



Compliance Issues Challenging Land Grant Universities

USDA CSREES

Administrative Officers'
Conference

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Session #39 (2:45 pm – 4:00 pm)

Today's Instructors

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Univ. of Wisconsin - Madison


- Total Students = 42,041
 - CALS Enrollment = 3,279 (Fall 2007)
- AAU Membership (1900)
- NSF Ranking (2006) – #2 overall
 - Includes Vet School, Ag School, Med School
- FY 2007 Funding Amount - \$1B
 - CALS Awards \$80.7 million
- Research Stations
 - 13 Agricultural Research Stations, CALS



University of Florida

- Total Number of Students = 51,599
 - CALS Enrollment = 4,728 (Fall 2007)
- AAU Membership (1985)
- NSF Ranking (2006) – #17
 - Includes Vet School, Ag School, Med School
- FY 2007 Funding Amount --\$583M
 - IFAS Awards \$93.5M
- # of Research Stations
 - 12 Agricultural Research Stations, IFAS





Today's instructors are not subject experts in matters of compliance. Consult your institutional officers (IRB, IACUC, EHS, etc.) for further guidance.



Agenda

- Human Research Protection Program
- Animal Care and Use Program
- Environmental Health & Safety
- Select Agents
- Final Comments / Questions



Human Research Protection Program

(Human Subjects)

- In both biomedical and social/behavioral research, regulations were developed to protect human subjects. Response to scandals made public in early 1970s underscored social concerns:
 - Importance of honoring basic ethical principles supporting humans as research subjects
 - Need for independent, objective review of research
 - Need to preserve public trust in research involving human subjects

Human Subjects (continued)

US Congress held hearings, leading to 1974 National Research Act:

- ❑ mandated Institutional Review Boards (IRBs) be established at any HHS-funded site
- ❑ formed *National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*
- ❑ *Commission* deliberated over the course of 4 years, creating an ethical guidance document still essential

Human Subjects (continued)

- The ***Belmont Report***, published in the Federal Register in 1979, delineates ethical principles for conduct of human research
 - Principle of Respect
 - Treat individuals as autonomous, respecting freedom of choice; use informed consent process
 - Principle of Beneficence
 - Research must be beneficial and should minimize risks of harm
 - Principle of Justice
 - Select subjects equitably and treat them fairly

<http://ohrp.osophs.dhhs.gov/humansubjects/guidance/Belmont.htm>

Human Subjects (continued)

- Institutional Review Boards (IRBs)
 - provide independent, objective review of research
 - protect rights and welfare of research participants
 - assure compliance with federal regulations
 - preserve public trust
- Research areas common for IRB review
 - Medical/Clinical/Health Sciences
 - Social & Behavioral Sciences
 - Education

Human Subjects (continued)

- Definition of “human subject”

- “A living individual about whom an investigator (whether faculty or student) conducting research obtains 1) data through intervention or interaction with the individual, or 2) identifiable private information.” 45 CFR 46.102(d)

- Definition of “Research”

“A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge.” 45 CFR 46.102(d)

- includes formal investigations, from which results will be publicly disseminated, and pilot and exploratory research
- includes research undertaken by students for purposes of independent study, theses, or dissertations



Human Subjects (continued)

Certain categories of research involving minimal risk to human subjects are defined as *exempt* in the federal rules.

IRBs determine whether proposed human research is eligible for exemption (determination not made by individual researchers).

Research involving special populations, e.g., vulnerable subjects such as children, pregnant women, prisoners, institutionalized individuals, or those with impaired decision-making capacity, requires extra review.



Social/Behavioral Research Situations

Surveys, focus groups, interviews

Exempt example:

- Retail restructuring of agrifood systems/markets
- Occupational plans of rural youth: a 21st century follow-up study

Full protocol example:

- Evaluating farm employee compensation
- Small towns and big stores: local controversies over siting of superstores



Social/Behavioral Research Situations

Taste/sensory panels

Exempt example:

- Testing beverage samples for a large Soft Drink company
- Consumer response to shockwave tenderized meat

Full protocol example:

- designing candy flavored string cheese for children; feedback from tasters in public space



Social/Behavioral Research Situations

Farm, agricultural research

Exempt example:

- Sustainable farmer identity and the new agrarian community
- Conducting interviews with Hispanic and Latino farmers

Full protocol example:

- Adolescent agricultural ergonomics field study
- Sociological investigation of raw milk

Human Subject Research Accreditation

- Association for Accreditation of Human Research Protection Programs, Inc.
<http://www.aahrpp.org/www.aspx>
- Institutional challenges
 - Commit resources
 - Change organizational structure
 - Invest in new IT solutions
 - Garner support from IRB, administration, faculty
 - Educate community

Animal Care and Use Program (Animal Subjects)

- In the 1860s, advocacy for research animal welfare led to the formation of state Humane Societies. But not until the 1966 introduction of the *Laboratory Animal Welfare Act* did Congress establish national standards for the care and use of research animals.
- Covers all laboratory animals including dogs, cats, nonhuman primates, guinea pigs, hamsters, rabbits, and marine mammals
- Excludes birds, rats of the genus *Rattus* and mice of the genus *Mus* bred for research, and farm animals used in production agriculture for food or fiber
- BUT, includes farm animals used for biomedical research
- Agency responsible for implementing and enforcing this law: USDA-APHIS (requires annual reporting of animal usage)

Animal Subjects (continued)

- PHS Policy on Humane Care and Use of Laboratory Animals (adopted 1973; 2002 most recent update)
 - Covers ALL vertebrate animal species
 - Requires *Animal Welfare Assurance* – institutional document describing the program for care and use of animals; valid for up to 5 years; then a new Assurance is required
 - Document mandates that the Guide for the Care and Use of Laboratory Animals be the program basis
 - Monitored by OLAW (NIH Office of Laboratory Animal Welfare); annual reporting required

Animal Subjects (continued)

- Essential guidance for agricultural animals, including those in farm settings
 - Guide for the Care and Use of Agricultural Animals in Agricultural Research and Teaching [Federation of Animal Science Societies (FASS), revised 1999]
 - Species-specific husbandry guidelines
 - Facilities and environment
 - Standard agricultural practices
 - Animal handling and transportation

Animal Subjects (continued)

- Under both USDA and PHS rules, institutions using animals are required to appoint an Institutional Animal Care and Use Committee (IACUC) to review and assure animal health and well-being.

- Through the experience and expertise of its members, the IACUC oversees and evaluates the institution's animal care and use program:
 - Institutional policies and responsibilities
 - Animal environment, housing and management
 - Veterinary medical care
 - Physical plant/facilities



Animal Subjects (continued)

Approval required by IACUC when:

- Using vertebrate animals for
 - Research
 - Teaching/Instruction
 - Testing
- Interacting with wildlife and aquatic animals in natural settings (intervention or observation)
- Approving housing and husbandry

Vertebrate Animal Use in Research

- The majority of all vertebrate animals used in a research setting are specialty-bred rats and mice
 - Studies of the progress or pathogenesis of diseases (diabetes, obesity, cancer)
 - Studies of diet and nutrition (vitamin deficiencies, nutrient absorption)
 - Studies in exercise physiology: gradual increase in exercise intensity to determine muscle adaptations (heart, skeletal)

Agricultural Animal Use in Research

■ Swine

- Effects of cranberry juice included in diet on improving cardiovascular health (lower LDL cholesterol, improved vascular function)
- Determining vitamin A supplement doses for children (same body weight as young swine, so equivalent doses safe & effective)

■ Sheep

- Effect of day length in late pregnancy on subsequent milk production in dairy ewes (day length = # of hours exposure to light)

Agricultural Animal Use in Research

■ Dairy cattle

- Feed/forage nutrition and related milk production
- Developing nutritional strategies for prevention of metabolic disorders (ketosis, fatty liver) in early lactation cows
- Designing methods for timed insemination of dairy cattle to enhance reproductive efficiency

■ Fish (yellow perch, tilapia, salmon, trout)

- Evaluating and comparing grow-out methods for yellow perch in open ponds, flow-through tanks and raceways: aquaculture production efficiency

Agricultural Animal Use in Research

■ Poultry

- As alternatives to antibiotics, discovering natural, dietary substances that prevent immune-induced growth suppression
- Using laying hens as source of high quality antibody production (in immune system, antibodies recognize and neutralize bacteria and viruses)
- Genetic study: transduce into chicken genome a modified protein, to reduce oxidation of fatty acids after poultry harvest (transduce = transfer of genetic material or characteristics from one cell to another)

Agricultural Animal Use in Teaching

- Teaching Protocols cover courses and labs in which students learn:
 - Reproduction and breeding science and procedures (horses, dairy & beef cattle, sheep, swine, poultry)
 - Animal physiology
 - Nutrition
 - Monogastric (single stomach) for swine and poultry
 - Ruminant (4 stomach compartments)
 - Animal management & standard agricultural practices
 - Swine Production and Teaching
 - Poultry Nutrition
 - Horse Management and Handling

Vertebrate Animal Use in Testing

- Clinical trial conducted to test drug treatment reducing mastitis (udder inflammation) in dairy COWS
- Use of rat lofts for environmental enrichment in cages: what do rats prefer?
- Microbiological safety of foods confirmed using FDA-established protocols detecting Botulinum toxin via mouse bioassay (measuring effects/response of a living organism)

Vertebrate Animal Use: Wildlife

■ IACUC approval for wildlife intervention

Be aware of state or federal permit/license requirements for scientific research (DNR, Endangered Species Act, Marine Mammal Protection Act)

- Anesthetizing animals to insert microchips that allow radio tracking
- Capturing deer to conduct tonsil biopsies, to assess rate of Chronic Wasting Disease transmission
- Radio-collaring black bears to monitor habitat dispersal
- Inventory and monitor banded Snail Kites (endangered bird species)

Vertebrate Animal Use: Wildlife

■ IACUC approval for wildlife observation

- Positioning video cameras to view bird nest predators
- Counting eggs laid or hatched in birds' nests
- Monitoring distribution, size, nesting and hole occupancy of American Alligator with respect to the restoration of Everglades
- Monitoring ability of white tail deer to jump fences of varying heights
- Using radio telemetry to find and remove Burmese Pythons from Everglades
- Any study in which human presence to conduct observation might compromise animal environment

Vertebrate Animal Use: Housing and Husbandry

■ IACUC approval for:

- Newly constructed facilities and spaces prior to animal occupancy
- Non-standard housing, if required for a specific research study
- Protocols and practices in animal management and production:
 - Dairy Herd Maintenance
 - Sheep Flock Management
 - Swine Production at Swine Research & Teaching Center

Vertebrate Animal Use: Outreach

- IACUC approval for Outreach events, a Land Grant mission
 - Breakfast on the Farm, with Petting Zoo
 - 4-H Dairy Camp; 4-H Livestock Camp
 - *Cows on the Concourse* at Farmer's Market
 - Livestock Selection and Judging Contest
(high school students)

Vertebrate Animal Use

- Institutional approval, vertebrate tissues and materials
 - Abattoir tissues for use in research and teaching (organs, tissues from slaughter)
 - IACUC-approved if used in living animals, e.g., ovaries, stem cells
 - Oversight by other institutional means: consultation with veterinary and risk management specialists, or biosafety committee

Vertebrate Animal Use

- Oversight beyond the regulations
 - Many institutions conduct all animal research in accord with PHS policy, without exception. (Wisconsin policy)
 - Some institutions establish separate committees to approve animal research not specifically regulated, interpreting USDA directives variously [e.g., Florida's Animal Research Committee (ARC)]

Challenges for the Land Grant

- Maintaining security vs. freedom of public access
 - Biosecurity, preventing disease transmission by visitors (hoof and mouth, influenza virus)
 - Vulnerability to animal activism or bioterrorism
- Meeting Bioterrorism Act requirements
 - Registration of food facilities with FDA, if food is manufactured, processed, packed or held for human or animal consumption
 - Dairy Store (campus and community sales + mail orders)
 - Meat Science Lab Store (campus sales + expanding prospects)

Challenges for the Land Grant

■ Bioterrorism Act requirements (continued)

- Farms devoted to growing and harvesting of crops and to raising animals are exempt from registration

■ Feed Mills

- IF all feed processed & produced is utilized within the institution, registration not required
- When feed is sold to the public (farmers) or to entities outside institution, registration IS required
- Feed produced for animal consumption must be labeled and dated

Challenges for the Land Grant

- Livestock identification/animal registration
 - National Food Animal Identification; tracking origin and distribution
- Maintaining communication and awareness between satellite facilities and the primary institution location
- Achieving AAALAC accreditation (Association for Assessment and Accreditation of Laboratory Animal Care) <http://www.aaalac.org/>
- Maintaining best practice standards for Occupational Health or OSHA requirements in agricultural units



Farm Site & Research Station Issues

Affecting Humans in Animal Work

- Needle stick injury risk (administering hormone doses, veterinary drugs)
- Respirator use (reducing exposure to allergy or asthma-inducing dusts from animal bedding or feed)
- Hearing protection (operating feed carts in barns)
- Rabies vaccination advised (wildlife contact)

Farm Site & Research Station Issues

Affecting All Farm Workers

- Pesticide and herbicide use on crops
- Confined space entry training
 - Requirements for air sampling and use of “buddy system” when working inside silos, grain bins, tanks, manholes
- Chemical safety plan (storage, inventory, disposal)
- Material Safety Data Sheets (MSDS)
 - Required for all chemicals and drugs at site
- Lockout/tagout requirements
 - Lock out energy sources (secure in **off** condition) when performing equipment repairs or maintenance



Environmental Health & Safety

Occupational

- *Occupational Safety and Health Act of 1970* created the Occupational Safety and Health Administration (OSHA)
 - To prevent work-related injuries, illnesses and death by enforcing standards for workplace safety and health
 - To protect workers from risks by reducing hazards



Environmental Health & Safety

Occupational

An institutional Occupational Health Program is a required component of an animal care and use program, as directed by The Guide, and is essential for AAALAC accreditation.

- ❑ Required Program enrollment promotes safety and health for researchers and workers with animal contact, addressing individual health needs:
 - Animal contact medical monitoring program
 - Annual health questionnaire
- ❑ Provides immunizations, and medical clearance for respirator protection



Environmental Health & Safety

Occupational

- ❑ Maintains information on zoonoses (diseases transmitted between animals and people)
 - ❑ ringworm, rabies, malaria, influenza, Herpes B
- ❑ Conducts site inspections and risk assessments
- ❑ Recommends personal protective equipment (PPE)
 - ❑ gloves, lab coats, coveralls, goggles, face shields, respirators, ear protection, boots, shoe covers
- ❑ Trains for risk awareness and avoidance, personal health, best health practices for working with animals, handling sharps, working with bloodborne pathogens

Other Laboratory Safeguards

■ Physical environment

- Emergency eyewash and safety shower
- Fume hoods (contain work with hazardous chemicals, radioactive materials)
- Biological Safety Cabinets (sterile, HEPA-filtered environment for work with microorganisms)
- Fire extinguishers on site
- Compressed gas cylinders secured



Environmental Health & Safety

Biological

Institutional Biosafety Committees (IBCs) were established under the *NIH Guidelines for Research Involving Recombinant DNA Molecules* (1976) to provide local review and oversight of nearly all forms of research utilizing recombinant DNA.

Over time, many institutions have assigned their IBCs the responsibility of reviewing a variety of experimentation that involves biological materials and other potentially hazardous agents.



Environmental Health & Safety

Biological

Biological Safety Office roles:

- Administrative home of Institutional Biosafety Committee (IBC)
 - Review and approval of biological safety protocols
- Risk Assessment
 - Via biosafety protocols and laboratory visits, assess materials, procedures, hazards, and precautions
 - Insure safe conduct of biological, recombinant, and acute toxin research
 - Assure handling of biological materials in accordance with local, state and federal regulations & guidelines



Environmental Health & Safety

Biological

Biological Safety Office roles:

- Provide guidance, information, review, monitoring and training when appropriate
 - Individuals and lab groups, personal interaction
 - Classroom and online opportunities:
 - Basic biosafety
 - Advanced biosafety
 - Hazardous materials packing and shipping
 - Biological Safety Cabinet use

Environmental Health & Safety

Biological

Biological Safety Office roles:

- Coordinate Select Agent Program requirements
- Review “Dual-Use Life Sciences Research”
 - *National Science Advisory Board on Biosecurity (NSABB)* recommendations to prevent misuse of biological research that could pose a threat to public health or national security
 - Materials/data may have both military and civilian use:
 - new pathogens, increased pathogen virulence, weaponization, synthesis of pathogen genome



Environmental Health & Safety

Biological

- CDC/PHS guidance and best practices in Biosafety in Microbiological and Biomedical Laboratories [5th Edition online; 4th Edition paper]
- Delineates Risk Groups for human disease, and Biosafety Levels (BSL-1, 2, or 3) for facility, containment, Personal Protective Equipment, and security requirements

Environmental Health & Safety

Biological

■ Protocols needed:

- microbiological agents infectious to humans and/or animals: viruses, fungi, bacteria, parasites (measles, mycotoxins, Salmonella, Listeria)
- exotic plants, animals, and microbes (e.g., nonindigenous plants or insect pathogens) [soybean rust; leaf-cutter ants & their symbiotic fungus]
- potentially infectious materials derived from humans (e.g., established cell lines) and from animals, including their blood, tissues, and cell lines, for which a potential for transmission of zoonotic agents exists

Environmental Health & Safety

Biological

- Protocols needed (continued):
 - Select agents (microbes and toxins regulated by CDC and USDA because of potential for bioterrorism)
 - Recombinant DNA molecules and recombinant DNA-containing organisms or cell cultures which are subject to the NIH guidelines (genes from one organism inserted into another)
 - Prions: proteins that reproduce independently and cause spongiform diseases (chronic wasting disease in deer, elk; mad cow disease in cattle; Creutzfeldt-Jakob disease in humans)



Environmental Health & Safety

Biological

■ Added Biosafety roles at Land Grants

- Administrative support for researchers needing USDA Animal and Plant Health Inspection Service (APHIS) permits for regulated plant or animal use
 - Import or interstate shipment of living plants and animals or any infectious agent known or suspected to cause disease in humans or animals
 - Import or interstate shipment of transgenic plants or animals
- Advising on appropriate disposition of post-research animals
 - continued research use
 - sale to market (cleared as food source)
 - disposal/rendering



Select Agents

Select Agents = pathogens or biological toxins declared by U.S. Departments of Health and Human Services and Agriculture to have the potential to pose a severe threat to public health and safety, to animal and plant health, or to animal and plant products as agents of bioterrorism.

Use of select agents in research requires unique restrictions on the traditional openness of the academic environment and imposes significant costs to an institution.

Select Agents

DHHS Centers for Disease Control and USDA-APHIS published final rules implementing provisions of the USA PATRIOT Act and Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (effective 4/18/2005)

- These set forth requirements for possession, use, and transfer of select agents and toxins, and require an institution to impose administrative controls and oversight over individuals with select agent access and over locations where select agents are used or stored

Select Agents

- Entity at which research is conducted must be registered with either CDC or APHIS. Process includes:
 - Application for possession, use and transfer of select agents and toxins
 - Department of Justice (DOJ) completion of a security risk assessment for the facilities and for the institution's designated Responsible Official (RO)
 - Facilities must meet biosafety requirements commensurate with risks posed by specific select agents/toxins
 - Must establish security measures providing graded protection in line with the threat posed by the agent or toxin
- Registration of personnel is essential
 - FBI background check + DOJ individual risk assessment

Select Agents

- SA program components
 - Controlled access to work areas and to agents/toxins by authorized (approved) personnel (PI and scientists, students)
 - Visitors, custodians, maintenance staff must be accompanied by authorized personnel
 - Inventory log required for each area where agents/toxins are stored or used
 - Monthly or quarterly, all logbooks and physical inventories must be compared and discrepancies must be reconciled
 - If electronic inventory record used, a cybersecurity plan must be implemented

Select Agents

- SA Program components
 - Written security, biosafety and emergency plans address all contingencies (fire, medical emergency, loss or theft of agent/toxin, key or access card loss, inventory alteration, suspicious events)
 - Security training for SA laboratories
 - Recurrent training specific to each lab group, pertinent to agent/toxin risks and use requirements
 - Drills and exercises conducted in response to simulated emergencies, including containment or security breaches

Select Agents

SA Program components

- Regular inspections by institutional RO (announced and unannounced) are required and must be documented
- CDC or APHIS will conduct site visit (can be unscheduled)
- Notification and reporting to CDC or APHIS required
 - for all transfers of agent/toxin, intra-and inter-facility
 - for destruction of select agent/toxin
 - for any theft, loss, or release (whether recovered or not)

Select Agents

■ “Bioterror” examples

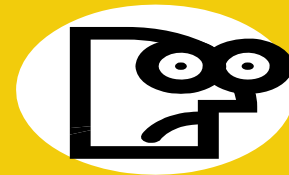
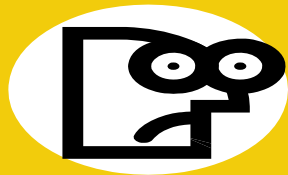
- examples of outbreaks caused by intentional contamination illustrate the ease with which food could be used for terrorist purposes
 - In a 1984 outbreak in the United States, members of the Rajneeshee cult contaminated a salad bar in Oregon with *Salmonella*, causing 751 illnesses.
 - In 1996, a disgruntled employee at a Texas hospital intentionally contaminated pastries, causing twelve cases of *Shigella dysenteria*
 - In Japan, curry laced with arsenic and sold at a community fair resulted in 60 illnesses and four deaths.
 - In a 2003 episode in the U.S., 200 pounds of meat at a Michigan grocery store were poisoned intentionally with an insecticide, sickening over 100 people. [WHO report, 2004]

Select Agents

Research with select agents/toxins

- Exploring the molecular pathogenesis of genetic material from the Ebola virus
- Developing rapid screening tests to detect botulinum toxins in food
- Learning how *Ralstonia solanacearum*, a plant pathogen causing bacterial wilt, can infect a broad range of host plants over much of the world (protecting vegetable crops, flowering plants)

Questions & Comments



It's QUESTION TIME !!

Human Subjects Regulations

- 45 CFR 46, as amended by 56 FR28003
http://www.access.gpo.gov/nara/cfr/waisidx_03/45cfr46_03.html
<http://www.hhs.gov/ohrp/humansubjects/guidance/63fr60364.htm>
- 21 CFR 50
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr50_02.html
- 21 CFR 56 (FDA)
http://www.access.gpo.gov/nara/cfr/waisidx_02/21cfr56_02.html
- Protecting Study Volunteers in Research, Dunn and Chadwick, 1999

Animal Welfare Regulations

- USDA Animal Welfare Act (PL 89-544, amended by PL 91-579, 94-279, 99-198) and USDA Regulations (CFR Title 9, Chapter 1, Subchapter A, Parts 1-4)
<http://www.nal.usda.gov/awic/legislat/usdaleg1.htm>
- PHS Policy on Humane Care and Use of Laboratory Animals
<http://grants.nih.gov/grants/olaw/olaw.htm>
- Guide for the Care and Use of Laboratory Animals http://dels.nas.edu/ilar_n/ilarhome/guide.shtml
- FAQs from OLAW: PHS Policy
<http://grants.nih.gov/grants/olaw/faqs.htm>

Occupational Health Guidelines

- Occupational Safety and Health Act, 1970
http://www.osha.gov/pls/oshaweb/owasrch.search_form?p_doc_type=oshact
- Laws, Regulations and Interpretations (current OSHA standards) <http://www.osha.gov/comp-links.html>
- Bloodborne pathogens (regulations)
http://www.osha.gov/pls/oshaweb/owadisp.show_document?p_table=STANDARDS&p_id=10051
- OSHA Standards for Agriculture
http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1928

Biological Safety Guidance

- 5th Edition of Biosafety in Microbiological and Biomedical Laboratories (BMBL)
<http://www.cdc.gov/od/ohs/biosfty/bmbl5/bmbl5toc.htm>
- NIH Guidelines: Recombinant DNA and Gene Transfer
<http://www4.od.nih.gov/oba/rac/guidelines/guidelines.html>
- Large Scale Biosafety Guidelines (ASM)
<http://www.asm.org/Policy/index.asp?bid=13634>
- National Science Advisory Board for Biosecurity
<http://www.biosecurityboard.gov/>

Select Agent Guidance

- Select Agent/Toxin List
<http://www.selectagents.gov/agentToxinList.htm>
- Agricultural Select Agent Program (USDA-APHIS) http://www.aphis.usda.gov/programs/ag_selectagent/
- CDC Select Agent Program <http://www.cdc.gov/od/sap/>
- CDC & APHIS Final Rules (effective 4/18/2005)
http://www.cdc.gov/od/sap/final_rule.htm
- Public Health Security & Bioterrorism Preparedness and Response Act of 2002
<http://www.fda.gov/oc/bioterrorism/Bioact.html>
- USA PATRIOT Act
<http://thomas.loc.gov/cgi-bin/query/z?c107:H.R.3162.ENR>