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EXECUTIVE DIRECTOR

February 4, 2021

Ms. Olga Abinader
New York City Department of City Planning
Environmental Assessment and Review Division
120 Broadway, 31st floor
New York, NY 10271

Re: New York Blood Center – Center East, CEQR # 21DCP080M

Dear Ms. Abinader:

On December 30, 2020, I submitted written comments on the Draft Scope of Work for the above referenced project. After the comment period closed, the applicant disclosed to FRIENDS material information regarding the project and the scope of the environmental review it requires.

On January 15, 2021, we learned that the proposed project will contain biosafety level 3 (BSL-3) laboratories. This is the second highest level of high-containment research laboratories, classified by the Center for Disease Control. BSL-3 laboratories store and handle infectious microorganisms and hazardous biological materials that are capable of causing serious and potentially lethal infections. A 2016 memo from the Department of Health and Mental Hygiene (DOHMH) detailed the risks associated with such facilities and the City's lack of information about their type, location, or operations.

*Work performed in a BSL-3 or BSL-4 facility would present **the greatest potential risk to public health** if an incident occurs…*

*The Department is concerned that an accident in a New York City-based high-containment research laboratory could **have catastrophic consequences**, given the population density of nearly 70,000 per square mile in Manhattan…*

Nowhere does the Draft Scope of Work disclose that the commercial laboratory being proposed is a BSL-3 laboratory. In fact, the Air Quality section discusses the potential for spills and their potential to impact air quality as if this will be a chemical laboratory, not a biological laboratory.

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As the CEQR Technical Manual instructs in section 242.1 *Reasonably Foreseeable Catastrophic Impacts,*

> *. . . an EIS may need to contain certain information regarding reasonably foreseeable catastrophic impacts. If information about reasonably foreseeable catastrophic impacts is unavailable or uncertain, and such information is essential to an agency's CEQR/SEQR findings, the EIS should:*
>
> *• Identify the nature and relevance of unavailable or uncertain information;*
> *• Provide a summary of existing credible scientific evidence, if available; and*
> *• Assess the likelihood of occurrence, even if the probability of occurrence is low, and the consequences of the potential impact, using theoretical approaches or research methods generally accepted in the scientific community.*

Considering that the DOHMH explicitly warned of the "catastrophic consequences" of an accident at the facility the applicant proposes, the DEIS needs to disclose this potential, the consequences thereof, and any measures taken to mitigate such potential. The omission of this detail in the Draft Scope of Work is a critical flaw, as it has robbed the public of an opportunity to understand the project and to comment on a Scope of Work based on the actual project, not the one described in the Project Description.

Further, I am concerned that the true nature of the proposal was withheld not only from the public, but from the Lead Agency. As you know, the CEQR Technical Manual instructs at least 15 separate times, "it is important for an applicant to work closely with the lead agency during the entire environmental review process." If information regarding the true nature of the project was withheld from the Lead Agency, it may wish to take a drastic action to correct the omission, including requiring a new Environmental Assessment and Draft Scope of Work, which properly describe the proposal.

In closing, the inclusion of BSL-3 laboratory is material to this proposal's environmental impacts and it needed to be disclosed to the public and the Lead Agency. The applicant's lack of transparency and disclosure is contrary to the very nature of CEQR and stifles not only the public's knowledge of the full extent of the project, but also silences opportunities for meaningful feedback in the public dialogue.

Please find attached to this memo, the referenced DOHMH memo regarding such facilities, and a page from materials presented to FRIENDS by the applicant on January 15, 2021.

FRIENDS of the UPPER EAST SIDE HISTORIC DISTRICTS

If you would like to discuss, please contact me at 212-535-2526 or rlevy@friends-ues.org.

Sincerely,

Rachel Levy
Executive Director

Cc:
Council Member Ben Kallos, New York City Council
Manhattan Borough President Gale Brewer
Edith Hsu-Chen, Department of City Planning
Russell Squire, Chair, Community Board 8
Paul Selver, Kramer Levin Naftalis & Frankel LLP
George M. Janes, AICP, George M. Janes & Associates
Dr. Fred Hyde, Fred Hyde & Associates

Department of Health and Mental Hygiene

Board of Health

Notice of Adoption of Amendments to Article 13 of the New York City Health Code

In compliance with §1043(b) of the New York City Charter (the "Charter") and pursuant to the authority granted to the Board of Health by §558 of said Charter, a notice of intention to amend Article 13 of the New York City Health Code (the "Health Code") was published in the City Record on March 25, 2016 and a public hearing was held on April 26, 2016. No one testified at the hearing, but five written comments were received. At its meeting on June 7, 2016 the Board of Health adopted the following resolution.

Statement of Basis and Purpose

Background

The Charter provides the Department of Health and Mental Hygiene (the Department) with jurisdiction over all matters concerning health in the City of New York. The Department conducts disease surveillance and control activities for diseases reportable pursuant to Article 11 of the New York City Health Code (Health Code). The Department is also required to comply with various provisions of Part 2 of the New York State Sanitary Code, found in Title 10 of the Codes, Rules and Regulations of the State of New York (NYCRR), with respect to control of communicable diseases. Health Code Article 13 ("Clinical Laboratories") requires clinical laboratories to report results of tests performed on human specimens to confirm or rule out a diagnosis. Clinical laboratories in New York State operate within parameters set by State Public Health Law and State Health Department rules, and are generally distinguishable from research laboratories, although both kinds of laboratories may be operated by institutions that both offer clinical care and conduct medical research.

"High-containment research laboratories" are facilities that store and handle infectious microorganisms or hazardous biological material and operate at biosafety level (BSL) 3 or 4, as defined by the US Centers for Disease Control and Prevention (CDC) and National Institutes for Health (NIH), in *Biosafety in Microbiological and Biomedical Laboratories* (BMBL), which delineates four BSLs based on the potential risks of working with infectious or hazardous agents.

> Biosafety level 1 (BSL-1) is the basic level of protection and is appropriate for agents that are not known to cause disease in normal, healthy humans. Biosafety level 2 (BSL-2) is appropriate for handling moderate-risk agents that cause human disease of varying severity by ingestion or through percutaneous or mucous membrane exposure. Biosafety level 3 (BSL-3) is appropriate for agents with a known potential for aerosol transmission, for agents that may cause serious and potentially lethal infections and that are indigenous or exotic in origin. Exotic agents that pose a high individual risk of life-threatening disease by infectious aerosols and for which no treatment is available are

restricted to high containment laboratories that meet biosafety level 4 (BSL-4) standards.[1]

Since 2001, hundreds of new high-containment research laboratories have been established in the United States. According to the U.S. Government Accountability Office (GAO), 1,495 BSL-3 and BSL-4 laboratories were registered with the Federal Select Agent Program (FSAP) in 2010 compared to 415 in 2004. This was considered an under-estimate, because it only addressed laboratories required to register with the FSAP.[2] With respect to those operating in New York City, the Department does not know when such facilities were or are being established, the total number operating in the City at any time, and the hazardous agents they store or handle.

Recent laboratory accidents, none of which occurred in New York City, have focused the Department's attention on this issue. In June and July 2014, CDC disclosed two potentially serious incidents involving H5N1 avian influenza[3] and *Bacillus anthracis*,[4] the bacterium that causes anthrax. A third incident at CDC involving an Ebola virus sample occurred in December 2014.[5] In 2007, another potentially serious incident occurred at CDC when the main and backup power supplies failed during a lightning storm, shutting down the negative pressure system in a newly constructed, but not yet operational, BSL-4 laboratory.[6]

Two incidents in the past two years involving high-containment laboratories further demonstrate the potential public health risks stemming from research conducted in BSL-3 and BSL-4 laboratories. In November 2014, two primates in the Tulane National Primate Research Center were diagnosed with melioidosis, a severe disease of animals and humans caused by a potential biological threat agent, *Burkholderia pseudomallei*. The strain infecting the animals was identical to the strain used in a Tulane University laboratory registered with the FSAP. In March 2015, CDC and the U.S. Department of Agriculture's (USDA) Animal Plant Health Inspection Service (APHIS) concluded that a number of

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[1] CDC (US) and NIH (US). Biosafety in Microbiological and Biomedical Laboratories. 5th ed. Washington (DC): Centers for Disease Control and Prevention (US) and National Institutes of Health (US). 2007; 409 p. Available from http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf

[2] GAO (US). High-Containment Laboratories: Assessment of the Nation's Need is Missing. Washington (DC): Government Accountability Office (US). 2013 Feb 25; 13 p. Report No.: GAO-13-466R. Available from http://www.gao.gov/products/GAO-13-466R

[3] CDC (US). Report on the Inadvertent Cross-Contamination and Shipment of a Laboratory Specimen with Influenza Virus H5N1. 2014 August 15. http://www.cdc.gov/about/pdf/lab-safety/investigationcdch5n1contaminationeventaugust15.pdf

[4] CDC (US). Report on the Potential Exposure to Anthrax. 2014 July 11. http://www.cdc.gov/about/pdf/lab-safety/Final_Anthrax_Report.pdf

[5] CDC (US). Report on the Potential Exposure to Ebola Virus. 2015 February 4. http://www.cdc.gov/about/pdf/lab-safety/investigation-into-dec-22-2014-cdc-ebola-event.pdf

[6] Government Accountability Office (US). High Containment Laboratories—National Strategy for Oversight is Needed. Washington (DC): Government Accountability Office (US); 2009 Sep. 99 p. Report No.: GAO-09-574. Available from http://www.gao.gov/products/GAO-09-574

biosafety deficiencies could have led to transmission of *B. pseudomallei* from the laboratory to the animals in the primate center.[7]

In May 2015, CDC started an investigation of a report that a U.S. Department of Defense high-containment laboratory might have inadvertently shipped live *B. anthracis* spores (the causative agent of anthrax) to a laboratory that was anticipating only deactivated spores. Ultimately, CDC concluded that this laboratory unknowingly shipped live *B. anthracis* spores on 575 separate occasions to laboratories worldwide over the course of a decade.[8]

As serious as these incidents have been, of even greater concern have been laboratory incidents over past decades that have caused outbreaks of contagious virus diseases, including smallpox, SARS, and foot and mouth disease.[9] The Department is concerned that an accident in a New York City-based high-containment research laboratory could have catastrophic consequences, given the population density of nearly 70,000 per square mile in Manhattan and the many other areas of high population density throughout the City.

Work performed in a BSL-3 or BSL-4 facility would present the greatest potential risk to public health if an incident occurs. Research laboratories that handle biological agents and toxins and hold government contracts or grants are required to adhere to the BMBL. Most, but not all, of the agents that are stored and handled in high-containment research laboratories and that represent potential public health risks are regulated by the FSAP. Federal regulations require reporting of certain incidents involving select agents to the CDC and local, state and federal law enforcement agencies only; timely notification to local public health authorities of these incidents is not always required by the federal regulations. Federal agencies are also constrained from disclosing to local or state health departments which laboratories within a local jurisdiction are registered to handle and work with select agents. The Department has been informed by the CDC that, with the proper safeguards, information identifying the registered laboratories can be made available to the Department. However, no other information about these laboratories or the biological agents they work with would be regularly available from CDC.

Several federal agencies exercise varying degrees of oversight over academic and private high-containment research laboratories. CDC and USDA APHIS regulate laboratories working with certain biological agents and toxins that have the potential to pose a severe risk to public health and safety, known as "select agents," pursuant to 42 CFR Part 73 (CDC regulations), and 9 CFR Part 121 and 7 CFR Part 331 (USDA regulations).

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[7] CDC (US). Conclusion of select agent inquiry into Burkholderia pseudomallei release at Tulane National Primate Research Center. 2015 Mar 13. Available from http://www.cdc.gov/media/releases/2015/s0313-burkholderia-pseudomallei.html

[8] HHS (US). Testimony of Daniel M. Sosin, MD, MPH, FACP, before the Subcommittee on Oversight and Investigations, Committee on Energy and Commerce, U.S. House of Representatives. Review of Department of Defense Anthrax Specimens. 2015 Jul 28. Available from http://docs.house.gov/meetings/IF/IF02/20150728/103816/HHRG-114-IF02-Wstate-SosinD-20150728.pdf

[9] Furmanski M. Threatened pandemics and laboratory escapes: self-fulfilling prophecies. Bulletin of the Atomic Scientists. 2014 Mar 31. Available from http://thebulletin.org/rened-pandemics-and-laboratory-escapes-self-fulfilling-prophecies7016

According to the GAO, "While some federal agencies do have a mission to track a subset of BSL-3 and -4 laboratories that work with select agents and know the number of those laboratories, no single regulatory agency has specific responsibility for biosafety in all high-containment laboratories in the United States."[6] If a laboratory is not working with a select agent or not operating with government funding or under a government contract, it is not bound by the federal regulatory scheme, and, unless there is applicable state or local law, a laboratory may be totally unregulated.

Because of this regulatory structure, the Department does not have any means of knowing the number of high-containment research laboratories operating in New York City, their locations, or the potentially hazardous biological agents that are stored and/or handled within them. Although clinical laboratories hold permits issued by the State Department of Health,[10] non-clinical research laboratories storing and/or handling biological agents are not currently regulated by the City or State. They do not currently need to hold permits, notify local authorities of their existence, or report incidents of public health concern to the Department, such as loss or theft of agents or suspected transmission of diseases caused by agents stored and/or handled in the laboratories. Unless high-containment research laboratories that store or use biological agents that could potentially threaten public health are required to register with the Department, pre-event planning between the Department and laboratories to mitigate the public health risks and to protect public health cannot take place.

Several state and local US jurisdictions currently regulate research laboratories working with biological agents. In 1996, Connecticut, which had already required all laboratories to register and be inspected before conducting any examination, determination, or test, enacted additional reporting requirements specifically applicable to BSL-3 laboratories, requiring reporting of any infection or injury relating to work with such agents or resulting in recommendations that employees or members of the public be tested or monitored for potential public health problems.[11] Since 2002, Maryland has had a Biological Agent Registration Program, which is nearly identical to the FSAP. The Boston Public Health Commission adopted its Biological Laboratory Regulations in 2006. These regulations establish operational biosafety requirements and require permitting, inspections and reporting of human exposures and other incidents to the Commission in research laboratories that work with select agents and other "high risk agents," as determined by the Commission's director. In 2009, Cambridge, Massachusetts adopted biosafety laboratory regulations and formed the Cambridge Biosafety Committee to enforce them.

The Board of Health is amending Article 13 to require registration of and reporting by all high-containment research laboratories in New York City. The registration form will identify and provide the contact information of owners, managers, operators, and other persons responsible for biosafety and list the biological agents stored and/or used onsite. The amendment also requires registered laboratories to report to the Department any loss or theft of, or exposure by a person to, the biological agents of concern so that the Department can, if necessary, investigate and limit public health risks from these agents. Registered laboratories will also be required to report changes in the information in their registration forms that pertain to any select agent or high-risk agent of public health concern.

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[10] See, e.g., New York Public Health Law Article 5-Laboratories.

[11] CONN. GEN. STAT. §19a-31a; CONN. AGENCIES REGS. §§ 19a-36-A1 to A56.

Laboratories that are currently operating solely as clinical laboratories, blood and tissue banks and those that conduct recombinant DNA experiments pursuant to Title 5 of Article 5, or Articles 43-B or 32-A, of the New York Public Health Law are excluded from these registration and reporting requirements.

Statutory Authority

These amendments to the Health Code are promulgated pursuant to §§558 and 1043 of the Charter. Sections 558(b) and (c) of the Charter empower the Board to amend the Health Code and to include in the Health Code all matters to which the authority of the Department extends. Section 1043 grants the Department rule-making authority. Section 556(c)(2) of the Charter authorizes the Department to "supervise the reporting and control of communicable and chronic disease and conditions hazardous to life and health…"

The proposal is as follows:

"Shall" and "must" denote mandatory requirements and may be used interchangeably unless otherwise specified or unless the context clearly indicates otherwise.

New material is underlined.

[Deleted material is in brackets.]

RESOLVED, that Section 13.01 of the New York City Health Code, set forth in Title 24 of the Rules of New York City is amended, to be printed together with explanatory notes, effective 180 days after adoption, to read as follows:

§13.01 [**Definition**] **Definitions.**

When used in this article ["laboratory"]:

(a) "Laboratory" or "clinical laboratory" [shall mean] means a facility, including a blood bank, regulated pursuant to Title 5 of Article 5 of the Public Health Law[, Title V, Article 5,] holding a permit issued by the New York State Department of Health, and operating in the City or testing a specimen taken from a City resident.

(b) "Research laboratory" means a laboratory used primarily for research, development, storage, examination or testing of one or more biological agents by or under the direct supervision of a technically qualified individual, but does not include: (i) clinical laboratories and blood banks holding permits issued pursuant to Title 5 of Article 5 of the Public Health Law; (ii) laboratories where recombinant DNA experiments are conducted pursuant to Article 32-A of the Public Health Law; (iii) tissue or organ banks holding permits issued pursuant to Article 43-B of the Public Health Law; and (iv) laboratory facilities operated by New York State or federal governments.

(c) “Biological agent” means an infectious microorganism or hazardous biological material, such as a bacterium, virus, fungus, parasite, or biological toxin that is associated with human disease.
(d) “High-containment research laboratory” means any research laboratory that operates at biosafety level 3 or biosafety level 4, as defined by the Centers for Disease Control and Prevention and National Institutes for Health in *Biosafety in Microbiological and Biomedical Laboratories*, or successor document available at http://www.cdc.gov/biosafety/publications/bmbl5/BMBL.pdf.
(e) “High-risk agent” means Middle East respiratory coronavirus (MERS-CoV), all *Mycobacterium tuberculosis* strains and any other biological agent that the Commissioner, upon notice, determines would be a severe risk to public health if released into the environment and could result in severe morbidity or high mortality.
(f) “Select agent” means a biological agent or toxin listed in 42 CFR §§ 73.3 or 73.4 or 9 CFR § 121.4, or any successor provisions, which requires laboratories that possess, use or transfer such agent to register with the Federal Select Agent Program, as described in 42 CFR Part 73, 9 CFR 121 and 7 CFR Part 331.
(g) “Exposure” means the ingestion, inhalation, inoculation, or contamination of skin or mucous membranes with a biological agent.
Notes: Section 13.01 was amended by resolution adopted by the Board of Health at its meeting on June 7, 2016, to be effective 180 days after adoption, to add definitions applicable to certain high-containment research laboratories.

RESOLVED, that Article 13 of the New York City Health Code, set forth in Title 24 of the Rules of New York City, is hereby amended, to add new sections 13.11 and 13.13, effective 180 days after adoption, to be printed together with explanatory notes, to read as follows:
§13.11 **High-containment research laboratories: registration**.
(a) *Registration*, Every person operating a high-containment research laboratory in the City of New York must register such laboratory with the Department. Registrations will expire and must be renewed every three years. An entity or person registering with the Department must provide all the information requested by the Department on the registration form, including but not limited to:
(1) Name, address and other contact information for the officers or persons in control of the operating entity;
(2) Locations and biosafety level rating or ratings for each research laboratory operated by the registering entity;
(3) Name, title and contact information of at least two designated persons who are individuals at the research laboratory designated to submit to the Department the reports required by §13.13 of this Article,

provided that one such designated person is the manager or other person in control of the research laboratory biosafety committee; and

(4) A listing of all biological agents stored or used in each high-containment research laboratory at the time of registration. The listing must include the parent strain of the agent and any derivative strains identified by the high-containment research laboratory as having unique virulence or pathogenic potential.

(b) *New facilities.* Any person intending to operate a new high-containment research laboratory must register such laboratory according to this section before such laboratory commences operation.

(c) *Changes in registration information.* The registrant must notify the Department within thirty (30) calendar days of any changes to the information provided on the registration form that pertains to any select agent or high-risk agent.

Notes: Section 13.11 was added to Article 13 by resolution adopted by the Board of Health at its meeting on June 7, 2016 to be effective 180 days after adoption, to require registration by high-containment research laboratories keeping or working with certain biological agents that pose a risk to public health. High-containment research laboratories in operation on the effective date of the resolution must register with the Department no later than one hundred eighty (180) calendar days after the effective date.

§13.13 **High-containment research laboratories; required reports**.

(a) *Loss or theft of a biological agent.* No later than four hours after determining that there has been a theft or loss of a biological agent from a high-containment research laboratory, the laboratory operator or a person designated on the registration form of such laboratory must notify the Department of such theft or loss at a telephone number designated by the Department. Any theft or loss must be reported even if the lost or stolen biological agent is subsequently recovered and/or the responsible parties are identified. The following information must be provided:

(1) The name of the biological agent and any and all of its identifying information (e.g., strain or other characterization information);

(2) The quantity or an estimate of the quantity of the biological agent that was lost or stolen;

(3) The time or an estimate of the time during which the theft or loss occurred;

(4) The location (building, room) from which the theft or loss occurred.

(b) *Exposure to or unintentional release of biological agents.* Within one hour of determining that a person may have been exposed to a biological agent stored or used in a high-containment research laboratory, or of any unintentional release of a biological agent, or of an illness associated with exposure to a biological agent used or stored in a high-containment research laboratory, the laboratory operator or a person designated on the registration form of such laboratory must notify the Department of the actual or

potential exposure at a telephone number designated by the Department. The following information must be provided:

(1) The name of the biological agent and any and all of its identifying information (e.g., strain or other characterization information);

(2) An estimate of the number of persons potentially exposed to the biological agent in or by the research laboratory and within the entity;

(3) An estimate of the quantity of biological agent that was released;

(4) An estimate of the time and duration of the release of the biological agent;

(5) The environment into which the biological agent was released (e.g., within vs. outside building, into a waste system);

(6) The location (building, room) from which the release of the biological agent occurred;

(7) Identification and contact information for all persons known to be exposed to the biological agent;

(8) Actions taken to respond to the release of the biological agent; and

(9) Hazards posed by the release of the biological agent.

(c) No requirement of this section affects any other obligation under any other law or regulation for a high-containment laboratory to report the loss, theft or release of a biological agent to any other law enforcement or regulatory agency.

(d) All information, records and reports required by this section shall be kept confidential, provided that the Commissioner may disclose to a city, state or federal agency information necessary to respond to an emergency after determining such an emergency exists.

Notes: Section 13.13 was added to Article 13 by resolution of the Board of Health adopted at its meeting on June 7, 2016, to be effective 180 days after adoption. The section requires reporting of incidents involving theft, loss, release of certain biological agents or exposure of persons to such agents.

RESOLVED, that the list of section titles in Article 13 of the New York City Health Code be, and the same hereby is, amended to be effective 180 days after adoption of this resolution, to be printed together with explanatory notes to read as follows:

ARTICLE 13

LABORATORIES

§13.01 [Definition] Definitions.

§13.03 Report of positive findings.

§13.05 Testing for tuberculosis.

§13.07 Reporting of Hemoglobin A1C.

§13.09 Neonatal herpes simplex specimens.

§13.11 High-containment research laboratories; registration.

§13.13 High-containment research laboratories; required reports.

Notes: Article 13 was amended by resolution of the Board of Health adopted at its meeting on June 7, 2016, to be effective 180 days after adoption of the resolution, to add new sections 13.11 and 13.13, requiring registration of high-containment research laboratories that work with certain biological agents and reporting of incidents involving loss or theft of, or exposures to such agents.

Capitalize on Pivotal Location

- Connect with adjacent Institutions
- Enhance Collaborations
- Facilitate R+D Partnerships

Modernize NYBC

- Maximize efficiency and flexibility
- Attract /retain scientists and staff
- Provide inspiring work environment

Expand Research

- Allow for 26 Principal Investigators
- Include Clean Rooms and BSL3 Labs
- Support commercial collaborations

Attract Life Sciences Partners

- Optimize floor plate size/efficiency: 30,000 sf
- Enable flexibility for multiple Partner sizes
- Allow for wet and dry research capability

Support Scientific Collaboration

- Bring together, co-locate NYBC and Partners
- Provide conference and education center
- Provide access to shared core facilities

Provide Robust Infrastructure

- Building Systems/ Technology
- Vibration Control
- Loading and service capability

Center East Design Goals