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# University of Pittsburgh Dual Use Research of Concern

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# What is DURC?

- ▶ Life sciences research that, based on current understanding, can be reasonably anticipated to provide knowledge, information, products or technologies that could be *directly misused* to pose significant threat with broad consequences to public health and safety, agricultural crops/plants, animals, the environment or national security





# DURC Policy

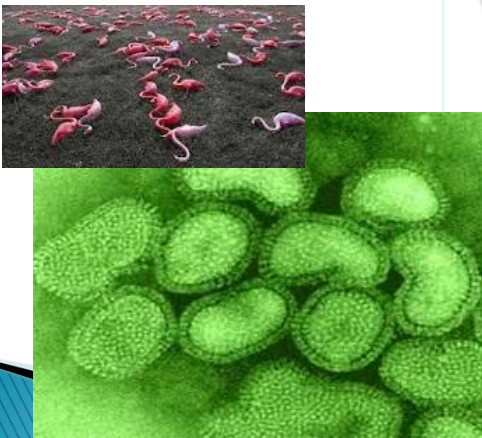
- ▶ September 25, 2014 – USG Policy for Institutional Oversight of Life Sciences DURC
  - Articulates responsibilities of institutions and investigators to identify and manage risks associated with DURC
  - *Policy must be in place September 24, 2015*
- ▶ March 29, 2012 – USG Policy for Oversight of Life Sciences Dual Use Research of Concern
  - Established regular review of federally funded research with specific high-consequence pathogens and toxins
  - Aim was to preserve benefits of life science research while minimizing risk



# What is Scope of Policy

- Currently applies 15 agent, primarily those on the Tier 1 Select Agent list
- Research with experimental effects that fall into one of 7 identified governmental categories

Avian Flu



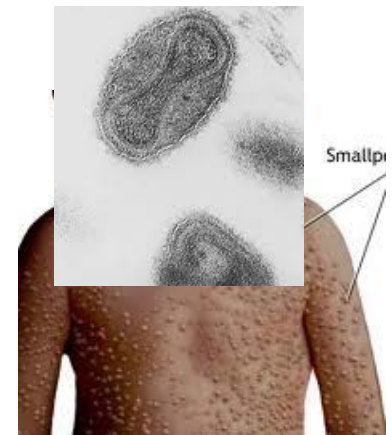
Anthrax



Plaque



Smallpox





# Seven Categories of Experiments

Enhances harmful consequences of agent or toxin

Disrupts immunity or effectiveness of immunization

Confers agent or toxin resistant to standard treatment

Increases stability, transmissibility or ability to disseminate

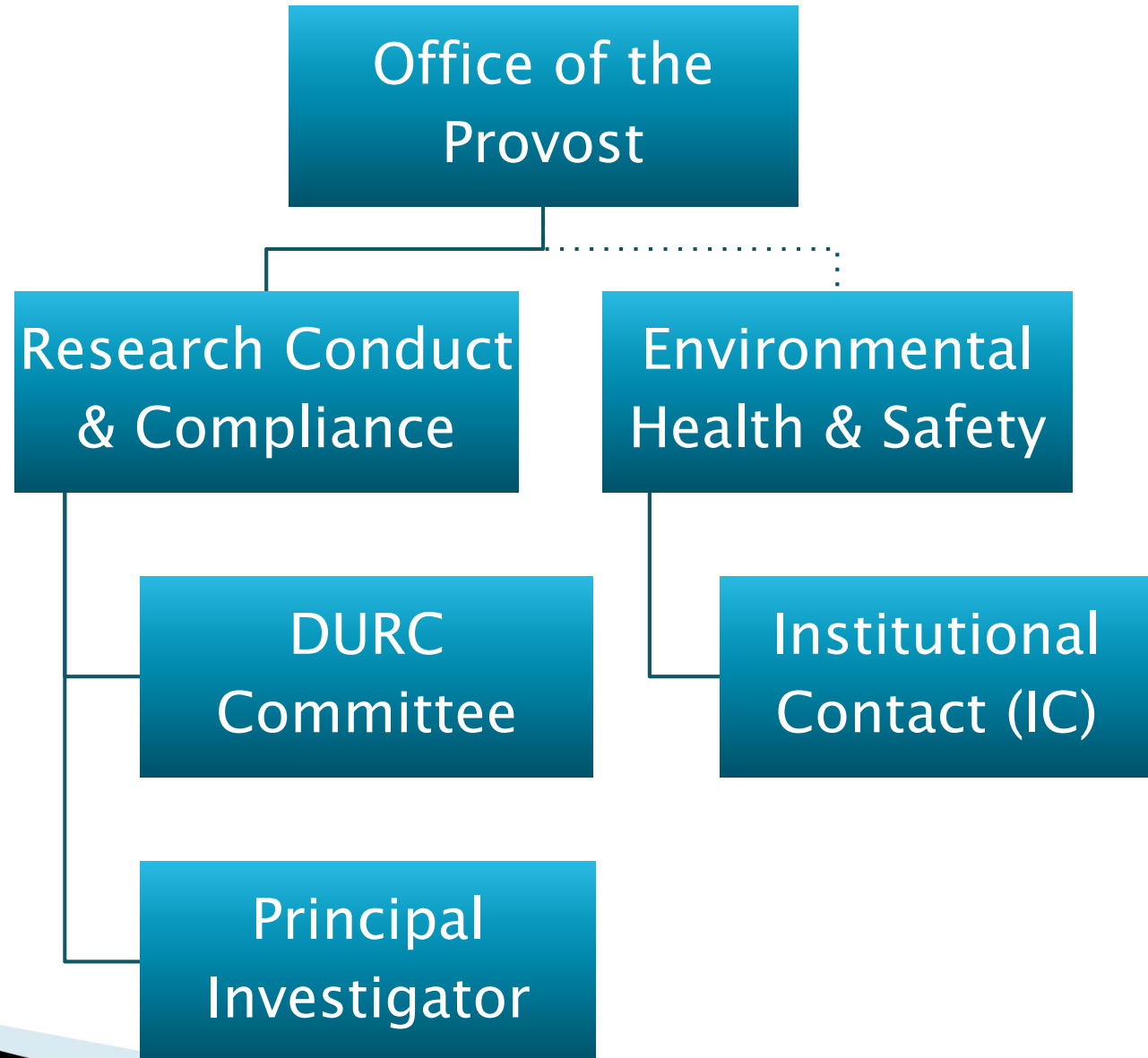
Alters host range or tropism

Enhances susceptibility of host population

Generates or reconstitutes an eradicated or extinct agent or toxin



# Responsibilities





# Responsibilities

## ▶ University

- internal policy for review of DURC
- institutional review and oversight process
  - Institutional Contact
  - DURC Committee
- notification of USG funding agency within 30 calendar days of determination of DURC
- ongoing oversight once Risk Mitigation Plan approved







# Responsibilities

- ▶ Research Conduct and Compliance
  - Primary responsibility center for assuring compliance with USG policy for DURC
  - Designates Institutional Contact for DURC
  - Supports DURC committee
  
- ▶ Environmental Health & Safety
  - Provide expertise on biosafety, biosecurity and risk assessment to DURC Committee
  - Primary responsibility center for assuring compliance with USG policies on Select Agents and Toxins



# Responsibilities

- ▶ Institutional Official
  - Designated point of contact
  - Collaborate with PIs to ensure project description complete and adequate for assessment of DURC
  - Assemble and facilitate review by DURC Committee





# Responsibilities

## ▶ DURC Committee

- Membership includes Institutional Contact, Responsible Official for Select Agents, and representatives from scientific departments
- Standing committee housed within RCCO
- Committee reviews potential projects reports to USG (whether DURC or not) within 30 days
- Work with PI and USG to draft Risk Mitigation Plan (when identified as DURC)
- Maintain records
- Provide training
- Ensure compliance





# Responsibilities

- ▶ **Principal Investigator**
  - Notify University Institutional Contact when planning research with DURC
  - Complete application for rDNA or EH&S
  - Provide written assessment on project to DURC Committee
  - Compose Risk Mitigation Plan and perform research accordingly
  - Ensure lab personnel trained on DURC
  - Communicate research findings responsibly



# Implementation

PI notifies IC of project in development with agent subject to DURC review

IC reviews project description/PI DURC assessment

IC sends protocol to DURC Committee for review

Project identified as NOT DURC

IC notifies USG of DURC Committee decision with 30d

PI and IC continue to communicate about project

Any changes in research that constitute DURC are reported



# Implementation

PI notifies IC of project in development with agent subject to DURC review

IC reviews project description/PI DURC assessment

IC sends protocol to DURC Committee for review

Project identified as DURC

PI, IC and USG designee develop Risk Mitigation Plan

For NIH funding, PI submits manuscripts/presentations within 10d

DURC research reassessed at least annually; reported to funding agency



# Research vs. Safety?

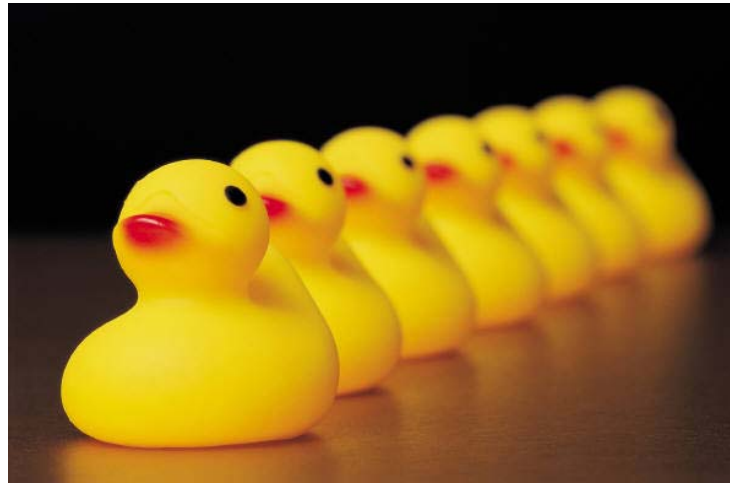
1. BSL3/SA research costs increasing while funding decreasing
2. Will new and increased regulations results in fewer investigators doing work on SA?
3. Should DURC be limited to selected high containment facilities?
4. How do we balance safety concerns with public perception / misperception?





# Research vs. Safety?

*GOAL: maximize scientific freedom  
while minimizing risk*







# How Does It All Fit?

