Section 4255.4 Biodefense Commercialization Fund

(a) Authority and Purpose

The New York State Urban Development Corporation d/b/a Empire State Development (hereinafter "ESD") hereby establishes the $40 million Biodefense Commercialization Fund ("the Fund") as a component of the Life Sciences Initiative Program. The Fund is intended to encourage and accelerate the development and commercialization of solutions for serious infectious disease threats, including COVID-19 and its variants, while fostering the creation of new life science businesses and supporting industry growth. The Fund will offer grants to startups and academic centers that are developing promising diagnostics, vaccines, therapeutics, and such other innovations as epidemiological surveillance tools, environmental controls, and clinical care advances that address or mitigate infectious disease threats. The Fund shall be managed by ESD, with participation from the New York State Department of Health (DOH), leading universities in New York state, infectious disease experts, and venture investors.

The Fund is intended to provide financial resources that will:

(1) Expand the state's life science ecosystem to enhance employment opportunities;

(2) Bolster the ecosystem by identifying, developing, and supporting commercial advancement of promising scientific innovations that generate solutions in the critical area of infectious disease and pandemic resilience;

(3) Fast track advanced intellectual property ("IP") from New York's research institutions, accelerate the growth of companies across the state, and encourage companies from outside of New York to relocate to expand the state's commercial life science industry;

(4) Increase the state's resilience to broadscale infectious disease threats;

(5) Help to further position New York State as a safe, healthy place for people to live, work, and recreate; and

(6) Expand opportunities available to a broad range of innovative companies.

(b) Fund Leadership and Structure

The Fund will reside within **ESD**, which shall retain the ability to render funding decisions and contract directly with awardees.

ESD will be guided and supported in the design, implementation, and ongoing work of the Fund by a **Fund Administrator**, **Executive Committee** and **Expert Review Panel.** Responsibilities of each entity are summarized as follows:

1. Fund Administrator

- To be retained by ESD as a contractor.
- To support the agency's administration of the Fund through activities such as application development and hosting, website development, communications with prospective applicants and awardees, and assisting in marketing the Fund.

2. Executive Committee

- To include at least one representative from ESD, at least one representative from DOH, and additional representatives from the life science community, including the venture capital community and the research community.
- To make recommendations to ESD regarding the key topics related to infectious diseases to which applications should be directed.
- To recommend and recruit members for the Expert Review Panel.

3. Expert Review Panel

- To include experts from the biopharma industry, life science venture investors, serial entrepreneurs, and academic scientists with deep domain expertise.
- To review and evaluate applications and provide funding-related recommendations directly to ESD.
- To serve as Mentors to awardees.

All members of the Executive Committee, Expert Review Panel and anyone designated as a Mentor shall perform their duties in accordance with and are subject to ESD's Biodefense Commercialization Fund Code of Conduct.

(c) Definitions

(1) "Academic Center" shall mean a public or private academic institution in New York State that is accredited by the New York State Education Department.

(2) "Applicant" shall mean New York-based companies and academic research centers developing innovations designed to address and minimize infectious health threats, as well as companies intending to relocate, or in the process of relocating, to New York State. This may include but is not limited to companies developing or improving diagnostics, therapeutics, or vaccines targeting infectious diseases and pathogens; companies developing innovative tools and devices that provide solutions for environmental disinfection; companies developing innovative solutions for tracking and epidemiological surveillance of infectious agents and

pathogens; and academic institutions with translational scientists investigating infectious disease solutions that offer near-term potential for formation of a startup or to be licensed to industry.

(3) "Corporation" or "ESD" shall mean the New York State Urban Development Corporation d/b/a Empire State Development.

(4) "Eligible Project" shall mean a project that meets the Eligibility Criteria set forth in Section F of these Guidelines.

(5) "Executive Committee" shall mean the group of individuals who will continue to provide guidance on the shaping, implementation and ongoing work of the Biodefense Commercialization Fund. The Executive Committee shall include, in addition to one or more representatives from ESD, one or more representatives from DOH, and representatives from the life science research and venture investment communities.

(6) "Expert Review Panel" shall mean a group that includes experts from the biopharma industry, life science venture investors, serial entrepreneurs, and esteemed academic scientists with deep domain expertise that will serve a variety of roles over the life of the Fund.

(7) "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.

(8) "Fund Administrator" shall mean the organization retained by ESD to manage administration of the Fund, including such activities as application development, website development, online application hosting, communications with applicants, and assisting ESD in the marketing of the Fund.

(9) "Mentor" shall mean an experienced professional skilled in facilitating commercialization of life science research or other types of innovations addressing infectious threats and establishing successful companies in New York State who may be, but is not necessarily, a member of the Expert Review Panel and who is providing guidance to grant recipients about how best to advance their technologies closer to commercialization.

(10) "Project" shall mean the scope of activities supported by a Biodefense Commercialization Fund grant.

(11) "Reimbursable Expenses" shall mean approved costs incurred by a Fund grantee to perform a Project. Reimbursable expenses must be incurred during the grant term and are subject to audit by ESD.

(12) "Reviewers" shall mean members of the Expert Review Panel who will evaluate and score grant applications from both a scientific and a business perspective, considering the criteria detailed in section (f)(5) and section (h).

(13) "Startup" shall mean an early stage company that is raising or has raised Seed, Series A or Series B funding.

(14) "Supplies" shall mean standard research laboratory supplies, as well as 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 advance the Project.

(d) Available Program Assistance

(1) The Fund makes available financial assistance in the form of grants to Applicants for Eligible Projects. The Fund may make grants to academic institutions and to startup companies, as outlined below.

(2) For **academic institutions** with translational innovations that are on the cusp of moving into a commercial development phase:

Grants of $250,000 to $500,000 will be available for validation of underlying science by entrepreneurial researchers just prior to the first stage of company development and formation. Through these grants to academic institutions, New York State aims to encourage and ensure that a continuous pipeline of commercially relevant, innovative ideas is being generated within academia that may ultimately be moved into the marketplace.

For grants to academic institutions, funding will be made on a reimbursement basis. Expenditures incurred prior to execution of an ESD Incentive Proposal or an award letter will not be eligible for reimbursement. For reimbursement, grantees will be required to submit supporting documentation of work performed and costs incurred, mid-year and annual progress reports, an updated budget, and any other documentation as required by ESD.

(3) For **startup companies**, funding will range from an expected minimum of **$1 million up to $4 million**. Reviewers will make a recommendation regarding the amount of funding to be awarded. Companies receiving awards ranging from $2 to $4 million will be required to match the grant amount 100%, in addition to having

a robust fundraising and financial plan. Parameters to be considered will include, but will not be limited to the following:

- Phase of development of the technology being advanced
- Experience raising capital from the private sector
- Team in place or access to team and resources that will allow achievement of projected milestones
- Demonstration of financial stability with a cash position that reflects the funding of a feasible and meaningful workplan and the ability, upon successful milestone achievement, to access capital markets

Upon receipt of an award letter, startup companies can receive an advance of either $250,000 or 50% of their first year of funding, whichever is less, to begin their work. Such advance is intended to cover no more than the initial six (6) months of work. At the end of the initial six-month period, grantees will submit supporting documentation of work performed and payment of eligible expenditures equal to at least 75% of the advance, as well as documentation of progress against R&D milestones, and an updated budget and work plan. Expenditures incurred prior to receipt of an award letter will not be eligible as a qualified expense.

Funding will continue to be allocated in six-month tranches throughout the entirety of the Project, with the grantee satisfying the requirement to document all eligible expenditures equal to at least 75% of the most recent six-month funding allocation and 100% of all advances previously disbursed, in addition to documentation of progress against milestones, in order to advance the project.

Specific R&D milestones and go/no-go checkpoints will be tied to each individual project's grant agreement with ESD, and their achievement will be reviewed and confirmed by the Reviewers and/or an assigned Mentor.

Examples of broad milestones and inflection points to be considered for therapeutics, diagnostics, and vaccines might include:

- For Therapeutics and Vaccines: such industry standard metrics as target to hit, hit to lead, lead optimization, and IND-enabling
- For Diagnostics: Laboratory assay equivalence (analytical sensitivity and specificity), diagnostic sensitivity, specificity, reproducibility, accuracy, speed and ease of clinical use, speed and ease of patient use

(4) It is expected that funding will be provided to recipients for grant terms of no more than three years.

(5) All startup company grant recipients shall be required to remain in New York State and continuously conduct business for a minimum of three years after completion of the grant. The grant shall be subject to full or partial recapture if this requirement is not met. ESD reserves the right to receive a warrant for options in start-up companies that are awarded funding.

(6) All grant recipients, whether academic institutions or startups, will be provided with guidance from industry-experienced Mentors skilled in facilitating commercialization of research and establishing successful companies in New York State. Mentors will provide guidance on such topics as navigating communications with regulatory agencies, securing additional investment support; Go-to-Market strategy GLP manufacturing, distribution; partnerships; and other relevant topics.

(e) Application Requirements, Process and Evaluation

(1) Initially, a short application to be completed by grant applicants will allow the Fund Administrator and Expert Review Panel to quickly determine which applicants will be invited to provide a more detailed, long-form application.

(2) The short application will require brief, non-confidential information that may include, but is not limited to inclusion of the following:

i. Project description and unmet clinical or environmental need, or improvements to currently available technology
ii. Competitive landscape
iii. High-level clinical development strategy
iv. Preclinical support
v. Intellectual property
vi. Project needs and budget

(3) The short application will be evaluated first by the Fund Administrator to ensure that the application conforms with the minimum eligibility requirements. Applications deemed eligible are then given a high-level review by members of the Expert Review Panel. This review for eligibility and feasibility covers appropriateness of field and indication, translational and commercialization potential, scientific merit, and a consideration of third-party encumbrances for research projects.

(4) Based upon this high-level review, applicants may be invited to complete and submit the long-form application. The long-form application will include questions designed to illustrate how well the Applicant has met the criteria and addressed the

considerations established in Section (f)(5)(i-v) and will also request such additional information about the applicant and project as ESD may require.

In addition to highlighting such information as unmet need, competitive landscape, path to commercialization, strength of intellectual property, proposed scope of work and project team experience, the applicant will be required to clearly articulate the following:

i. Key research and development milestones to be achieved during the period of the grant and how they will be measured
ii. Anticipated budget and timeline to meet each milestone. A Gantt chart with work packages described is to be included.

(5) Companies invited to submit a long-form application also will be required to submit the following types of documentation, where feasible and applicable:

i. Financial and business models
ii. Investment pitch deck
iii. Financing history
iv. Intellectual property holdings
v. Proof of business location and operation
vi. Business tax returns
vii. Schedule of business ownership and CAP Table
viii. Employee list payroll documentation
ix. Bank account information
x. Go-to-Market and Commercialization plan

(6) Each long-form application will be reviewed and scored by members of the Expert Review Panel against the criteria detailed in section (f)(5)(i-v) and following the procedure detailed in Section (h). The Expert Review Panel will make recommendations to ESD regarding which applicants are deserving of funding. ESD will make the final determination regarding grant recipients and amounts to be funded to each, as well as any additional terms or conditions of the funding.

(7) Applications from both startup companies and academic institutions will be accepted on a rolling basis, and grant awards are anticipated to be announced twice annually. Timelines for the opening and close of each application period will be announced when available.

(8) ESD will establish periodic reporting requirements for Program grantees to provide information to ESD. These reporting obligations may extend beyond the completion of the project for a period of three years.

(f) Eligibility Criteria

(1) The following organizations are eligible to apply for grant assistance:

i. New York-based academic institutions with advanced IP and translational innovations that are on the cusp of moving into a commercial development phase.
ii. Startups based in New York that have recently raised or are in the process of raising Seed, Series A, or Series B funding.
iii. Startups from outside of New York State that meet the above qualifications and intend to relocate to New York State.

(2) Applicants relocating to New York State will be required to provide evidence of their intention to relocate and will be required to complete relocation prior to distribution of any funds.

Documentation is subject to ESD approval and may include:

i. Executed lease agreement
ii. Deed to commercial property
iii. New York State payroll record, or other documentation of employees in New York State
iv. Other documentation deemed necessary by ESD to establish commercial residence in New York.

(3) Preference may be given to companies developing needed COVID-related solutions, after which relevance to serious infectious disease threats more broadly will be considered.

(4) Successful Grantees will have demonstrated a strong likelihood that the project will be successful in further developing and commercializing a valuable solution to COVID, its variants, or other infectious disease threats.

(5) Criteria that will be considered by the Expert Review Panel to award a grant include, but are not limited to, the following:

<u>i. Innovation & Value Proposition</u>

- Does the proposed project have strong potential to lead to a marketable product, process, or service?
- Is this a novel technology? What advantages does it offer over any existing product?
- How crowded is the proposed field of products/potential products for the proposed use?

- Does the Commercialization Plan demonstrate a high probability of success?
- Is there a strong scientific premise for the project?
- How will successful completion of the project change the treatments, services, or preventative interventions that drive this field, or are needed for it?

ii.. Intellectual Property

- Does the company have a strong competitive position based on patents, patent applications, or other intellectual property?
- Is there a plan for continuing to strengthen IP protection?

iii. Team Experience & Capabilities

- Does the applicant have training and experience that is well suited to the project?
- Does the applicant demonstrate a record of research innovation with clear potential for commercialization?
- Does the applicant have a history of entrepreneurship, such as by patent applications, patent approvals and licensing or commercialization of research, and previous success in obtaining venture funding?
- Is there a team established to execute on the commercialization plan and a syndicate of investors that can support the company through commercial success?

iv. Approach & Feasibility

- Is the proposed strategy/methodology well-reasoned and appropriate to accomplish the specific aims of the project?
- Have meaningful milestones been established that will enable the project to move toward commercialization?
- Is there an appropriate timeline and can the anticipated steps to market/clinical use be accomplished in that timeline?
- Has the applicant demonstrated solutions or alternatives to mitigate potential problems that may occur and will de-risk the path forward?
- Is the business model realistic to achieve commercial success?

v. Relevance & Applicability to Future Infectious Disease Threats

- How well can the research/product flex or respond to the next infectious need/outbreak/epidemic/pandemic? How versatile will it be in responding to several infectious disease threats?
- Does the project address an important problem or a critical barrier to progress?

(g) Allowable Use of Funds

(1) Program grants are intended to accelerate the development and commercialization of infectious disease solutions and related public health innovations, while encouraging the creation of new life science businesses and growing the life science sector in New York State.

(2) Grants may be used for working capital to cover such costs as staff critical to the proposed project, specialized and other supplies required for the conduct of the proposed project, and other costs directly related to the eligible project. Grant funding must be used for expenses directly related to the Eligible Project.

(3) Grant funds may not be used to pay back loans, to pay interest on a loan, to provide a return to shareholders, or for any purpose other than operations and expenses directly related to the Eligible Project.

(4) Grants shall not duplicate payments received, or receivable, from other sources.

(5) The grant term is to be determined by the project described and is not expected to extend beyond three years after commencement of the grant. Expenditures made in connection with a funded project will not be eligible for reimbursement if incurred prior to either a) approval by the ESD Board of Directors or b) execution of an Incentive Proposal provided by ESD.

(6) No expenditures submitted 13 months or more after completion of the grant term will be reimbursed.

(7) Failure to comply with reporting or other requirements may result in withholding of disbursements.

(8) ESD, in its sole discretion, 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. ESD may seek the recommendation of the Executive Committee in this decision.

(h) Selection Criteria and Scoring

(1) For each of the criteria below, reviewers of each long-form application will assign a score of one (1) to five (5), with five being the highest/recommendation for funding and one being the lowest, no funding recommendation. A written summary of the Reviewer's evaluation also may be provided.

Review Criteria

i. Innovation & Value Proposition
ii. Intellectual Property
iii. Team Experience & Capabilities
iv. Approach & Feasibility
v. Relevance and Applicability to Future Infectious Disease Threats

(2) Based on the final scoring of applications, the Expert Review Panel will make award recommendations to ESD, which will make the final determination regarding grant recipients and funding amounts.

(i) Recapture

A grant may be subject to full or partial recapture should any of the following occur:

i. Failure by the grant recipient to provide the required information in a manner that is timely and otherwise satisfactory to ESD;
ii. Falsification of data;
iii. Misuse of grant funds;
iv. Knowingly misrepresenting the potential value of the technology under development; or
v. Failure to remain in New York State for at least three years after completion of the grant.

(j) Program Metrics and Measures of Success

Evaluation of program success will be measured from both a business and an outcome perspective. Success measures may include, but are not limited to, the following metrics:

i. Number of eligible applications submitted
ii. Number of companies receiving grants
iii. Revenue and growth of these companies
iv. New products, services and processes delivered
v. Progress toward commercialization of products under development
vi. Increase in Gross Value Added (GVA), jobs, profitability and revenue
vii. Equity raises and other funding
viii. Number of university spinouts
ix. Number of IP licenses
x. Number of commercial exits

(k) Reporting Requirements

(1) ESD 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) ESD will establish periodic reporting requirements for Program grantees to provide information to ESD so that ESD may accomplish its statutory reporting obligations. These reporting obligations may extend beyond the completion of the project for a period of three years.