect of the technology on health-care quality or cost effectiveness;
- itemize the timelines and milestones associated with completion of the project;
- delineate how the technology solution will benefit health-care quality or cost effectiveness;

- show how the project’s success has the potential to leverage substantial additional resources to achieve benefits on a larger scale; and
- explain why LSDF funding is a necessary or particularly appropriate source of funding for the proposed research.

Proposals will be evaluated on scientific and technical merit, innovative application of technology, and potential to improve health-care quality or cost effectiveness. LSDF-funded research is also intended to leverage benefits beyond the immediate results targeted in the RFP. Thus, every proposal for this inaugural grant program will also be evaluated for its potential to attract follow-on resources such as research or commercialization funding or to foster broad implementation within a health-care environment.

Proposals with the potential to have near-term impact on improving health-care quality or promoting cost-effective health care within the state are particularly desirable. Elucidation of how such impacts will be achieved will be an essential component of funded proposals.

#### **2.4. Follow Up to Successful Projects**

Applicants must describe not only how a successful project makes a beneficial impact on health-care quality or cost effectiveness but also what the next steps are in capitalizing on that success. Research teams will be expected to show a long-term commitment to advancing their technology toward widespread use. Proposals should detail how the technology will be moved toward broader use upon successful completion of the project. Projects with the capacity to marshal additional resources to enable broader implementation of the technology to health care are preferred for funding. Types of additional resources might include follow-on research funding and/or investor funding; commercial development of the technology through the formation of a new company or licensing of the technology to an existing company; and commitments from research partners or other interested parties to adopt the successfully demonstrated technology.

### **3. Application Process**

Compliance with this RFP and assurance that application materials are accurate, complete, and timely is the sole responsibility of the applicant. Application materials that do not adhere to content requirements, are incomplete or incorrect, or are late will not be reviewed.

The application process consists of two steps: a letter of intent (LOI) followed by a proposal. LOIs and proposals will be submitted electronically via an on-line application system available on the LSDF website, [www.lsdfa.org](http://www.lsdfa.org). Instructions for submitting the LOIs and proposals are provided in the LSDF application system. Applicants will be given a discrete log-in identity during their first use of the system. Proposals will not need to be completed in one session.

Each proposal must contain approval from an individual within the applicant organization who is authorized to submit grant proposals to external sponsors. The form of such approval may vary among applicant organizations.

**Note that at the date of release of this RFP, the on-line application system has not been activated. It is expected that the submission system for LOIs will be active by March 14, 2007, and that the system for proposals will be active in early April. The LSDF will post a note on its website, advising applicants of the availability of the on-line application system.**

Applicants who discover an error or omission after submitting a proposal, but before the final deadline for submissions, may notify LSDF and seek authorization to submit a corrected proposal. But only complete and fully compliant proposals received by the deadline will be reviewed.

### **3.1. Key Dates**

Letter of Intent due	5:00PM PDT, Wed., March 28, 2007
Proposal due	5:00PM PDT, Wed., May 23, 2007
Review of proposals	May-Sept, 2007
LSDF Trustees award selection	September 18, 2007
Awards announcement	September 19, 2007
Start date	Upon completion of the grant agreement between LSDF and the applicant organization

### **3.2. Letter of Intent** (*See Appendix B.*)

Prospective applicants must submit an LOI stating their intent to submit a proposal. The LOI does not bind the prospective applicant to submit a proposal. However, no proposal will be reviewed unless an LOI has been received by the deadline of 5:00PM PDT, Wednesday, March 28, 2007.

The LOI is not a pre-proposal. It is not intended to be a screening mechanism. In the rare circumstance that an LOI describes a project that is clearly not suited for LSDF 07-01 funding, the sender will be notified of that determination. As a general rule, however, proposed projects will be assumed to fit the requirements of the RFP and to advance the program goals of the LSDF. Evaluation of proposals will therefore begin only after the proposal deadline.

The LOI is to be submitted by the principal investigator, on behalf of the applicant organization that employs her or him and that will be legally and financially responsible for the activities supported by the award.

In addition to other information, LOIs include a brief abstract of fewer than 500 words, stating the objectives of the project to be proposed, the technology to be studied, the

strengths and resources the project will build upon, and the anticipated improvements in health-care quality and/or cost effectiveness.

LOIs are expected to consist of the same subject matter as the full proposals later submitted. Although the text of the LOI abstract may be different than the text in the proposal, the overall content of the proposal must be the same as that of the LOI.

LSDF reserves the right to release the contents of the LOI to the public. Therefore, applicants should not include any confidential information in the LOI.

The LOI is to be submitted electronically, via an application system on the LSDF website. It may be submitted anytime between March 14, 2007, and March 28, 2007. The final deadline for LOIs is 5:00PM PDT, Wednesday, March 28, 2007.

Upon receipt of the LOI by LSDF, an acknowledgement will be sent to the principal investigator, reiterating the invitation to the applicant organization to submit a proposal in the current funding competition.

### **3.3. Proposal Requirements**

The proposal is to be submitted electronically, via an application system on the LSDF website. It is expected that the on-line application system for proposals will be active by early April. The final deadline for proposals is 5:00PM PDT, Wednesday, May 23, 2007.

Upon receipt of the proposal by LSDF, an acknowledgement will be sent to the principal investigator.

The proposal consists of several sections—

- face page,
- narrative,
- budget,
- biographical information,
- personnel roster, and
- intellectual property certification.

It may also include two further attachments as needed—letters of support and an intellectual property rights agreement.

All but the narrative and attachments will be submitted using electronic templates supplied by LSDF. The narrative will be free-form, but strict format rules apply. Each section of the proposal is described below.

#### *3.3.1. Face Page (See Appendix C.1.)*

The face page contains essential information for identifying, processing, and tracking the proposal. Much of the face page information is taken from the LOI and will not have to

be re-entered when completing the face page. The face page includes the project title; the name of, and contact information for, the principal investigator; the names of collaborators and the names and types of their organizations; the name, address, type, and entity identification number of the applicant organization; the dates of the proposed research; the budget amount being requested (including summary and detailed project costs); key words related to the research being proposed; an abstract (which can be taken from the LOI) not to exceed 500 words; the names and contact information of persons at the applicant organization responsible for (i) financial matters, (ii) contractual issues, (iii) intellectual property management, and (iv) grant business oversight; notification of whether the proposal includes any confidential information; notification of whether the proposed research involves the use of human subjects or vertebrate animals (and the Federal Assurance Numbers, as appropriate); and the name and contact information of the authorizing individual from the applicant organization.

Each proposal must contain certification from this authorizing individual that the proposal is consistent with the organization's policies, that it accurately represents institutional capacity and commitment to the proposed project, and that the institution is aware that the facilities and administration (indirect cost) allowance for LSDF 07-01 is fixed at 15%. It is the responsibility of the applicant to ensure that this certification is obtained in a manner consistent with the applicant organization's policies and practices regarding the submission of electronic proposals to external sponsors.

### *3.3.2. Proposal Narrative*

Length and Format. The proposal narrative should be as clear and succinct as possible. It should be no longer than 20 pages, though shorter narratives are strongly encouraged. It should conform to the following format requirements:

- 8½" by 11" page dimensions
- Single spaced with all margins measuring at least 1"
- At least 12 point font in Times New Roman or Arial
- Type density of no more than 15 characters per inch
- No more than 6 lines of type within a vertical space of 1"
- In the upper right-hand corner of each page, include a header with the name of the principal investigator, the grant competition number (*i.e.*, LSDF 07-01), and the page number, using the form: "Page x of xx."
- Each page on which confidential information occurs should be clearly marked with the word "Confidential" in the upper right-hand corner (see section 6.2: Confidentiality below).

All tables, graphs, figures, diagrams, charts, and bibliography must be included within the 20-page limit. The narrative should be self-contained. Internet website addresses (URLs) or attachments should not be used to provide additional information necessary to the project description.

Instructions for submitting the narrative are included in the electronic application system.

Proposals that do not comply with these length and format requirements will not be reviewed.

Content. (See also Section 2.) The proposal narrative should include sufficient information needed to evaluate the scientific and technical merit and beneficial returns of the project, independent of any other document. The general purpose of the narrative is to answer these questions: What do you intend to do? Why is the work important? What has already been done? Why are you asking LSDF (as opposed to other funding sources) to support the proposed research? How are you going to do the work? Who will the key project personnel be? How long will it take? How will you measure success? How does the successful project leverage additional resources for implementation of the technology in health care?

*A. Specific Aims*

(recommended length: 1 page)

List the broad, long-term objectives and the goal of the specific technology-application research being proposed, *e.g.*, to test a stated hypothesis, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a new procedure or treatment to improve health-care quality or increase cost effectiveness.

*B. Background, Significance, and Relevance to LSDF Program Goals*  
(recommended length: 2 pages)

Briefly sketch the background leading to the present research, critically evaluate existing knowledge, and specifically identify the gaps that the project is intended to fill. State concisely the importance and health-care relevance of the research described in the proposal. For proposals addressing cost effective health care, state the prevailing cost environment and detail how what is learned during the research is expected to impact those conditions.

Relate the specific aims of the project to the three broad, long-term objectives of LSDF—scientific innovation, improved health, and economic benefit. Show how the proposed project achieves the particular program aims of LSDF 07-01—the beneficial application of technology to health care for the purpose of improving health-care quality or increasing cost effectiveness. If the goals of the proposal are achieved, state how scientific knowledge or clinical practice will be advanced. Describe the beneficial effect of the proposed research on the established concepts, methods, technologies, treatments, services, outcomes, systems and efficiencies of health care.

*C. Preliminary Studies*

(recommended length: 4 pages)

Provide an account of the principal investigator's preliminary studies pertinent to this proposal, including relevant data and his or her earlier experience with technology development and health-care practice. This information will help to establish the experience and competence of the investigator to pursue the

proposed project. (Note that bibliographic reference pages count toward the total narrative page limit.)

#### *D. Research Design and Methods*

*(recommended length: 5 pages)*

Describe the research design, the conceptual or clinical framework, procedures, and analyses to be used to accomplish the specific aims of the project. Include how the data will be collected, analyzed, and interpreted. Describe any novel concepts, approaches, tools, or technologies deployed for the proposed studies.

#### *E. Challenges*

*(recommended length: 2 pages)*

Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieving the project's aims. Point out any procedures, situations, or materials that may be hazardous to personnel and the precautions to be exercised.

#### *F. Timeline and Milestones*

*(recommended length: 1 page)*

Provide a timeline for the research, including specific project components, keyed to the project's objectives. Identify major milestones, propose target dates for their accomplishment, and define the criteria by which achievement of each of the milestones will be assessed. Both the milestones and the dates by which they will be met are important conditions for LSDF funding. They will be incorporated in the grant agreement for each funded project. LSDF also expects to make phased funding disbursements contingent upon grantees achieving the milestones, to which they and LSDF have agreed.

#### *G. Personnel*

*(recommended length: 1 page)*

Identify all the key project personnel—principal investigator, collaborators, and other individuals who will be responsible for key aspects of the project. Define their roles, and explain how their work will be coordinated. Support personnel should not be listed in the narrative.

Detailed biographical information should not be included in the narrative. Biographical information on key personnel and a list of all project personnel is provided through a separate part of the on-line application system. (See Appendices C.3 and C.4 for further information about key personnel bio sketches and a staff personnel roster.)

#### *H. Budget Justification*

*(recommended length: 1 page)*

The budget justification should include a description of the complete funding plan, describing the funding rationale for the proposed project, its appropriateness for LSDF support, its expectations for follow-on funding from other sources, and the amount and sources of any cost-sharing contributions. The

budget justification should also highlight and explain the essential need for any extraordinary expenditures.

In addition to the budget justification in the proposal narrative, forms for full-project budget summaries and full-project detailed budgets are provided by LSDF in a separate part of the on-line application system.

In preparing budgets, applicants are reminded that LSDF funds will be disbursed in phases during the life of the project and will be contingent on the timely accomplishment of milestones confirmed in the grant agreement.

#### *I. Facilities and Equipment*

*(recommended length: 1 page)*

Describe the facilities, equipment, and resources available for the project. If new equipment is part of the proposal request, describe available equipment suitable for the project and explain why it cannot be used. If the new equipment will be available to support other efforts, outside the scope of the LSDF-funded proposal, explain how time and LSDF funding support will be allocated to it. Describe plans for facilities and equipment maintenance necessary to complete the project.

#### *J. Future Plans*

*(recommended length: 2 pages)*

Describe the next steps in capitalizing on the project's success. Proposals should detail how the technology being studied during the funding period will be moved toward broader use in health care. Outline the additional resources that can be marshaled to enable broader implementation—*e.g.*, follow-on research funding or investor funding; commercial development of the technology through the formation of a new company or licensing of the technology to an existing company; and commitments from research partners or other interested parties to adopt the successfully demonstrated technology. Detail plans that are in place for leveraging these future resources.

### *3.3.3. Budget*

A budget summary form and a detailed budget form are to be completed using the on-line application system (see Appendix C.2). A budget justification is to be included in the proposal narrative.

In preparing budgets, applicants should consider the following.

#### *A. Cost-sharing*

No special requirement for cost-sharing is included in the current funding program (LSDF 07-01).

In proposals including for-profit collaborating companies, the companies will be expected to pay for their own internal research costs.

Matching funds supplied for the proposed work from other sources, *e.g.*, the applicant organization, granting agencies, companies, and investors, should be listed.

#### *B. Allowable Direct Costs*

The following direct costs associated with the performance of a project are allowable for LSDF grant support:

- salaries (including wages, benefits, stipends, and education fees for trainees),
- equipment specifically required for the grant project,
- supplies,
- services, and
- grant-related travel.

Expenses for the following are not allowed to be charged to an LSDF grant as direct costs:

- facilities construction or remodeling,
- patient care, and
- computers not essential for performance of the proposed research.

#### *C. Facilities and Administration Allowance*

F&A support for LSDF 07-01 will be limited to 15% of those direct costs that are allowable (as described below). This rate is fixed, regardless of the established F&A rate of the applicant organization.

With this limitation on the F&A allowance, most grantees will bear a portion of their F&A expenses. In bearing these costs they contribute financially to achieving the return-on-investment goals of the LSDF program.

The following direct costs of proposed research are allowable for F&A support:

- salaries (including wages, benefits, stipends, and education fees for trainees),
- equipment at unit prices at or below \$5,000,
- supplies,
- services, and
- grant-related travel.

The direct costs of equipment at unit prices above \$5,000 are not allowable for F&A support:

The F&A costs incurred by a for-profit company collaborating with a nonprofit in a funded project are not eligible for payment by LSDF.

#### *3.3.4. Additional Sections*

In addition to the face page, narrative and budget, proposals must contain biographical information on key personnel, a roster of all personnel working on the project and an intellectual property certification. Forms for each of these sections are available through

the on-line application system. See Appendix C for more detailed information on the content to be included in the following required forms.

- Biographical information --biographical sketches of the principal investigator and other key project personnel. (See Appendix C.3.)
- Personnel roster --identifying the research and administrative staff, other than the principal investigator and his or her lead collaborators, who will work on the project. (See Appendix C.4.)
- Intellectual property ownership and management certification—detailed description of how intellectual property will be owned and managed. (See Section 6.7 for further information, and Appendix C.5.)

Supplementary materials may also be appropriate or required. Applicants may submit letters of support and may be required to include an intellectual property rights agreement (see Section 6.7 to determine if this agreement is required). If these supplementary materials are included in a proposal, they should be uploaded in PDF format according to the instructions included in the on-line application system on the LSDF website, [www.lsdfa.org](http://www.lsdfa.org).

## **4. Evaluation**

### **4.1. Key dates**

May-September 2007                      Peer review of proposals

### **4.2. Peer Review**

All proposals will be subject to confidential peer review. The review will be conducted by expert reviewers from outside Washington State engaged by LSDF to evaluate the scientific and technical merit, health-care importance, and economic leveraging benefit of proposals. Peer-evaluated proposals will be submitted to the LSDF Board of Trustees for the selection of award recipients (see Section 5: Selection below).

LSDF reserves the right to invite applicants for a personal interview or to require a site visit as part of the peer review process. LSDF will be responsible for any travel cost incurred by invited applicants for these visits.

The LSDF is subject to Washington public disclosure laws (RCW 42.17.350) and will hold all proposals confidential, subject to these laws (see Section 6.2: Confidentiality below). Peer reviewers will be required to sign nondisclosure agreements.

Names of reviewers will not be made available to applicants. Applicants and their representatives are not permitted to contact reviewers or members of the LSDF Board of Trustees regarding submitted applications. Any attempt by an applicant or representatives of an applicant to contact reviewers or LSDF Board members concerning pending

applications may result in the disqualification of that applicant's application from the LSDF 07-01 grant competition.

### **4.3. Evaluation Criteria**

Following the proposal deadline, all proposals will be screened for compliance with this RFP. Those that are judged to be compliant will be submitted to independent peer review. Reviewers will evaluate the proposals according to the criteria described here.

All funded proposals will be expected to have the potential to contribute to LSDF's primary strategic goals: to leverage LSDF dollars to promote the health of Washington's citizens, to advance its life sciences sector, and to strengthen the state's economy. Within this general framework, the specific evaluation criteria reviewers will use to evaluate proposals for LSDF 07-01 are as follows:

- scientific and technical merit,
- the importance of the technology to health-care quality or cost effectiveness, and
- the potential to create future economic benefits for Washington State.

#### *A. Scientific and Technical Merit*

The research must be innovative, with high scientific and technical originality. The research plan must be clear and concise. It must clearly identify the core innovation, scientific approach, major technical hurdles, and attendant risks of the project. It must also clearly establish technical feasibility. The design and methods of the research must be appropriate to the specific aims of the proposal. The research team must possess the level of scientific and technical expertise needed to conduct the research. Access to the necessary research facilities must be guaranteed. The proposed research must have a strong potential for contributing significantly to the scientific and technical knowledge base of Washington State.

The proposal must define a critical problem in health care; describe the technical barriers that have prevented improvement in the specific area of the project; outline the proposed solution; and make clear how the proposed solution will overcome the technical barriers. The technology must already exist or be in such a late stage of development that it can be applied during the project period. The proposal will discuss why the proposed solution may not have previously been attempted or accomplished and show how the proposed solution is superior to possible alternative approaches.

#### *B. Importance of the Technology to Health-care Quality or Cost Effectiveness*

Competitive proposals will detail how the proposed technology application will improve health-care quality or cost effectiveness in Washington State. Though proposals are not required to do both, those with the potential to benefit both the quality and cost effectiveness of health care will be evaluated as especially strong.

Proposals to advance health-care quality must describe the current state of care and demonstrate how the project will promote improvements in a particular area of health-care delivery, *e.g.*, diagnosis, testing, treatment, patient management, surgical procedures, drug therapy, disease surveillance, patient compliance, systems improvement. Priority will be given to proposals that address widespread problems and that have the potential to yield near-term beneficial impacts. Proposals also will be expected to show that successful application of the technology will have potential widespread benefit for health-care practice throughout the state.

Proposals designed to affect costs will be expected to show that the application of technology to health care leads to demonstrable improvements in cost effectiveness. Applicants should describe in detail the current costs of the health-care practice they are proposing to improve, and they should explain specifically how their proposed technology application will bring about measurable gains in cost effectiveness. The proposal must make clear how current cost effectiveness is measured, and how the increases in cost effectiveness are identified and quantified.

### *C. Potential to Create Future Economic Benefits for Washington State*

All proposals must have the potential to contribute to Washington's economy. In order to be selected for an LSDF grant, the project must have the potential to generate economic benefits for the state. These benefits and the clear pathway to them must be described convincingly. Economic benefits can include the economic activity entailed directly in the conduct of the research; developing training and employment opportunities in Washington; attracting life sciences researchers, companies, and jobs to Washington; stimulating investment in health-related technology; developing intellectual property, new patents, and licensing opportunities; and creating new collaborations, research infrastructure, or commercial or scientific enterprises leading to future research or investment funding in Washington. The proposals should specifically identify any direct benefits to state agencies and entities as well as any ways in which the costs of state-financed health care may be reduced.

## **5. Selection**

### **5.1. Key dates**

September 18, 2007

LSDF Board of Trustees selects awardees

### **5.2. Selection process**

The peer review panel will recommend the most meritorious proposals for funding to the LSDF Board of Trustees, which will make the final awards decisions. The Board will make final selections based on peer evaluations, availability of funds, and the goals of the LSDF program. Consistent with its enabling legislation, the Board may use geographic

diversity of finalists among its selection criteria. However, all awards will be based on merit.

The Board reserves the right to require award finalists to negotiate with LSDF the cost, scope, and milestones associated with the proposed work

All funding decisions are final and cannot be appealed.

Successful and unsuccessful applicants will receive evaluative feedback, including comments from reviewers upon request.

## **6. Additional Information**

### **6.1. Application submission limits**

Each application submitted to the LSDF must have a single principal investigator. Principal investigators may submit only one application for this competition. There is no limit, however, to the number of proposals that may be submitted from the organizations with which they are affiliated.

### **6.2. Confidentiality**

When information in a proposal is confidential, it is furnished to LSDF with the understanding that the information shall be used or disclosed only for evaluation of that proposal or as required by law. LSDF will hold all proposals confidential, subject to the public disclosure laws of the State of Washington (for more information, applicants are referred to RCW 42.17.350 and to the amendments to the exemption provisions in RCW 42.56.270). LSDF will require reviewers to sign nondisclosure agreements. It is understood that some proposals may need to include confidential information in order to make clear the innovation they propose. No proposal should include information that might compromise the applicant's subsequent ability to secure patent or other intellectual property protection.

If confidential information is included in a proposal because it is deemed essential for proper evaluation of the proposal, the page or pages on which it occurs should be clearly marked with the word "Confidential" in the upper right-hand corner. The presence of confidential information in the proposal should also be indicated in the appropriate check box on the proposal face page, as described in paragraph 3.3.1 above. If the LSDF receives a request for disclosure of portions of the proposal that have been designated as confidential, it will promptly notify the applicant organization of such request in order to allow the applicant organization to assert timely objections to disclosure in any applicable proceeding.

### **6.3. Conflict of interest**

Financial conflict of interest has become an increasingly important issue in research. When performing research, it is essential that the personal interests of investigators do not impede their judgment or compromise their objectivity. Even the perception of conflict has the potential to erode the public's confidence in the research process. It is essential that applicant organizations have a financial conflict of interest policy in place and that all proposals submitted to the LSDF will have been vetted according to that policy before a proposal has been funded. In accepting an LSDF award, the applicant organization will certify to the LSDF in the grant agreement that potential financial conflicts of personnel performing the funded project have been disclosed and that all conflicts have been eliminated or mitigated. Applicant organizations that do not have a financial conflict of interest policy should consult with the LSDF early in the application process to discuss how the financial conflict of interest review will be performed.

### **6.4. Funding amounts and award length**

The number of proposals selected for LSDF awards will generally depend upon the availability of funds and the number of meritorious proposals. The LSDF does not expect to establish prescribed caps for grant amounts or for the length of awards. However, it is anticipated that for LSDF 07-01 the Board of Trustees will select projects whose budgets range between \$250,000 and \$1 million dollars and whose length extends from one to three years.

Funds for this inaugural grant program (LSDF 07-01) are being provided by private contributions. The expected total amount of funds available will be \$3-\$6 million. Funding will be distributed to grantees in increments, according to a schedule specified within the grant agreement and based upon timely reporting and the achievement of milestones during the project.

### **6.5. Grant agreement**

Following the selection of grant recipients by the LSDF Board of Trustees and after the public announcement of the awards, grant agreements will be negotiated between the grant recipient organizations and the LSDF. The agreements will include specification of the principal investigator and any co-investigators responsible for conducting and completing the project, the funding amount and duration of the grant, project milestones and timelines for their achievement, the criteria to be used for assessment of milestone completion, the financial and other resource contributions of the recipient organization, auditing and reporting requirements, the budget, and other standard terms and conditions.

As part of the grant agreement, the LSDF will reserve the right to withhold research funding if timely progress reports have not been provided or agreed upon project milestones have not been met. Failure to meet milestones in instances that are beyond the control of the project team will be reviewed and evaluated on a case by case basis.

## **6.6. Human subjects and vertebrate animal research requirements**

If a proposed research project involves human subjects, the applicant organization is responsible for ensuring 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 National Institutes of Health (NIH) human-subjects-related policies. In accepting an award from the LSDF, an organization certifies that it has a system that complies with federal, state and local government regulations to protect the rights, well-being and personal privacy of human subjects in research and that the project for which an award is to be made has been reviewed and approved by the applicable human subjects oversight bodies.

For research involving vertebrate animals, the applicant organization must ensure that all performance sites hold Office of Laboratory Animal Welfare (OLAW)-approved assurances. In accepting an award from the LSDF, an organization certifies that it has a system that complies with federal, state and local government regulations to humanely, efficiently, effectively and legally use live vertebrate animals in research and that the project for which an award is to be made has been reviewed and approved by the applicable animal use and care oversight bodies.

The necessary approvals for human subjects or vertebrate animal research will need to have been received prior to execution of the grant agreement.

## **6.7. Intellectual property**

LSDF grants are intended to support research that may lead to the development of knowledge with commercial potential. Intellectual property (IP) resulting from the project will be owned by the applicant or collaborating organization(s), as appropriate, not by the LSDF. However, proposals are expected to make clear specifically who will own the IP that may result from a project. If a party other than the applicant or collaborating organization(s) will own or have rights to IP developed under an LSDF-funded project, the applicant must provide an explanation of and justification for such provisions.

Applicants must describe in detail how IP developed in the project will be managed. Applicant organizations with established IP management infrastructures can meet this requirement by referencing the policies, practices, and structures they already have in place for IP management. Institutions without such established infrastructures should explain in detail how they plan to manage and commercialize the IP associated with the proposed project. Applicant organizations that do not have an IP policy or mechanisms to manage and commercialize IP should consult with the LSDF early in the application process to discuss how IP will be managed.

Proposals submitted for collaborative projects must make explicit provision for an IP rights disposition agreement among the collaborators. Such an agreement must clearly

allocate the rights that the collaborators will have in any IP developed within the project and identify which of the parties will be responsible for commercialization of the IP. One example of an appropriate form of agreement to use for this purpose can be found in that used by the Federal Small Business Technology Transfer Research Program -- <http://www.dodsbir.net/solicitation/pdf/AllocationofRights.pdf> -- "*The Allocation of Rights in Intellectual Property and Rights to Carry Out Follow-On Research, Development, or Commercialization.*"

Electronic forms for describing the IP management plans of the applicant are available on the LSDF website, as part of the on-line application system for LSDF grant proposals. Additional information to assist applicants in preparing their content is included in Appendix C.5.

### **6.8. Principal investigator requirements**

LSDF grant proposals must have a single principal investigator, regardless of how many investigators or organizations will be involved in the project. The principal investigator must be employed by the applicant organization. She or he will be responsible for leading the research, ensuring that the scientific and technical requirements of the grant agreement are met, and reporting the progress and results of the project as required by LSDF. To be a principal investigator on an LSDF grant, individuals must meet the requirements set by their employer for such status.

Awards cannot be reassigned or transferred without the express written authorization of the LSDF Board of Trustees. If the principal investigator of a funded project changes his or her employment status with the recipient organization or relocates outside of Washington during the award period, the recipient organization must, within 30 days, identify an alternate principal investigator, acceptable to the LSDF, to assume leadership of the project. If such an arrangement is not feasible, the portion of the award remaining after payment of the recipient organization expenditures will be rescinded.

### **6.9. Reporting requirements**

Given the character of LSDF as an investment by the State of Washington in the future of its citizens, full and timely reporting by principal investigators has great importance for calculating the returns on investment. The progress and results of funded projects will be the primary means by which the LSDF's performance and effectiveness can be measured. Therefore, the LSDF depends on grantees' meeting their reporting responsibilities fully. Noncompliance with these reporting requirements may jeopardize the continuation of funding to a recipient organization.

Reporting requirements, specific for each funded proposal, will be finalized in the grant agreement. But LSDF requires, at minimum, the following reports: semi-annual progress reports and post-project annual reports for a period of five years. Site visits and in-person briefings by principal investigators may be used by the LSDF as tools to track the progress of funded projects.

#### **6.10. Start date**

The start date for projects funded in this grant competition (LSDF 07-01) may be as early as September, 2007. In no case will funds be released by LSDF to the recipient organization until the grant agreement between LSDF and the grantee institution is completed.

#### **6.11. Publicity**

The LSDF reserves the right to publicly disseminate information about its granting activities through a variety of means. Such communications could include lists of LOIs and proposals received and of proposals funded, short synopses of funded proposals and reports about the progress and outcomes of funded projects.

#### **6.12. Contact information**

For information about LSDF, procedures and requirements of this competition, or grant administration of LSDF 07-01, contact [info@lsdfa.org](mailto:info@lsdfa.org).

# Appendices

## Appendix A. Frequently Asked Questions

The following questions and answers are meant to provide a convenient summary of the issues of most frequent interest to potential LSDF applicants. This FAQ may be amended from time-to-time in response to questions received from the community. The most current version of the FAQ is available on the LSDF website at [www.lsdfa.org](http://www.lsdfa.org).

### *A. What is the Life Sciences Discovery Fund?*

#### A.1 What is LSDF?

The Life Sciences Discovery Fund (LSDF) Authority is a Washington State agency, established in 2005 and authorized to distribute up to \$350M over 10 years to life sciences research--to promote the health of the state's citizens, to advance its life sciences sector, and to strengthen the economy.

#### A.2 Where does LSDF's money come from?

Generous private donors contributed an initial \$3 million to launch the LSDF's grant-making. However, the bulk of LSDF's resources comes from the tobacco settlement bonus payments being received by the State of Washington in annual increments of \$35 million from 2008 to 2017.

#### A.3 What does it mean when I hear that LSDF awards are considered to be "investments"?

The Governor and Legislature created the LSDF expressly to leverage its tobacco settlement bonus payments for the benefit of the citizens of Washington State. The LSDF is expected to use these public dollars in its grant programs to catalyze tangible public gains. Proposals for funding therefore are expected to demonstrate the potential to earn returns on the state's investment.

#### A.4 What types of returns on investment is the LSDF seeking?

The goal of LSDF is to promote economic vitality in the State of Washington by fostering innovative scientific research designed to improve the health of the state's citizens. Knowledge gains will enhance the reputation of Washington as a global center of life sciences research and provide a source of leverage for follow-on research and investment funding. Scientific discovery will contribute to robust industry development and economic growth. Research will lead to innovations that will improve health-care outcomes, efficiencies in delivery, and cost effectiveness.

***B. What kinds of grants does LSDF make?***

**B.1** Where can I find information about grant programs or proposal guidelines?

General inquiries about grant programs and questions about proposal guidelines may be addressed to LSDF by email -- [info@lsdfa.org](mailto:info@lsdfa.org).

**B.2** What size grants does LSDF make?

LSDF grants vary in size depending on the range of programs being offered and the availability of funds. In the first grant competition of 2007, the LSDF is distributing \$3-\$6 million. Grant sizes for this competition are expected to be in the range of \$250 thousand to \$1 million.

**B.3** Are LSDF awards made for one year or can they be multi-year?

Both one-year and multi-year proposals are expected to be funded.

**B.4** The inaugural LSDF RFP (07-01) invites proposals related to applications of technology in health care; what is meant by “technology”?

Viewed broadly for the purposes of LSDF 07-01, the term “technology” refers to tools to accomplish a task, including, but not limited to, devices, instruments, tests, computerized systems, software, and drugs and other chemical and biological substances.

**B.5** I am in the early stages of developing a new technology with health-care applications; can I use LSDF 07-01 funding for my development project?

No. Projects that focus on technology development in the absence of application or on modes of practice independent of an innovative application of technology will not be competitive.

**B.6** Does the LSDF make equity investments in companies?

No. The LSDF makes grants to nonprofit entities for the purposes of research.

***C. Who may apply for an LSDF grant?***

**C.1** Who may apply for LSDF funding under LSDF-07-01?

Applicants must be nonprofit Washington State institutions or organizations, including public and private universities, nonprofit research institutions, public health departments, and nonprofit hospitals and clinics.

**C.2** How can I receive grant funding from LSDF?

You can receive funding by submitting an application—on behalf of an eligible organization—in response to an RFP announced by LSDF. Notices of RFPs are published on the LSDF website ([www.lsdfa.org](http://www.lsdfa.org)). There is at least one funding program announced each year. In 2007, there are two grant competitions, LSDF 07-01 and LSDF 07-02.

C.3 Can for-profit or out-of-state entities apply?

No, but they may join Washington nonprofit applicants in collaborative proposals.

C.4 Is collaboration required for LSDF proposals?

No, but it is encouraged, to foster an even more vibrant and competitive life sciences sector for Washington State.

C.5 Who within eligible organizations may apply?

Though prepared and submitted by the principal investigator, proposals officially come from the applicant organization, not the principal investigator. To be a principal investigator on an LSDF grant, individuals must meet the requirements of their employer regarding such status.

C.6 Is there a preference for senior level researchers?

There is no preference in the evaluation of proposals for senior level researchers.

C.7 Can a principal investigator submit more than one proposal in a single grant competition?

No.

C.8 Will the LSDF cap the number of proposals it is willing to review from a single organization in LSDF-07-01?

No.

***D. What are the requirements for submitting an LSDF application?***

D.1 How are application materials submitted?

Proposals are submitted electronically via an on-line application system accessed through the LSDF website, [www.lsdfa.org](http://www.lsdfa.org).

D.2 Is there a pre-proposal process for applying for LSDF grants?

No. A letter of intent is required to be able to submit a proposal. The letter of intent is not a pre-proposal and is not used as a screening mechanism for invitation of full proposals.

D.3 What information is required in an LSDF application?

Specific requirements for LSDF grants are included in the RFP, but applications generally consist of two elements: (1) a letter of intent and (2) a proposal, which includes a face page, project narrative, budget, and supplementary materials.

D.4 What is a letter of intent?

The letter of intent (LOI) is the first part of the application process. It is an electronically submitted notification to LSDF of an applicant's intention to submit a proposal. The LOI does not bind the prospective applicant to submit a proposal. It is not a pre-proposal. Its purpose is to assist LSDF in planning the review process.

D.5 Can I submit a proposal if I do not submit an LOI?

No. The LOI is an essential requirement of an LSDF application.

D.6 When is the LOI due?

Key dates for all parts of the application process are included in the RFP for each LSDF funding program. For LSDF 07-01, the deadline for the LOI is 5:00PM PDT March 28, 2007.

D.7 What is the page limit on the narrative portion of the proposal?

The proposal narrative should be no longer than 20 pages, though shorter narratives are strongly encouraged.

D.8 What is the deadline for submitting an LSDF proposal?

The proposal deadline for LSDF 07-01 is 5:00PM PDT May 23, 2007.

D.9 How may I obtain more information if I have questions?

General information about LSDF funding programs can be sought at

[info@lsdfa.org](mailto:info@lsdfa.org)  
206-732-6770.

***E. Important questions about LSDF grant policy***

**E.1 Which costs are allowable for funding by LSDF?**

Direct costs allowable for grant support include salaries, equipment, supplies, services, and travel. Costs that are not allowable include facilities construction or remodeling, patient care, and computers not essential for performance of the research.

**E.2 Will LSDF grants support facilities and administration (F&A or “indirect”) costs related to funded research?**

Yes. An F&A allowance of 15% of selected items of a proposal’s direct costs will be available for grants under LSDF-07-01. The F&A allowance is fixed, regardless of the established F&A rate of the applicant organization.

**E.3 Which direct costs are allowable for use in determining the F&A allowance under LSDF- 07-01?**

Direct costs allowable for F&A support include salaries, supplies, services, and grant-related travel, as well as equipment at unit prices at or below \$5000.

**E.4 Is cost-sharing required?**

No.

**E.5 Are the LSDF granting programs carried out in a confidential manner?**

Yes. LSDF will hold all proposal documents confidential, subject to the public disclosure laws of the State of Washington. For more information, see RCW 42.17.350 and the amendments to the exemption provisions in RCW 42.56.270. LSDF will require grant reviewers to sign nondisclosure agreements. The LSDF reserves the right to publicly disseminate the subject matter of the proposals it receives.

**E.6 Who owns the intellectual property developed during an LSDF-funded project?**

Normally it is expected that intellectual property (IP) resulting from a funded project will be owned by the applicant organization, not by the LSDF. However, proposals are expected to make clear specifically who will own the IP, who will be responsible for managing it, and in the case of a collaborative project how rights to the IP will be shared by collaborators.

E.7 Will LSDF fund projects involving human subjects?

Yes. If a proposed project involves human subjects, the applicant organization is responsible for ensuring that the research site and project operate under an appropriate Office of Human Research Protections (OHRP)-approved assurance for the protection of human subjects and comply with all NIH human-subjects-related policies.

E.8 Will LSDF fund projects involving animal subjects?

Yes. For research involving vertebrate animals, the applicant organization must ensure that all performance sites and projects hold Office of Laboratory Animal Welfare (OLAW)-approved assurances and approvals.

E.9 Must I already have human subjects approval or animal use approval at the time I submit my application?

No, but the necessary approvals for human subjects or vertebrate animal research will need to have been received prior to execution of the grant agreement.

***F. How are LSDF proposals evaluated and selected for funding?***

F.1 What evaluation criteria are used to evaluate LSDF proposals for funding?

Specific evaluation criteria are described in the RFPs for each funding competition. The general criteria for LSDF awards, however, are scientific and technological merit and strong potential for economic and health benefits for the State of Washington.

F.2 How are proposals selected for awards?

Independent peer reviewers provide evaluations to the LSDF Board of Trustees regarding the strengths, weaknesses and overall merit of submitted proposals. The Board makes the final selections based on peer evaluations, availability of funds, and the goals of the LSDF program.

F.3 Can LSDF funding decisions be appealed?

No. All funding decisions are final and cannot be appealed.

F.4 What are some ways LSDF grants differ from federal grants in their expectations and requirements?

LSDF grants are investments with expected returns. They require the establishment of specific milestones and timelines. Their fund-disbursement

schedule is phased and contingent upon milestone achievement. Also, they require frequent reporting.

F.5 Do LSDF grants have standard terms and conditions?

Yes. These are the guiding principles which establish the legal procedures and responsibilities for LSDF and its grantees in all funding competitions of the program. Specific terms and conditions are established in the grant agreement for individual grant awards.

F.6 When will a recipient organization receive funds once a proposal is selected for funding?

The disbursement schedule will be established as part of the grant agreement. Funding will be distributed to recipient organizations in increments, based upon timely reporting and the achievement of milestones during the project. Disbursements will be authorized by LSDF when recipient organizations have achieved the specific milestones delineated in the grant agreement.

F.7 If I receive an LSDF award, will I have to submit progress reports? If so, how often?

Yes. Reporting by principal investigators is the primary way that the LSDF is able to track project progress and return on investment. Reporting requirements, specific for each funded proposal, will be finalized in the grant contract. But LSDF requires, at minimum, semi-annual financial and technical progress reports and post-award annual reports for a period of five years. Site visits and in-person briefings by principal investigators may be used by the LSDF as tools to track the progress of funded projects.

## **Appendix B. Letter of Intent (See Section 3.2.)**

*[Note: Except for the narrative and some supplementary materials, all the parts of the application will be submitted using the on-line application system provided by LSDF via its website. The content to be provided through the on-line system is included here to assist applicants in planning their applications.]*

- Title of project (with character limitation)
- Principal investigator
  - name
  - degrees
  - position title
  - mailing address
  - e-mail address
  - department
  - telephone number
  - fax number
- Co-investigators
  - name
  - employer
- Applicant organization
  - name
  - address
  - Entity Identification Number
- Estimated dates of proposed period of support
- Estimated costs for year one (direct and F&A)
- Estimated total costs (direct and F&A)
- Key words related to the research being proposed
- Abstract (500 word maximum)

## Appendix C. Proposal Forms

### *C.1. Face Page (See Section 3.3.1.)*

- Title of project (with character limitation)
- Principal investigator
  - name
  - degrees
  - position title
  - mailing address
  - e-mail address
  - department
  - telephone number
  - fax number
- Co-investigators
  - name
  - degrees
  - position title
  - employer
    - Type of organization
      - public: federal, state, local
      - private: private nonprofit
      - for-profit: general, small business
  - mailing address
  - e-mail address
  - department
  - telephone number
  - fax number
- Applicant organization
  - name
  - address
  - Entity Identification Number
  - Type of organization
    - public: federal, state, local
    - private: private nonprofit
- Dates of proposed period of support
- Proposed costs for year one
- Proposed total costs
- Key words related to the research being proposed
- Abstract (500 word maximum)
- Applicant organization contacts:
  - For administrative/contractual matters:
    - name
    - title
    - address
    - telephone number

- fax number
    - e-mail address
  - For financial matters:
    - name
    - title
    - address
    - telephone number
    - fax number
    - e-mail address
  - For intellectual property matters:
    - name
    - title
    - address
    - telephone number
    - fax number
    - e-mail address
  - Departmental business contact:
    - name
    - title
    - address
    - telephone number
    - fax number
    - e-mail address
- Does this proposal:
  - Contain confidential information?
  - Involve the use of human subjects?
    - Federal Assurance Number
  - Involve the use of vertebrate animals?
    - Federal Assurance Number
- Official certifying for the applicant organization:
  - name
  - title
  - address
  - telephone number
  - fax number
  - e-mail address
  - signature line
- Certification:
  - This proposal is consistent with the applicant organization's policies.
  - It accurately represents institutional capacity and commitment to the proposed project.
  - The applicant organization is aware that the facilities and administration allowance for LSDF 07-01 is fixed at 15%.

## **C.2. Budget**

*[Note: Budget detail will be submitted using the on-line application system provided by LSDF via its website. Both a summary budget and a detailed budget will be submitted. Budgets will include budget categories, total direct costs, and allowable direct and F&A costs. The total of the F&A allowance will be automatically calculated on the form, based on the total of the allowable F&A costs. The total budget will also be automatically calculated on the form, adding the total direct costs and the F&A allowance.]*

### **C.2.1. Summary Budget**

- | • Budget categories:        | Allowable direct costs | Allowable F&A |
|-----------------------------|------------------------|---------------|
| ○ Personnel/fringe benefits | yes                    | yes           |
| ○ Equipment > \$5,000       | yes                    | no            |
| ○ Equipment ≤ \$5,000       | yes                    | yes           |
| ○ Supplies                  | yes                    | yes           |
| ○ Services                  | yes                    | yes           |
| ○ Travel                    | yes                    | yes           |
- Total allowable direct costs
  - F&A allowance (automatically calculated) at 15% of total direct costs allowable for F&A support
  - Total amount requested

### **C.2.2. Detailed Budget**

*(for each year of the grant)*

- Personnel
  - name
  - salary
  - percent effort
  - total
- Equipment
  - Enumerate individual pieces of equipment and their cost
- Supplies
  - *E.g.*, consumables, small equipment (≤\$5K), lab animals
- Services
  - Services to be purchased
- Travel
  - Detailed travel expenses

## **C.3. Biographical Information (See Section 3.3.4.)**

*(For all key personnel, using NIH biosketch format.)*

- name
- position title
- role in proposed project
- education/training

- institution and location
- degree
- year(s)
- field of study
- positions and honors in chronological order
- selected peer-reviewed publications in chronological order
- research support: selected projects relevant to the proposed research, with dates of support, project goals and role in the project

***C.4. Personnel Roster (See Section 3.3.4.)***

*(For each person on the project; if a staff position has not been filled at the time of application, “to be named” can be included in the roster.)*

- name
- degree(s)
- organization
- role in the project

***C.5. Intellectual Property Ownership and Management Certification (See Section 6.7.)***

- Does the applicant organization:
  - have written policies regarding ownership and management of intellectual property developed by its employees?
  - have an internal administrative structure for managing commercialization of intellectual property (*e.g.* a technology transfer office)?
- If the applicant organization does not have an internal administrative structure for managing intellectual property, how will commercialization of intellectual property resulting from a grant made subject to this LSDF proposal be managed? Applicant organizations without established procedures for managing intellectual property are urged to consult with the LSDF early in the application process to discuss how intellectual property will be managed.
- Who will own intellectual property developed under a grant made subject to this LSDF proposal?
- If any entities other than the applicant organization will own or have any other rights in intellectual property developed under a grant made subject to this LSDF proposal, please list them and explain the circumstances by which such ownership or other rights have been conveyed.
- If the proposed research involves multiple collaborating parties, please submit documentation that the collaborating parties have agreed in principle about how rights in intellectual property are to be allocated among the collaborators and how commercialization of intellectual property is to be managed.

## **Supplementary Attachments**

### ***Letter(s) of Support and Intellectual Property Rights Agreement***

In addition to the sections included above, a proposal may also include letters of support (see Section 3.3.4, *e.g.* from collaborating entities, documentation of matching funds from other sources, *etc.*) and an intellectual property rights agreement (see Section 6.7). If one or both of these are added, they should be uploaded to the application in PDF format.

## **Appendix D. Checklist**

### **Letter of Intent**

Letter of intent submitted between March 14 and 5:00PM PDT March 28, 2007

### **Proposal**

Face page with all essential components

Proposal certification from authorizing individual at the applicant organization

Narrative

Budget (summary budget and detailed budget for each year of the grant)

Biographical Information

Personnel Roster

Intellectual Property Ownership and Management Certification

Letters of Support

Intellectual Property Rights Disposition Agreement

Proposal submitted by 5:00PM PDT May 23, 2007