USA PATRIOT ACT of 2001
and
RESTRICTIONS ON ACCESS TO SELECT AGENTS

Frequently Asked Questions

1. Q: What are the restrictions imposed by the USA Patriot Act on access to "select agents"?
   
   A: Section 817 of HR 3162 (the USA Patriot Act) amended 18 USC by adding § 175b, making it a criminal offense for a "restricted person" to ship, transport, receive or possess (in interstate or foreign commerce) non-exempt "select agents". The offense is punishable by fine or imprisonment not to exceed ten years.

2. Q: Who is a "restricted person"?
   
   A: Restricted persons are defined in §175b by the use of eight characteristics and include, for example, illegal aliens, fugitives from justice, persons dishonorably discharged from the U.S. Armed Services or nationals of countries determined by the Secretary of State to have repeatedly provided support for acts of international terrorism.

   The attached model "Annual Statement of Eligibility to Handle Designated Select Biological Agents or Toxins" contains the eight characteristics as listed in questions 1 through 8, including the seven countries on the Secretary of State's list (which does not yet include Afghanistan).

3. Q: What is a "select agent"?
   
   A: A select agent is a biological agent or toxin that has been listed by the Public Health Service in Appendix A of 42 CFR Part 72. Select agents include viruses such as the Ebola and Yellow Fever virus; bacteria such as Bacillus anthracis and Clostridium botulinum; and toxins such as Botulinum toxins and T-2 toxin. The complete list is appended to the attached Statement of Eligibility.

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4. Q: Are there select agents exempt from the restrictions on access?

A: Yes, Part 72 does contain exemptions from the restrictions, both within Appendix A and in §72.6(h). For example, toxins inactivated for use as vaccines are exempt as are certain agents of lower concentrations used for legitimate medical purposes or biomedical research.

5. Q: What responsibilities does the Act place on Universities or employers of individuals with access to select agents?

A: The Act does not place any explicit requirements on Universities or employers of individuals and does not impose criminal sanctions on an employer who may unknowingly permit a restricted person to have access to select agents. The criminal sanctions in 18 USC §175b are imposed only on a restricted person shipping, transporting, receiving or possessing select agents.

However, sound policy and compliance with the recommended procedures issued by the U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, Office of Health and Safety, in the publication entitled Biosafety in Microbiological and Biomedical Laboratories, dictates that employers or others having select agents within their possession and control take reasonable steps to prevent unauthorized access. Accordingly, the attached model “Annual Statement of Eligibility to Handle Select Biological Agents or Toxins” has been developed to assure compliance with the provisions of the Act.

In addition, the Act added provisions (18 USC §2339) making it a criminal offense for a person to “harbor or conceal” an individual if the person knows, or has reasonable grounds to believe, that the individual has committed, or is about to commit, a violation of §175—knowingly possessing a biological agent for non-peaceful purposes. These provisions could be used to prosecute a researcher who is too lax in allowing a restricted person, including a student, into a lab in which select agents are available, if the researcher knows the person is restricted.

6. Q: Should faculty and staff, as well as students, complete and sign a Statement of Eligibility if they are going to have access to select agents?

A: Yes, the Act applies to any person having access to select agents so the prohibition applies equally to faculty, staff or any students who may possess the select agents for any reason. The provisions added by the
USA Patriot Act of 2001 makes criminal otherwise normal research activity if conducted by a restricted person and actual handling of the select agent is not necessarily required. Anyone who has the responsibility to ship, transport, receive or who has access to select agents should be carefully screened and should sign the form.

The questions posed in the Statement of Eligibility are taken directly from the Act and are not necessarily models of clarity. If the faculty, staff or students asked to sign the form have questions about the certification, especially if the answer to any question appears to be “yes”, those persons may wish to consult with an attorney or seek clarification from the component’s Office of Legal Affairs or the System Office of General Counsel. There has been no judicial construction of the Act so there are unanswered questions at this time regarding legislative intent. Please be aware that this model Statement of Eligibility may change as Congress considers and passes further legislation on this subject.

7. Q: Does a University of Texas System Component have to use the attached form exactly as drafted?

A: No, a Component may tailor the form to speak to its individual circumstances. The model Statement of Eligibility contains all the elements contained in the Act, and also provides questions eliciting additional information so that if a Component desires to verify the information certified to, the form could be provided to the campus police, the FBI or an authorized third party verifier and should contain sufficient information within the form to accomplish the verification, without resorting to other sources of identifying information. The Statement of Eligibility is one means to assure compliance with the requirements of the Act; it is neither a mandatory nor an exclusive approach to assure compliance.

8. Q: What happens if a person refuses to sign a Statement of Eligibility?

A: If a person with access to select agents refuses to sign the certification, the Component has full discretion to prohibit that person from continuing to have access to any select agent until the person’s eligibility under the Act is determined.

9. Q: Does the Act mandate “background checks” before access to select agents should be permitted?

A: No, the Act is silent on the subject of background checks but verification of the information certified to may be prudent in certain circumstances. The
form is designed to put the person signing on notice that verification of the information certified to may be undertaken.

10. Q: How does a Component generate a list of all individuals who should sign a Statement of Eligibility?

A: Each Component should have a complete, accurate and up-to-date inventory of all select agents on the premises of the Component. The Component should also know and understand the purposes for which the select agent is being used and only the quantities justified by that purpose should be authorized. Only those persons with a legitimate need for access to or possession of the select agent should be authorized to have access. It is those persons who should complete a Statement of Eligibility.

12. Q: How did the USA Patriot Act change the previous law? Didn’t the provisions of the 1990 Biological Weapons Act and the Antiterrorism and Effective Death Penalty Act of 1996 cover a much broader range of biological agents and toxins?

A: Prior to the passage of the USA Patriot Act, it was a federal crime, punishable by life imprisonment, to develop, produce or possess “any biological agent, toxin or delivery system for use as a weapon....” The original definition of biological agent and toxin is much broader than the list of “select agents” referenced in the new law. The USA Patriot Act added “bona fide research” to the list of peaceful purposes and criminalized the possession of biological agents or toxins of a type or in a quantity that under the circumstances is not reasonably justified by a prophylactic, protective, bona fide research or other peaceful purpose. Components can avoid any exposure under this provision by assuring that the types and quantities of agents and toxins possessed are justified by current research activities and by using proper inventory controls.

13. Q: If I have additional questions, whom can I contact?

A: Bob Giddings in the Office of General Counsel is the lead attorney for Patriot Act issues and can be contacted at (512) 499-4462 or emailed at bgiddings@utsystem.edu.