Date: September 3, 2013

To: All Case Faculty and Staff

From: Environmental Health and Safety

RE: Select Agents

Please Note that the list of agents has changed. We have attached the list of the exclusion amounts to this memo. Please report your inventory of agents to EHS regardless of your possession of agents below the exclusion level. For details and the most current information go to www.selectagents.gov

Stimulated in part by the attacks in Oklahoma City and the World Trade Center, Congress passed the Antiterrorism and Effective Death Penalty Act of 1996. It directed the Secretary of Health and Human Services to promulgate regulations identifying biological agents that pose a potential threat to human health and safety ("select agent") and governing their intentional or inadvertent transfer. On October 26, 2001 Congress sent to the President legislation affecting the possession of and access to biological agents and toxins with bioterrorism potential. This legislation, Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism (USA PATRIOT ACT) Act of 2001, extended the 1996 act. Ongoing national concerns in regards to the security and possession of select agents prompted the passage of the Public Health and Security and Bioterrorism Preparedness and Response Act of 2002, signed into law on June 12, 2002. Regulations implementing this act became effective on February 7, 2003. The regulations include many new provisions such as: a revised list of select agents; registration with the Centers for Disease Control and Prevention to possess the select agents; submission of the names of individuals with access to select agents to the Department of Justice for background checks; development of biosecurity and biosafety plans for entities wanting to use select agents for research; significant recordkeeping (including inventories and those accessing select agents) and training. Shipping of all Select Agents must be cleared through Safety Services as there are possibly special requirements for shipping locally and overseas. **There are significant criminal penalties that apply to individuals who attempt to circumvent the legislation and for failure to comply.** If you have any of the select agents on the next page, complete the following and FAX a copy to 368-2236, OR send the original via campus mail to EHS, Service Building, LC: 7227 (if you have any questions, contact Marc Rubin at 368-1518).

Please note: EHS will be sending this questionnaire out bi-annually. In the event that your lab will begin the use of a select agent, approval from EHS is required. This form is also available on our website, http://www.case.edu/ehs.
# Select Agent Registration Form

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<th>Principal Investigator/Faculty Member</th>
<th>Alternate Contact (when PI is away)</th>
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**Department/College**

**Office Address (room #, building and LC)**

**Mailing Address (if different)**

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<th>Telephone #</th>
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**Planned Starting Date:**

**Project Title**

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<thead>
<tr>
<th>Name of Select Agent(s)</th>
<th>Current/Expected Quantity (mg)</th>
<th>Storage Location</th>
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**Laboratory’s Location** (Building Name, Room Number, Locator Code)
The select agent regulations (7 CFR Part 331, 9 CFR Part 121, and 42 CFR Part 73) established a procedure by which an attenuated strain of a select biological agent or toxin that does not pose a severe threat to public health and safety, animal health, or animal products may be excluded from the requirements of the select agent regulations.

Final Rule (October 5, 2012)
On October 5, 2012, the final rule excluded any low pathogenic strains of avian influenza virus, any strain of Newcastle disease virus which does not meet the criteria for virulent Newcastle disease virus, all subspecies Mycoplasma capricolum except subspecies capripneumonae (contagious caprine pleuropneumonia), and all subspecies Mycoplasma mycoides except subspecies mycoides small colony (Mmm SC) (contagious bovine pleuropneumonia), provided that the individual or entity can verify that the agent is within the exclusion category.

In addition, the final rule included the removal of the South American genotypes of Eastern Equine Encephalitis virus (EEE), all Venezuelan Equine Encephalitis virus (VEE) subtypes except IAB and IC, the West African clade of Monkeypox virus and all conotoxins except the sub-class of conotoxins generally called "short, paralytic alpha conotoxins," exemplified by α-conotoxin GI and α-conotoxin MI and containing the following amino acid sequence X1CCX2 PACGX3X4X5X6CX7.

To prevent confusion on how an entity should handle samples that have been determined to be within a general taxonomic classification (e.g., EEE) but not within a particular genotype or subtype (e.g., North American EEE virus), the current general taxonomic listing of HHS and overlap select agents was maintained as opposed to listing a specific strain and adding an exclusion for the strains, subtypes, or pathogenicity levels which are not considered to have the potential to pose a severe threat to public health and safety. When an agent is initially identified by taxonomic classification, it is subject to the select agent regulations until further testing is accomplished to exclude the particular agent by strain, subtype, or pathogenicity level.

North American EEE virus (NA-EEE) genotype strains, which are the strains responsible for human and equine disease, are all genetically very similar to each other (less than 3 percent divergence at the nucleotide level) and can be easily distinguished from South American EEE virus (SA-EEE) genotype strains using diagnostic molecular techniques.

We also note that there are published diagnostic tests that differentiate the Congo Basin clade of Monkeypox virus from the West African clade.
Attenuated Strains of HHS and USDA Select Agents and Toxins

Based upon consultations with subject matter experts and a review of relevant published studies and information provided by the entities requesting the exclusions, the Federal Select Agent Program has determined that the following attenuated strains or toxin proteins are not subject to the requirements of the select agent regulations if used in basic or applied research, as positive controls, for diagnostic assay development, or for the development of vaccines and therapeutics.

However, an individual or entity that possesses, uses, or transfers an excluded attenuated strain will be subject to the regulations if there is any reintroduction of factor(s) associated with virulence or other manipulations that modify the attenuation such that virulence is restored or enhanced. In addition, attenuated strains that are excluded from the requirements of the select agent regulations are not exempt from the requirements of other applicable regulations or guidelines (e.g., NIH guidelines, USDA/APHIS permits, etc.).

Attenuated strains of HHS Select Agents and Toxins excluded

- Botulinum neurotoxins
- Conotoxins
- Coxiella burnetii
- Eastern Equine Encephalitis virus
- Ebola virus
- Francisella tularensis
- Junin virus
- Lassa fever virus
- Monkeypox virus
- Yersinia pestis

Attenuated strains of Overlap Select Agents excluded

- Bacillus anthracis
- Brucella abortus
- Burkholderia pseudomallei
- Rift Valley Fever Virus
- Venezuelan Equine Encephalitis virus

Attenuated strains of USDA-only select agents excluded

- Avian influenza virus (highly pathogenic)

The above information was copied from the link below, additional information can be found here: http://www.selectagents.gov/Select%20Agents%20and%20Toxins%20Exclusions.html