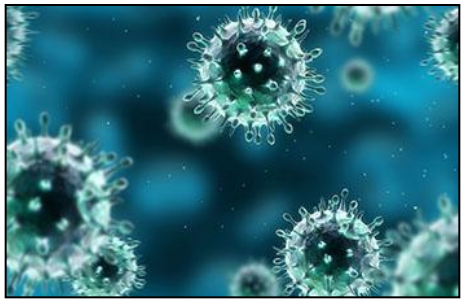
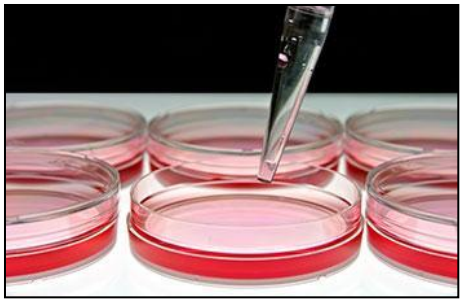
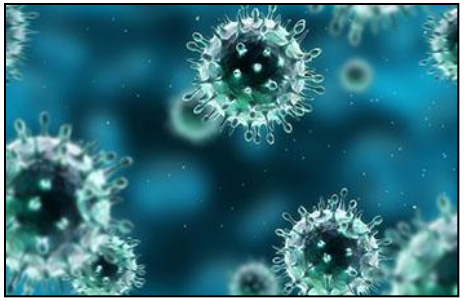




A Case Study Approach to the Institutional DURC Oversight Policy

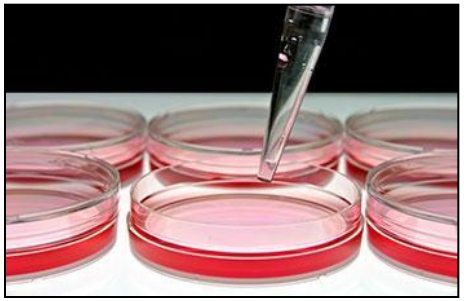
July 22, 2015



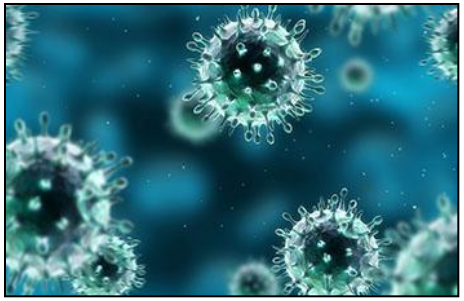
Webcast

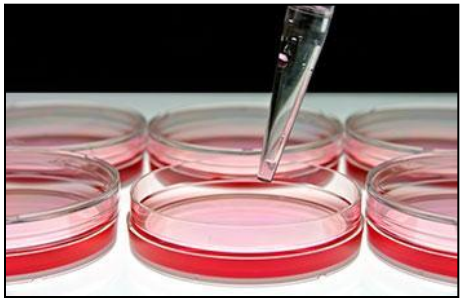
For those joining us by webcast, please follow along!

- Access the:
  - Case Study and Institutional DURC Oversight Policy at: www.phe.gov/DURCworkshop



- Submit comments on the Case Study at DURC@ostp.gov



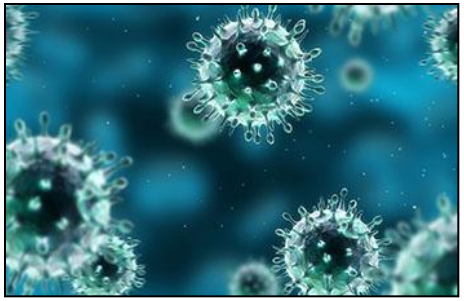


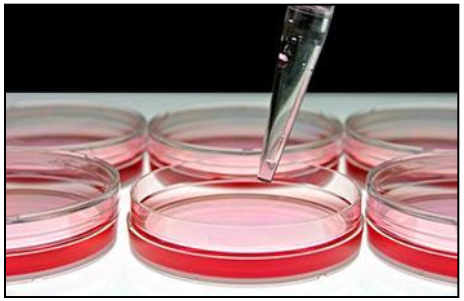
Guidelines

The case study is fictional. There is no intentional representation of, or connection to, real persons, institutions, or research protocols by the U.S. Government.

Today's Goals:

- **Illustrate the iDURC review process**
- Promote collaboration
- Facilitate interactive exchange and learning
- Emphasize a culture of responsibility for DURC oversight and the responsible conduct and communication of DURC research

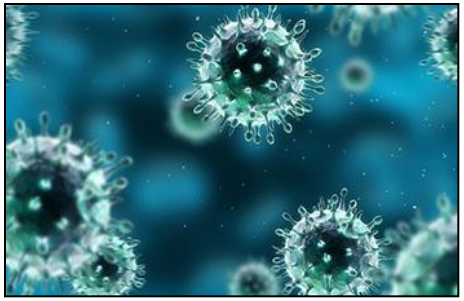




Guidelines

Learning Objectives

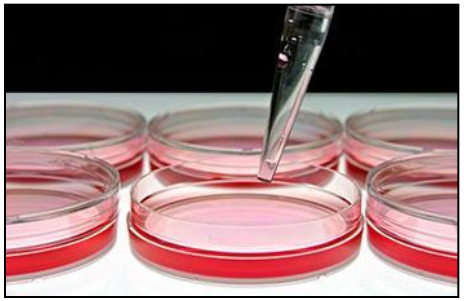
- **Define** Dual Use Research of Concern (DURC)
- **Understand** the scope of the institutional DURC oversight policy
- **Clarify** the roles and responsibilities of policy stakeholders:
  - Institution
  - Principal Investigator
  - Institutional Review Entity (IRE)
  - Institutional Contact for Dual Use Research (ICDUR)
  - U.S. Government Funding Agency



Overview

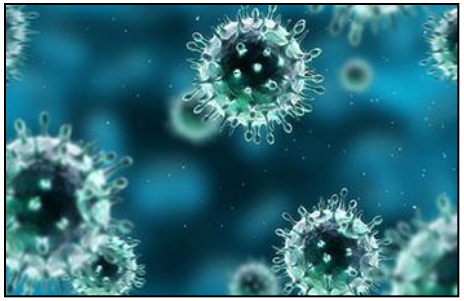
Why *Francisella tularensis spp.?*

- In the United States, research activities are primarily conducted in **Biosafety Level 3** conditions*



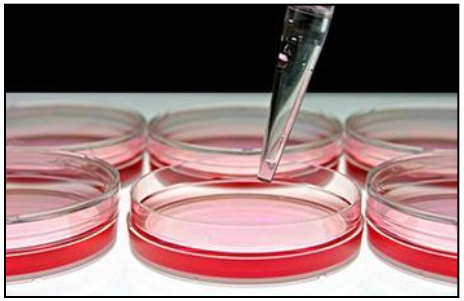
- *F. tularensis spp.* include strains that are subject to and exempt from Federal Select Agent Regulations

** based on protocol specific biological risk assessment*



Part 1

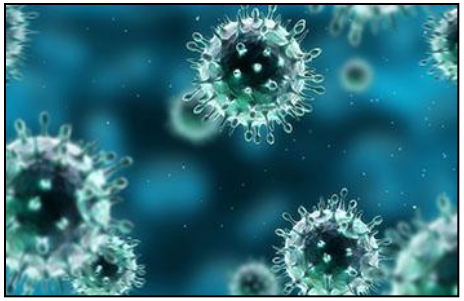
Three factors for consideration of DURC under the Policy:



1. Does the research involve one of the 15 agents or toxins listed in the Policy?

2. Will the research produce any of the seven experimental effects listed in the Policy?

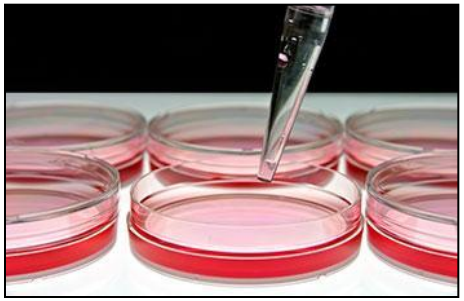
3. Does the research meet the Policy's definition of DURC?

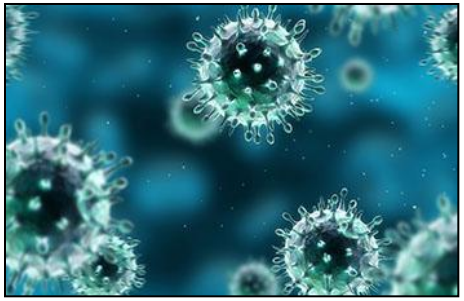


Part 1

Experiment 1

Evaluate how ***F. tularensis novicida*** Type III Secretory System (T3SS) proteins influence infection in mammalian cells

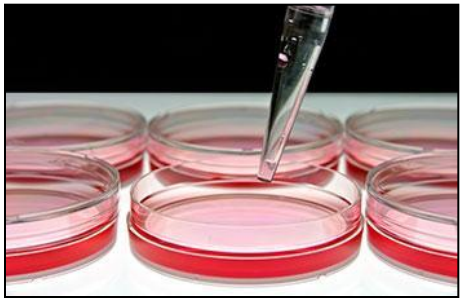


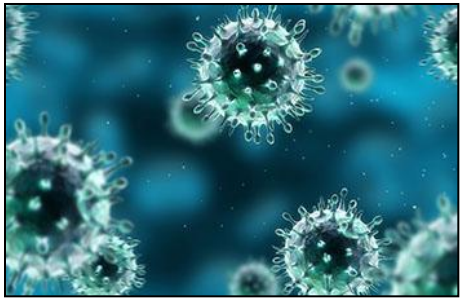


Part 1

Three factors for consideration of DURC under the Policy:

1. Does the research involve one of the 15 agents or toxins listed in the Policy? **NO**

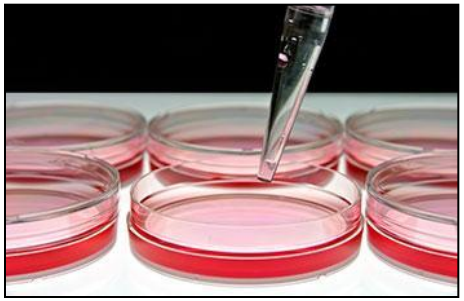


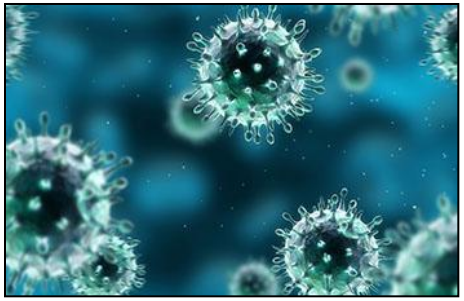


Part 1

Experiment 2

Evaluate how T3SS proteins in ***F. tularensis tularensis*** influence infection in mammalian cells

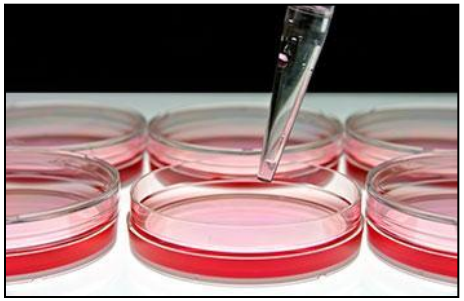




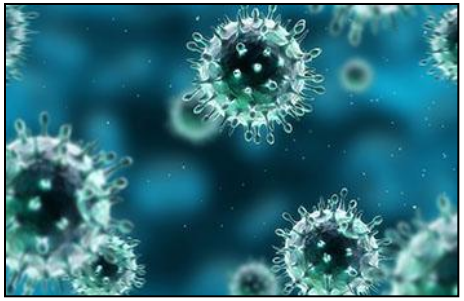
Part 1

Three factors for consideration of DURC under the Policy:

1. Does the research involve one of the 15 agents or toxins listed in the Policy? **YES**



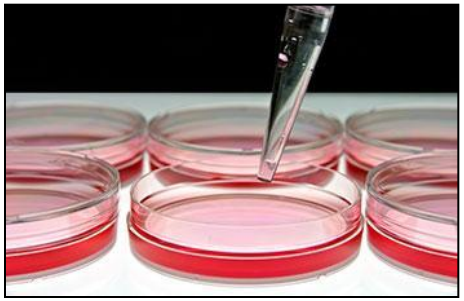
2. Will the research produce any of the seven experimental effects listed in the Policy? **NO**

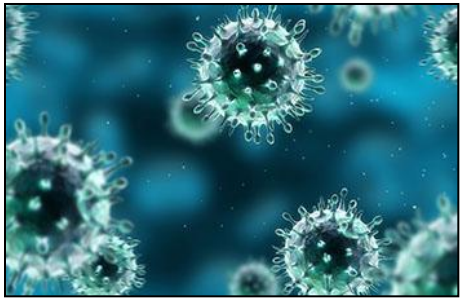


Part 2

Experiment 3

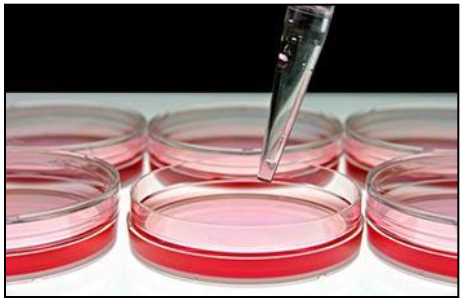
Modify ***F. tularensis tularensis*** surface protein to enhance its ability to survive and replicate in infected cells





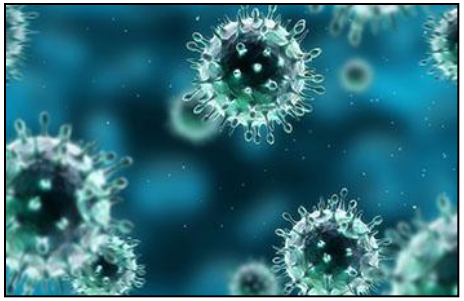
Part 2

Seven Listed Experimental Effects:*



1. Enhances the harmful consequences of the agent or toxin
2. Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification
3. Confers to the agent or toxin resistance to clinically and/or agriculturally useful prophylactic or therapeutic interventions against that agent or toxin or facilitates their ability to evade detection methodologies
4. Increases the stability, transmissibility, or the ability to disseminate the agent or toxin
5. Alters the host range or tropism of the agent or toxin
6. Enhances the susceptibility of a host population to the agent or toxin
7. Generates or reconstitutes an eradicated or extinct agent or toxin listed in 6.2.1, above

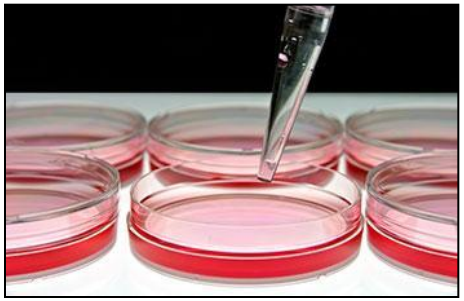
** USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, Release Date September 24, 2014*



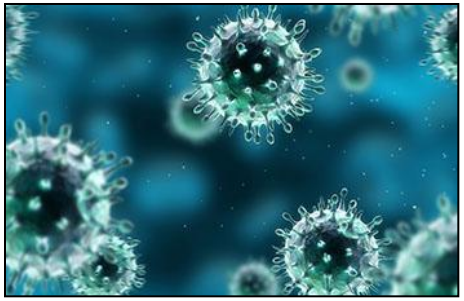
Part 2

Experiment 3:

1. Will increase the pathogenicity of *F. tularensis*, thus *"Enhances the harmful consequences of an agent or toxin;"* and

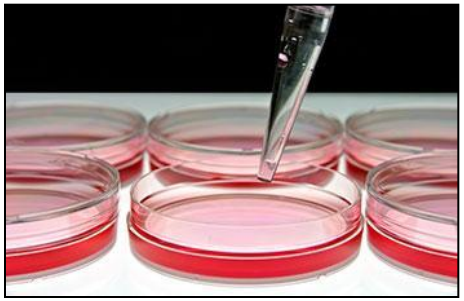


2. May result in *F. tularensis* having an increased ability to avoid clearance by the host immune system, thus *"Disrupts immunity or the effectiveness of an immunization against the agent or toxin without clinical and/or agricultural justification."*



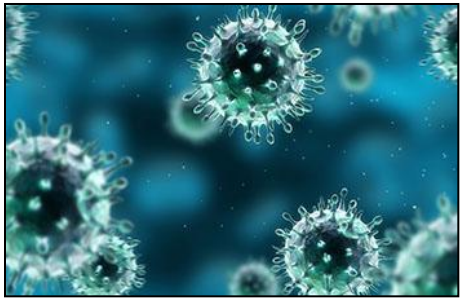
Part 2

Definition of DURC under the Policy:*



"Life sciences research that, based on current understanding, 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."

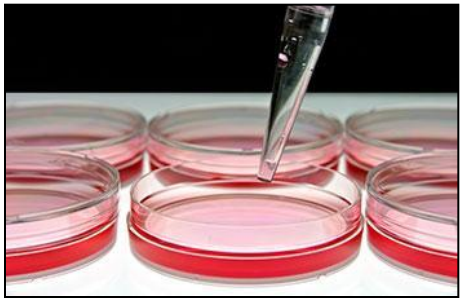
** USG Policy for Institutional Oversight of Life Sciences Dual Use Research of Concern, Release Date September 24, 2014*



Part 2

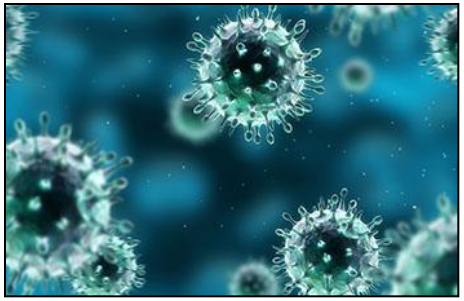
Three factors for consideration of DURC under the Policy:

1. Does the research involve one of the 15 agents or toxins listed in the Policy? **YES**



2. Will the research produce any of the seven experimental effects listed in the Policy? **YES**

3. Does the research meet the Policy's definition of DURC? **YES**



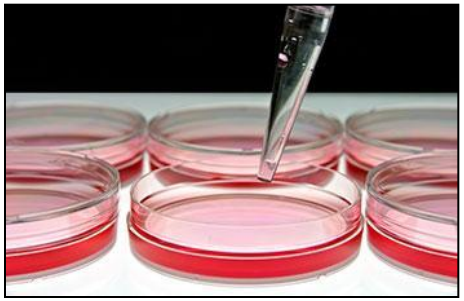
Parts 1 and 2

Question 17:

What notifications are required to be made and when?

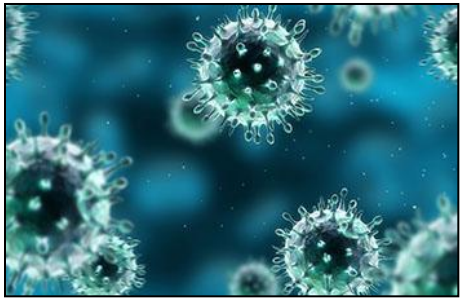
- If the research involves one of the 15 agents or toxins listed in the Policy …

  AND



- The research produces any of the seven experimental effects listed in the Policy …

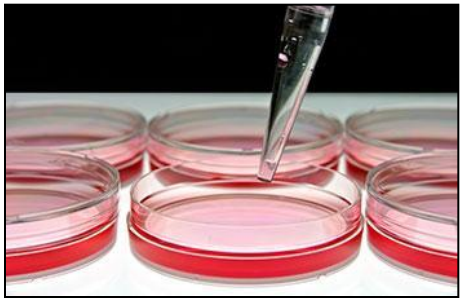
The institution MUST advise the funding agency of the outcome of the IRE's decision within 30 days of the IRE decision, whether the outcome identifies DURC or not.



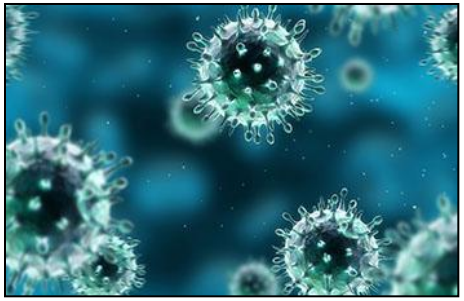
Parts 1 and 2

Question 20:

How long after determining that a project constitutes DURC must a draft risk mitigation plan be submitted to the funding agency?



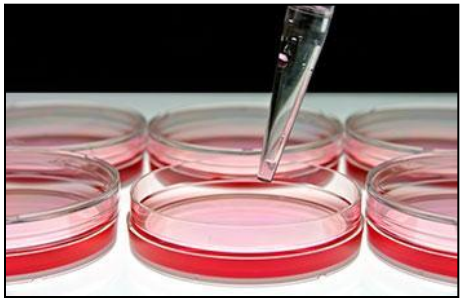
- The institution must submit the draft risk mitigation plan within 90 days of the IRE decision of determining that the project constitutes DURC.

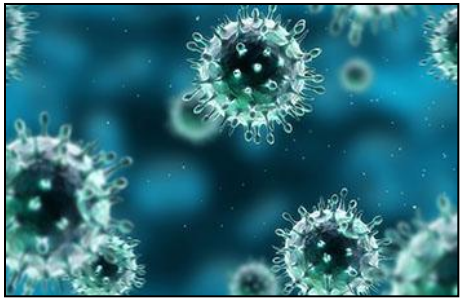


Part 3

Risk Mitigation

Apply the ***Institutional Oversight of Life Sciences Dual Use Research of Concern*** policy to develop and implement a risk mitigation plan to manage research resources and research information

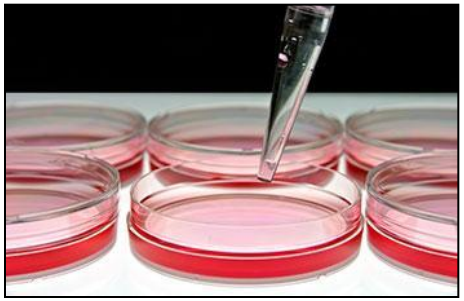


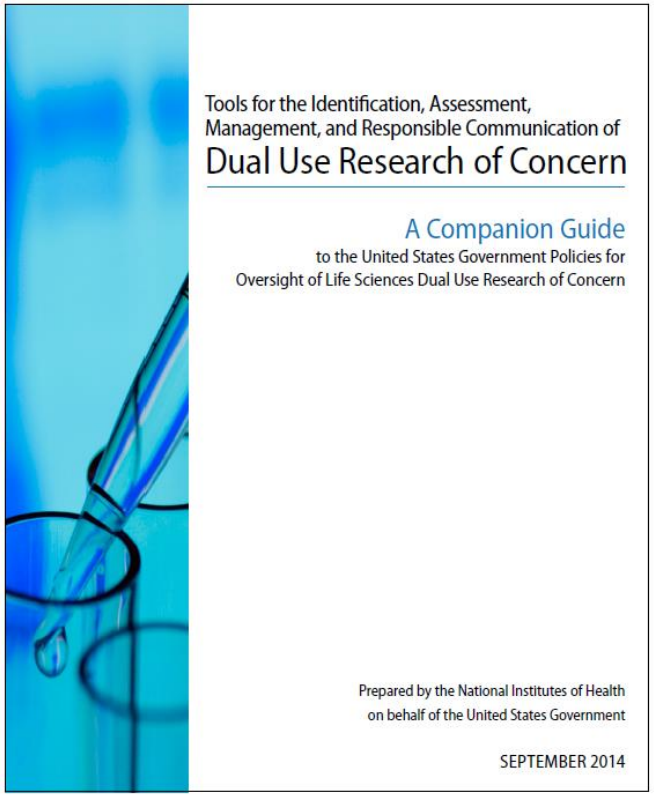


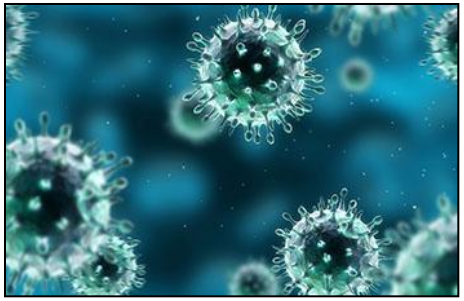
Part 3

Companion Guide to iDURC Policy:

www.phe.gov/s3/dualuse



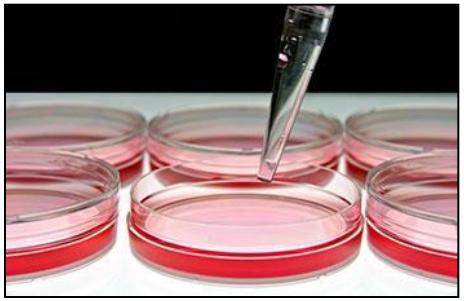




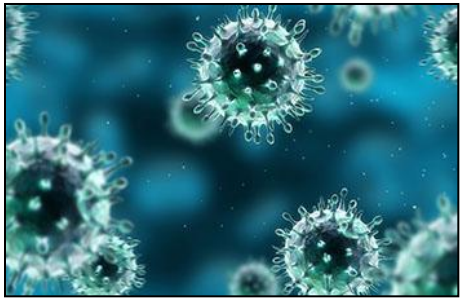
Part 3

Risk Mitigation Plan:
Biosafety and Biosecurity Measures

Considerations:



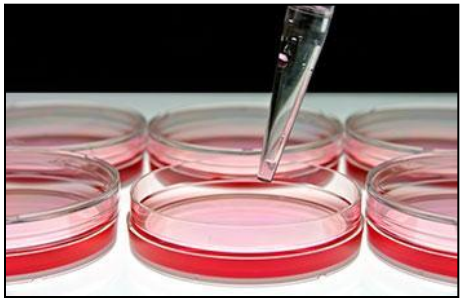
- Increase Biocontainment Level
- Add Security Enhancements
- Change Experimental Design



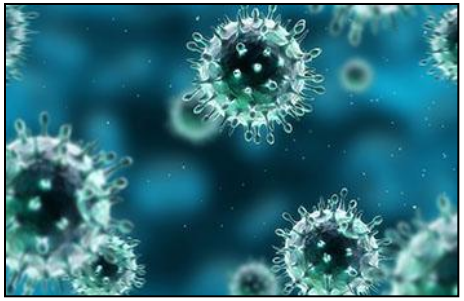
Part 3

Risk Mitigation Plan:
Impact on Medical Countermeasures

Considerations:

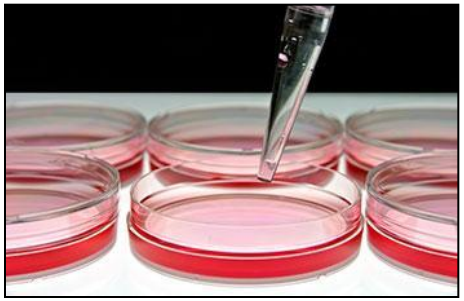


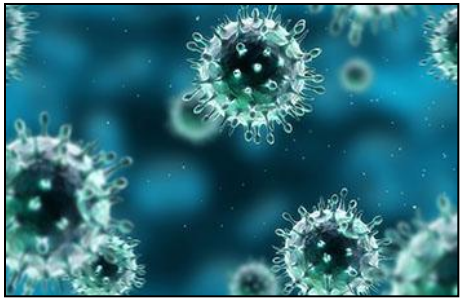
- Do medical countermeasures exist?
- Is the new strain susceptible to MCM?
- Are existing MCM as effective against this strain as other strains?



Part 3

Risk Mitigation Plan: Communication

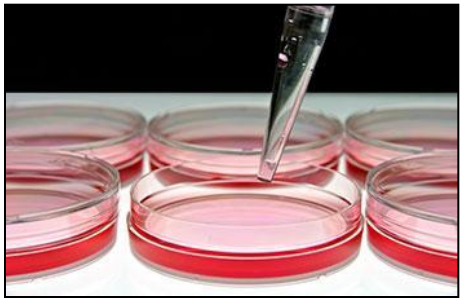




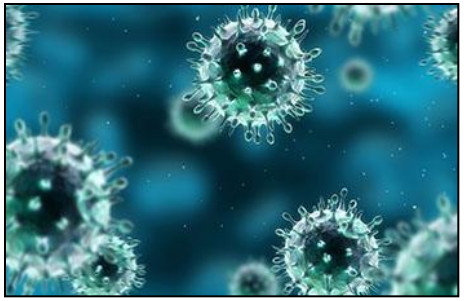
Part 3

Risk Mitigation Plan: Communication

•Describe biosafety and biosecurity measures



•Emphasize public health benefits of research

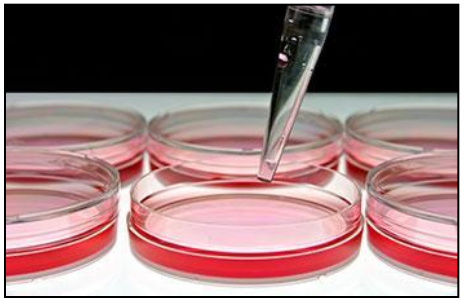


Part 3

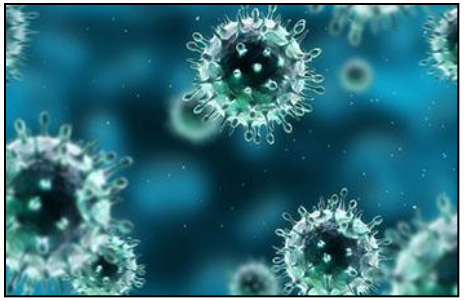
Risk Mitigation Plan:

Training Research Personnel

•Provide education and training on the Institutional DURC Oversight policy for individuals conducting research with one or more of the 15 listed agents



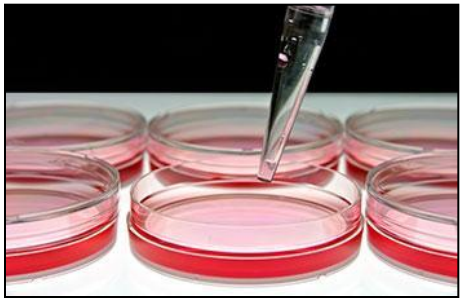
•Provide refresher training on an annual basis



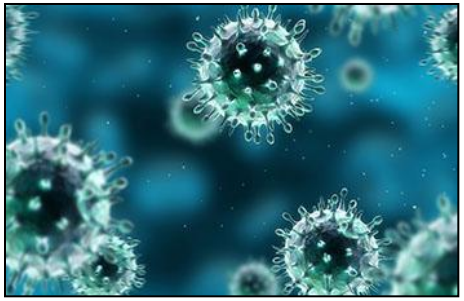
Part 3

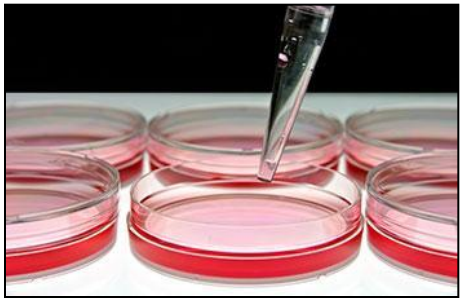
Question 28:

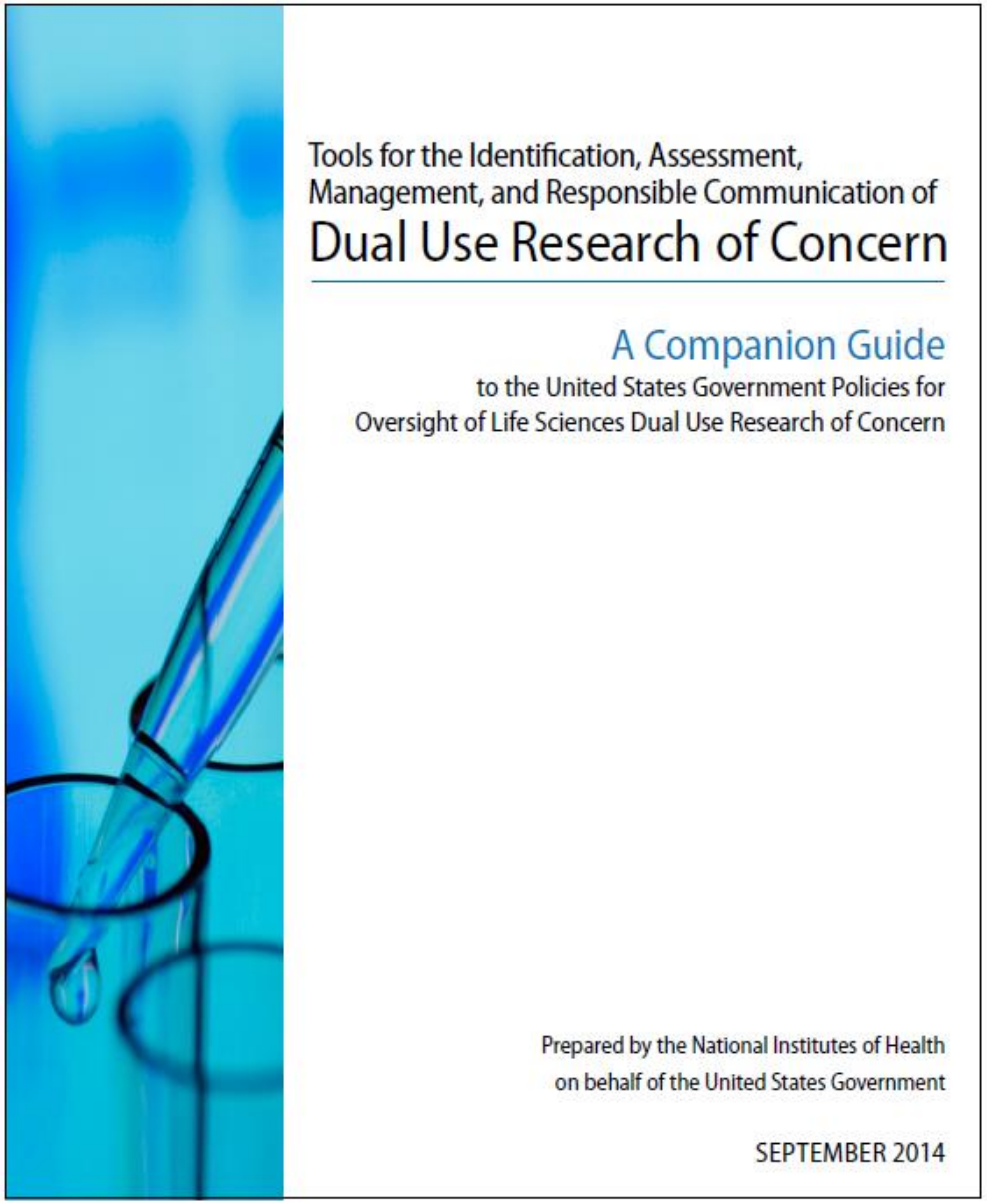
How long after the ICDUR's submission of the draft risk mitigation plan does the funding agency have to finalize and approve the plan?



- USG agencies must provide an initial response within 30 calendar days and should finalize the plan within 60 calendar days of receipt of the draft plan







www.phe.gov/s3/dualuse