III. 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, marketing the Fund, and establishing a mentor program for grantees.

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.
- To review and offer perspective to ESD on funding recommendations made by Expert Review Panel.
- To review projects considered for early termination of funding based on failure to meet milestones, and provide such recommendations to ESD.

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, evaluate, and score applications and provide funding-related recommendations to ESD and the Executive Committee.
- To serve as Mentors to awardees, if desired.

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. Applicants may include but are 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) "Capital" shall mean non-grant funding, including funding from venture investors, angel investors, or other private funding sources that may require a commitment to provide a return on investment.

(4) "Capital Expenditures" shall mean monies spent by a business or organization to acquire or maintain fixed assets, such as property, buildings and equipment.

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

(6) "Direct Cost" shall mean expenses directly related to a specific project, producing goods or providing services.

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

(8) "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.

(9) "Expert Review Panel" shall mean a group of experts from the biopharma industry, life science venture investors, serial entrepreneurs, and esteemed academic scientists with the expertise required to review, score, evaluate and make funding recommendations regarding the applications submitted to the Fund.

(10) "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.

(11) "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.

(12) "Grant Disbursement Agreement (GDA)" shall mean the official contract between ESD and the grantee. The GDA outlines all terms and conditions for the disbursement of funds and is issued as soon as possible after ESD Board of Directors Approval.

(13) "Incentive Proposal (IP)" shall mean a document executed by both ESD and the grantee that lays out the project being undertaken, an overview of the funds awarded for the project, the scope, budget and timeline of the project, and the requirements for commencement of the project. Following execution of the IP, the grantee can begin to incur expenses to be reimbursed by the grant.

(14) "Indirect Cost" shall mean the overhead costs involved with maintaining and running a company. Indirect costs include such items as rental or ownership expenses, general use office equipment and furniture, utilities, phones, internet services, and the like.

(15) "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.

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

(17) "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.

(18) "Reviewers" shall mean members of the Expert Review Panel who will evaluate and score grant applications from both a scientific and a business perspective, and also will make funding recommendations, considering the criteria detailed in section F (5) and section H.

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

(20) "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.

(21) "Working Capital Expense" shall mean expenses required for day-to-day functioning of a business, such as consumable supplies, payroll, and research costs.

D. Available Program Assistance

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.

(1) 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, an executed Incentive Proposal will be required to begin incurring expenses against the grant. Funding will be provided on a reimbursement basis following ESD Board of Directors Approval and execution of a Grant Disbursement Agreement. 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.

(2) 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 after careful review of the Company's proposed project, development timeline, and budget details. 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, financial, and commercial development plan. Parameters to be considered for the amount of funding to be awarded will include, but will not be limited to the following:

- Phase of development of the technology under development (preference will be given to projects that are more 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 ESD Board of Directors' approval and execution of a Grant Disbursement Agreement, startup companies will be eligible to 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. Grants that require matching funds will also need to show documentation of an equivalent expenditure of matching funds for the project. Expenditures incurred prior to Board Approval will not be eligible as a qualified expense.

Following the initial six months of work, funding will continue throughout the entirety of the Project, as long as the grantee satisfies ESD requirements, including documentation of progress against milestones, documentation of all eligible expenditures equal to at least 75% of the most recent six-month funding allocation and 100% of all advances previously disbursed (along with equal matching spend, for grants of $2 million or greater), in addition to timely provision of six-month and annual reports, 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 assigned Mentor and may also be reviewed by the Executive Committee.

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

(3) It is expected that funding will be provided to recipients for grant terms of no more than three years, although a project's term may be less than three years. A "no-cost" extension will not be considered for startup companies receiving a Biodefense Commercialization Fund grant. For academic institutions, a "no-cost" extension is strongly discouraged, but may be considered in unique circumstances.

(4) Regardless of the term of a project or its disbursement schedule, all startup company grant recipients will be required to submit six-month and annual reports on their progress for as long as funding is provided. In addition, grantees will be required to provide annual reports of their progress for three years following the final disbursement of funds.

(5) All startup company grant recipients shall be required to remain in New York State and continuously conduct business in the state 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.

(6) ESD reserves the right to receive a warrant for options in startup companies that are awarded funding.

(7) 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:

a. Project description and unmet clinical or environmental need, or improvements to currently available technology
b. Competitive landscape
c. High-level commercial development strategy
d. Preclinical support
e. Intellectual property
f. Project needs and top-line budget for key line items such as personnel, scientific supplies, and other research expense.

(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, and shall give priority to late stage projects that are:

a. Applications for novel platforms for development of rapid point-of-care (POC) diagnostics (examples include but are not limited to, CRISPR and/or Isothermal-based platforms, systems based on microfluidics and microelectronics, and methodologies to support manufacturing and scale up). Of particular interest are point-of-care diagnostics that can perform as well as or better than existing lab tests,
b. Innovations that integrate easy-to-use sample preparation steps and allow for access in low resourced settings, and
c. Novel tools for sequencing and serology-based tests that support infectious disease surveillance.

(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) (a-e) 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:

a. Key research and development milestones to be achieved during the period of the grant and how they will be measured
b. Anticipated budget and timeline to meet each milestone. A Gantt chart indicating timeline for achievement of each milestone 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:

a. Financial and business models, with five-year financial projections
b. Investment pitch deck
c. Bios of company principals
d. Financing history, including listing of investors and funding sources
e. Intellectual property holdings
f. Proof of business location and operation
g. Current balance sheet with assets
h. Business tax returns
i. Schedule of business ownership and CAP Table
j. Employee list and payroll documentation (including current employees and where located, as well as personnel to be hired in coming five years)
k. Company organizational structure
l. Proof of incorporation status [Note that all startup company grant recipients must be incorporated in order to receive grant funds.]

m. Bank account information
n. 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) (a-e) and following the procedure detailed in Section H. The Expert Review Panel will make recommendations to ESD regarding which applicants are deserving of funding and also will make recommendations regarding the level of funding to be awarded. The Executive Committee will review the funding recommendations of the Reviewers and will opine to ESD on the appropriateness of those funding recommendations. 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 following a Call for Applications, which is anticipated to take place twice annually until the Fund is fully committed. Timelines for the opening and close of each application period will be announced at the opening of each application period.

(8) In addition to the six-month and annual reports required of Grantees during the term of a grant, ESD requires annual reports for the three years following the final disbursement of funds.

F. Eligibility Criteria

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

a. New York-based academic institutions with advanced IP and translational innovations that are on the cusp of moving into a commercial development phase.
b. Startups based in New York that have recently raised or are in the process of raising Seed, Series A, or Series B funding.
c. Startups from outside of New York State that meet the above qualifications are eligible to apply for a grant and will be required to document their relocation plans and presence in New York State if selected for an award (as described in Section (F)2), prior to release of funds.

(2) Applicants relocating to New York State will be required to provide evidence of their relocation plans and will be required to complete relocation prior to distribution of any funds. All out-of-state applicants invited to submit a long proposal will be provided with the specific requirements to be fulfilled to demonstrate their commitment to relocate and must sign a document indicating their acceptance of those requirements.

These requirements include, but are not limited to the following:

a. An executed lease agreement with a lease term of at least one year within New York State or
b. A certified deed for commercial property located within New York State
c. A New York State payroll record, or other documentation of employees in New York State
d. 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 infectious disease threats, including but not limited to COVID-19 and its variants.

(5) Criteria that will be considered by the Expert Review Panel when reviewing and scoring applications include, but are not limited to, the following:

a. Innovation & Value Proposition

- 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?

b. 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?

c. 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?

d. 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?

e. 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 working capital costs directly related to the eligible project.

(3) Grant funding cannot be used for capital expenditures.

(4) For academic projects, a grant may be used to cover indirect costs not to exceed 25% of the total grant amount.

(5) For startup projects, grant funding cannot be used to cover indirect costs. If the project calls for matching funding, no more than 25% of the matching funding may be used to cover indirect costs.

(6) 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 working capital expenses directly related to the eligible project.

(7) Grant funds may not be used to cover marketing costs.

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

(9) 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, but may be shorter than three years. 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.

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

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

(12) ESD, in its sole discretion, may terminate the Program grant for any Eligible Project that does not achieve its milestones, 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 one being the highest/recommendation for funding and five being the lowest, no funding recommendation.

Review Criteria

a. Innovation & Value Proposition
b. Intellectual Property
c. Team Experience & Capabilities

d. Approach & Feasibility
e. Relevance and Applicability to Future Infectious Disease Threats
f. Commercial Potential & Development Plan (*startup applicants only*)

(2) Based on the final scoring of applications, the Expert Review Panel will make award and funding recommendations to the Executive Committee, which will review those recommendations and will opine to ESD on their appropriateness. 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.

I. Recapture

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

a. Failure by the grant recipient to provide the required information in a manner that is timely and otherwise satisfactory to ESD;
b. Falsification of data;
c. Misuse or improper use of ESD grant funds;
d. Knowingly misrepresenting the potential value of the technology under development;
e. Failure to remain in New York State for at least three years after completion of the grant; or
f. Failure to submit six-month and annual reports, or other required information to ESD in a way that is timely and satisfactory;

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:

a. Number of eligible applications submitted
b. Number of companies receiving grants
c. Revenue and growth of these companies (including growth in number of employees and salary growth)
d. New products, services and processes delivered
e. Progress toward commercialization of products under development
f. Increase in Gross Value Added (GVA), jobs, profitability and revenue
g. Equity raises and other funding
h. Number of university spinouts
i. Number of IP licenses
j. Number of commercial exits

K. Reporting Requirements

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; this information may include any of the metrics described in Section J, as well as others not described that are typically linked to life science economic benefit.

ESD may establish additional reporting requirements for Program grantees to provide information to ESD so that ESD may accomplish its statutory reporting obligations.