

Regulation of Biological Materials Under Export Controls and Bioterrorism Laws

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In the post-September 11, 2001 world, our federal government regards export controls and trade sanctions and embargoes as tools to guard against terrorism, and is devoting heightened focus to compliance and enforcement in academic research settings. Congress and the defense-oriented interests at the export control, major science funding, and defense agencies are presently questioning and assessing the effectiveness of export controls to stem what they perceive to be a threat that academic institutions might transfer sensitive technology to potential terrorists. Export controls apply to many types of equipment, chemicals, biological agents and toxins, materials, goods, and software code (“materials or items”) that are used by academic research institutions, and to certain information, training, and instruction relating to controlled materials or items.² (This does not mean, however, that a license is required for most activities on campus as discussed below.) Congress and Federal agencies have particularly sought to increase regulations of chemicals, biological materials and related equipment for law enforcement and anti-terrorism purposes, rather than only for the traditional personal safety purposes, and there is an increase in the scope and type of laws and regulations governing transfer of biological materials and related equipment. Two federal laws enacted after September 11, 2001, Section 817 of the Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001 (“USA PATRIOT Act”)³ and the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“BPARA”)⁴ and its regulations impose new and very stringent requirements on the transfer of, and on certain other activities with, biological agents, toxins and related equipment. Certain covered chemicals and biologicals are subject to the requirements of export controls in addition to the requirements of the BPARA and its regulations and Section 817 of the USA PATRIOT Act. This heightened law enforcement (not just research safety) focus on chemicals and biologicals has a potentially great effect on academic research, as the life sciences are among the fastest growing areas of academic research.⁵ This article addresses principal U.S. statutory and

¹ Until recently, Ms. Keith was the Senior Counsel of Massachusetts Institute of Technology. This article does not represent the opinions or positions of the University of Florida or MIT.

² See Commerce Control List, *infra* note 49, and U.S. Munitions List, *infra* note 55.

³ USA PATRIOT Act, Pub. L. No. 107-56, 115 Stat. 272 (2001)(to be codified in scattered sections of 5, 8, 12, 15, 18, 20, 21, 22, 28, 31, 42, 47, 49, 50 U.S.C).

⁴ BPARA, Pub. L. No. 107-188, 116 Stat. 594 (2002). See Part I.C of this article.

⁵ Biological research (including research in biological sciences, medical sciences, other life sciences, and biological and biomedical engineering) has grown at a rate of 97% over the ten years ending in 2001, as compared with all other areas of scientific research and development which grew at a rate of 55%, according to a National Science Foundation survey. And these fields continue to be among the most productive in academic research today. See National Science Foundation, Academic Research and © Massachusetts Institute of Technology, University of Florida; Jamie Lewis Keith, author. This article includes portions of other publications authored by Ms. Keith from 2004 through September 2006 when she was the Senior Counsel of the Massachusetts Institute of Technology. Ms. Keith included additional and updated information in this article in October 2006 when she became Vice President and General Counsel of University of Florida.

regulatory regimes that govern the transfer of materials or items, particularly biological agents and toxins and chemicals, and related technical information.

I. Bioterrorism Laws

A. All Biological Agents and Toxins and Their Delivery Systems—USA PATRIOT ACT

One provision of the USA PATRIOT Act, Section 817(1), amends Chapter 10 of Title 18 of the United States Code (the “U.S. Criminal Code”) to criminalize a greater range of activities involving all types of biological agents and toxins (not only the so-called “select agents” addressed in Part I.B below) and the equipment that may be considered a delivery system for such materials.⁶ Section 175(a) of the U.S. Criminal Code remains in effect and provides that anyone who “*knowingly develops, produces, stockpiles, transfers, acquires, retains, or possesses any biological agent, toxin, or delivery system for use as a weapon,*” not including (under Section 175(b)) activities that are prophylactic, protective, or peaceful, or who knowingly helps a foreign state or organization to do so, or who attempts to do these things, may be punished by criminal fines of up to \$500,000 for entities, and by imprisonment for any term of years or for life, criminal fines of up to \$250,000, or by both for individuals, both subject to increase or decrease for certain aggravating and mitigating factors.⁷

Section 817(1) of the USA PATRIOT Act amends Section 175(b) of the U.S. Criminal Code, renumbering this section as 175(c) and redefining “[f]or use as a weapon” as this phrase is used throughout Section 175 to include “*development, production, transfer, acquisition, retention, or possession of any biological agent, toxin, or delivery system for other than prophylactic, protective, bona fide research, or other peaceful purposes.*”⁸ Section 817(1) then creates a new Section 175(b), adding as an additional offense “*knowingly possess[ing] any biological agent, toxin, or delivery system 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.*”⁹ This offense excludes any biological agent or toxin that is in its natural environment, meaning that the agent or toxin “has not been cultivated, collected, or otherwise extracted from its natural source.”¹⁰ This additional offense makes the mere knowing possession of agents or toxins a crime under certain circumstances, even if it is not known that the agents or

Development Expenditures, 2001, available at <http://www.nsf.gov/sbe/srs/rexp/start.htm> (lasted visited October 5, 2006).

⁶ USA PATRIOT Act § 817(1), 115 Stat. at 385–86 (codified at 18 U.S.C.A. § 175 (2000 & West Supp. 2003)).

⁷ 18 U.S.C.A. § 175(a), (b) (2000 & West Supp. 2003); § 3571(b)–(d) (2000) (emphasis added).

⁸ USA PATRIOT Act § 817(1), 115 Stat. at 385 (codified at 18 U.S.C.A. § 175(c) (2000 & West Supp. 2003)) (emphasis added).

⁹ *Id.* § 817(1), 115 Stat. at 385 (codified at 18 U.S.C.A. § 175(b)) (emphasis added).

¹⁰ *Id.*

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toxins or their delivery systems are “for use as a weapon.”¹¹ Such offense is punishable by up to ten years in prison, or criminal fines of up to \$250,000, or both for individuals, and by criminal fines of up to \$500,000 for entities, both subject to increase or decrease for certain aggravating or mitigating factors.¹²

Section 175 (a) and new Sections 175(b) and 175 (c) of the U.S. Criminal Code expand the criminal prohibition beyond knowing involvement with biological materials for use as a weapon. These sections together make it a crime for the university or college, as well as for the individual researcher or other personnel (such as research support staff, purchasing staff, or shipping and receiving staff, depending on their roles), to *possess or transfer or acquire* any biological agent or toxin or related equipment of a type or in a quantity that is not reasonably justified by a prophylactic, protective, bona fide research, or other peaceful purpose.¹³ And outsiders such as federal law enforcement and ultimately the courts, not the researchers or other personnel of universities, will decide what is “reasonably justified,” making it critical for institutions and individuals to view the law from a law enforcement perspective. The section criminalizes a wide range of activities and omissions involving biological agents and toxins and their delivery systems, and requires a significant reorientation for academic researchers who have not been accustomed to strict controls on how long excess materials are retained or on how much of a material is acquired or transferred in the first place. Regarding research from a law enforcement perspective is not a natural act in our academic culture.

B. Select Biological Agents and Toxins—USA PATRIOT ACT

Another Section of the USA PATRIOT Act, Section 817(2), adds § 175b to the U.S. Criminal Code, prohibiting any “restricted person” from *shipping, transporting, possessing, or receiving* biological agents or toxins listed and not exempted under the regulations implementing Section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 (“AEDPA”),¹⁴ and making such activities by a restricted person a

¹¹ *Id.*

¹² 18 U.S.C.A. §§ 175(b), 3571(b)–(d).

¹³ *See supra* notes 4-12. Unlike the prohibition in Section 817(2) of the USA PATRIOT Act, which created 18 U.S.C. § 175b to prohibit certain individuals from possessing, receiving, or transporting biological agents and toxins listed and not exempted under the regulations implementing Section 511(d)(1) of the Antiterrorism and Effective Death Penalty Act of 1996 and its successor, Section 817(1) of the USA PATRIOT Act amends the U.S. Criminal Code to prohibit certain activities involving *any* biological agent or toxin, or related equipment, that are not “reasonably justified” for prophylactic, bona fide research or other peaceful purposes, without regard to whether the agent or toxin is listed in or exempted from regulations and without any specific quantity thresholds. *Id.*; *supra* notes 11-16 and accompanying text.

¹⁴ Pub. L. No. 104-132, 110 Stat. 1214 (1996) (codified as amended in scattered sections 7, 8, 15, 18, 19, 21, 22, 28, 40, 42 U.S.C.) [hereinafter AEDPA]. The AEDPA’s regulations at 42 C.F.R. § 72.6(h), (j) listed select biological agents and toxins that are subject to registration requirements of the Secretary of Health and Human Services, Centers for Disease Control and Prevention, and exempted certain agents and toxins, including toxins with a Lethal Dose 50 “for vertebrates of more than 100 nanograms per kilogram of body weight [] used for legitimate medical purposes or biomedical research” or not being adequately potent to pose a severe risk to human health. 42 C.F.R. § 72.6(h) (2003).

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federal crime.¹⁵ This prohibition applies to the individual, not to the institution and, in addition to covering individuals who are researchers using listed, non-exempt agents or toxins, may cover individuals who are responsible for arranging for or undertaking shipping, receiving, transportation, or storage of listed, non-exempt agents or toxins.¹⁶ Violations by individuals of new Section 175b are subject to criminal penalties of up to ten years in prison and/or up to \$250,000 in fines, subject to increase or decrease for certain aggravating or mitigating factors.¹⁷ Although the prohibition applies directly to the individual, the institution could suffer adverse publicity and unwanted law enforcement attention if its researcher or other personnel were to violate the prohibition. The enactment of the BPARA, which is companion legislation to the USA PATRIOT Act, extends an obligation to the institution to not allow access to select agents and toxins to “restricted persons,” as addressed in Part I.C of this article.

Individuals who are “restricted persons” under the USA PATRIOT Act are not permitted to continue to possess the relevant biological agents and toxins, or to ship, receive, or transport them, or, with the enactment of the BPARA, to have access to them.¹⁸ Any support, custodial, shipping and receiving and other staff who are restricted persons and who may need to undertake or arrange for any of the prohibited activities, must at least be reassigned to work that does not involve proscribed activities with listed, non-exempt agents or toxins and may lose their positions if this is not possible; and any researcher who is a restricted person must abandon research involving such agents or toxins and change the focus of his or her career, very significant effects indeed.

A “restricted person” under the USA PATRIOT Act is anyone who:
[1] *is* under indictment for, or *has been* convicted of, a crime punishable by imprisonment for over one year [(e.g., felonies, including certain moving motor vehicle violations), whether or not the person was actually punished with imprisonment]; or [2] *is* a fugitive from justice; or [3] *is* an unlawful user of any controlled substance [e.g, an illegal drug or a drug used illegally as defined and listed in 21 U.S.C. 802 and 812]; or [4] *is* an alien illegally or unlawfully in the United States; or [5] *has been* adjudicated as a mental defective or *has been* committed to any mental institution [which could arguably include anyone who has been self-committed for depression or drug or alcohol abuse, although this has not been decided by a court]; or [6] *is* an alien [including a legal alien in the United States, but not including a lawful permanent resident of the United States or green card holder, who is a national of [Cuba, Iran, North Korea, Iraq, Libya, Sudan, or Syria] which includes individuals with dual citizenship of the United States and of any of the

¹⁵ USA PATRIOT Act § 817(2), 115 Stat. at 385–86 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)).

¹⁶ *See id.*, 115 Stat. at 386.

¹⁷ *See* 18 U.S.C.A. § 175b(c) (West Supp. 2003), § 3571(b), (d) (2000).

¹⁸ USA PATRIOT Act § 817(2), 115 Stat. at 385–86 (codified at 18 U.S.C.A. § 175b(a)). *See infra* Part I.C of this article.

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listed countries]; or [7] *has been* [dishonorably] discharged from the Armed Services of the United States.¹⁹

C. Select Biological Agents and Toxins—BPARA

Another federal law, the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (“BPARA”)²⁰, was enacted by Congress and signed into law by

¹⁹ USA PATRIOT Act § 817(2), 115 Stat. at 386 (codified at 18 U.S.C.A. § 175b(d)(2)) (emphasis added). There are no reported cases interpreting the USA PATRIOT Act’s definition of a restricted person or challenging the constitutionality of the Act’s criteria for defining a restricted person. One may question whether the USA PATRIOT Act’s definition of restricted person would be upheld in the event of a constitutional challenge. With the possible exception of the sixth criterion (i.e., aliens from the enumerated countries), however, the definition of restricted person does not appear to include any classification that receives heightened judicial scrutiny. Consequently, it is likely in most constitutional challenges that the government would have to show only that it has a rational basis for determining the categories of restricted persons in relation to achieving the Act’s legitimate national security purposes, and that such determinations, as implemented by the executive branch, are not arbitrary or capricious. *See City of Cleburne v. Cleburne Living Center*, 473 U.S. 432, 440 (1985) (noting that legislation is presumed to be valid and will be sustained if the classification drawn by the statute is rationally related to a legitimate state interest); 5 U.S.C.A. § 706(2)(A) (1996 & West Supp. 2003) (arbitrary and capricious standard for administrative agency action). Moreover, where national security is involved, Congress is given considerable discretion. *See Hirabayashi v. United States*, 320 U.S. 81, 93 (1943). This standard requiring a reasonable relationship of the law’s requirements to legitimate government purposes is generally easy to meet. The standard may be somewhat more difficult to meet, however, in narrow circumstances such as where an individual is determined to be a restricted person only because he or she was discharged dishonorably from the military due only to sexual orientation. In that particular case, there may be good arguments that the law should be held to violate the First Amendment or the Fourteenth Amendment (substantive due process or equal protection), made applicable to the federal government through the Fifth Amendment; however, the law otherwise is likely to be upheld.

In contrast to review of the classification of individuals as restricted persons under most of the USA PATRIOT Act criteria to which the reasonable relationship standard applies, the classification of individuals as restricted persons based only on their nationality is likely subject to a stricter standard of judicial review, the strict scrutiny standard. As the Supreme Court held in *City of Cleburne*, “race, alienage, or national origin . . . are so seldom relevant to the achievement of any legitimate state interest that laws grounded in such considerations are deemed to reflect prejudice and antipathy. . . . [T]hese laws are subjected to strict scrutiny and will be sustained only if they are suitably tailored to serve a compelling state interest.” *City of Cleburne*, 473 U.S. at 440. Despite this heightened standard of judicial review, it may be difficult to prevail in a constitutional challenge of even this criterion. The enumeration of a limited list of countries in the definition of a restricted person is tied to those countries that are suspected to be state sponsors of terrorism, and arguably may be closely related to the USA PATRIOT Act’s goal of preventing or deterring bioterrorist acts. In the current environment, the objective tailoring of criterion may be narrow enough to survive a challenge. The question under strict scrutiny is whether all legal aliens of such countries must be excluded from research with select biological agents and toxins in order to achieve the compelling interest of preventing bioterrorism.

It is important for academic institutions to document how the government is administering and enforcing the law to ensure that the relevant agencies are not doing so in a discriminatory fashion (e.g., against individuals of only certain religions) or in a manner that otherwise abuses the agencies’ discretion. It is also important for academic institutions to document the adverse effect of the law on important research if the academic community seeks to influence the development of more effective laws against bioterrorism that will safeguard our nation without undermining the research that makes the United States an international leader of education, innovation, and the world economy. While such information may be of limited value in a constitutional challenge to the USA PATRIOT Act’s restricted persons criteria, it would support reasoned arguments to Congress for amendments to the law.

²⁰ *Supra* note 4. The BPARA’s implementing regulations are at 42 C.F.R. pt. 73, 7 C.F.R. pt. 331, and 9 C.F.R. pt. 121.

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the President on June 12, 2002, to further protect against the use of certain particularly dangerous biological agents and toxins in bioterrorism. Title II, Subtitle A, Section 201(a) of BPARA (“Title II”) adds a new Section 351A to the Public Health Service Act,²¹ which is a companion federal law to Section 817 of the USA PATRIOT Act. The USA PATRIOT Act continues to apply to individuals who are “restricted persons” with respect to so-called select biological agents and toxins. Title II, Subtitle A is implemented by the Secretary of Health and Human Services (“HHS”) and its Centers for Disease Control and Prevention (“CDC”). Title II, Subtitle B, creates the Agricultural Bioterrorism Protection Act of 2002 and is implemented by the Secretary of Agriculture (“USDA”) and USDA’s Animal and Plant Health Inspection Service (“APHIS”). Violations of the BPARA are punishable by criminal fines of up to \$500,000 for entities and criminal fines of up to \$250,000, imprisonment for up to five years, or both, for individuals, and civil penalties of up to \$250,000 for individuals and \$500,000 for entities.²²

Title II is broader in its application than Section 817(2) of the USA PATRIOT Act or Section 511(e)–(g) of the AEDPA, applying to any institution, as well as to any individual, who *possesses, uses, or transfers* certain select biological agents and toxins that have the potential to pose a severe risk to human, animal, or plant health, or animal or plant products.²³ Such institutions and individuals may allow “access” to select agents and toxins only to individuals who have been approved for access by the applicable Secretary and cleared through background checks by the Attorney General, or who are escorted by those who are cleared in accordance with implementing regulations.²⁴ “Access” is a broad term that may apply not only to researchers and others who work directly with listed agents and toxins, but also to custodial and shipping and receiving

²¹ BPARA § 201(a), 116 Stat. at 637–46 (codified at 42 U.S.C.A. § 262a).

²² *Id.* § 201(a), 116 Stat. at 637 (codified at 42 U.S.C.A. § 262a(i)) (adding Section 351A(i) to the Public Health Service Act) (establishing civil monetary penalties); § 212(i), 116 Stat. at 655–56 (codified at 7 U.S.C.A. § 8401(i) (West Supp. 2003)) (establishing civil monetary penalties); § 231, 116 Stat. at 660 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)) (establishing criminal penalties); 18 U.S.C.A. § 3571 (2000) (criminal fines and sentences). *See also* Centers for Disease Control and Prevention, Select Agent Program: FAQ for New Regulation, available at <http://www.cdc.gov/od/sap/faq.htm>.

²³ *See* BPARA § 201(a), 116 Stat. at 637–46 (codified at 42 U.S.C.A. § 262a); § 212, 116 Stat. at 647–56 (codified at 7 U.S.C.A. § 8401 (West Supp. 2003)). The AEDPA and its regulations required the registration of listed non-exempt agents only prior to their transfer or receipt. AEDPA § 511(d)–(e), 110 Stat. 1214, 1284–85 (not codified, but published as 42 U.S.C.A. § 262 note (2003)). The USA PATRIOT Act only prohibits “restricted persons” from shipping, transporting, possessing and receiving listed, non-exempt agents and toxins. USA PATRIOT Act § 817(2), 115 Stat. at 385–86 (codified at 18 U.S.C.A. § 175b (West Supp. 2003)). APHIS’ list of regulated agents and toxins under Section 212 of the BPARA and its regulations is new, although APHIS had previously regulated and continues to regulate the importation and inter-state transportation of certain organisms, diseased or treated animals, and plant pests. *See* 9 C.F.R. pt. 122 (2004); 7 C.F.R. § 330.200 (2004).

²⁴ BPARA § 201(a), 116 Stat. at 638–42 (codified at 42 U.S.C.A. § 262a) (adding Section 351A(b)–(e) to the Public Health Service Act); § 212(b)–(e), 116 Stat. at 647–52 (codified at 7 U.S.C.A. § 8401 (West Supp. 2003)); 42 C.F.R. 73.7, 73.10; 9 C.F.R. §§ 121.7, 121.10; 7 C.F.R. §§ 331.7, 331.10.

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staff and visitors who enter areas where listed agents or toxins are stored, used, shipped, or received and who either have possession, or have the ability to gain possession, of a listed non-exempt agent or toxin.²⁵

Export control laws and regulations continue to govern the transfer to foreign nationals or U.S. citizens abroad of biological agents and toxins and certain related equipment that are governed by the BPARA (as well as additional chemicals, agents, and toxins), the provision of controlled technical information about such materials or items to foreign nationals or U.S. citizens abroad, and the provision of controlled technical information about such materials or items to foreign nationals in the United States.²⁶ U.S. Department of Transportation laws and regulations continue to apply to transportation of agents and toxins as hazardous materials.²⁷

Generally, Title II of BPARA and its implementing regulations prohibit any entity or individual from possessing, using, transferring, receiving, or having access to listed, non-exempt biological agents and toxins within the United States, except for a “lawful purpose”²⁸ and unless and until the entity, any individual who owns or controls the entity, certain individuals who are responsible for BPARA compliance at the entity (i.e., the institution’s designated BPARA responsible officials), and all individuals who will possess, use, transfer, or have unescorted access to the agents or toxins are registered with the Secretary of HHS or Agriculture,²⁹ as appropriate, following their clearance through background checks, referred to as “security risk assessments,” to be conducted by the Attorney General.³⁰ Approval of registration is conditioned on the development and implementation of security, safety, training, and emergency preparedness and response plans and measures, record-keeping and inventory protocols, transfer protocols and other measures in accordance with the regulations implementing the Act.³¹ The BPARA required the Secretaries of HHS and Agriculture (collectively “Secretaries”) to adopt regulations by mid-December 2002 to implement the Act.³²

²⁵ See 42 C.F.R. § 73.10(b); 9 C.F.R. § 121.10(b); 7 C.F.R. § 121.10(b).

²⁶ See Part II of this article.

²⁷ See 49 C.F.R. pts. 171-180 (2003).

²⁸ See BPARA § 201(a), 116 Stat. at 637–46 (codified at 42 U.S.C.A. § 262a); § 212, 116 Stat. at 647–56 (codified at 7 U.S.C.A. § 8401).

²⁹ See BPARA § 201(a), 116 Stat. at 638–39 (codified at 42 U.S.C.A. § 262a) (adding Section 351A(d) to the Public Health Service Act); § 212(d), 116 Stat. at 648–49 (codified at 7 U.S.C.A. § 8401); 42 C.F.R. §§ 73.7; 9 C.F.R. § 121.7; 7 C.F.R. § 331.7 (registration requirements).

³⁰ See BPARA § 201(a), 116 Stat. at 639–42 (codified at 42 U.S.C.A. § 262a) (adding Section 351A(e) to the Public Health Service Act); § 212(e), 116 Stat. at 649–52 (codified at 7 U.S.C.A. § 8401); 42 C.F.R. § 73.7, 73.10; 9 C.F.R. §§ 121.7, 121.10; 7 C.F.R. §§ 331.7, 331.10. The FBI is the arm of the Justice Department that conducts the security risk assessments.

³¹ *Id.*

³² BPARA § 202(b), 116 Stat. at 646 (not codified, but published as 42 U.S.C.A. § 262a note (2003)); § 213(c), 116 Stat. at 657 (not codified, but published as 7 U.S.C.A. § 8401 note (West Supp. 2003)). Within 180 days after enactment of the BPARA, the HHS Secretary was required to promulgate an interim final rule for carrying out the provisions of § 351A of the Public Health Service Act (i.e., Title II of the © Massachusetts Institute of Technology, University of Florida; Jamie Lewis Keith, author. This article includes portions of other publications authored by Ms. Keith from 2004 through September 2006 when she was the Senior Counsel of the Massachusetts Institute of Technology. Ms. Keith included additional and updated information in this article in October 2006 when she became Vice President and General Counsel of University of Florida.

The regulatory requirements under the BPARA are extensive and complex. This article will not fully address them and provides references to further resource materials for additional details. It is particularly important, however, for researchers and others who are involved with receiving, using, possessing or transferring biological materials and toxins to be aware that the USA PATRIOT Act, the BPARA, and export controls and trade sanctions may apply to the use and transfer of these materials and toxins. Compliance with each statutory and regulatory regime must be separately evaluated, achieved and maintained. The aims of each regime are different in some respects, although certain uses and transfers of biological agents and toxins are regulated under all of them. The BPARA and its regulations are aimed at physical security, not security of technical information, export controls are aimed at physical and information security for purposes of protecting the military and security interests as well as the commercial interests and foreign policy goals of the United States, and trade sanctions are aimed at implementing our nation's trade and economic sanctions in furtherance of our foreign policy.

Under the BPARA, an entity or other person is prohibited from transferring any listed, non-exempt agent or toxin to another entity or other person in the United States, or from receiving in the United States any such agents or toxins from any entity or person inside or outside the United States, unless (i) the sender and recipient are registered appropriately; (ii) the sender and the U.S. recipient fulfill the CDC's or APHIS' requirements, as applicable, for securing agency pre-transfer approval and for filing transfer documentation with the agency, and are registered under the regulations for the agent or toxin being transferred, (iii) the sender from outside the United States satisfies all import requirements, (iv) all senders satisfy applicable packaging and shipping laws, (v) the BPARA responsible official for the recipient sends the required transfer documentation to the sender and the HHS or USDA Secretary (through CDC or APHIS) within two business days of receipt of such agent or toxin, (vi) the BPARA responsible official for the recipient "immediately" reports to the Secretary (through CDC or APHIS) if the agent or toxin is not received within forty-eight hours of its expected delivery or if the packaging is leaking or damaged, and (vii) the BPARA responsible official for the transferor also ensures that listed, non-exempt agents and toxins are only transferred to recipients who are registered and in compliance with the transfer requirements of the BPARA regulations.³³ These requirements do not apply to intra-entity transfers if the sender and the recipient are under the same registration certificate, but do apply if the

BPARA), provided that the effective dates for such regulations must "minimize disruption of research or educational projects that involve [listed] biological agents and toxins . . . and that were underway as of the effective date of such rule." *Id.* § 202(b)–(c), 116 Stat. at 646–47 (not codified, but published as 42 U.S.C.A. § 262a note). On March 18, 2005, final regulations were published. 70 Fed. Reg. 13242, 13294 (March 18, 2005).

³³ 42 C.F.R. , §73.16; 9 C.F.R. § 121.16; 7 C.F.R. § 331.16.

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sender and the recipient are not under the same registration certificate.³⁴ If an entity has more than one location, it will have a separate registration certificate for each location and, consequently, will have to comply with transfer requirements when transferring agents or toxins from one of its locations to any other.³⁵ Transfers to an entity or person outside of the United States may be governed by export controls and/or trade sanctions.³⁶

II. Export Controls and Trade Sanctions

A. Regulatory Regimes

The three principal export control and trade sanction and embargo regimes in the United States are the International Traffic in Arms Regulations (ITAR) of the State Department, the Export Administration Regulations (EAR) of the Commerce Department, and the regulations of the Office of Foreign Assets Control (OFAC) of the Treasury Department.³⁷ Export controls and trade sanctions and embargoes are intended to advance the United States' foreign policy goals, to restrict exports of goods, technology, and information that could enhance the military potential or economic superiority of other countries (both adversaries and friendly nations), to prevent the proliferation of nuclear, chemical, and biological weapons of mass destruction, to prevent terrorism, and to perform the United States' obligations under various foreign treaties and agreements with other nations, such as the Nuclear Non-Proliferation Treaty.³⁸ When export controls apply, they apply to U.S.-origin materials or items and certain related technical information, training, and instruction, wherever they are located or take place, whether in the United States or abroad.³⁹ Underlying the export control regimes and their criminal and civil penalties for violations, is the principle that it is a privilege and not a

³⁴ See 42 C.F.R. §§ 73.16(a), n.4; 73.7(g); 9 C.F.R. §§ 121.16, 121.7(g); 7 C.F.R. §§331.16, 331.7(g). Note that export control laws and regulations govern transfers abroad of certain agents, toxins and other chemicals. See Part II of this article.

³⁵ *Id.* (the regulations provide that the transfer requirements do not apply to intra-entity transfers if the same registration certificate applies; consequently, if there are two locations and two certificates, the transfer requirements do apply). A campus may be one location.

³⁶ See Part II of this article.

³⁷ ITAR, 22 C.F.R. §§ 120-130; EAR, 15 C.F.R §§, 730-774; and OFAC, 31 C.F.R. § 500. Refer to resource materials available at <http://www.generalcounsel.ufl.edu/exportControl/>, to *Export Controls and Universities: Information and Case Studies*, published by the Council on Government Relations, and to the report, *Restrictions on Research Awards: Troublesome Clauses, A Report of the AAU/COGR Taskforce* by Julie T. Norris, then-Director of the Office of Sponsored Programs, MIT, at <http://www.aau.edu> and <http://www.cogr.edu>.

³⁸ See, e.g., 15 C.F.R. § 730.6 (national security, foreign policy, nonproliferation and terrorism); 15 C.F.R. § 742.3(b)(viii)(A) (Nuclear Non-Proliferation Treaty).

³⁹ For example, the State Department regulates the sending or taking of a defense article out of the United States or disclosing technical data to a foreign person whether in the United States or abroad. 22 C.F.R. § 120.17(1), (4). The Commerce Department regulates actual shipments out of the U.S. as well as a release of technology or source code subject to the controls in a foreign country, or to a foreign national in the United States. 15 C.F.R. § 734.2(b)(1)–(2).

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right for U.S. citizens and permanent residents (individuals and entities) to “export” covered materials or items and certain related technical information.⁴⁰

Academic institutions and their researchers can take steps to qualify much of their campus research and teaching for regulatory exclusions from export controls, but they must understand and adhere to the prerequisites for exclusion. There are a number of exclusions from export controls and exemptions from licensing that permit the transfer of qualifying information, but not related materials or items, without a license. Particular care is needed for transfers of materials or items abroad or under circumstances where the recipient in the U.S. can be reasonably expected to export the materials or items abroad. Institutions and individuals must obtain export licenses, fulfill their conditions, and otherwise comply with export controls when an exclusion or exemption does not apply and a license is required.⁴¹

The export regulations are complicated, and determining whether or not materials or items or related technical information are controlled is an intricate and time consuming task, requiring both technical expertise about the characteristics of the materials or items and technology, and regulatory expertise about the controls.⁴² If only technical information, not materials or items, is involved in a proposed transfer or disclosure to anyone abroad or to a foreign national in the U.S., it is easier to first consider whether the fundamental research, publicly available/public domain, or another exclusion from controls (discussed below in Part II.B of this article) applies. If an exclusion applies, it is not necessary to undertake the detailed and complicated assessment of whether export controls apply to the information and, if so, whether a license is required and is likely to be obtainable.

Where materials or items are proposed to be transferred abroad, or an exclusion from controls or exemption from licensing does not apply to a proposed transfer or disclosure of technical information abroad or to a foreign national in the U.S., it is necessary to determine whether export controls apply. If so, it is imperative to confirm that an export or deemed export license has been obtained and that the proposed transfer or disclosure complies with the license conditions before the transfer occurs.

Violation of export controls or trade sanctions and embargoes can carry significant criminal and civil penalties against the individual involved as well as against the

⁴⁰ 15 C.F.R. § 764.3(a)(2).

⁴¹ See 15 C.F.R. § 764.3 (2004) (providing civil and criminal penalties for willful violation of the Commerce Department’s EAR); 22 C.F.R. § 123.1 (2000) (requirement for export or temporary import licenses).

⁴² See Fundamentals of Export Controls and Embargoes/Trade Sanctions for Research Universities” that may be found at http://www.generalcounsel.ufl.edu/exportControl/Fundamentals_of_Export_Control.pdf. © Massachusetts Institute of Technology, University of Florida; Jamie Lewis Keith, author. This article includes portions of other publications authored by Ms. Keith from 2004 through September 2006 when she was the Senior Counsel of the Massachusetts Institute of Technology. Ms. Keith included additional and updated information in this article in October 2006 when she became Vice President and General Counsel of University of Florida.

institution.⁴³ The possibility of losing export privileges and of damage to an institution's reputation are also significant penalties for violations.

1. EAR

EAR,⁴⁴ implementing the Export Administration Act of 1979, as amended,⁴⁵ among other federal authorizations,⁴⁶ is administered by the Bureau of Industry and Security ("BIS") of the Commerce Department under the Secretary for Industry and Security. EAR generally governs "exports,"⁴⁷ of materials or items (including certain biological agents and toxins and chemicals and the equipment used to deliver them) that may have a "dual use," meaning that they are largely commercial but may have both commercial and military applications, as well as certain "technologies" and "technical data" (i.e., information and data beyond general and basic marketing materials on use, development or production of materials or items controlled for such information).⁴⁸ EAR lists the items subject to its regulation on the Commerce Control List ("CCL"), which includes a "catch-all" category, EAR 99.⁴⁹

2. ITAR

ITAR,⁵⁰ implementing the Arms Export Control Act among other federal authorizations,⁵¹ is administered by the Directorate of Defense Trade Controls ("DDTC") of the State Department, under the Under Secretary for International Security and the Assistant Secretary for Political-Military Affairs.⁵² ITAR generally governs "exports"⁵³ of "defense articles" (i.e., certain materials or items), related "technical data" (i.e., information beyond basic marketing material on use, development and production of controlled materials or items) and "defense services" (i.e., information, training, and instruction) (a) that are "specifically designed, developed, configured, adapted, or

⁴³ Criminal penalties for willful violations under the Commerce Department's EAR are up to \$250,000 and/or up to ten years imprisonment for each violation for individuals, and up to the greater of \$1,000,000 or five times the value of the export for entities, depending on when the violation occurred. 15 C.F.R. § 764.3(b). Civil fines are from \$10,000 to \$100,000 per violation depending on when the violation occurred and the classification of the goods or technology involved. The Commerce Department can assess multiple violations per shipment. *Id.* § 764.3(a). Criminal penalties assessed against individuals and entities for willful violation of the State Department's ITAR are up to \$1,000,000 and/or up to ten years imprisonment for each violation. 22 U.S.C. § 2778(c) (2000). Civil fines are up to \$500,000 per violation. *Id.* § 2778(e). Criminal penalties for violation of OFAC's regulations are up to \$1,000,000 in fines for entities and \$250,000 in fines for individuals, along with the potential for up to ten years of imprisonment. 31 C.F.R. § 515.701 (2003). Civil fines are up to \$55,000 per violation. *Id.*

⁴⁴ 15 C.F.R. §§ 730–774.

⁴⁵ 50 U.S.C.A. §§ 2401–2420 (2003 & West Supp. 2003). The Export Administration Act has lapsed. Its provisions are being implemented through Executive Order.

⁴⁶ E.g., Executive Orders under the International Emergency Economic Powers Act, *id.* §§ 1701–1706 (2003).

⁴⁷ 15 C.F.R. § 734.2(b).

⁴⁸ *Id.* §§ 730.1–730.3, 730.5–730.7, 734, 772, 774, Supp 1 and 2.

⁴⁹ *See id.* § 774 [hereinafter Commerce Control List].

⁵⁰ 22 C.F.R. §§ 120–130.

⁵¹ 22 U.S.C.A. § 2778 (1990 & West Supp. 2003).

⁵² 22 C.F.R. § 120.1.

⁵³ *See id.* § 120.17, 120.19 ("export" and "reexport," respectively).

modified for a military application . . . [do] not have a predominant civil application[], and . . . [do] not have [a] performance equivalent . . . to those of an article or service used for civil applications” or (b) that are “specifically designed, developed, configured, adapted, or modified for a military application, and [have] a significant military or intelligence applicability.”⁵⁴ Many regulated defense articles are listed on the United States Munitions List (“USML”),⁵⁵ although this list is not as specific as the CCL under EAR, and ITAR regulation relies as well on general standards. ITAR regulates materials or items (and related information constituting defense services or technical data) that are designed to kill or injure in a military context, as well as materials or items and certain related information that are designed to defend against such death and injury.⁵⁶ Seemingly innocuous equipment, such as mini research submersibles (even if not intended by the creator for a military application),⁵⁷ can be included on the USML depending on their configuration. Articles or services that, in the State Department’s judgment, are specifically designed, developed, configured, adapted, or modified for a military application and do not have predominant civil applications, as well as those articles and services with significant military or intelligence application that, in the State Department’s judgment, require control, fall under the ITAR.⁵⁸ In addition to regulating USML-listed defense articles and related defense services and technical data, ITAR regulates other materials or items (and certain related information, training and instruction), when there is reason to know that they will be used in or for weapons of mass destruction or when they are designed or modified for military use.⁵⁹

3. OFAC Regulations

Supplementing EAR and ITAR are the regulations of OFAC within the U.S. Treasury Department. The OFAC regulations govern payments to, transfers of any service, materials or items of value to, or travel to, certain sanctioned and embargoed foreign countries, and transactions with and transfers to certain embargoed individual and entity end-users who are deemed to be involved in terrorism, the drug trade, or other illicit activities.⁶⁰ These regulations implement United States’ trade embargoes and economic sanctions against specified countries, entities, and individuals.⁶¹ OFAC’s regulations prohibit the payment or transfer of any thing and any service of value to sanctioned or embargoed countries, subject to the scope of the particular sanctions or embargoes applicable to each country, and to specified sanctioned or embargoed individuals and

⁵⁴ *Id.* § 120.3(a)–(b). See also *id.* § 120.6 (“defense article”), § 120.9 (“defense service”), 120.10 (“technical data”).

⁵⁵ *Id.* § 121.1 [hereinafter U.S. Munitions List].

⁵⁶ *See id.* .

⁵⁷ *See id.* § 121.15 (vessels of war and special naval equipment, including all submarines designed, modified or equipped for military purposes).

⁵⁸ *Id.* §§ 121.1, 120.3(b).

⁵⁹ *See id.* § 120.3 (policy on designating and determining defense articles and services, including those that are specifically designed, developed, configured, adapted or modified for a military application, which do not have predominant civil applications as well as those with significant military or intelligence applicability); *id.* § 121.1, at Category XVI: Nuclear Weapons, Design and Testing-Related Items.

⁶⁰ *See* 31 C.F.R. § 500 (2003).

⁶¹ *Id.*

organizations whether or not their countries are sanctioned or embargoed.⁶² Sanctions and embargoes may apply to U.S. citizens, as well as to foreign nationals. OFAC regulations may apply to bar transfer of information (even in academic research collaborations and technology transfers), providing instruction or services, planning and conducting surveys and conferences, physically transferring materials or items, entering contracts, making payments, and traveling, even when exclusions from EAR and/or ITAR apply. Similarly, the fact that an OFAC regulatory general license or other permission allows a transfer under OFAC of items or materials or technical information does not mean that the transfer is permitted under EAR or ITAR without an export license. Even when export controls and/or OFAC regulations do not apply, the BPARA regulatory requirements may apply to biological agents and toxins. Evaluation of the requirements of each regulatory scheme is required.

4. Basic Prohibitions and Requirements of Export Controls and OFAC Regulations

As a general matter, an “export” under the EAR and ITAR is the transfer outside of the United States or to a foreign embassy of any controlled materials or items (i.e., those on the CCL or USML or otherwise covered by the regulations). An export also includes the disclosure abroad of any controlled software, or of controlled “technologies” or “technical data” (i.e., information and data beyond general and basic marketing materials) on use, development or production of materials or items controlled for use (i.e., “operation, installation...maintenance...repair, overhaul, and refurbishing”), product development or production technology or technical data,⁶³ regardless of the medium in which such information is transmitted (whether oral, visual, via computer or other electronic means, wire, radio transmission, or physical conveyance).⁶⁴ “Export” also includes transfer of ownership or control of such, materials or items.⁶⁵ It does not matter for purposes of defining “export” whether the recipient abroad is a U.S. citizen or lawful permanent resident or is a foreign national. The mere travel abroad by an individual whose personal knowledge includes controlled technical data/technologies, however, is not an “export” as long as the controlled information is not communicated to anyone abroad.⁶⁶

“Deemed exports” are the transfer or disclosure, visually, electronically, or in any other medium, of controlled software or “technologies” or “technical data” (i.e.,

⁶² 31 C.F.R. § 500 et seq. The particular sanction for each embargoed country establishes the scope of the prohibitions.

⁶³ See 15 C.F.R. 772, 774, Supp. 1 and 2; 22 C.F.R. § 120.10 (“technologies” and “technical data”). See 15 C.F.R. § 772, 774; 22 C.F.R. 120.10 (“use”). The regulatory definition of “use” under EAR lists “operation, installation...repair...and refurbishing,” among other activities, as “use,” literally requiring all of the listed activities to be conducted to constitute “use.” The Commerce Department confirmed that it will not change this definition and considers it adequate for the time-being in a Federal Register notice on May 22, 2006. 71 Fed. Reg. No. 98, 29301-29303 (May 22, 2006).

⁶⁴ See 15 C.F.R. § 734.2.

⁶⁵ *Id.*

⁶⁶ See 22 C.F.R. § 120.17 (“export”), 120.19 (“reexport”), § 120.10 (“technical data”), 120.9 (“defense service”); 15 C.F.R. § 734.2(b). Note that traveling abroad with a computer on which EAR or ITAR-regulated encrypted software code is loaded may be an export. See 15 C.F.R. § 734.2.

information, beyond general and basic marketing materials, on use, development or production of materials or items controlled for such technology and data) to a foreign entity, individual or embassy in the U.S. Deemed exports do not include the mere transfer in the U.S. of the actual controlled materials or items without any accompanying information. U.S. campuses are rife with opportunities for deemed exports because many U.S. colleges' and universities' students, faculties, visitors, research collaborators and licensees are foreign.⁶⁷

Unless an exclusion from regulation applies, before any export of materials or items (or deemed export or export of related information constituting technical data or technologies) regulated under the ITAR may occur, and before some such exports or deemed exports regulated under the EAR may occur, a license must be obtained from the relevant agency, DDTC or BIS.⁶⁸ This means that before a faculty member may send controlled materials or items or controlled technologies or technical data to a United States or foreign colleague or student in a foreign country—and before a faculty member may collaborate with, share technical information with, or train a United States or foreign colleague or student abroad or a foreign colleague or student in the United States in any manner that involves transfer of controlled technical data or technologies—a license must be obtained, if an exclusion or exemption from regulation does not apply and a license is required. (Exclusions and exemptions generally, with very limited exceptions, cover information but not materials or items as addressed below.) Obtaining a license can take a few months (typical) to half a year or, in some cases, longer. Licenses may be required for exports and deemed exports to “friendly” foreign locales and nationals, such as those in Canada, countries in Europe, and Australia, as well as for exports and deemed exports to unfriendly or terrorist foreign locales and nationals.⁶⁹ If an exclusion from regulation does not apply and a license is required but denied, the export abroad or deemed export in the United States (even on campus) may not occur and the faculty member may not pursue the activities that require an export license.⁷⁰

Transferring export controlled information (controlled technology or technical data) to a foreign jurisdiction as part of a technology disclosure in order to seek patent protection in that jurisdiction does not require an EAR or ITAR license.⁷¹ However, transfer of the same information abroad to anyone for any other purpose, or in the U.S. to a foreign national, before the patent is published may require a license (depending on the applicable controls and nationalities involved and on whether exclusions from controls

⁶⁷ See 15 C.F.R. § 734.2; 22 C.F.R. § 120.17(2)-(5) (“deemed exports”) and 15 C.F.R. § 772, 774, Supp. 1 and 2; 22 C.F.R. § 120.10 (“technologies” and “technical data”). There are some limitations on transfers of certain ITAR-controlled materials or items in the U.S. For more information on deemed exports see the guidance for researchers developed by Julie Norris, then-Director of the Office of Sponsored Programs of the Massachusetts Institute of Technology with input by Ms. Keith, then-the Senior Counsel of MIT, at http://www.generalcounsel.ufl.edu/exportControl/Deemed_Export_Information_September.pdf

⁶⁸ The State Department regulates the sending or taking of a defense article out of the U.S. or disclosing technical data to a foreign person whether in the U.S. or abroad. 22 C.F.R. § 120.17(1), (4). The Commerce Department regulates actual shipments out of the U.S. as well as a release of technology or source code subject to the controls to in a foreign country, or to a foreign national in the United States. 15 C.F.R. § 734.2(b)(1)–(2)(2004).

⁶⁹ See Country Control Chart, 15 C.F.R. § 738, Supp. 1 (2004).

⁷⁰ See supra notes 63-68 and accompanying text

⁷¹ See 15 C.F.R. 734.3(b)(1)(v); 15 C.F.R. 734.10(b); 22 C.F.R. 125.2(b).

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may apply).

When an EAR or ITAR license is not required for controlled materials or items, and when an export is exempt from licensing, export documentation is still required.⁷² Even if an exclusion from export controls applies, as discussed below, there may still be restrictions on travel to, payments to, and/or transactions and transfers with certain sanctioned or embargoed locales, organizations, and/or individuals under the OFAC regulations.⁷³

Before materials or items or related information are transferred abroad or to individuals in the U.S., and before any payment, advice or service is provided abroad or in the U.S., the OFAC sanctions lists should be consulted to ensure that the transfer is not to a prohibited person, entity or country. As a practical matter, it is necessary to decide how frequently and before what actions this screening against OFAC lists will be done.⁷⁴ If it is prohibited, the transfer may not be made or the payment, advice or service may not be provided, unless OFAC grants a license. The likelihood of obtaining a license depends on which sanctioned country, individual or entity is involved, why the sanction was imposed, and the sanction's terms and conditions.

B. Regulatory Exclusions

The following part summarizes two exclusions from export controls, the “fundamental research” exclusion and the “publicly available”/“public domain” exclusion, that are used most frequently by academic research institutions. Additional exclusions are summarized in slides and an outline, “Fundamentals of Export Controls and Embargoes/Trade Sanctions for Research Universities” that may be found at [http://www.generalcounsel.ufl.edu/exportControl/Fundamentals of Export Control.pdf](http://www.generalcounsel.ufl.edu/exportControl/Fundamentals%20of%20Export%20Control.pdf).

1. Fundamental Research Information

The “U.S. university fundamental research” exclusion under EAR and ITAR is one of the most commonly known and applied exclusions from export controls by academic research institutions. This exclusion is based on National Security Decision Directive 189 (“NSDD 189”), which defines “fundamental research” as “basic and applied research in science and engineering, the results of which ordinarily are published and shared broadly within the scientific community, as distinguished from proprietary research and from industrial development, design, production and product utilization, the results of which ordinarily are restricted for proprietary or national security reasons.”⁷⁵ NSDD 189 was issued during the Reagan Administration despite concerns that the former Soviet

⁷² See 22 C.F.R. § 123.6 (2003); 15 C.F.R. § 740.1(f).

⁷³ 31 C.F.R. § 500 et seq.

⁷⁴ See <http://www.treas.gov/offices/enforcement/ofac>;
<http://www.ustreas.gov/offices/eotffc/ofac/sdn/index.html>;
<http://www.ustreas.gov/offices/eotffc/ofac/sanctions/index.html>

⁷⁵ See <http://www.fas.org/irp/offdocs/nsdd-189.htm>

Union might take advantage of U.S. openness. The Directive provides that the classification process is the appropriate means of securing information related to “fundamental research” by colleges and universities when security is warranted, and otherwise, except as required by statute, fundamental U.S. university research should be open and freely disseminated because the dissemination of knowledge supports our nation’s security. The George W. Bush Administration, in November 2001 and again in October 2004 confirmed that NSDD 189 continues to be the policy of the federal government.⁷⁶

The fundamental research exclusion under EAR and ITAR applies literally to (a) information (but not to export controlled materials or items) (b) “*resulting from*” or “*arising during*” “basic and applied research in science and engineering” (c) conducted at an “accredited institution[] of higher education” (EAR) or “higher learning” (ITAR) (d) “located in the United States” (e) that is “ordinarily published and shared broadly within the scientific community” and (f) that is not “restricted for proprietary reasons or specific national security reasons” (EAR) or subject to “specific U.S. Government access and dissemination controls” (ITAR).⁷⁷ This exclusion permits U.S. universities to allow foreign members of their communities (e.g., students, faculty, and visitors) to participate in research projects involving export-controlled information on campus in the United States. Also, once fundamental research is created on campus in the U.S. in accordance with the exclusion’s prerequisites, the research results (otherwise controlled information constituting technologies and technical data) may be transferred abroad without restriction. The nature and purpose of this information is to be public; hence it is *excluded*, not merely exempted, from controls. This exclusion does not allow the transfer of controlled materials or items abroad (with very limited exceptions under ITAR).⁷⁸ There is a dialog underway among academic research institutions and the federal government (particularly the Commerce Department) concerning whether or not this exclusion allows the deemed export, while conducting fundamental research on campus in the United States, of certain controlled technologies and technical data that do not “arise during” or “result from,” but that are already existing and “used in” or “necessary

⁷⁶ In a November 2001 letter to Dr. Harold Brown, Co-chairman of the Center for Strategic & International Studies, Dr. Condoleezza Rice, Assistant to the President for National Security Affairs, stated, “the policy on the transfer of scientific, technical, and engineering information set forth in NSDD 189 shall remain in effect, and we will ensure that the policy is followed” while a “broad-based review” ensues of “technology transfer controls.” See <http://www.aau.edu/research/Rice11.1.01.html>. Dr. Rice, in an October 2004 letter to then MIT president Charles M. Vest and 21 other research university presidents, confirmed the importance of both fundamental research and security. See http://www.generalcounsel.ufl.edu/exportControl/Condoleezza_Rice_Letter.pdf.

⁷⁷ 15 C.F.R. § 734.3(b)(3), 734.8(a),(b); 22 C.F.R. § 120.11(8).

⁷⁸ The limited exception relates to an expanded “fundamental research” exclusion involving research satellites and related information exports to government research institutions and to universities in European Union countries, NATO countries, major non-NATO allies, and European Space Agency countries where only nationals of these countries will have access. See 22 C.F.R. 121.1 XV(a) or (e), 123.16(b)(10)(equipment), and 125.4(d)(services/information/instruction).

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for,” fundamental research. This interpretation is consistent with NSDD 189. It has long been the reasonable interpretation of the academic research community that, for fundamental research to have any meaning, it must allow research group members to freely disclose among themselves information on how to use controlled equipment and materials in the research. The government has not previously challenged this interpretation, but over the last two years has been discussing and assessing the Commerce Inspector General’s interpretation as well as that of academic research institutions.

If a university accepts a condition from a government agency funding the research that requires the agency’s approval prior to publication of the research results or restricts access to the research results or participation in the research to U.S. citizens, the fundamental research exclusion is destroyed and export controls apply if the materials or items and/or related information constituting technologies or technical data, are controlled under EAR or ITAR.⁷⁹ Seeking to impose such restrictions, rather than classifying research that presents real security concerns is contrary to the principles of NSDD 189.⁸⁰ The same loss of exclusion occurs if a non-government sponsor imposes proprietary restrictions on publication of or access to the research results.

⁷⁹ See 15 C.F.R. 734.8(b); 15 C.F.R. 734.11; 22 C.F.R. 123.16(b)(10)(ii). EAR provides a limited exception from licensing requirements when the federal government imposes specific national security controls in a funding contract provided that the university adheres to all of the national security controls. These controls are typically as or more stringent than the security that would have to be implemented in connection with an export licenses. If the controls are not satisfied, export licensing requirements apply (and a violation will arise if a license was required and not obtained) and the fundamental research exclusion is not available.

⁸⁰ The report, Restrictions on Research Awards: Troublesome Clauses, of a joint task force of the Association of American Universities and the Council on Government Relations issued in March 2004 finds that over a six-month period (August 2003 through February 2004), the 20 institutions participating in the task force experienced 138 instances of publication or foreign national restrictions being imposed by federal funding agencies on unclassified federally-funded research. This report is available on COGR’s website at <http://www.cogr.edu> and on AAU’s website at <http://www.aau.edu>. The task force was headed by Julie T. Norris, then Director of MIT’s Office of Sponsored Programs, who also authored the report, and included representatives of California Institute of Technology, Carnegie Mellon University, Duke University, Georgia Institute of Technology, Harvard University, MIT, Northwestern University, University of Pennsylvania, Stanford University, Texas A&M, University of California at Berkeley and San Diego, University of Cincinnati, University of Colorado at Boulder, University of Maryland at College Park, University of Michigan, University of Minnesota, University of Texas at Austin, University of Wisconsin, and Washington University in St. Louis. The restrictions sometimes were imposed directly in an award to a university and other times were passed through a prime commercial company awardee to a university under a subcontract. A minority of schools accepted the restrictions as initially imposed; a minority of schools declined the funding; some schools negotiated changes in the conditions to eliminate unacceptable restrictions (although the negotiations took many months and delayed the research); and some schools were still negotiating at the time of the report. In accepting these types of restrictions, institutions accept the application of export controls and corresponding fundamental changes to campus openness and nationality blindness in the related research. If export controls apply to research, foreigners cannot participate or an export or deemed export license must be obtained and/or other requirements satisfied, and © Massachusetts Institute of Technology, University of Florida; Jamie Lewis Keith, author. This article includes portions of other publications authored by Ms. Keith from 2004 through September 2006 when she was the Senior Counsel of the Massachusetts Institute of Technology. Ms. Keith included additional and updated information in this article in October 2006 when she became Vice President and General Counsel of University of Florida.

Note, however, that a short delay in publication only for purposes of allowing sponsor review to ensure that sponsor-provided proprietary information is not inadvertently included or to allow the institution or the sponsor to seek patent protection is permitted without destroying the exclusion.⁸¹ *In any event, the results of the research itself may not be proprietary or the fundamental research exclusion will not apply.*⁸² And, if a sponsor provides proprietary information to the university researcher concerning materials or items or related technologies or technical data that are subject to the EAR or ITAR, that sponsor information is subject to export controls, and both the university and the sponsor must comply.⁸³

2. Public Information

The “public domain” exclusion under ITAR⁸⁴ and the “publicly available” exclusion under EAR⁸⁵ are the broadest available exclusions from export controls. These exclusions, if they apply, allow deemed exports of otherwise controlled information to foreign nationals in the United States and exports of otherwise controlled information to anyone abroad, without export controls applying at all, even if the export involves a prohibited, embargoed, or restricted country.

These exclusions expressly apply only to the export or deemed export of information (including technologies and technical data), not to the export of USML or CCL-listed or otherwise controlled materials or items (such as covered equipment, encrypted software, chemicals, or biological agents or toxins), or services. To qualify for these exclusions, there must not be a reason to believe that the exported information will be used in or for weapons of mass destruction. In addition, the federal government must not have imposed export controls or restrictions as a funding condition. It is critical that neither the institution, nor the principal investigator, agrees to restrict public disclosure, to limit participation by foreign nationals, or to accept any other dissemination controls as a condition to funding, or the information will not qualify for these public domain and

security measures must be implemented to ensure that foreigners do not have access to the controlled research except as permitted under the license and other controls.

⁸¹ See 15 C.F.R. § 734.8(b)(2)–(3). The ITAR does not provide specific guidance on this point but prevailing wisdom applies the same guidelines to both regulatory schemes.

⁸² See 15 C.F.R. § 734, Supp. 1 (2004), at Section D: Research, Correspondence, and Informal Scientific Exchanges, Question D(7) and Answer.

⁸³ See 15 C.F.R. § 734.8(b)(4)–(5); 22 C.F.R. § 120.11(8). It is best to use controlled sponsor proprietary information only at the sponsor’s site if possible. This places the primary burden for securing the information from unlicensed disclosure to foreign nationals on the sponsor. Note, however, that a faculty member who is permitted under the sponsor’s license or because he or she is a U.S. citizen to have access to the controlled information and who takes notes on or acquires the controlled information at the sponsor’s site, must take care to secure the notes and to not disclose the information to foreign nationals in violation of applicable licenses and controls. If the university will accept this information, appropriate security must be implemented to prevent an unauthorized deemed export in the U.S. or an export abroad.

⁸⁴ 22 C.F.R. §§ 120.10–120.11.

⁸⁵ 15 C.F.R. §§ 734.3(b)(3), 734.7.

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public availability exclusions.⁸⁶

Information, including non-encrypted software code, that is already published (not just ordinarily published), through or at one or more of the following means or outlets are in the “public domain” or are “publicly available,” and consequently are not subject to export controls: a) libraries open to the public, including most university libraries; b) unrestricted subscriptions, newsstands, and/or bookstores for a price not exceeding reproduction and distribution costs plus a reasonable profit; c) U.S. patents and open (published) patent applications; d) conferences, meetings, seminars, trade shows, and exhibitions held in the United States, which are generally open to the public for a fee reasonably related to the cost, and at which attendees may take notes and from which attendees may leave with their notes; and e) web sites that are accessible to the public, free of charge, and without the host’s tracking or control of who visits or downloads software or information.⁸⁷ If only EAR information and non-encrypted software are involved (and ITAR is definitely not implicated), the information and software may be published through or at such conferences, meetings, seminars, trade shows, and exhibitions, wherever they are held (in the United States or abroad).⁸⁸ Only these methods of publication prescribed in the regulations qualify, regardless of how readily available any particular information is around the world. However, the public domain/publicly available exclusions are very useful and are much broader in their coverage than is the fundamental U.S. university research exclusion which (with a very limited exception relating to satellites) can only be exercised on campus in the U.S.

C. Licensing Triggers

Knowing the common triggers for licensing requirements when exclusions do not apply fosters compliance. Research and other staff and faculty should be aware of these triggers and consider them whenever an exclusion is not clearly applicable. Staff and faculty should confer with the office having expertise in export controls and responsibility for administering the institution’s compliance program and licensing whenever it is possible that a license may be required.

An ITAR license will be required, and likely will be denied (meaning that the export will be prohibited), if the proposed export of an ITAR regulated defense article (including USML-listed and otherwise regulated materials or items, which may include certain

⁸⁶ The acceptance of any of these restrictions also will result in the invalidation of the fundamental research exclusion under the ITAR at 22 C.F.R. § 120.11(8) and the EAR at 15 C.F.R. § 734.8, although, under the EAR, the acceptance of national security controls in government sponsored research that is solely subject to the EAR may qualify for a licensing exemption under 15 C.F.R. § 734.11.

⁸⁷ Information in the “public domain” and “publicly available” is outlined in the ITAR under 22 C.F.R. § 120.11 and § 120.10(5). Information in the “public domain” and “publicly available” is outlined in the EAR under 15 C.F.R. § 734.3(b)(3) and §§ 734.7–734.9. Information on export controls on patent applications can be found at 22 C.F.R. § 125.2(b) and 15 C.F.R. § 734.10 (EAR), as well as 37 C.F.R. § 5 (Secrecy of Certain Inventions and Licenses to Export and File Applications in Foreign Countries). Web sites are clearly an authorized means of publication under EAR and are probably an acceptable means of publication under ITAR, although there is no formal guidance on this point from the Department of State.

⁸⁸ 15 C.F.R. §§ 734.3(b)(3), 734.7.

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biological agents and toxins and chemicals, as well as the equipment that can be used to deliver them) or related defense service (technical data, training, or instruction) is to an ITAR prohibited country or a United Nations Security Council arms embargoed country.⁸⁹ Otherwise, a license will be considered and granted or denied on a case-by-case basis.⁹⁰ The same analysis applies to deemed exports of controlled technical data/technologies in the U.S.

An EAR license may be required for a proposed export of materials or items (or related technologies or technical data) listed on the CCL under the catch-all EAR 99 category, if the export involves an entity or person on the EAR entity list or denied person list, a prohibited end-use such as a weapons of mass destruction program, an OFAC embargoed country, any other U.S. embargoed country, or anyone listed on the OFAC prohibited list.⁹¹ Otherwise no license will be required for EAR 99 listings.⁹² An EAR license may be required, and will be considered and granted or denied on a case-by-case basis, if the proposed export concerns CCL-listed materials or items (or controlled technologies or technical data) in CCL categories other than EAR 99, depending on the destination and end user.⁹³ Licenses may be required under the EAR for exports to certain entities or individuals in a country, even when exports to other entities or individuals in the same country do not require a license. Again, the same analysis applies to deemed exports of controlled technical data/technologies in the U.S.

An EAR license is required for the export of most chemicals or biological agents or toxins listed on the CCL for chemical and biological weapons control (“CB”) purposes to any country (even Canada). Such license will be denied (meaning the export will be prohibited) if the proposed export is to Syria or an OFAC or other U.S. embargoed country or to an end user who is on the EAR denied person list. Otherwise a license will be considered on a case-by-case basis.⁹⁴ An EAR license will be required and likely will be denied (meaning the export will be prohibited) for exports of chemicals or biological agents or toxins listed on the CCL for chemical weapons convention (“CWC”) compliance purposes, including for Ricin D and E and Saxitoxin, to any country that is not a party to the Chemical Weapons Convention.⁹⁵

⁸⁹ 22 C.F.R. § 126.1. See <http://www.generalcounsel.ufl.edu/exportControl/AppendixG.pdf> and <http://www.generalcounsel.ufl.edu/exportControl/AppendixI.pdf> for a current listing (subject to change) of such countries.

⁹⁰ 22 C.F.R. § 120.20.

⁹¹ 15 C.F.R. § 732.3.

⁹² See, e.g., 15 C.F.R. § 732.3(d)(5) and following General Prohibitions. See also <http://www.generalcounsel.ufl.edu/exportControl/AppendixG.pdf> and <http://www.generalcounsel.ufl.edu/exportControl/AppendixI.pdf> for a current listing (subject to change) of such countries.

⁹³ 15 C.F.R. § 732.1.

⁹⁴ See 15 C.F.R. § 738, Supp. 1; 15 C.F.R. § 774, Supp. 1, at 1C 351-54. See also 70 Fed. Reg. 19688 (April 14, 2005) (expanding CB controls of equipment used in biological research).

⁹⁵ See 15 C.F.R. § 742.18 (license required for export to non-Chemical Weapons Convention country, unless an end user certificate is issued by the governments of all importing countries). If an item or technology is listed for chemical weapons convention compliance purposes as well as chemical and biological weapons control and/or anti-terrorism purposes, the license requirements for all such listing

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Certain biological agents and toxins that are regulated under the BPARA and its regulations and/or the USA PATRIOT Act are also regulated under EAR and ITAR. All three regulatory regimes, as well as OFAC regulations, should be reviewed for their applicability to transfers of these materials in the U.S. and abroad.

III. Resources and Conclusion

Export controls are a complex regulatory scheme. Export controls apply to a very wide range of materials and items, including a number of biological agents and toxins and chemicals. The BPARA and USA PATRIOT Act also apply to certain biological agents and toxins. Controlling the export, transfer and use of biological agents and toxins and chemicals are increasingly the focus of law enforcement efforts to defend the country from terrorist threats, whether or not the applicable regulatory regimes are effective for this purpose in our global world of easy Internet access for purchasing and communications. Research universities are at the center of this focus.

For more information about export controls and trade sanctions and embargoes, exclusions and exemptions from controls, and current developments refer to the resources at <http://www.generalcounsel.ufl.edu/exportControl/> including:

- October 2006 Update on Developments in “Deemed” Export Controls in the University Context at http://www.generalcounsel.ufl.edu/exportControl/Update_on_Developments_in_Deemed_Export_Controls_in_the_University_Context.pdf
- “Deemed Exports” for Faculty Members and Senior Research Staff- Massachusetts Institute of Technology, http://www.generalcounsel.ufl.edu/exportControl/Deemed_Export_Information_September.pdf
- Export Controls (EAR/ITAR) and Embargoes (OFAC) Requirements and Exclusions, <http://www.generalcounsel.ufl.edu/exportControl/AppendixI.pdf>
- Export Controls and Embargoes Country Key, <http://www.generalcounsel.ufl.edu/exportControl/AppendixG.pdf>
- Export Controls of Chemicals and Bio-Agents/Toxins, <http://www.generalcounsel.ufl.edu/exportControl/AppendixH.pdf>

Also refer to *Export Controls and Universities: Information and Case Studies*, published by the Council on Government Relations, and to the report, *Restrictions on*

purposes apply. 15 C.F.R. § 774, Supp. 1, at 1C 355 (regarding chemical weapons convention compliance), 1C 350 (regarding precursors for toxic chemicals); 15 C.F.R. § 738, Supp. 1 at 1C 355 (regarding weapons control and anti-terrorism). See <http://www.generalcounsel.ufl.edu/exportControl/AppendixG.pdf> and <http://www.generalcounsel.ufl.edu/exportControl/AppendixI.pdf> for a current listing of Chemical Weapons Convention countries and <http://www.generalcounsel.ufl.edu/exportControl/AppendixH.pdf> for a chart on export control of chemicals and biologicals (all subject to change).

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Research Awards: Troublesome Clauses, A Report of the AAU/COGR Taskforce” by Julie T. Norris, Office of Sponsored Programs, MIT, at <http://www.aau.edu> and <http://www.cogr.edu>.

For more information about the USA PATRIOT Act bioterrorism provisions and the BPARA and its regulations, see parts II and III of *The War on Terrorism Affects the Academy: Principal Post-September 11, 2001 Federal Anti-Terrorism Statutes, Regulations and Policies That Apply to Colleges and Universities*, by Jamie Lewis Keith, then-Senior Counsel, Massachusetts Institute of Technology, published in Vol. 30, No. 2 of the *Journal of College and University Law*. The author’s copy is available at http://www.generalcounsel.ufl.edu/exportControl/Final25_Apr04_JLKversion_Same_As_PDF_Journal_version.pdf.

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