

Biosafety and Gain-of-Function Research

Janet Peterson
University of Maryland College Park



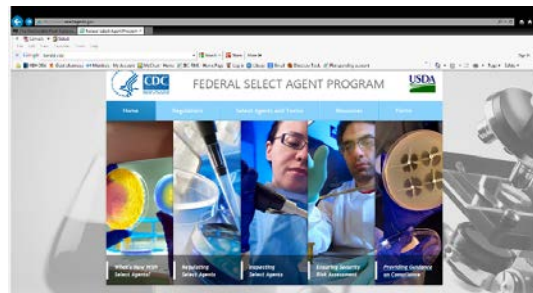
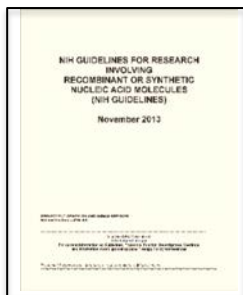
Risk Mitigation

- Regulations and guidelines
- Containment facility and practices
- Institutional oversight committees
- Risk assessment
- Facility features
- Personal protective equipment
- Occupational health program
- Education and competency assessment



Regulations and Guidelines

- CDC/NIH Biosafety in Microbiological and Biomedical Laboratories
- NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules
- Federal Select Agent Regulations
- USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern



Institutional Oversight Responsibilities

- Institutional Biosafety Committee (IBC) – *NIH Guidelines*, recombinant or synthetic nucleic acid molecules, infectious agents. Protocol-specific risk assessment.
- Institutional Review Entity – *USG DURC Policy*: 15 agents and toxins, 7 categories of experiments. Risk-benefit analysis and risk mitigation plan.
- Responsible Official – Implements Select Agent program.



Containment Levels

	Agents	Facility and Practices
BSL1	Well-characterized agents not known to consistently cause disease in immunocompetent adult humans	Standard lab plus Standard Microbiological Practices
BSL2	Agents that pose moderate hazards to personnel and the environment.	Plus Special Practices, aerosols in BSC
BSL3	Indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure.	Specific training, facility special engineering features, all procedures in BSC
BSL3-enhanced	High consequence livestock pathogens, including HPAIV	BSL3 plus select features from BSL4 (shower out, HEPA exhaust, etc.)
BSL4	Dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, <i>for which there are no vaccines or treatments</i>	Cabinet lab and suit lab, special engineering & design features



Facility Features: BSL3-Enhanced

- HEPA filtered exhaust, directional airflow, exhaust fan redundancy, back-up emergency generator
- Annual verification and testing
- PPE: clothing change, PAPR respirators, multiple layers of gloves and shoe covers, shower and shampoo out
- HEPA filtered animal isolators
- Pass-through autoclave
- Inventory controls, locked freezers
- Controlled access: multiple layers of locks, background checks, intrusion detection with police response



Education and Competency Assessment

- Competency testing: donning and doffing PPE, working in BSL2 using BSL3 practices and PPE, working in BSL3 under direct supervision until able to demonstrate proficiency
- Initial and annual biosafety, biosecurity and incident response training
- Frequent review of standard operating procedures
- Annual biosafety, biosecurity and incident response tabletop drill
- Additional training for new procedures
- Occupational health plan: annual vaccine, post-exposure procedures, illness evaluation, respiratory protection program



THE HUFFINGTON POST

"NIH has been working on Ebola vaccines since 2001. It's not like we suddenly woke up and thought, 'Oh my gosh, we should have something ready here,'" Collins told The Huffington Post on Friday. "Frankly, if we had not gone through our **10-year slide in research support**, we probably would have had a vaccine in time for this that would've gone through clinical trials and would have been ready." 10/12/2014

JAMA /The Journal of the American Medical Association

An HIV Cure : Feasibility, Discovery, and Implementation

Anthony S. Fauci, MD¹; Hilary D. Marston, MD, MPH¹; Gregory K. Folkers, MS, MPH¹

The discovery and deployment of antiretroviral therapy (ART) for human immunodeficiency virus (HIV) infection is one of the most extraordinary achievements in recent biomedical history. Between 1996 and 2012, ART averted an estimated 6.6 million AIDS-related deaths worldwide.¹ For HIV-infected individuals with access to ART, **life expectancy at diagnosis now approximates that of uninfected individuals—a remarkable feat.**

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