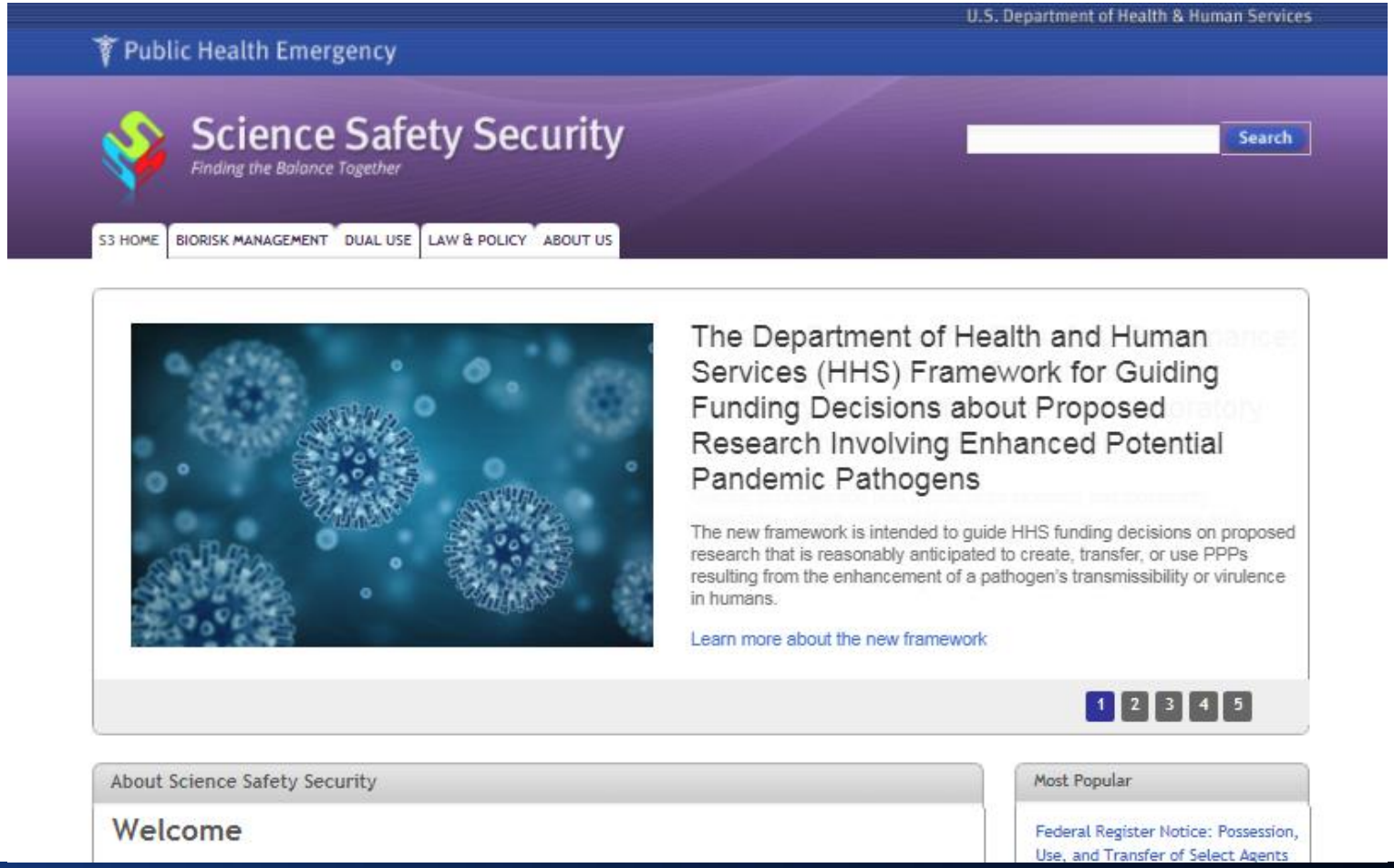
# Laboratory Safety: Regulations, Guidance and Resources

**Margy Lambert, PhD**

**May 10, 2018**

# ASPR Mission

# ASPR Priorities for Building Readiness for 21st Century Threats


U.S. Department of Health & Human Services
Public Health Emergency
Science Safety Security
Finding the Balance Together
Search
S3 HOME
BIORISK MANAGEMENT
DUAL USE
LAW & POLICY
ABOUT US
The Department of Health and Human Services (HHS) Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens
The new framework is intended to guide HHS funding decisions on proposed research that is reasonably anticipated to create, transfer, or use PPPs resulting from the enhancement of a pathogen's transmissibility or virulence in humans.
Learn more about the new framework
1 2 3 4 5
About Science Safety Security
Welcome
Most Popular
Federal Register Notice: Possession, Use, and Transfer of Select Agents

# Laboratory Safety: Hazard Type

- Biological
- Chemical
- Physical
  - Radiation
  - Noise
  - Ergonomic
- General
  - Electrical
  - Fire
- Mixed

# Laboratory Safety Oversight: Source

- Regulations
  - Federal
  - State, Local, Tribal, and Territorial, (SLTT)
- Guidance
  - Federal
  - State, Local, Tribal, and Territorial, (SLTT)
  - Private (e.g., Safety Associations)
  - Public-Private Partnerships
- Funding Requirements
  - Federal
  - Non-Federal
- Institutional

# Federal Acronyms

- HHS: Dept. of Health and Human Services
- ASPR: Assistant Secretary for Preparedness and Response
- OSHA: Occupational Safety and Health Administration
- CDC: Centers for Disease Control and Prevention
- USDA APHIS: U.S. Dept. of Agriculture, Animal Plant Health Inspection Service
- DOC: Dept. of Commerce
- DOT: Dept. of Transportation
- EPA: Environmental Protection Agency
- DHS: Dept. of Homeland Security
- DEA: Drug Enforcement Agency
- NRC: Nuclear Regulatory Commission
- OSTP: White House Office of Science Technology and Policy
- USG: United States Government

# Laboratory Biological Safety: Non-OSHA Regulations

- Regulations
  - Biological Select Agents and Toxins (CDC; USDA APHIS)
  - Import/Export Permits (USDA, DOC)
  - Hazardous Materials Transportation Act (DOT)
  - Resource Conservation and Recovery Act (Hazardous Waste Management) (EPA)
  - State, Local, Tribal, and Territorial (SLTT)

# Laboratory Chemical and Radiation Safety: Non-OSHA Regulations

- Regulations
  - Toxic Substances Control Act (EPA)
  - Controlled Facility Anti-Terrorism Standards (DHS)
  - Import/Export Permits (DOC)
  - Hazardous Materials Transportation Act (DOT)
  - Resource Conservation and Recovery Act (Hazardous Waste Management) (EPA)
  - Controlled Substance Act (DEA)
  - Standards for Protection Against Radiation (NRC)
  - State, Local, Tribal, and Territorial (SLTT)

# Laboratory Biological Safety: Non-OSHA Guidance

- Federal
  - Biosafety in Microbiological and Biomedical Laboratories (CDC; NIH)
  - NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (NIH Guidelines) (NIH)
  - Inter-Agency
    - ✓ Federal Experts Security Advisory Panel (FESAP)
    - ✓ Fast Track Action Committee – Select Agent Regulations (FTAC-SAR)
    - ✓ Interagency Biorisk Management Working Group (IBMWG)
- State, Local, Tribal, and Territorial (e.g., state & local public health departments)
- Private (e.g., Safety Associations, NASEM)
- Public-Private Partnerships (e.g., FDP)

# Federal Expert Security Advisory Panel (FESAP)

- Following a series of incidents involving BSAT in 2014, FESAP was tasked to:
  - Identify needs and gaps; Make recommendations to optimize biosafety, biosecurity, oversight, and inventory management and control for BSAT.
  - Identify actions and any regulatory changes to improve biosafety and biosecurity.
  - Identify an approach to determine appropriate number of U.S. high-containment laboratories required to possess, use, or transfer BSAT.
- FESAP delivered the Report of the Federal Experts Security Advisory Panel (https://www.phe.gov/s3/Documents/fesap.pdf) in December 2014.
- Working groups were formed for a number of the recommendations and tasked with devising ways to implement the FESAP recommendations.

# Federal Expert Security Advisory Panel (FESAP) Recommendation 2.8

- **FESAP Recommendation 2.8: Support OSHA Infectious Diseases Rulemaking**
- **FESAP 2.8 Implementation Working Group (Interagency)**
- **Expanded awareness-raising efforts:**
  - **Current OSHA regulations and guidance pertaining to laboratories**
  - **Key information on federal research funding requirements related to OSHA compliance**
  - **Voluntary OSHA safety and health programs and campaigns**

# Fast Track Action Committee (FTAC)

- 2015 – Report on Select Agent Registration Program (FTAC-SAR)
  - Review the current regulatory controls over biological select agents and toxins and recommend improvements.
  - Recommendations provided on topics that include: Sharing best practices, emergency situations, inventory control, customer service, inspections, peer advisory mechanism, and international engagement.
- FTAC-SAR Report (https://www.phe.gov/s3/Documents/ftac-sar.pdf)

# Interagency Biorisk Management Working Group

- Established in 2012 by White House Office of Science and Technology Policy (OSTP)
- Examines the current framework for local and Federal research laboratory biorisk management oversight
- Coordinates Federal outreach and educational programs to inform scientists, biosafety professionals, institutional officials, and the public on biorisk management and relevant federal regulations
- Leads oversight of a number of the FESAP and FTAC-SAR recommendations

# Laboratory Safety: Funding Requirements

- Funding Requirements
  - Federal
    - NIH Grants Policy
    - DOD Contract Requirements
    - National Policy Requirements (NSF 2017 Rule) – Multiple Federal Funding Agencies; Adherence to Multiple Federal Regulations Including OSHA Regulations
    - NIH Guidelines (Biosafety)
    - Dual Use Research of Concern (DURC) (Biosafety)
  - Non-Federal

# NIH Grants Policy Statement (OSHA): 4.1.12 Health and Safety Regulations and Guidelines

"Recipients are responsible for …. establishing and implementing necessary measures to minimize their employees' risk of injury or illness in activities related to NIH grants. In addition to applicable Federal, State, and local laws and regulations, the following regulations must be followed when developing and implementing health and safety operating procedures and practices for both personnel and facilities:"

- 29 CFR 1910.1030, Bloodborne Pathogens;
- 29 CFR 1910.1450, Occupational Exposure to Hazardous Chemicals in Laboratories; and
- Other applicable OSHA Occupational and Health Standards included in 29 CFR 1910.

**Regulations available at http://www.osha.gov/pls/oshaweb/owastand.display_standard_group?p_toc_level=1&p_part_number=1910.**

# 2017 Final Rule: Standardized Terms and Conditions for Federally Funded Research

- NSF Final Notice of Research Terms and Conditions (82 FR 13660) - standardized terms and conditions for federal research grants for many federal funding agencies, including:
  - NIH
  - NSF
  - USDA National Institute of Food and Agriculture (USDA/NIFA)
  - EPA
  - NASA
  - DOE
  - DHS

- Core requirements in the updated National Policy Requirements Matrix (Appendix C) specifically cites compliance with OSHA regulations as a core government-wide requirement for receiving federal research funds.

# Gain-of-Function (GOF) Studies

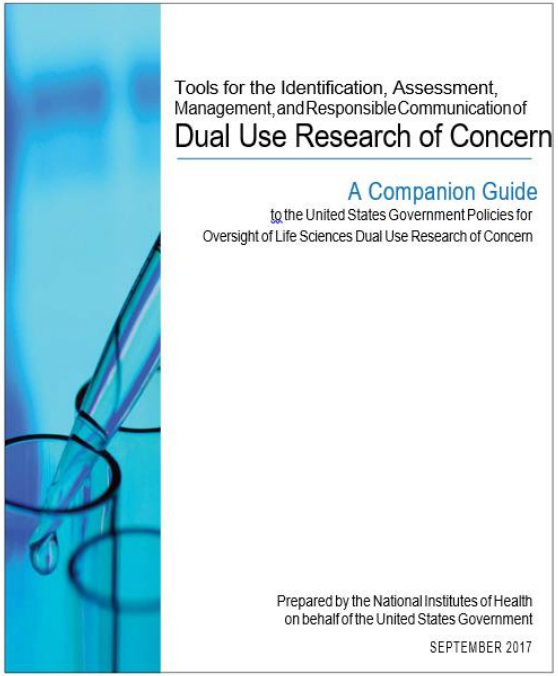
- United States Government (USG) supports research aimed at understanding pathogens toward the goal of preventing and treating infections;
- GOF and loss-of-function (LOF) approaches have been used to better understand the genetic determinants of pathogenicity, transmissibility, and host range in certain pathogens;
- GOF and LOF approaches are common in life sciences research. However, the specific subset of studies anticipated to generate enhanced potential pandemic pathogens (PPP) have raised concerns.

# Dual Use Research of Concern (DURC)

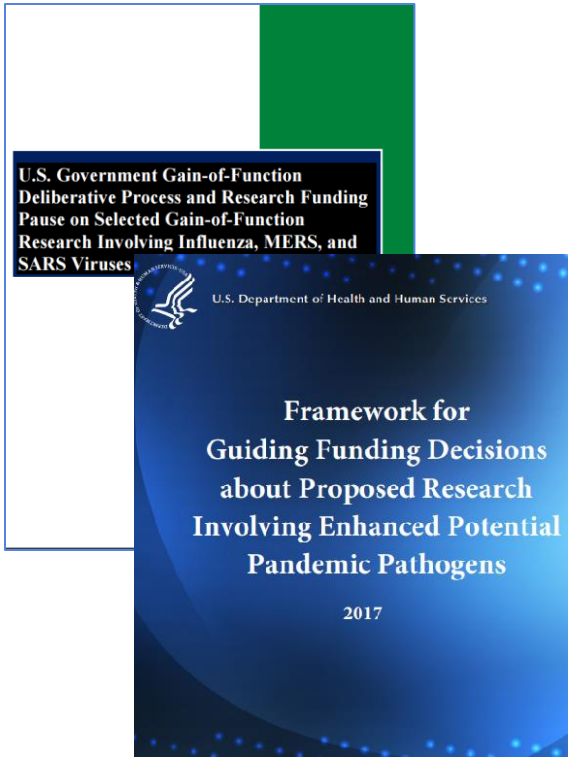
- DURC is Gain of Function Research that receives a pre-funding review by the USG and Institutional review;
- DURC scope includes a list of 15 agents and toxins and seven categories of experiments;
- DURC Definition: Research that can be reasonably anticipated to provide knowledge, information, products, or technologies that could be directly misapplied to pose a significant threat with broad potential consequences to public health and safety, agricultural crops and other plants, animals, the environment, materiel, or national security.

# DURC Institutional Review

- Institutional Review Entity (IRE) reviews DURC research
  - United States Government Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern (September 24, 2015)



# Enhanced Potential Pandemic Pathogen Research (PPP)




- *HHS Framework for Guiding Funding Decisions about Proposed Research Involving Enhanced Potential Pandemic Pathogens* (*HHS P3CO Framework*)
  - Enhanced PPP is a subset of DURC research reasonably expected to enhance both the transmissibility and the virulence of a PPP in humans;
  - HHS P3CO provides a mechanism for a USG pre-funding review that lifts a 2014 pause in funding enhanced PPP research;
  - Enhanced PPP is not reviewed by the IRE.

# Laboratory Safety Resources

- National Policy Requirements Matrix for Federal Funding (Appendix C) (https://www.nsf.gov/bfa/dias/policy/fedrtc/appc_march17.pdf)
- National Academy of Sciences' *Prudent Practices in the Laboratory*, Table 11.1: Federal Safety Laws and Regulations That Pertain to Laboratories (https://www.ncbi.nlm.nih.gov/books/NBK55862/table/ch11.t1/?report=objectonly)
- ASPR Website (https://www.phe.gov)
- Science Safety Security Website (https://www.phe.gov/s3)


U.S. Department of Health & Human Services
Preparedness
Emergency
About ASPR
Office of the Assistant Secretary for Preparedness and Response
Public Health Emergency
Public Health and Medical Emergency Support for a Nation Prepared
Search
Public Health & Medical Services Support
Legal Authorities, Policies, Guidance & Committees
Federal, State, & Local Planning
Medical Countermeasures
International Preparedness & Response
Responders, Clinicians, & Practitioners
Public Health Emergency Response
Hurricane Preparedness Week
Learn more
Most Popular
ASPR Blog
PHE Newsroom
Watch, Listen, Subscribe
Disaster Response
Declared disasters & emergencies
Disaster assistance
More disaster response...
State Coordination
Public Health:
Select a state
Go
Emergency Management:
Select a state
Go
Featured Resources and Initiatives
Tools and Technical Assistance
Technical

U.S. Department of Health & Human Services

Public Health Emergency

# Science Safety Security

*Finding the Balance Together*

Search

S3 HOME | BIORISK MANAGEMENT | DUAL USE | LAW & POLICY | ABOUT US

## NIH Lifts Funding Pause on Gain-of-Function Research

The National Institutes of Health announced that it is lifting a funding pause dating back to October 2014 on gain-of-function (GOF) experiments involving influenza, SARS, and MERS viruses.

Read the NIH Director's Statement

1 2 3 4 5

About Science Safety Security

## Welcome

Most Popular

Federal Register Notice: Possession,

# Thanks!

- Audience
- Co-Presenter Tom Nerad
- ASPR Colleagues
  - Katie Danskin
  - Tricia Delarosa
  - Theresa Lawrence
  - Jenna Overington
  - Dana Perkins
  - Matt Sharkey

# Questions and Comments?

Contact Info: Margy.Lambert@hhs.gov