REQUEST FOR APPLICATIONS (RFA)

Life Science Investment Fund (LSIF)

Purpose:

The Life Science Investment Fund (LSIF) exists to meet the needs of Maryland companies developing products addressing human health that require approval from the U.S. Food and Drug Administration (FDA) for commercialization. While addressing significant societal and economic needs, these companies are burdened with long, complicated commercialization pathways that require multiple investments over a long period of time to get a product to market. The LSIF program helps to move products along this pathway by making investments that will enable companies to reach critical milestones early in their product development efforts, to increase the company's valuation, and to better position the company for follow-on investment, product commercialization, and job creation.

Eligibility:

A company is eligible for LSIF investment if it meets all of the following criteria:

(i) The company must be a for-profit entity located in Maryland with fewer than 16 FTE (Full-Time Equivalent) employees (i.e., a majority of its employees must work in Maryland and the company's proposed project must have the potential to lead to future growth of the company within the State); **AND**

(ii) The company is pre-revenue **OR** has received less than an aggregate of $1,000,000 in equity investments from 'Accredited' investors (as defined in Rule 501 Reg. D); **AND**

(iii) The company is developing a product (i) that requires FDA approval through the New Drug Application (NDA) or Biologic License Application (BLA) pathway, e.g., drugs, vaccines, biologics, etc., **OR** (ii) that is defined by the FDA as a Class II or Class III medical device requiring approval through the 510(k) or Pre-Market Approval (PMA) pathways, e.g., medical devices, diagnostics, etc. (hereinafter a "Medical Product").

It is expected that the applicant has initiated preliminary discussions with the FDA prior to submitting an LSIF application, and that the product development proposed is consistent with FDA recommendations.

Companies developing health-IT, EMR/EHR, Research tools or other life science related products that do not require FDA approval for commercialization are not eligible for this funding mechanism.

Investment Amount:

TEDCO will make investments of up to $200,000 for a period of 1 year through the LSIF program to support milestone-based projects that advance a Medical Product toward commercialization (an "Investment"). TEDCO plans to make 5 – 6 Investments per year or 2 – 3 in each of two review cycles.

Due to the high demand for the LSIF program and the limited funding available, the program is highly competitive. Companies early in the development of their Medical Products are encouraged to first apply for TEDCO's Technology Commercialization Fund [http://tedco.md/program/technology-commercialization-fund-tcf/]. Completion of a project through this program or other programs including the Maryland Industrial Partnerships Program [http://www.mips.umd.edu/], Small Business Innovation Research (SBIR)/Small Business Technology Transfer Research (STTR) [http://www.sbir.gov], or similar programs will likely position an applicant to better compete for a LSIF Investment.

Investment Mechanism:

Investments through the LSIF program are made in the form of a five-year, convertible note to the company. Interest will accrue on the note at a rate of 8% per annum. In the event that the company receives an aggregate outside investment of $500,000 or more prior to the maturity date of the note, or in the event of another sale of substantial assets or equity (i.e., an acquisition), TEDCO may, at its sole option, call the note or convert the principal and interest due on the note to equity on the same terms and conditions received by the most recent investors (See Closing Process section for more detail).

Company Match Requirement

The applicant company must provide a 50% match to TEDCO's Investment in support of the proposed project. This match must be in the form of cash and must be included in the project budget (See Budget and Budget Justification section).

Applying for a LSIF Investment:

There are no deadlines for application. Applications for LSIF investment can be submitted at any time through TEDCO's on-line application management system ("TEDCO Web Portal"), which can be accessed at: tedco.md/apply. Prior to submitting an application through the TEDCO Web Portal, companies must set-up an account in the system. Applicants are encouraged to create an account and to start uploading their applications well before the deadline to ensure that

they are familiar with the system. The full review cycle takes approximately 90 days from date of submission.

Application Components:

There are two major components to the LSIF Application – the General Application Information and the Full Proposal. The General Application Information is entered directly into the on-line application submission system and includes:

- A proposed project title (15 words max.),
- An abstract of the proposal (300 words max.),
- A brief company description (50 words max.),
- The total budget (direct and indirect costs) requested for the proposed project,
- An indication of whether the application is new or is revised/(resubmitted),
- Number of full-time employees,
- Third party funds received to date,
- Last year's revenue,
- FDA pre-submission meeting status
- List 3 project milestones (or groups of milestones) (200 words max.),
- How will the cash match requirement be met? (50 words max.)

The Full Proposal must be uploaded ***as a single document in Adobe PDF format*** and it must adhere to the guidelines described below. A project budget for the Investment must be included in the Full Proposal. See Exhibit A for an example of a budget for the Investment with proper classifications. The maximum file size for the Full Proposal is five megabytes (5120KB).

Full Proposal Guidelines:

The Full Proposal may not be more than 15 pages (one-sided) in length, including References, Pro Forma Financials, support letters, and other items submitted as part of the appendix. Proposals exceeding this 15 page limit will be rejected for non-compliance. All materials that the applicant wants to be considered by the review committee must be submitted in the Full Proposal within the page limit. No other document will be considered.

Please note that the historical financials and a resubmission summary (as applicable) are the only two items that are excluded from this 15-page limit.

The Full Proposal should have at least **one inch margins** and a **12 point font**, and each page must be **numbered**. The 12 point font requirement does not apply to figures/graphs/charts; however, they must be sufficiently large to be legible. Applications not meeting these requirements will be rejected and returned after the initial Compliance Review (see Review Process).

In drafting the Full Proposal, applicants should understand that most LSIF reviewers have relevant technical and/or business backgrounds but might not be well-versed in the applicant's specific scientific discipline; therefore, sufficient background information should be included so the reviewers can understand the relevance of the technical innovation associated with the Medical Product within the target markets. Conversely, any technical description should also be sufficient for someone substantially trained in the specific field to fully assess the merits of the technology relative to competing technologies within the target markets.

The Full Proposal should contain the following sections:

Header Information:

The first page of the Full Proposal must include the **project title**, the **name of the** applicant **company, and the name of the company's official contact person with their phone number, e-mail address and company (or official contact person's) address** at the top of the page. This information should match the information included in the General Application Information on the TEDCO Web Portal.

Abstract:

A brief description of the company and its technology (about one paragraph) should be included as an abstract. The abstract should be **non-proprietary** in nature. TEDCO will use this abstract during its due diligence process. In the event that TEDCO makes an investment in the applicant's company, TEDCO will use the abstract publicly on its website and in other capacities. This section may use the same text as the abstract required for the General Application Information.

The Header and the Abstract should not extend beyond the first page of the Full Proposal.

Business Opportunity:

This section should describe the business opportunity that the applicant is addressing including a succinct description of the problem, identification of the customer segment and value proposition of the solution. The applicant should also provide sufficient background to describe the origin of the problem or opportunity, how the demand is currently being addressed, and why the currently available products or services are inadequate to meet the demand.

Product or Service Description:

The applicant should describe its company's product or service and how it will address the problem or opportunity, and therefore, meet the demand described in the previous section. The project description should include:

- A Target Product Profile for the candidate. Include, where appropriate, (a) a description of the technology; (b) novelty and significance; (c) indication(s); (d) activity and efficacy endpoint (in patients); (e) safety; (f) route; (g) regimen; (h) risk versus benefit and (i) clinical competitiveness.
- The Technology Development Status, with a description of the studies completed and the conclusions derived. Include preliminary data or other results suggesting that the Technology is likely to work as predicted should be included.
- Benefit of the technology over any directly or indirectly competing technologies that might be described in the technical literature or included in products that are already on the market.
- A brief overview of Intellectual Property (IP) secured for the Technology, the IP landscape and strategies for strengthening the Technology's intellectual property portfolio. If the technology is owned by another party (e.g., a university, federal laboratory, or another company) and licensed to the applicant company, include a brief description of the license terms, the name of the licensor, and the effective date of the license.
- A description of the FDA regulatory pathway and justification for the regulatory strategy proposed, including recommendations, if any, from the FDA.
- A clear product development pathway that addresses a strong regulatory and reimbursement strategy should be described.

Applicants are encouraged to include diagrams, illustrations, photos, or other means to support written descriptions of the technology or the products being developed.

Market Analysis & Marketing:

The applicant should demonstrate that they have a clear understanding of the market for their products or services. The proposal should:

- Describe the general market size and general market trends. Market segmentation analysis should be included with initial and secondary markets identified, market sizes and a justification for pursuing these market segments. The applicant should provide appropriate source references for any data provided.
- Describe how these products will solve a problem in the market and describe the overall importance of solving that problem.
- Provide the value proposition (ideally in dollars) that these products will bring to customers – cost savings, time savings, convenience, improved outcomes, etc.
- Using tables, provide an analysis of competitive products, advantages and barriers to entry for new products.

- Describe a compelling revenue model that will lead to profitability. The model should include price points with a proper justification that takes into consideration gross margins. The applicant should also include a viable reimbursement strategy for their medical product.
- Describe the company's marketing and sales strategy, including manufacturing and distribution channels as well as potential partnerships, if any, to bring the product to market

Business Operations:

This section should describe key aspects of the company operations, including:

- Describe the anticipated general operations of the company and an operational growth plan that describes how the company's operations will change over the course of the next five years. Any relevant regulatory and compliance hurdles should also be addressed.
- A summary of the management team and their qualifications should be included with an explanation of how these qualifications enable the team to execute its operational plan. A description of advisors and their level of commitment to the company should also be included. The applicant should describe any gaps in needed skills and describe how these gaps will be overcome.
- Describe the financing required to develop its product or service, to take it to market, and to generate revenues and profits. The financing required should be consistent with the product development and operational plans referenced above. A milestone-based strategy for obtaining the necessary financing should be included with a rationale for the proposed sources of financing. The applicant should describe their strategy for becoming profitable and getting to an exit, if applicable, including potential exit partners, rationale, and comparable deals.
- All applicants should provide a summary 5 year pro forma profit and loss statement (in the format provided in Exhibit B). The pro forma statement should start with the current year. For applicant companies in business more than one year, the companies should also provide detailed historical financial statements for 3 years or, if the company is less than three years old, for the life of the company. Detailed historical financial statements (Income Statement, Balance Sheet, and Cash Flow Statement) should be included as supplemental materials. The applicant should provide a brief, narrative description of the financials to include any relevant information for the historical data, if applicable, and any general assumptions for the pro forma statements and their rationale.
- Provide a summary of funding (e.g., seed grants, SBIR/STTR, Angel/VC) to date.

Project Plan and Milestones (for the LSIF Investment):

The Project Plan should include,

- A clear description of the proposed technology with relevant preliminary data,
- A discussion of how this project will increase the company's valuation and ability to obtain follow-on funding,
- A justification for how the anticipated results will advance the company's products and services for commercialization,
- A justification for how the product development milestones specifically address FDA approval guidelines,
- A clear description of three major technical milestones or three major groups of technical milestones. **For each milestone, please indicate the total amount being requested from TEDCO, description of work and the timeline for deliverables.**
- Anticipated product development risks and mitigation plans.

Projects are limited to a maximum duration of 12 months. Applicants should be sure that upon execution of an investment agreement that they have the resources to complete the proposed project within the 12 month timeline.

Projects involving the use of laboratory animals or human subjects must comply with all applicable regulations and guidelines including approval from an Institutional Animal Care and Use Committee (IACUC) or Institutional Review Board (IRB), respectively, as applicable. Evidence of such approvals will be required before an investment will be made.

Project Team:

A list of project personnel (company's staff and project collaborators) should be provided with a brief summary of their background, their position with the applicant company, and their role in the proposed project. The applicant should justify that the project team is qualified to carry out the proposed work.

Budget & Budget Justification:

A detailed budget for the proposed project must be included. A sample of a project budget is included in Exhibit A (pg.14) of this RFA. A justification for each line item in the budget should be included in a narrative form. In addition to the line item descriptions, the budget should have three additional columns: the TEDCO Budget (for funds provided by TEDCO through the Investment), the Company Match (for company matching funds, as described below), and the Total Project Budget (the total of the first two columns). See Exhibit A for an example.

The LSIF program requires a minimum 50% match for each TEDCO dollar invested in the First Investment. This match must be provided in the form of cash. The Company Match description must include information on the source and availability of the matching funds.

Please note- It is TEDCO policy that 80% of the TEDCO Investment and the total project costs must be directed to product development activities (i.e., direct costs). All subcontracted funds are considered direct costs regardless of the subcontractor's indirect costs charged to the project. The budget justification should include total hours committed to the proposed project, the cost/hour for each individual included in the budget, and the associated fringe benefits. TEDCO will also not accept hourly rates above $60 per hour ($125,000 per year) for company's staff and management time. Costs for external contractors and consultants are specifically excluded from this constraint. Equipment and materials related to the proposed project may be included in the budget. Travel costs may not be included unless justified as critical to completion of the proposed project.

Attachments to the Full Proposal

Attachments to the Full Proposal should be limited to the components described below. Any additional documents (e.g., business plans, technology descriptions, publications, etc.) will not be considered by the reviewers and should not be included.

References

The applicant should include a list of citations for any relevant references. Please be aware that references are **included** in the page count for the application.

Support Letters:

Applicants are encouraged to consider opportunities for collaboration with Maryland's universities and federal laboratories. Letters of support from potential partners, customers or users of the applicant's product may be included in the application and often strengthen an application. Please be aware that such letters are **included** in the page count for the application.

Review Process:

All completed LSIF applications received through TEDCO Web Portal by the Application Deadline will be reviewed in the subsequent review cycle. The review process for each cycle comprises four stages: Compliance Review, Preliminary Review, Final Review, and Final Decision. Applications may be rejected at any stage of the process.

Compliance Review

All LSIF applications will undergo a compliance review to ensure that the applicant has adhered to all of the requirements of this RFA. Applications not meeting these requirements, which include meeting the eligibility requirements, conforming to format requirements (length, format, page numbering, etc.), and other requirements, will be rejected.

Applications rejected at this stage of the review may be corrected and resubmitted in the next review cycle.

Preliminary Review

LSIF applications passing the Compliance Review will undergo an in-depth preliminary review by the Review Committee, which comprises of TEDCO staff and others from the business and investment community. Based on the strength of the Full Proposal, the Review Committee will recommend applicants to be invited for a Final Review presentation.

Applicants not selected for the Final Review, will receive feedback from the reviewers so proposals can be improved and resubmitted in the next round. TEDCO provides this information to help the applicants improve their products, business plans, and proposals.

Applications rejected at this stage of the review may be modified and resubmitted in a subsequent review cycle provided the applicant can sufficiently address all of the reviewers' concerns.

Final Review

The applicants selected in the Preliminary Review will be invited to give a brief 15 minute presentation to the Review Committee, followed by approximately 30 minutes of questions by the reviewers. The company will then be asked to leave so the review committee can discuss the application. Based on all information gathered throughout the review cycle, the Review Committee will make a final recommendation.

There may be a follow-up due diligence after the presentation. Periodically, the committee may recommend a technical review or a reference check based on the information provided. These additional due diligence will be performed on case-by-case basis as deemed necessary by the Review Committee.

Applications rejected at this stage of the review may be modified and resubmitted in a subsequent review cycle provided the applicant can sufficiently address all of the reviewers' concerns.

Review committee meetings will generally be held on the second Thursday of the month following the month of the submission deadline (approximately 8 weeks following the submission deadline) at the TEDCO offices between 9:00 am and 5:00 pm. All applicants should hold this time on their calendars in the event they are invited to present to the committee.

Final Decision:

All review committee recommendations will be taken to TEDCO's President for a final review and decision. Once a final decision is made, the applicant will be notified. Actual Investments will be made subject to a formal Closing Process comprising the execution of an investment agreement, as further described below.

Review Criteria:

The Review Committee will make its recommendations using the following general criteria:

- Completeness of RFA requirements
- Technology, competitive advantage, and rationality of project milestones to meet regulatory requirements
- Market need and strength of the commercialization plan
- Business team and success in attracting third party funding
- Investment and growth opportunity

Closing Process:

Once an application is approved for investment, the program manager will notify the applicant. The applicant will then have up to ninety days to execute the funding agreement and effect a Closing on an Investment. The Closing will be managed by TEDCO's appointed counsel. The applicant will be asked to provide a list of documents for the Closing including the following:

- A certificate of good standing from the Maryland Department of Assessments and Taxation dated no more than 30 days prior to the Closing Date AND from the State in which the corporation is organized, if other than Maryland;
- A copy of its Articles of Incorporation & Bylaws (for corporations) or Articles of Organization & Operating Agreement (for LLCs), as applicable;
- The Board of Directors Resolution authorizing execution of the Convertible Note Purchase Agreement (corporations only);
- A copy of the company's most recent financial statements;

- Evidence of Institutional Review Board (IRB) and Institutional Animal Care and Use Committee (IACUC) approvals, as applicable, for research projects involving human or animal subjects; and
- Information necessary to complete a Convertible Note Purchase Agreement and its Exhibits.

In addition to the closing documents, the applicant will receive a copy of TEDCO's Convertible Note Purchase Agreement and Exhibits, which will be signed at the time of the Closing. The Closing will occur at TEDCO's offices in Columbia, Maryland at a date and time that is mutually acceptable to the parties. The Closing must occur within ninety days of the date of the award notification. The Convertible Note Purchase Agreement and Exhibits provide additional details regarding the company's payback requirements, conversion triggers, and other information. A copy of the document is posted under 'Downloads' on TEDCO's website at: http://tedco.md/program/life-science-investment-fund-LSIF/ .

Investment Payments:

Upon successful completion of the Closing, the applicant will receive a check for 50% of the total Investment. Subsequent distributions of funds will be made in a minimum of two tranches; 25% upon submission and approval of a Mid-term Report, and 25% of the total investment upon completion of a final report and close-out meeting. Each tranche of funding will follow TEDCO's approval of a project status report submitted to TEDCO and the applicant's achievement of designated project milestones. All Investments are subject to the availability of funds.

Reporting Requirements:

As a condition of accepting an investment from TEDCO, the applicant will be required to submit periodic reports, as follows:

Financial Reports. *For as long as TEDCO holds a note or any securities in applicant's company*, the company shall provide TEDCO with quarterly financial statements, which include an Income Statement, Balance Sheet, and Cash Flows Statement. The financial statements for the first quarter of each calendar year shall include complete State and federal income and payroll tax returns.

Milestone Reports.
A Mid-Project Report will be due approximately 6 months from executed start date and should be provided as a written as well as in-person presentation at TEDCO's offices.
The written report (5 page-limit) must include a description of project activities and results to date, the progress toward meeting mid-term milestones, an accounting of expenditures

charged to the award, and details on the proposed Commercialization Plan and budget, along with an invoice requesting the next tranche of payment for the LSIF award.
Dates for the meeting will be provided approximately a month ahead of the meeting and TEDCO will request copies of the presentation slides in advance.

A Final Project Report (written only; 5 –page limit) will be due within 90 days of completion of the project. The report will describe the company's accomplishments related to the proposed specific aims, the achievement of any designated project milestones, any intellectual property created or improved during the project, impact on FDA regulatory pathway, fundraising success and other commercialization activities related to the project, and company's employment data (Full-time equivalents and total payroll) at the completion of the project.

Annual Economic Development Reports. *Beginning the first April following completion of the funded project and until the last to occur of (i) five years following completion of the funded project, or (ii) until TEDCO no longer holds a note or any securities in company*, the company will provide to TEDCO an Annual Economic Development Report. The report will include State and federal income and payroll tax returns, an employee census reflecting the current number of full-time equivalent employees who are Maryland residents, and such other information which TEDCO may reasonably request from time to time.

All reports provided to TEDCO will be held in confidence to the extent reasonably permitted by Title 10, Subtitle 6 of State Government Article of the Annotated Code of Maryland. Confidential reports should be designated as "Business Proprietary".

Portfolio Manager:

All companies in which TEDCO makes an investment through its LSIF program will be assigned a Portfolio Manager. The Portfolio Manager will be the company's contact person for TEDCO. The Portfolio Manager's role is to provide general assistance and mentorship to the company, as needed and subject to the availability of resources, and to help the company take advantage of the many training, networking, and other opportunities available to TEDCO's portfolio companies.

Program Manager Information:

Inquiries regarding the LSIF program should be directed to:

Arti Santhanam
asanthanam@tedco.md
410-715-4182

Exhibit A – LSIF Budget Example

iCure4All Therapeutics

	TEDCO Funding	Company Match	Total Project Costs
Personnel – Salaries			
H. Lacks ($100K Annual Salary/20% Commitment)	10,000	10,000	20,000
L. Pasteur ($80K Annual Salary/10% Commitment)	8,000	0	8,000
C. Darwin ($20K Annual Salary/50% Commitment)	10,000	0	10,000
Total Personnel - Salaries Cost	**28,000**	**10,000**	**38,000**
Personnel - Fringe Benefits			
H. Lacks	3,000	3,000	6,000
L. Pasteur	2,400	0	2,400
C. Darwin	3,000	3,000	3,000
Total Personnel - Fringe Benefits	**8,400**	**6,000**	**14,400**
Equipment			
Centrifuge	0	15,000	15,000
ThermoCycler	5,000	0	5,000
Computer Software	2,000	0	2,000
Total Equipment Costs	**7,000**	**15,000**	**22,000**
Materials & Supplies			
Reagents	23,000	11,000	24,000
Cell lines	13,600	11,000	24,600
Animal Study	30,000	12,000	42,000
Total Materials & Supplies	**66,600**	**34,000**	**100,600**
Other Direct Costs			
CMO Consultant	15,000	10,000	25,000
GLP/cGMP Product development	62,000	15,000	77,000
Total Other Direct Costs	**77,000**	**25,000**	**102,000**
Indirect Costs			
Accounting, Rent , Patent fees etc	13,000	10,000	23,000
Total Other Indirect Costs	**13,000**	**10,000**	**23,000**
TOTAL PROJECT BUDGET	**200,000**	**100,000**	**300,000**

Exhibit B – Pro Forma Example

Pro-Forma P&L-Cash Forecast

	Year 1	Year 2	Year 3	Year4	Year 5
Revenue[1]	0	0	0	0	0
Cost of Sales[2]	0	0	0	0	0
Gross Margin $[3]	0	0	0	0	0
Gross Margin %[4]	0	0	0	0	0
SG&A[5]	0	0	0	0	0
R&D[6]	0	0	0	0	0
Other[7]	0	0	0	0	0
Total Operating Expense[8]	0	0	0	0	0
Operating Earnings[9]	0	0	0	0	0
Capital Spending[10]	0	0	0	0	0
Investment Funds Received[11]	0	0	0	0	0
Cash at beginning of yr[12]	0	0	0	0	0
Cash at end of year[13]	0	0	0	0	0

Note: Do not include interest expenses, taxes, depreciation or amortization.

Notes:

1. Report all revenues from sales of products and services; include any licensing fees or royalties received. Do not include Investment Funds Received.
2. Report all costs associated with the revenues. Include cost to build and deliver the product or service. Also include royalties paid and fees paid to distributors.
3. Gross Margin = Revenue minus Cost of Sales
4. Gross Margin % = Gross Margin divided by Revenue and expressed as a %.
5. Report all expenses associated with sales team, marketing team and administration, including rents, insurance, utilities, salaries and benefits of teams, trade shows, supplies, etc.
6. Report all expenses associated with product development, team salaries, benefits, contract R&D etc.
7. Any other expenses not included in SG&A or R&D.
8. Total of SG&A, R&D, and Other expenses.
9. Operating Earnings = Gross Margin minus Total Operating Expense
10. Report purchases of assets (e.g., buildings, equipment, vehicles, lab equipment) costing over $1,000 per item. Items costing less than $1,000 (e.g., computers) should be included as an expense in SG&A, R&D, or Other.
11. Report any grants and/or investment funds received. These amounts should not be included as Revenue.
12. Report Cash on hand at beginning of year. This should equal the Cash on hand at end of previous year.
13. Cash at end of year equals Cash at beginning of year plus Operating Earnings plus Investment Funds Received minus Capital Spending.