

Guidelines For
Financial Assistance

**Life Sciences
Initiative Program
Guidelines**



State of New York
Kathy Hochul, Governor

Empire State Development

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**

**Adopted July 27, 2017 and as amended January 24, 2018 and January 17, 2019,
Updated December 21, 2021**

TABLE OF CONTENTS

| SECTIONS | HEADINGS | PAGE #s |
|-----------------|---|----------------|
| | Overview – Life Sciences Initiative Program | 03-04 |
| I | Life Sciences Capital Assistance Program | 05-09 |
| II | New York Fund for Innovation in Research And Scientific Talent (“NYFIRST”) Program | 10-17 |

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.

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.

I. Capital Assistance Program

A. Definitions

- (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, biogenetics, 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 business corporation, partnership, firm, or any other entity engaged in life sciences research, development, manufacturing or commercialization or collaborating with entities 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 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 New York state 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. 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. The recruited or retained researchers will demonstrate proven scientific accomplishments and a history of entrepreneurship and grant funding. NYFIRST funds will be used to support the establishment or upgrading of laboratories for these researchers, for purchases of capital equipment and specialized supplies needed for their research and as working capital to cover costs of professional staff (including staff scientists, postdoctoral fellows, and technicians, but excluding the recruited researcher) critical to the proposed research.

The NYFIRST Program is intended to:

- (1) increase the number of patent applications and patentable discoveries at medical schools and the number of patents licensed from these schools;
- (2) increase the recruitment/retention rate of medical school faculty focused on Translational Research;
- (3) enhance and expand the expertise, qualifications, and capabilities residing within these institutions; and
- (4) increase federal and philanthropic funding, as well as venture capital funding, to medical schools awarded NYFIRST grants.

B. Definitions

- (1) "Applicant" or "Eligible Applicant" shall mean a medical school within the State that 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 lead 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 that 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 NYFIRST Program grant and the grantee’s Matching Share.
- (10) “Reimbursable Expenses” shall mean approved costs incurred by the NYFIRST 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) “Specialized Supplies” shall mean consumables, including but not limited to, antibodies, assay kits, proteins, reagents, enzymes, DNA/RNA and PCR products, nucleosides and nucleotides, specialized media, substrates and other bioproducts required to conduct the research specified.
- (12) “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 NYFIRST 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 provided by the grantee 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 the recruited Principal Investigator 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 Principal Investigator's team; relocation expenses for the aforementioned Principal Investigator or associated team; other expenses as are necessary for recruitment purposes; the cost of preparing and equipping work space for the Principal Investigator or associated team; other expenses required to conduct the relevant research undertaken by the Principal Investigator or associated team, such as laboratory supplies; and the cost of new faculty lines in research areas to complement the recruited Principal Investigator and his/her team.
 - c. All Matching Funds must be expended during the Program grant term and where practicable 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 an annual reimbursement basis. Grantees shall submit invoices once yearly with supporting documentation satisfactory to the Corporation, as work is performed and costs incurred.

D. Eligibility Criteria

- (1) Program grants are intended to encourage the recruitment and retention by the state's medical schools of exceptional life science researchers and world-class talent focused on accelerating Translational Research. NYFIRST grants may be used to support the establishment or upgrading of laboratories for these researchers, for purchases of capital equipment and Specialized Supplies needed for their research, and as working capital to cover costs of professional staff (including staff scientists, postdoctoral fellows, and technicians, but excluding the recruited Principal Investigator) critical to the proposed research.
- (2) ESD will make no more than one award per Applicant per application cycle.
- (3) The scientific talent recruited or retained as a Principal Investigator to head a laboratory 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, such as by patent applications, patent approvals and commercialization of research, and by success in obtaining funding;
 - d. have sufficient funding to support the project being undertaken 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 two scientists or doctoral students/post-doctoral fellows full-time (40hrs/week) or at least four scientists or doctoral students/post-doctoral fellows who each work a minimum of 20hrs/week; the scientists and post-doctoral fellows must be recruited from outside of New York State, and
 - g. be employed by an institution or company outside New York State at the time an offer of employment is made by the Applicant or have a verifiable offer from an institution from another state that would lead him/her to leave New York State (see Section E(2)(b)).

- (4) The offer of employment to the Principal Investigator by the Applicant must be made between the date of availability of the NYFIRST application for a given application cycle and the application deadline for that cycle. Acceptance of such offer also must occur between the date of availability of the NYFIRST application for a given application cycle and the application deadline for that cycle.
- (5) A copy of the accepted employment offer must be submitted with the NYFIRST application.
- (6) The grant term is four years, and all expenditures for which Program funding is approved must be commenced and completed no more than four years from commencement of the grant. The Corporation, in its sole discretion, may extend the grant term if acceptable justification is provided by Grantee or may terminate the Program grant for any Eligible Project that 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, the Principal Investigator, and the project as ESD may require. The application shall highlight the following information relevant to the research being undertaken: unmet clinical need, market potential, and an approximate timeline and anticipated steps 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 also will include details regarding the following:

- a. therapeutic need for the research; e.g., extent of the unmet need for therapeutics, diagnostics or other intellectual property; what alternatives are already available market size and market environment;
- b. anticipated path to commercialization; key milestones to be met as this research moves toward commercialization;
- c. uniqueness of the research and competitive edge;
- d. summary of supporting proof of concept data and other relevant research, publications;
- e. strength of Principal Investigator's intellectual property/entrepreneurial history, and intellectual property potential and patent considerations of proposed research;
- f. proposed scope of work, timeline and feasibility of timeline;
- g. profile(s) of the recruited or retained Principal Investigator and the proposed team members;

- h. budget;
 - i. total amount of NIH and other funding that will accompany the recruited Principal Investigator, as well as his/her funding history; and
 - j. documentation establishing that the term of employment between the institution (the grantee) and the Principal Investigator, as well as each member of the team accompanying the Principal Investigator is, at a minimum, for a period coextensive with the grant term.
- (2) The application also must be accompanied by:
- a. a signed statement of support of the proposed project executed by the chief executive officer or dean of the Applicant medical school, and in a format approved by the Corporation, recommending the application to the Corporation and authorizing an official of the Applicant institution to execute documents necessary for the project;
 - b. a copy of the dated and accepted offer letter by the Principal Investigator, indicating the specific position offered and tenure status and including agreement on anticipated commencement of employment. (Confidential information unrelated to the position, date of offer and signed acceptance may be redacted) or, in the case of retention of a Principal Investigator considering an offer from an institution outside of New York State, a signed statement by the chief executive officer or dean of the Applicant medical school, verifying that the Principal Investigator had indicated his/her intention to relocate to another institution outside of New York State, with details regarding the potential offer, including position and salary, and that a counteroffer has been made and accepted. A copy of the counteroffer and of the acceptance of same must be provided.
 - c. verification that the recruited Principal Investigator was employed at an institution from outside of New York State prior to receipt and acceptance of the offer letter; and
 - d. 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 D and the documentation provided pursuant to 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 Principal Investigator’s intellectual property history and patent potential of proposed research | 15% |
| 5. Feasibility of development timeline | 10% |

- (3) The Corporation intends to make Program grant awards through a competitive grant solicitation to qualifying Applicants twice annually until the funds under this Program are fully committed.
- (4) For each Application cycle, the period between application availability and the application deadline shall be six months.

G. Eligible Uses

- (1) Program grants must be used for expenses directly related to the Eligible Project including but not limited to:
- a. costs relating to the design, acquisition, construction, reconstruction and rehabilitation of laboratory space;
 - b. capital equipment purchases;
 - c. Specialized Supplies purchases; and
 - d. working capital to cover costs of professional staff critical to the research to be undertaken by the Principal Investigator (including staff scientists, doctoral students/post-doctoral fellows and technicians, but excluding the Principal Investigator).
- (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.