April 25, 2016

New York City Department of Health and Mental Hygiene
Gotham Center, 42-09 28th Street, CN 31
Long Island City, NY 11101-4132

To whom it may concern,

The Icahn School of Medicine at Mount Sinai has a faculty of internationally recognized experts in the area of Infectious Disease research. While we acknowledge the importance of public health notifications and appreciate that the accounting of all high containment laboratories and infectious microorganisms or hazardous biological material within New York City informs public policy and helps mitigate public health risks, we are concerned with several aspects of the proposed amendments to Article 13 of the New York City Health Code.

Please see, below, our comments and suggestions to the proposed amendments:

Registration of facilities 13.11 High-containment research laboratories: Registration

a) *Registrations.* Registrations will expire and must be renewed every two years: For consistency and to reduce regulatory burden we propose that the three (3) year registration period under the Federal Select agent program be adopted.

4) Listing of all biological agents kept or in use within the biological facilities.
In the case of select agents and toxins there are significant security concerns and resultant confidentiality that must be maintained regarding these agents. This is particularly true for agents of Dual Use Research Concern, DURC. What provisions have been considered under the proposed amendments to ensure confidentiality of the information requested? [1]

Reporting requirements 13.13

There are two reporting requirements under 13.13:

1) Reporting of loss or theft of biological agents within one hour:

While we fully understand and support the need for timely reporting, the one hour time requirement seems to place undue burden on our researchers and the institution. We

[1] Also please note that non-select, non-clinical agent BSL-3 laboratories have been in operation at many academic medical centers within New York City and the State for many years, some in excess of two decades. Studies involving *Tuberculosis*, low-pathogen influenza (vaccine strains), and more recently West Nile Virus, are routinely conducted with no reports of serious disease. Therefore, it is difficult to understand the inclusion of these entities under the proposed registration requirements.

propose prompt reporting , within a 24 hour time limit, of confirmed loss or theft, which will provide adequate time for investigation of incidents and to develop an institutional response plan. The first hour of any such incident is likely to be very active and this reporting time line will place the institution in a high probability of non-compliance, not due to negligence, but rather as a result of over-exuberant regulatory expectations.

2) Reporting of suspected exposure of personnel to biological agents within one hour.

Under section 2.10 of the NYSDOH health code for reporting of suspected cases of communicable diseases, the requirement is to report within 24 hours. This is a well established standard for reporting in the medical community. We are concerned that the proposed amendments impose a reporting requirement in excess of other communicable disease concerns. We propose that the 24 hour standard apply to the proposed amendments.

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Re: Proposed Amendment to Article 13 of the New York City Health Code regarding Non-Clinical Laboratories that Work with Certain Biological Agents

On behalf of Weill Cornell Medicine (WCM), we appreciate the opportunity to comment on the New York City Department of Health and Mental Hygiene (DOHMH) proposed amendment to Article 13 of the New York City Health Code regarding non-clinical laboratories that work with certain biological agents. At WCM, we are committed to exceptional patient care. At our research facilities our investigators, fellows and graduate students are leading the way in biomedical research, translating scientific advances into innovative medical applications and clinical advances.

The safety of our staff, patients and community is of utmost importance to us and is consequently reflected throughout our institutional policies and procedures. WCM commends the Department of Health and Mental Hygiene's proposal to establish a more active role in the monitoring and oversight of laboratories working with biological agents. However, we feel that the proposed regulations as written are too broad in their scope and could negatively impact the operations of our research laboratories. Additionally, the examples of recent laboratory accidents cited in the *Notice of Public Hearing and Opportunity to Comment on Proposed Amendments to the New York City Health Code* are those found in select agent research laboratories. Our research laboratories, including biosafety level 3 (BSL3) laboratories, are non-select agent facilities and are already governed by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and the U.S. Department of Agriculture (USDA) as well as peer-reviewed by our WCM Institutional Biosafety Committee (IBC). The WCM IBC is registered with the NIH as required and includes community members representing community risks and concerns. Our BSL3 facility is registered, permitted and inspected and meets or exceeds all BSL3 requirements.

In reviewing the proposed regulations, we respectfully present the following comments:

1. **The overall scope of the proposed regulation should be focused on Select Agents as defined by the Select Agents and Toxins Regulations (7 CFR Part 331; 9 CFR Part 121; and 42 CFR Part 73), rather than all BSL3 and BSL4 laboratories.** As written, the current proposal includes registration and reporting requirements for all BSL3 and BSL4 laboratories. While we understand and concur

with the need for registration and incident reporting of biological agents that can pose an imminent public health threat, many BSL3 and BSL4 laboratories work with agents that do not pose the same level of community risk and should not be subject to the same reporting requirements.

2. **The definition of a "biological agent" should be more explicit.** As defined in section 13.01 of the proposed amendment, biological agents subject to the regulation should be listed in full and should be consistent with those determined by the Federal Select Agent Program (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) to present a potential risk to the community. This program has been in existence for more than a decade and has undergone rigorous scrutiny and revision since its inception. Other cities and states requiring the additional registration and reporting requirements have used the Federal Select Agent Program as a guide.

3. **Registration requirements should be tiered to reflect the relative risk to public health and safety posed by laboratories that do not work with Select Agents.** We agree there are benefits to registering and reporting BSL-3/BSL-4 (high and maximum) containment facilities in order to ensure the safety of the research staff working within the facilities, the community surrounding the facility, and the environment. The currently proposed amendment includes registration requirements for all BSL-3/BSL-4 facilities, which would include laboratories that do not have the same public health risks as select agent laboratories. For this reason, we propose a tiered registration system. We recommend registration of select agent BSL-3/BSL-4 facilities to comply and align with the Federal Select Agent Program (FSAP) regulations (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). Due to the decreased level of risk to public health, we recommend that all other facilities (non-FSAP) be exempt from registration requirements or provide a registration similar to CDC Form 0.753 (Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States) to the HHS/CDC Import Permit Program. If laboratory inspections are required as part of Article 13, we recommend the regulatory agencies, e.g., USDA, CDC, NYCDOH, adopt the same standards and the validity of licenses or permits granted by the other in order to reduce the administrative burden, time related burden, and number of on-site inspections for the registered facilities.

4. **The information that would be required for registration documents as delineated in section 13.11 (a) should be defined in greater detail.** As an example, the regulation states that a "listing of all biological agents kept or used" would be required information on registration documents, but it is unclear what level of granularity that listing would require. If multiple strains of an agent are kept in the facility, would each one need to be delineated? If so, would the use of one of these strains be considered a "change in registration information" that would require NYCDOH notification as described in section 13.11 (c)?

5. **The regulation should include safeguards to protect the security of information regarding the inventory and location of biological agents.** If this sensitive biosecurity and facility security information provided to the NYCDOH, as required in section 13.11 (2) and 13.11 (4), were made public, it would present both a public health threat and a security vulnerability to the

institutions maintaining these laboratories. We recommend the proposed resolution contain safeguards of both the physical location and provisions for information security access consistent with the Code of Maryland Regulations (COMAR) *10.10.11.13 Biological Agent Registry (*BAR) Information Confidentiality and Release of BAR Information and the Federal Select Agent Program (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73).

6. **Registration requirements would increase reporting burdens for high-containment research laboratories working with agents outside the scope of the regulation.** Due to space and other concerns, laboratories may currently opt to put agents lower than BSL3 status within a BSL3/BSL4 laboratory. Under the proposed regulation, laboratories will have to report the unintentional release of these agents as they would a BSL3 or BSL4 biological agent. As stated previously in recommendation #2, a delineation of the specific biological agents that would require reporting on the event of exposure or unintentional release would limit the reporting burden on laboratories to those events that could pose a potential public health risk.

7. **The requirement to provide identification and contact information for all persons exposed to a biological agent as described in section 13.13 (b) conflicts with the need to protect patient information.** It is not clear how the confidentiality and security of protected health information (PHI) when it is transferred, received, handled, or shared can be maintained under this aspect of the reporting requirement, and is consequently in conflict with U.S. Department of Health and Human Services rules. We feel safeguards would need to be put into place to protect the privacy of employees and other impacted individuals.

8. **The regulation should be more explicit with regard to the definition of a potential exposure to or release of biological agents and provide a more realistic time frame for reporting.** As delineated in section 13.13 (b), the regulation is currently vague as to what would constitute the parameters of a spill or release that would require reporting. Additionally, the one hour reporting requirement specified in 13.13 (a) and (b) is an unreasonable timeframe. It is noted that Article 11 of the New York City Health Code currently establishes reporting requirements for confirmed exposures to communicable diseases. We recommend DOHMH take into account the detailed reporting requirements already promulgated in Article 11 that would apply to non-FSAP facilities. We would suggest language that states that confirmed exposure; theft or loss; or unintentional release from the facility should be reported as soon as possible, but within 24 hours.

We appreciate the opportunity to comment on this proposal.

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Re: Proposed amendment to Article 13 of the New York City Health Code regarding non-clinical laboratories that work with certain biological agents

The Rockefeller University appreciates the opportunity to comment on the New York City Department of Health and Mental Hygiene (NYCDOH) proposed amendment to Article 13 of the New York City Health Code regarding non-clinical laboratories that work with certain biological agents.

The Rockefeller University is committed to the mission of improving the understanding of life for the benefit of humanity. As part of this mission, the University is also committed to the health and safety of its faculty, staff, students and the greater community. We are also committed to ensuring that the facilities and materials required for the conduct of our world-renowned research are operated and handled with the highest level of environmental stewardship.

The University commends the NYC DOH's proposal to play a more active role in preparing for and mitigating the possibility of a release of or exposure to biological materials used in the city's many non-clinical research laboratories. The University thinks, however, that the proposed regulations as written are more broad than needed to meet the NYCDOH's stated goal and could potentially have a negative impact on the operations of our research laboratories.

After reviewing the proposed regulations, we respectfully ask for your consideration of the following comments:

1. **The overall scope of the proposed regulation should be focused on Select Agents as defined by 42 CFR-Select Agent Regulations, rather than all BSL3 and BSL4 laboratories, and should be limited to incident and injury reporting requirements.** As written, the current proposal includes registration and reporting requirements for all BSL3 and BSL4 laboratories. While we appreciate the need for incident reporting of biological agents that can pose an imminent public health threat, most BSL3 laboratories work with agents that do not pose the same level of community risk and should not be subject to the same reporting requirements.

2. **The definition of a "biological agent" should be more explicit.** As defined in section 13.01 of the proposed amendment, biological agents subject to the regulation should be specifically identified, listed in full and

should be consistent with those determined by the Federal Select Agent Program (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) to present a potential risk to the community. The Federal Select Agent Program has been in existence for more than a decade and has undergone rigorous scrutiny and revision since its inception. Other cities and states that require additional registration and reporting requirements use the Federal Select Agent Program as a guide.

3. **Registration requirements should be tiered to reflect the relative risk to public health and safety posed by laboratories that do not work with Select Agents.** While there may be benefits to registering and reporting BSL-3/BSL-4 (high and maximum) containment facilities to the NYC DOH, the currently proposed amendment includes registration requirements for all BSL-3/BSL-4 facilities, which would include laboratories that do not have the same public health risks as select agent laboratories. For this reason, we propose a tiered registration system. We recommend limiting the registration requirement to those BSL-3/BSL-4 facilities that all already registered with and/or would be required to register with the Federal Select Agent Program (FSAP) regulations (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). Due to the decreased level of risk to public health, we recommend that all other facilities (those not required to register under the FSAP) be exempt from NYC DOH registration requirements. If laboratory inspections are required as part of Article 13, we recommend the NYC DOH adopt the same standards and accept the validation of licenses or permit granted by the USDA or CDC in order to reduce the administrative burden for the registered facilities.

4. **The information that would be required for registration documents as delineated in section 13.11 (a) should be defined in greater detail.** In addition to limiting application of the registration requirement to those facilities covered by the FSAP, the NYC DOH proposed rules should be very clear in indicating what, if any additional information about the select agents is required. As an example, if multiple strains of an agent are kept in the facility, would each one need to be delineated? If so, would the use of a different strain of an already registered agent be considered a "change in registration information" that would require NYC DOH notification as described in section 13.11 (c)?

5. **The regulation should include safeguards to protect the security of information regarding the inventory and location of biological agents**. This sensitive biosecurity and facility security information provided to the NYC DOH, as required in section 13.11 (2) and 13.11 (4), risks being made public and presenting both a public health threat and a security vulnerability to the institutions maintaining these laboratories. We recommend the proposed resolution contain safeguards of both the physical location and provisions for information security access consistent with the Federal Select Agent Program (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73).

6. **Registration requirements would increase reporting burdens for high-containment research laboratories working with agents outside the scope of the regulation.** For space, collaboration and other logistical reasons, laboratories may currently opt to work with agents that do not require BSL3 containment status within a BSL3/BSL4 laboratory. Under the proposed regulation, laboratories will have to report the unintentional release of <u>any</u> biological agent used in the facility, regardless of whether the agent requires high containment. As stated previously in recommendation #2, a delineation of the specific biological agents that would require reporting on the event of exposure or unintentional release would limit the reporting burden on laboratories to those events that could pose a potential public health risk.

7. **The requirement to provide identification and contact information for all persons exposed to a biological agent as described in section 13.13 (b) conflicts with the need to protect patient information.** It is not clear how the confidentiality and security of protected health information (PHI) when it is transferred, received, handled, or shared can be maintained under this aspect of the reporting requirement, and is consequently in conflict with U.S. Department of Health and Human Services rules. We feel safeguards

would need to be put into place to protect the privacy of employees and other impacted individuals.

8. **The regulation should be more explicit with regard to the definition of a potential exposure to or release of biological agents and provide a more realistic time frame for reporting**. As delineated in section 13.13 (b), the regulation is currently vague as to what would constitute a reportable spill or release. Additionally, the one hour reporting requirement specified in 13.13(a) and (b) is an unreasonable timeframe. We suggest revising this to state that confirmed exposure, theft or loss, or unintentional release from the facility should be reported within 24 hours.

   We appreciate the opportunity to comment on this proposal.

4/26/2016

Comment on proposed resolution to amend Article 13 (Laboratories) of the New York City Health Code, requiring non-clinical laboratories that work with certain biological agents to register with the Department.

Thank you for the opportunity to comment on the proposed amendment to Article 13 (laboratories) of the NYC Health Code on "High containment research laboratories" (http://www1.nyc.gov/assets/doh/downloads/pdf/notice/2016/noi-article-13.pdf). Columbia University is committed to ensuring safe operation of their high containment research laboratories to protect the health of laboratory workers and the community at large. Columbia University appreciates the intent of the proposed amendment. There are some issues with the code that we believe warrant further review and consideration.

1. The amendment §13.11(a)(4) is unclear as to which agents require reporting. For example, are biological agents that are handled at BSL-2 but stored in the high containment research laboratory (BSL-3) subject to reporting? Are biological agents that are in long term archived storage (never manipulated) subject to the reporting? A list of biological agents that require reporting should be provided by DOHMH.

2. The amendment §13.13(a) requirement to report loss, theft, exposures etc., within one hour of discovery is an unreasonable expectation. The amendment reporting times do not differentiate between events of high public health risk (e.g. sick/exposed person) and low public health risk (e.g. missing specimen). For example, in the case of a missing biological agent, the high containment research laboratory will need more than one hour to conduct initial fact finding. We propose that the reporting should be aligned with the "Select Agent Program Select Agents and Toxins Theft, Loss or Release Information Document" which requires information should be submitted as it becomes known (but no later than 24 hours). This is also in line with physician reporting of reportable communicable disease, which is also within 24 hours.

3. The Federal Select Agent Program strongly encourages entities to refrain from publishing detailed information about locations of select agents and toxins, quantities on site, or researchers. Furthermore, any records or information systems that could allow an individual to gain access to the select agents or toxins should be safeguarded to prevent unauthorized access, theft, loss, or release of these materials. What assurances will DOHMH provide that electronic information submitted to them would be secured?

4. Would information submitted to DOHMH under amendment §13.13(a) be subject to Freedom of Information Act (FOIA) requests and therefore become public? If so, there is a concern that: (1) protected health information (PHI) of sick/exposed persons may not be safeguarded. (2) such information presents a security vulnerability to the institution since locations (rooms and buildings) are submitted and select agents may be among the reported inventories, and (3) intellectual property of researchers may be compromised.

5. The amendment §13.11(a)(4)(c) requirement to notify the DOHMH within thirty (30) calendar days of any changes to the information provided on the registration form will be a burden. This amendment is an unfunded mandate and represents an administrative burden for

high containment research laboratories, especially those such as the Columbia University Center for Infection and Immunity (CII) which uses molecular techniques to routinely identify numerous known and novel viruses in specimens. What assurance can DOHMH provide to minimize the burden on investigators of compiling forms for multiple biological agents with the advent of the registration process? The amendment also represents a potential financial burden in registration fees.

Thank you for your consideration of these issues.

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Re: Proposed amendment to Article 13 of the New York City Health Code regarding non-clinical laboratories that work with certain biological agents

On behalf of Memorial Sloan Kettering Cancer Center (MSK), we appreciate the opportunity to comment on the New York City Department of Health and Mental Hygiene (DOHMH) proposed amendment to Article 13 of the New York City Health Code regarding non-clinical laboratories that work with certain biological agents. At MSK, we are committed to exceptional patient care. At our research facility, the Sloan Kettering Institute (SKI), our investigators, fellows and graduate students are leading the way in biomedical research, frequently translating scientific advances into innovative medical applications and clinical advances.

The safety of our staff, patients and community is of utmost importance to MSK and is reflected throughout our institutional policies and procedures. Further, research laboratories at MSK and other institutions are regulated by the National Institutes of Health (NIH), Centers for Disease Control and Prevention (CDC), and United States Department of Agriculture (USDA), and they are peer-reviewed by NIH-registered Institutional Biosafety Committees (IBC), which include community members representing community risks and concerns. While MSK commends the DOHMH's proposal to play a more active role in the monitoring and oversight of laboratories working with biological agents, we feel that the proposed regulations as written are too broad in their scope and could potentially have a negative impact on the operations of our research laboratories. In reviewing the proposed regulations, we respectfully present the following comments:

1. **The overall scope of the proposed regulation should be focused on Select Agents as defined by 42 CFR-Select Agent Regulations, rather than all BSL3 and BSL4 laboratories.** As written, the current proposal includes registration and reporting requirements for all BSL3 and BSL4 laboratories. While we understand and concur with the need for registration and incident reporting of biological agents that can pose an imminent public health threat, many BSL3 and BSL4 laboratories work with agents that do not pose the same level of community risk and should not be subject to the same reporting requirements.

2. **The definition of a "biological agent" should be more explicit.** As defined in section 13.01 of the proposed amendment, biological agents subject to the regulation should be listed in full and should be consistent with those determined by the Federal Select Agent Program (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) to present a potential risk to the community. This program has been in existence for more than a decade and has undergone rigorous scrutiny and revision since its inception. Other cities and states requiring the additional registration and reporting requirements have used the Federal Select Agent Program as a guide.

3. **Registration requirements should be tiered to reflect the relative risk to public health and safety posed by laboratories that do not work with Select Agents.** We agree there are benefits to registering and reporting BSL-3/BSL-4 (high and maximum) containment facilities in order to ensure the safety of the research staff working within the facilities, the community surrounding the facility, and the environment. The currently proposed amendment includes registration requirements for all BSL-3/BSL-4 facilities, which would include laboratories that do not have the same public health risks as select agent laboratories and presents the potential for causing undue alarm. For this reason, we propose a tiered registration system. We recommend registration of select agent BSL-3/BSL-4 facilities to comply and align with the Federal Select Agent Program (FSAP) regulations (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73). Due to the decreased level of risk to public health, we recommend that all other facilities (non-FSAP) be exempt from registration requirements or provide a registration similar to CDC Form 0.753 (Application for Permit to Import Biological Agents or Vectors of Human Disease into the United States) to the HHS/CDC Import Permit Program. If laboratory inspection are required as part of Article 13, we recommend the regulatory agencies, e.g. USDA, CDC, DOHMH, adopt the same standards and the validation of licenses or permits granted in order to reduce the administrative burden for the registered facilities.

4. **The information that would be required for registration documents as delineated in section 13.11 (a) should be defined in greater detail.** As an example, the regulation states that a "listing of all biological agents kept or used" would be required information on registration documents, but it is unclear to what level of granularity that listing would require. If multiple strains of an agent are kept in the facility, would each one need to be delineated? If so, would the use of one of these strains be considered a "change in registration information" that would require DOHMH notification as described in section 13.11 (c)?

5. **The regulation should include safeguards to protect the security of information regarding the inventory and location of biological agents**. This sensitive biosecurity and facility security information provided to the NYC DOHMH, as required in section 13.11 (2) and 13.11 (4), risks being made public and presenting both a public health threat and a security vulnerability to the institutions maintaining these laboratories. We recommend the proposed resolution contain safeguards of both the physical location and provisions for information security access consistent with the Code of Maryland Regulations (COMAR) *10.10.11.13 Biological Agent Registry (*BAR) Information Confidentiality and Release of BAR Information and the Federal Select Agent Program (7CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73).

6. **Registration requirements would increase reporting burdens for high-containment research laboratories working with agents outside the scope of the regulation.** Given space concerns or other similar reasons, laboratories may currently opt to work with agents lower than BSL3 status within a BSL3/BSL4 laboratory. Under the proposed regulation, laboratories will have to report the unintentional release of these agents as they would a BSL3 or BSL4 biological agent. As stated previously in recommendation #2, a delineation of the specific biological agents that would require reporting on the event of exposure or unintentional release would limit the reporting burden on laboratories to those events that could pose a potential public health risk.

7. **The regulation should be more explicit with regard to the definition of a potential exposure to or release of biological agents and provide a more realistic time frame for reporting**. As delineated in section 13.13 (b), the regulation is currently vague as to what would constitute the parameters of a spill or release that would require reporting. Additionally, the one hour reporting requirement specified in 13.13(a) and (b) is an unreasonable timeframe. We would suggest language that states that confirmed exposure, theft or loss, or unintentional release from the facility should be reported soon as possible, but within 24 hours.

We appreciate the opportunity to comment on this proposal.