



# Training at Duke University on the USG Policy for Institutional Oversight



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“I serve as co-chair of the Duke IBC and IRE. The opinions expressed here are my own, not necessarily those of the IBC or IRE.”



NIAID Regional Biocontainment Laboratory at Duke



# Outline



- Review of dual use research at Duke (2003-2015)
- Lessons learned from dual use review at Duke
- USG Policy: Whom do we teach?
- USG Policy: What do we teach?

# Review of dual use research at Duke (2003-2015)



# Dual-use review by SERCEB PEL core



- In 2003, NIH funded the Southeast Regional Center of Excellence for Emerging Infections and Biodefense (SERCEB).
- SERCEB included a Policy, Ethics, and Law Core. The PEL core reviewed all SERCEB projects for dual use potential beginning in 2003.



# Dual use review by Duke IBC



- Screening questions were added to rDNA registration form in 2005.
- All IBC members were trained in 2006 using the SERCEB training module.
- Dual use was considered during review of rDNA protocols.
- Other protocols were reviewed upon request of investigator or program officer.
- We used no specific definition or threshold for review

SCIENCE AND SECURITY

## Practical Experiences in Dual-Use Review

E. Megan Davidson,<sup>1</sup> Richard Frothingham,<sup>2</sup> Robert Cook-Deegan<sup>3\*</sup>

The U.S. government is debating how to handle national security risks posed by bioscience research. A research consortium shares lessons learned from their research oversight scheme.



Davidson EM, Frothingham R, Cook-Deegan R. Science and security: Practical experiences in dual-use review. *Science* 2007;316:1432-3.

# Lessons learned from dual use review at Duke



# Lessons learned



- Many protocols reviewed by the IBC have some dual use potential.
- Most PIs don't understand the concept of dual use, and so could not review their own research for dual use potential.
- Duke IBC members COULD NOT reach consensus on the classification of dual use potential for specific protocols.
- Duke IBC members COULD agree on management strategies.



# Duke research proposals with dual use potential



- Examples of protocols with dual use potential:
  - Cytokine expression by ectromelia (2004)
  - Virulence factors in uropathogenic E. coli (2006)
  - Retroviral expression of tetanus toxin light chain (2007)
  - Adaptation of dengue virus for growth in Drosophila (2007)
- None of these 4 protocols were identified by the PI as having dual use potential.



# How has the potential for dual use been identified at Duke?



- NIH study section (cytokine expression in ectromelia)
- NIH program officer (dengue in drosophila)
- Dual-use questions on registration form
- Duke IBC members identify dual use potential during the review process



# Can an IBC reach consensus during dual-use review?



- The Duke IBC often reached consensus that there was “no significant dual-use potential” or that “risk is typical for biomedical research.”
- Other protocols were difficult or impossible to classify. Discussion of dual use potential often became tangential to the specific protocol. IBC members raised concern about setting precedent, and introduced other hypothetical research.
- However, it was relatively easy for IBC to reach consensus on an appropriate management.



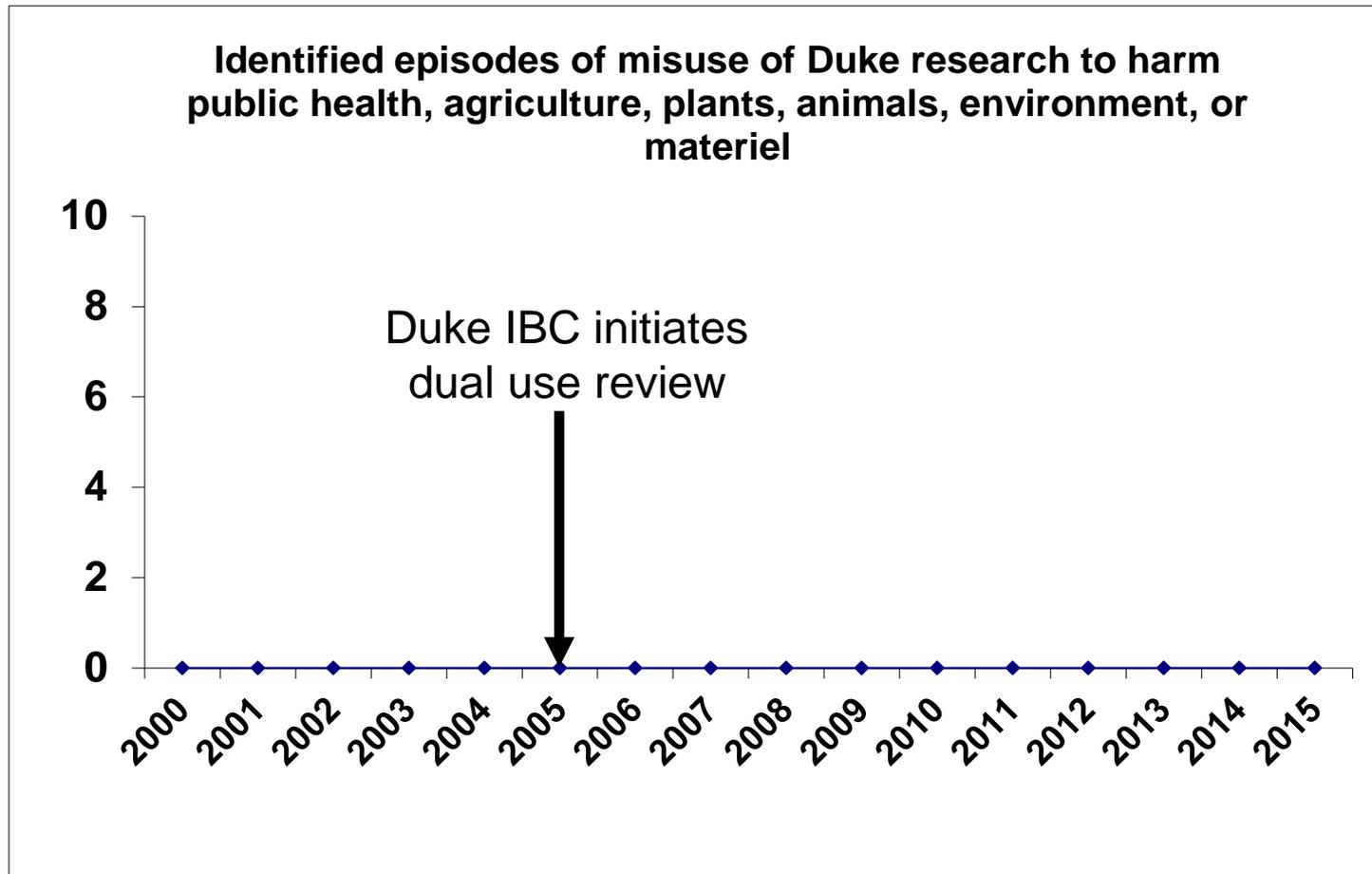
# Management strategies for research with dual-use potential



- **Education:** PI and/or lab members complete an online training module.
- **More information:** PI provides additional scientific information to assist in the risk assessment process.
- **Contingency plan:** The PI identifies potential outcomes of the research that could result in dual-use material or knowledge, then identifies a contingency plan.
- **Modification:** PI changes the research plan to reduce the dual-use potential.



# Benefit of Duke review for dual use research



# USG Policy: Whom do we teach?



# Whom do we teach?



- We are required to train all researchers working with any of the 15 agents.
  - We have trained all Duke personnel with current Select Agent registration.
  - We will train all identified Duke personnel who conduct clinical or laboratory research with any quantity of botulinum toxin. We have identified zero so far.
- We have trained all members of the Institutional Review Entity (IRE).
- We plan to train multiple “gatekeepers.”
  - IBC, IACUC, IRB, Stem Cell Research Overview Committee
  - Safety office lab audit team
  - Grants and contract staff

# USG Policy: What do we teach?



# What do we teach our gatekeepers on the new USG Policy?



- Identify new USG Policy for Institutional Oversight of Life Sciences DURC.
- Introduce two questions for all research proposals:
  - Does this research involve any Select Agents?
  - Does this research involve Botox<sup>®</sup> or any other form of botulinum toxin in any quantity?
- If either answer is YES, contact Duke's Biological Safety Officer.



# What do we teach our researchers on the new USG Policy?



- Identify new USG Policy for Institutional Oversight of Life Sciences DURC.
- Discuss the general concept of dual use research.
- Discuss management approaches to dual use research.
- Identify the research covered by the USG Policy.
- BRIEFLY outline the USG Policy flow chart for review.



# Dual use teaching points



- Define dual use research:
  - Dual use research has a beneficial purpose but could be misused to cause harm.
  - Dual use potential includes both materials and knowledge.
- Contrast dual use research with other research issues:
  - Biosafety
  - Biocontainment
  - Biosecurity
- Provide examples of dual use research or technology.
- Provide examples of dual use management.

Can you give an example of a dual-use technology that is misused many times each month with fatal consequences?



# Example of dual-use technology: automobile



- Arturo Casadevall has suggested the automobile as an example of a dual-use technology:
  - Automobiles have many beneficial uses.
  - Automobiles can be misused to harm human populations.
- How can this risk be managed?

March 29, 2009: BAGHDAD —

Sixteen people died Thursday when a bomb in a parked car detonated at a market in Baghdad.

This was the fifth big explosion this month in Iraq.





# Management of dual-use technology: automobile



- Dual use potential from automobiles is rarely managed by excluding automobiles completely.
- Dual use risk from automobiles can be managed by vehicle barriers, checkpoints, mirrors, or open-chassis design.



# What do we teach our IRE members on the new USG Policy?



- Identify new USG Policy for Institutional Oversight of Life Sciences DURC.
- Discuss the general concept of dual use research.
- Discuss management approaches to dual use research.
- Identify the research covered by the USG Policy.
- Review **IN DETAIL** the entire USG Policy.



# People



## Debra Hunt

- Select Agent program Responsible Official (RO)
- Biological Safety Officer (BSO)

## Wayne Thomann

- IRE co-chair

## Raphael Valdivia

## Megan Davidson

## Bob Cook-Deegan

## IRE members

- Brian Letourneau
- Scott Alderman
- Randall Reynolds
- Pat Condreay
- Arlene Sena
- David Pickup
- Carol Epling
- Peg Hogan
- Tai-Pong Sun