LESSONS LEARNED: CDC YEAR THREE
THE “NEW” SELECT AGENT INSPECTION

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10 Commandments of the “New” CDC Inspection
Commandment #I:
• Thou Shalt Not Assume Thy Researchers Know Anything About Biosafety
  – Have Detailed SOPs:
    • “don’t put your head in the BSC”
  – Extensive Training

Commandment #II:
• Thou Shall Not Steal
  -SOPs from another institution
Commandment #III: Know Thy Vials

• Impressed that our researcher knew # of vials.
• Inventory – using their form
Commandment #IV:

- Thou shall have an even better Medical Surveillance Program
- Health Hazard Assessment
- Serum Banking Program
- “...The individual that received the exposure or potential exposure will be given a medical consultation and advised of available treatments.”
Health Hazards Assessment
For Laboratories using Select Agents & Toxins

Arizona State University
Department of Environmental Health & Safety

PRINCIPAL INVESTIGATOR: ___________________________ Phone No: ___________________________
Department: ____________________________________ Fax No: ___________________________
Building, Room, Mail Code: ______________________ Email: ___________________________

Please fully complete each section. It may be helpful to refer to the Population and Health Branch of the Canadian’s

1. Agent Identification

Name (genus/species):

Type of Agent (check all that apply)

- Bacterium
- Virus
- Fungus
- Rickettsia
- Prion
- Parastomal
- Toxin derived from living organisms
- Recombinant DNA

For recombinant DNA, the following questions must be answered:

1) Does the inserted gene encode a known toxin or a relatively uncharacterized toxin?
   - No: ☐ Yes: ☐ If yes explain:

2) Does the modification have the potential to alter the host range or cell tropism of the virus?
   - No: ☐ Yes: ☐ If yes explain:

3) Does the modification have the potential to increase the replication capacity of the virus?
   - No: ☐ Yes: ☐ If yes explain:

4) Does the inserted gene encode a known oncogene?
   - No: ☐ Yes: ☐ If yes explain:

5) Does the inserted gene have the potential for altering the cell cycle?
   - No: ☐ Yes: ☐ If yes explain:

6) What is the probability of generating replication-competent viruses?
   - No: ☐ Yes: ☐ If yes explain:
Commandment #V:

• Obey your application
  – Prepare as if you are in full operation!!!
  – Signs
  – Drills
  – Training

Commandment #VI:

• Respect thy PAPR
Commandment #VII:

• Thou shall not drip outside of “primary” containment

• Select Agent and Toxin Theft, Loss and Release Information Document


• READ IT, KNOW IT, LIVE IT
Commandment #VIII:

- Respect Available Resources
- Checklists – National Select Agent Registry
- BSL3 Inspection Video

Commandment #IX:

- Honor the past, but look to the future
Commandment #X

• Continued Guidance from CDC
  —shipping
I – Detailed SOPs
II – Steal SOPs
III – Inventory
IV – Medical Surveillance
V – Prepare as if you are in full operation
VI – PAPR/PPE
VII – Report Drips
VIII – CDC Resources
IX – Future
X – Guidance
Thanks!

Questions?

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