UPDATE: Looking at the Law for Biodefense Researchers

**Purpose**
The Law, Policy and Ethics Core (LPEC) seeks to support the areas of focus for the WRCE through research, study and analysis of policy, laws and regulations which impact research and scientists in biodefense.

**Areas of Focus**
The LPEC focuses on six areas to support the WRCE scientific program development of therapeutics, diagnostics, and vaccines for category A-C agents. The work focuses on six areas of law, ethics and policy:

1. **Animal and Primate Testing**
   - 21 CFR 314 Subpart (I) Drugs
   - 21 CFR 601 Subpart (H) biologics

2. **Scientific Publications**
   - CBER and CDER approve products using the Animal Rule

3. **Select Agents**
   - Regulation 42 CFR Part 73

4. **International Human Subject Testing**
   - Legal update

5. **Vaccine and Approval Processes**
   - 71 Fed Reg 6499 (Feb 8, 2006)
   - Request from CDC to OMB for continuation of paperwork collection for select agent reporting
   - Select agent Audit Guide, HHS/OIG Office is available (Sept 27, 2004) for compliance with 42 CFR Part 73

6. **Intellectual Property**
   - July 2005 Intel Property
   - Legal Scholars propose compensation act as a method to avoid liability for researchers and IRBs
   - Most recent guidelines for research in undeveloped countries 2002 CIOMS, Council for International Organizations of Medical Sciences (Available)

**Regulatory update**

- Executive Order 13402
- 71 Fed Reg 32827 (Effective June 7, 2006)
- Exception from Informed Consent for use of medical devices during a public health emergency

**Highlights**
  - The U.S. Supreme Court ruled that public employees are limited in their speech about their job-related work. The Supreme Court found this limitation to be in the public interest. This would also apply to federally-employed biodefense researchers.
  - Congress responded to the US Sup Court decision by proposing new legislation to protect whistleblowers, March 14, 2007 the House passed HR 985.

**The Center for Biodefense, Law and Public Policy**
Following a recommendation by the Texas Tech University System Task Force on Anti-Terrorism and Public Security in April 2002, the Center for Biodefense, Law and Public Policy was formally established in the fall of 2002. The Establishment of the Center is to provide an opportunity for interdisciplinary collaboration to move in the direction of solutions in the complex, and cross-disciplinary area of biodefense. A wide range of disciplines, from law to forensic pathology, are represented by the Center's 15 faculty members. Dr. Victoria Sutton, from the Texas Tech School of Law, was named the Director of the Center in September 2002.

**Contact**
Victoria Sutton, MPA, PhD, JD
Director
Texas Tech University
School of Law
1802 Hartford
Lubbock, Texas 79409
email: vickie.sutton@ttu.edu
Phone: (806) 742-3990 ext.264