Financial Assistance

# Life Sciences Initiative Program Guidelines



## State of New York Andrew M. Cuomo, Governor

## **Empire State Development**

As of January 24, 2018

#### LIFE SCIENCES INITIATIVE PROGRAM

#### **Statutory Authority**

Section 16-aa of the New York State Urban Development Corporation Act, Chapter 174 of the Laws of 1968, as amended

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#### **Life Sciences Initiatives Program Guidelines**

#### Overview

#### **Statutory Authority**

Section 16-aa of the New York State Urban Development Corporation Act, Section 1 of Chapter 174 of the Laws of 1968, as amended, entitled "Life Sciences Initiatives Program," as added by Part TT of Chapter 58 of the Laws of 2017.

#### **Program Background**

The Life Sciences Initiatives Program (the "Program") is established for the purpose of nurturing, growing and retaining new life sciences companies in New York State, attracting existing companies from outside New York State, promoting critical public and private sector investment in emerging life sciences fields in the State, creating and expanding life sciences related businesses and employment, and developing and enhancing New York State's life sciences ecosystem. It is intended to operate in areas identified by the New York State Urban Development Corporation (the "Corporation") as having significant potential for economic growth in New York, or in which the application of new life sciences technologies could significantly enhance the productivity and stability of New York businesses. The Corporation will endeavor, through its life sciences programs, to provide benefits, to the extent practicable, taking into consideration regional balance, anticipated job creation and retention, and economic development benefits.

#### **Program Assistance**

The first component of this Program, Capital Assistance, is a critical component to this Initiative as it endeavors to attract new life sciences technologies to the State, promote critical public and private sector investment in emerging life sciences fields in the State and create and expand life sciences related businesses and employment throughout the State. This program includes securing established accelerator firms to facilitate the creation and implementation of a statewide Bio-accelerator initiative. The Bio-accelerator will provide scientists with entrepreneurial training, access to venture capital and a network of mentors to help expedite the translation of their scientific insights into commercially viable products. It also includes the establishment of a collaboration among three upstate research institutions to accelerate the pathway from discovery research to commercialization.

The second component of this Program, the New York Fund for Innovation In Research and Scientific Talent ("NYFIRST"), is intended to encourage the recruitment and retention of

exceptional life science researchers and world-class talent at the state's medical schools to accelerate translational research by supporting the establishment or upgrading of their laboratories.

The Corporation anticipates other elements of the program to include support for venture investments.

#### **Program Administration**

The Corporation may allocate funds from the Program to cover the Corporation's administrative costs associated with the Program.

#### **Approval of Projects**

If the proposal satisfies the applicable requirements and Program funding is available, the proposal may be presented to the Corporation's Directors or President/Chief Executive Officer for consideration and approval in accordance with applicable law and regulations. The Directors normally meet once a month. If the project is approved for funding and if it involves the acquisition, construction, reconstruction, rehabilitation, alteration or improvement of any property, the Corporation will schedule a public hearing in accordance with the Act and will take such further action as may be required by the Act and applicable law and regulations. After approval by the Corporation and a public hearing, if required, the project may then be reviewed by the State Public Authorities Control Board ("PACB"), which also generally meets once a month, in accordance with PACB requirements and policies. Following Directors' approval, and PACB approval, if required, documentation will be prepared by the Corporation. Notwithstanding the foregoing, no Program project shall be funded if sufficient Program monies are not received by the Corporation for such project.

Notwithstanding any of the terms set out in these guidelines below, the President and CEO of the Corporation reserves the right to waive one or more of the provisions of these guidelines at his sole discretion.

#### I. Capital Assistance Program

#### A. <u>Definitions</u>

- (1) "Life Sciences" shall mean advanced and applied sciences that expand the understanding of human physiology and have the potential to lead to medical advances or therapeutic applications including, but not limited to, academic medical centers, agricultural biotechnology, biogenerics, bioinformatics, biomedical engineering, biopharmaceuticals, biotechnology, chemical synthesis, chemistry technology, diagnostics, genomics, image analysis, marine biology, marine technology, medical devices, nanotechnology, natural product pharmaceuticals, proteomics, regenerative medicine, RNA interference, stem cell research, clinical trials, including, but not limited to, neurological clinical trials and veterinary science.
- (2) "Life Sciences Entity" shall mean a non-retail business corporation, partnership, firm, or any other non-retail business entity, not for profit organization or academic medical center, unincorporated association, or other entity engaged in life sciences research, development, manufacturing or commercialization.
- (3) "Corporation" shall mean the New York State Urban Development Corporation doing business as Empire State Development.
- (4) "Life Sciences Economic Development Benefits" means the creation, expansion, enhancement or acceleration of life sciences programs throughout the State that leads to:
  - a. the commercialization of life sciences in New York State;
  - b. the creation or retention of jobs in the life sciences industry employing full time permanent employees;
  - c. the promotion of the life science ecosystem within a region of the State;
  - d. new patents in life science;
  - e. additional commercial laboratory space; or
  - f. additional venture capital money for Life Sciences Entities in New York State.
- (5) "Evaluation Criteria" shall mean the criteria set forth in paragraph D of this Section I to be applied by the Corporation in evaluating applications for Capital Assistance Program funding.
- (6) "Full-Time Permanent Employee" shall mean (i) a full-time, permanent, privatesector employee on a Life Sciences Entity's payroll, who has worked at the Project Location for a minimum of 35 hours per week for not less than four consecutive

weeks and who is entitled to receive the usual and customary fringe benefits extended by the entity to other employees with comparable rank and duties; or (ii) two part-time, permanent, private-sector employees on the Life Sciences Entity's payroll, who have worked at the project location for a combined minimum of 35 hours per week for not less than four consecutive weeks and who are entitled to receive the usual and customary fringe benefits extended by the entity to other employees with comparable rank and duties.

#### **B.** Available Capital Assistance

The Capital Assistance Program makes available financial assistance in the form of grants or loans (secured or unsecured), or a combination of such assistance, or contracts for services, in the Corporation's discretion, for use by Life Sciences Entities for Eligible Uses as set forth in paragraph E of this Section I.

#### C. Application Process

- (1) Applications from Life Sciences Entities will be accepted on a rolling basis throughout the year. Life Sciences Entities requesting Capital Assistance shall provide information about the project and the applicant, as applicable, in a form provided by, or otherwise acceptable to, the Corporation, including without limitation, the following:
  - a. a description of the project or activity, including information indicating how the proposed project or activity will create, expand, enhance or accelerate the commercial life science industry through programs, research, job creation and retention within New York state and will result in the other Life Sciences Economic Development Benefits as defined in paragraph A (4) of this Section I;
  - b. the number and amount of other funding, including federal, that the applicant has applied for, is eligible for or has received for the same initiative;
  - c. the number of jobs in the life sciences industry employing Full Time Permanent Employees to be created or retained as a result of the proposed project or activity, the titles or classifications of such jobs and the average annual salaries associated with each;
  - d. information about the applicant, including but not limited to, its history, ownership, size, primary products offered or services rendered, major customers, its market and marketing strategy;
  - e. information about the proposed project financing including, but not limited to, total project cost, total Program assistance requested, a budget breakdown of the sources and proposed uses of all funding, a description of the need for the requested Program funding and justification for the amount requested

- f. a description of how the project will be implemented, including a project schedule, and the current status of the project;
- g. anticipated project results; and
- h. information with respect to the site of the project and the impact, if any, on the environment and any landmark or historic properties.
- (2) Depending on the nature of the project or activity (such as acquisition of machinery and equipment; acquisition, construction or renovation of property, etc.) and the type of assistance requested, Life Science Entities may be required to provide other information about the project, including some or all of the following, as may be appropriate:
  - a. a complete set of financial statements for at least the three preceding fiscal years, operating pro formas going forward three years, and current financial statements for any proposed guarantors;
  - b. a list of proposed collateral, with any available appraisals;
  - c. resumes of principal officers and a list of owners, shareholders, or partners;
  - d. a copy of any related real estate purchase option or contract for sale;
  - e. a legal description and survey of the property;
  - f. a construction-to-occupancy schedule; and
  - g. copies of any preliminary architectural drawings, scope of work, cost estimates and schematics.
- (3) Applications may include a request for funding for single or multiple Life Sciences projects or activities.
- (4) Upon receipt of the application, the Corporation shall review the application for eligibility, completeness, and conformance with the applicable requirements of these guidelines. Applications shall be processed in full compliance with the applicable provisions of section 16-aa of the Urban Development Corporation Act.
- (5) The Corporation may issue a request for proposals for contracts for services in lieu of an application where it deems it appropriate. Such request for proposals will set forth eligibility guidelines, which may differ from those contained herein.

#### D. Evaluation Criteria

The Corporation shall evaluate applications for Capital Assistance in accordance with the following criteria as applicable:

(1) the financial condition of the entity undertaking the project, including its profitability or potential to generate profits; liquidity; ability to service debt and its leverage ratio;

- (2) management experience, ability and relevant knowledge and the relevant entity's general ability to carry out the project;
- (3) satisfactory credit references;
- (4) the absence of state or local tax judgments; provided however, in the case of a tax certiorari proceeding a life sciences entity would not be considered in arrears until a final decision is made with respect to such proceeding;
- (5) whether the applicant clearly demonstrates how the proposal will result in Life Sciences Economic Development Benefits and the likelihood that the project will result in Life Sciences Economic Development Benefits to the State;
- (6) the availability of other sources of funding, including offers of assistance from locations outside of the State, including the federal government, and the amount of private financing leveraged by Program funds; and
- (7) The Corporation may consider the terms of any economic development assistance available as an incentive for the location of the proposed project outside the State.

#### E. Eligible Uses

Capital Assistance Program funds may be used for:

- (1) new construction, renovation or leasehold improvements;
- (2) the acquisition or leasing of land, buildings, machinery and equipment;
- (3) working capital, including, without limitation, workforce development;
- (4) feasibility or planning studies related to the development of commercial life sciences in the State; and
- (5) contracts for services to support New York life sciences' ecosystem.

#### F. Ineligible Uses

Institutions that are exclusively health care providers and/or requests for the purchase of equipment associated with standard healthcare delivery are not eligible for Capital Assistance Program funding.

#### G. Reporting requirements

Applicants shall submit an annual report satisfactory to the Corporation on the operation and accomplishments of the project including, without limitation, a description of the activities undertaken, the economic impact of the project, the number and amount of other sources of funding for the project including federal funds, jobs employing Full Time Permanent Employees created and retained, and the average salary of such jobs.

### II. New York Fund for Innovation in Research and Scientific Talent ("NYFIRST") Program

#### A. Authority and Purpose

The New York State Urban Development Corporation hereby establishes the New York Fund for Innovation in Research and Scientific Talent ("NYFIRST") Program as a component of the Life Sciences Initiatives Program. NY First is intended to encourage the recruitment and retention of prominent life science researchers and world-class talent at the state's medical schools to accelerate Translational Research by supporting the establishment or upgrading of their laboratories. These individuals will demonstrate proven scientific accomplishments and a history of entrepreneurship and grant funding.

#### The NY First Program is intended to:

- (1) increase the number of patent applications and patentable discoveries at medical schools:
- (2) increase the number of patents licensed from these schools; and
- (3) increase the recruitment/retention rate of medical school faculty focused on Translational Research.

#### **B.** Definitions

- (1) "Applicant" or "Eligible Applicant" shall mean a medical school within the State which applies for NYFIRST assistance.
- (2) "Corporation" or "ESD" shall mean the New York State Urban Development Corporation doing business as Empire State Development.
- (3) "Eligible Project" shall mean a project that meets the Eligibility Criteria set forth in paragraph D of Section II of these Guidelines.
- (4) "Federal Assistance" shall mean funds available, other than by loan, from the federal government, either directly, or through allocation by the State for program purposes pursuant to any federal law or program.
- (5) "Life Sciences Economic Development Benefits" shall mean the creation, expansion, enhancement or acceleration of life sciences programs throughout the State that leads to:
  - a. the commercialization of life sciences in New York State;
  - b. the creation or retention of jobs in the life sciences industry employing full time permanent employees;

- c. the promotion of the life science ecosystem within a region of the State;
- d. new patents in life science;
- e. additional commercial laboratory space; or
- f. additional venture capital money for Life Sciences Entities in New York State.
- (6) "Match," "Matching Share," or "Matching Funds" shall mean that portion of the total cost of a project which the grantee must provide, pursuant to Paragraph C (2) of Section II of these Guidelines.
- (7) "Medical School" shall mean a public or private medical school in New York State that is accredited by the liaison committee on medical education or the commission on osteopathic college accreditation, or such medical school together with an affiliated entity, located in New York State.
- (8) "Principal Investigator" shall mean the holder of an independent grant administered by a university and the lead researcher for the grant project who makes the final decisions and supervises funding and expenditures on a given research project.
- (9) "Project" shall mean the scope of activities supported by a NY First Program grant and the grantee's Matching Share.
- (10) "Reimbursable Expenses" shall mean approved costs incurred by the NY First grantee to perform the project. Reimbursable expenses must be incurred during the grant term. An item included as a Match cannot also be included as a reimbursable expense.
- (11) "Translational Research" shall mean research that applies, or translates, existing knowledge about biology into techniques and tools for treating human disease: translational research takes knowledge from bench to bedside. This differs from academic research, which is focused on careful study of a subject or field to discover facts or principles that are added to the general body of scientific knowledge.

#### C. Available Program Assistance

- (1) The NYFIRST Program makes available financial assistance in the form of grants to Applicants for Eligible Projects. The maximum grant amount for any Eligible Project is \$1 million.
- (2) Matching Funds. Grantees will be required to provide \$2 of Matching Funds for every \$1 of NY First Program assistance. The Match is a non-reimbursable

component of the project's total cost and is reflective of the grantee's long-term commitment to the project.

- a. The Match the grantee provides may be cash, including federal assistance, or in-kind services. If in-kind services, any Match item may be donated by the grantee or reflect the grantee's use for the project of such an item donated by a third party (such as industry or alumni/ae). However, no financial assistance made available to the grantee by the Corporation or any other New York state agency or public authority may be included as part of any Program grantee's Match. Nothing in this subdivision shall prohibit the State University of New York or the City University of New York from using a portion of their respective operating funds as Match.
- b. Items eligible to be approved are Matching Funds directly related to the purpose of the project including, but not limited to: compensation for a newly recruited faculty member meeting the eligibility criteria described in Paragraph D (3) of Section II of these Guidelines; financial support for research staff and graduate students who are members of the newly recruited faculty member's team; relocation expenses for the aforementioned faculty or associated staff; other expenses as are necessary for recruitment purposes; the cost of preparing and equipping a faculty member's work space; other capital expenses such as supplies; and the cost of new faculty lines in research areas to complement the recruited faculty member and his/her team.
- c. All Matching Funds must be expended during the Program grant term and generally on a pro rata basis with Program grant funding.
- d. All items identified as Matching Funds will be reviewed by the Corporation, which will approve such Matching Funds as the Corporation may determine, in its sole discretion, to be reasonable as to amount and relation to the Project.
- (3) Program grant funds will be disbursed on a semiannual reimbursement basis. Grantees shall submit quarterly invoices and supporting documentation satisfactory to the Corporation, as work is performed and costs incurred.

#### D. Eligibility Criteria

- (1) Program grants may be awarded to create new laboratory space or to upgrade existing laboratory space at recipient institutions to attract or retain Principal Investigator(s) to head such laboratories and engage in Translational Research.
- (2) ESD will make no more than one award per Applicant per year.
- (3) The scientific talent recruited or retained to head these laboratories must:
  - a. demonstrate a record of Translational Research with clear potential for commercialization;

- b. demonstrate that the research to be undertaken focuses on the development of an innovative solution for an identified healthcare-related problem, with the potential to result in significant Life Sciences Economic Development Benefits in New York State;
- c. demonstrate a history of entrepreneurship and funding;
- d. have sufficient funding to support the research project being undertaken by the Principal Investigator at the new or upgraded laboratories for three years;
- e. be tenured or be on a tenure track and provide sufficient documentation to ESD to corroborate such track:
- f. hire or retain (or cause to be hired or retained by the medical school) at least one scientist or doctoral student full-time (40hrs/week) or at least two scientists or doctoral students who each work a minimum of 20hrs/week; and
- g. be employed, or have been recently employed, by an institution or company outside New York State, or have a bona fide offer from an institution from another state that would lead him/her to leave New York State.
- (4) Projects seeking Program funding must be completed within no more than four years from commencement of the grant. The Corporation, in its sole discretion, may terminate the Program grant for any Eligible Project which does not adhere to the timelines established in the grant agreement or otherwise fails to demonstrate satisfactory performance.

#### E. Application Requirements, Process and Evaluation

- (1) On an application provided by ESD, the Applicant shall provide such information about the applicant and the project as ESD may require. The application shall highlight the unmet clinical need, market potential, and a clear path to market/clinical use. There are no restrictions in terms of therapeutic area of research. The completed application shall illustrate how the applicant has met the criteria established in Paragraph D (3) of Section II and include details regarding:
  - a. therapeutic need for the research, market size, and anticipated path to commercialization;
  - b. uniqueness of the research and competitive edge;
  - c. summary of supporting proof of concept data and other relevant research, publications;
  - d. proposed scope of work, timeline, and anticipated milestones toward commercialization;
  - e. intellectual property and patent considerations;
  - f. profile(s) of the recruited or retained Principal Investigator and proposed team members;
  - g. budget;
  - h. funding history; and

- i. documentation establishing that the term of employment between the institution (the grantee) and each participating recruited and/or retained faculty member is, at a minimum, for a period coextensive with the grant term;
- (2) The application must also be accompanied by:
  - a. assigned statement of support of the proposed project executed by the chief executive officer or dean of the medical school, and in a format approved by the Corporation, recommending the application to the Corporation and authorizing an official of the applicant to execute documents necessary for the project; and
  - b. such other information as the Corporation may require to implement this program.
- (3) To the extent practicable, ESD will attempt to make awards to as many medical schools as possible within the state, assuming equivalent qualifying evaluation scores and taking into consideration regional balance, anticipated job creation and retention, and economic development benefits.

#### F. Selection Criteria/Scoring

- (1) Applications will be evaluated on the criteria detailed in Paragraph E (1) of Section II on a scale of one to five, where:
  - "1" = does not meet qualification expectation
  - "3" = meets qualification expectations; and
  - "5" = exceeds qualification expectations.
- (2) Selection criteria will be weighted as follows:

Criteria Category	Weight
1. Unmet need	30%
2. Novelty & competitiveness of proposed solution	30%
3. Preliminary/supporting data	15%
4. Strength of intellectual property	15%
5. Feasibility of development timeline	10%

(3) The Corporation intends to make Program grant awards through a competitive grant solicitation to qualifying Applicants, once annually for up to three years or until the funds under this Program are fully committed.

#### G. Eligible Uses

- (1) Program grants must be used for capital expenses directly related to the project including but not limited to:
  - a. costs relating to the design, acquisition, construction, reconstruction and rehabilitation of laboratory space;
  - b. the purchase of equipment; and
  - c. other capitalizable expenses.
- (2) The Corporation may determine not to reimburse eligible expenses if the award recipient fails to maintain its required level of Match during a specific grant disbursement period.
- (3) Program grants shall not duplicate payments received, or receivable, from other sources.

#### **H.** Reporting Requirements

- (1) The Corporation is required by statute to submit to the Governor, the Temporary President of the New York State Senate, and the Speaker of the New York State Assembly an annual report on the operations and accomplishments of the Life Sciences Initiatives programs on or before October 1 annually. The report must include, but is not limited to, information and statistics detailing the economic impact of the activities undertaken with Program funds; the number and amount of federal funds procured after an investment of Program funds; jobs created and maintained after receipt of Program funds; and the average salaries of such jobs created and maintained.
- (2) The Corporation will establish periodic reporting requirements for Program grantees to provide information to the Corporation so that the Corporation may accomplish its statutory reporting obligations. These reporting obligations may extend beyond the completion of the project for a period of three years.
- (3) Failure by a grantee to provide the required information in a manner that is timely and otherwise satisfactory to the Corporation may subject the grant to full or partial recapture.