

# Career Options for PhDs in Biosafety & Research oversight

Torsten A. Hopp, PhD, RBP

University Biosafety Officer / Responsible Official for the UofL Select Agent Program

University of Louisville

Department of Environmental Health & Safety

School of Public Health & Information Sciences

August 2018

A career path is rarely a path at all. A more interesting life is usual a more crooked, winding path of missteps, luck and vigorous work. It is almost always a clumsy balance between the things you try to make happen and the things that happen to you.

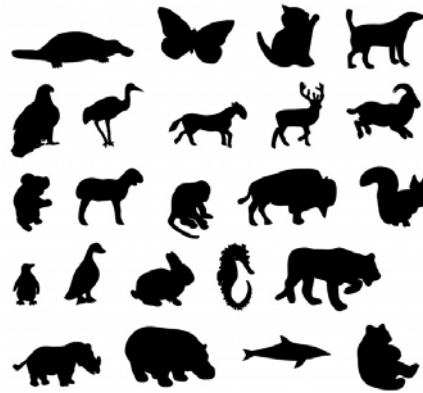
Tom Freston

American entertainment industry executive



# What Careers Are We Going To Cover Today?

- ▶ Research Oversight Administration
  - ▶ IACUC administrator
  - ▶ IBC Administrator
- ▶ Biosafety
  - ▶ Biosafety Officer
    - ▶ High Containment Facility Manager
    - ▶ Responsible Official for Select Agent Program



# What's My Professional Path?

- ▶ Undergraduate in Biology at the University of Kaiserslautern, Germany and Christian-Albrechts-Universität zu Kiel, Germany
  - ▶ Diploma in Biology (Major in Microbiology and Zoology, Minor in Biochemistry)
- ▶ Graduate school at University of Luebeck (Molecular Biology)
- ▶ Two postdoctoral fellowships
  - ▶ Neurobiology
  - ▶ Breast cancer
- ▶ In 2003 moved from research focused career to administrative position (IACUC administrator)
- ▶ In 2005 added IBC administrator to my responsibilities
- ▶ In 2009 became Biosafety Officer / BSL-3 Facility Manager / Select Agent Responsible Official
- ▶ In fall 2015 accepted position as UofL Biosafety Officer and Select Agent Responsible Official



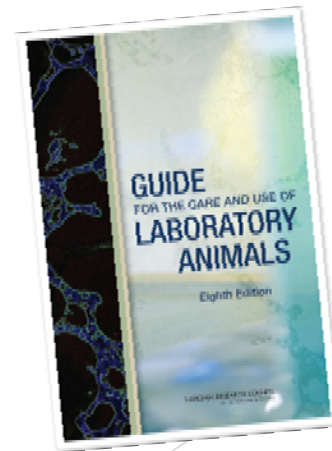
I describe my career path as a zigzag, not a ladder.

Denise Morrison  
Chief Executive Officer of  
Campbell Soup



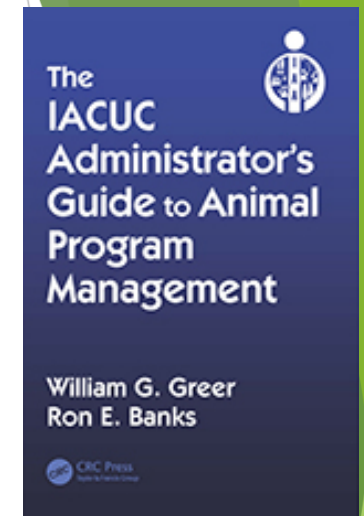
# What Does The IACUC Do?

- ▶ Reviews and approves all research using animals
- ▶ Inspects animal facilities
- ▶ Reviews/evaluates the animal care program
- ▶ Prepares reports to the Institutional Official (IO)
- ▶ Reviews animal welfare concerns
- ▶ Makes recommendations to the IO
- ▶ Be authorized to suspend an activity involving animals



# IACUC Administrator

- ▶ Directs and manages operation of the IACUC
- ▶ Advises investigators and committee members
- ▶ Responsible for the scheduling and coordination of IACUC meetings
- ▶ Prepares reports to federal agencies, accrediting bodies and university officials
- ▶ Schedules and plans the semi-annual research facilities inspections program
- ▶ Compiles and finalizes semi-annual reports
- ▶ Assists in the development and delivery of animal care and use training programs
- ▶ Interfaces with the Office of Sponsored Program and committees (IBC, IRB, etc.)
- ▶ Supervises IACUC staff.



# IACUC Administrator Certification

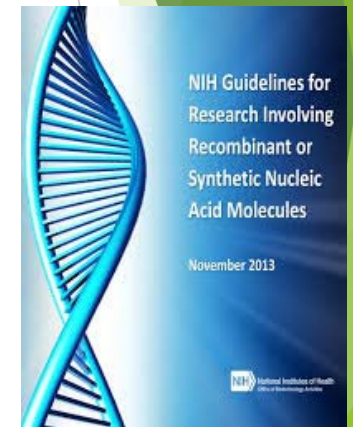
- ▶ CPIA (Certified Professional in IACUC administration) managed by Public Responsibility in Medicine and Research (PRIM&R)
- ▶ Requires at least two years of work experience within the last 7 years





# What Does The IBC Do?

- ▶ Established under the *NIH Guidelines* to review of research involving rNA or sNA
- ▶ IBCs are typically assigned additional review responsibilities
  - ▶ Select agents and toxins, Blood borne pathogens, Xenotransplantation, Stem cell research, "Dual Use" research, Nanotechnology
- ▶ Reviews and approves research or teaching activity
- ▶ Independently assesses the containment levels of the work
- ▶ Assesses the facilities, procedures, practices, and training and expertise of personnel
- ▶ Adopt emergency plans covering accidental spills and personnel contamination
- ▶ Reports significant problems with or violations of the *NIH Guidelines* and significant research related accidents or illnesses
- ▶ Suspends or terminates approval of research that is not being conducted in accordance with the IBC's requirement



# IBC Administrator

- ▶ Directs and manages operation of the IBC
- ▶ Advises investigators and committee members
- ▶ Responsible for the scheduling and coordination of IBC meetings
- ▶ Prepares reports to federal agencies, accrediting bodies and university officials
- ▶ Assists in the development and delivery of biosafety training programs
- ▶ Interfaces with the Office of Sponsored Program and committees (IACUC, IRB, etc.)
- ▶ Supervises IBC staff

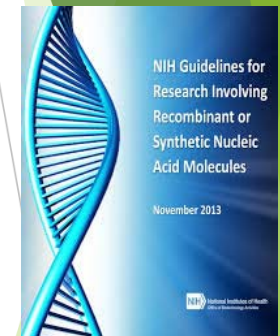
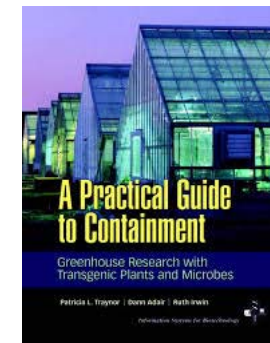
# IBC Administrator Certification

- ▶ Currently none



# Biosafety Program

- ▶ To protect employees and their families from acquiring work-associated infectious diseases or harm from biological agents/toxins
- ▶ To prevent contamination of the environment
- ▶ To comply with all local, state, national and international guidelines and regulations



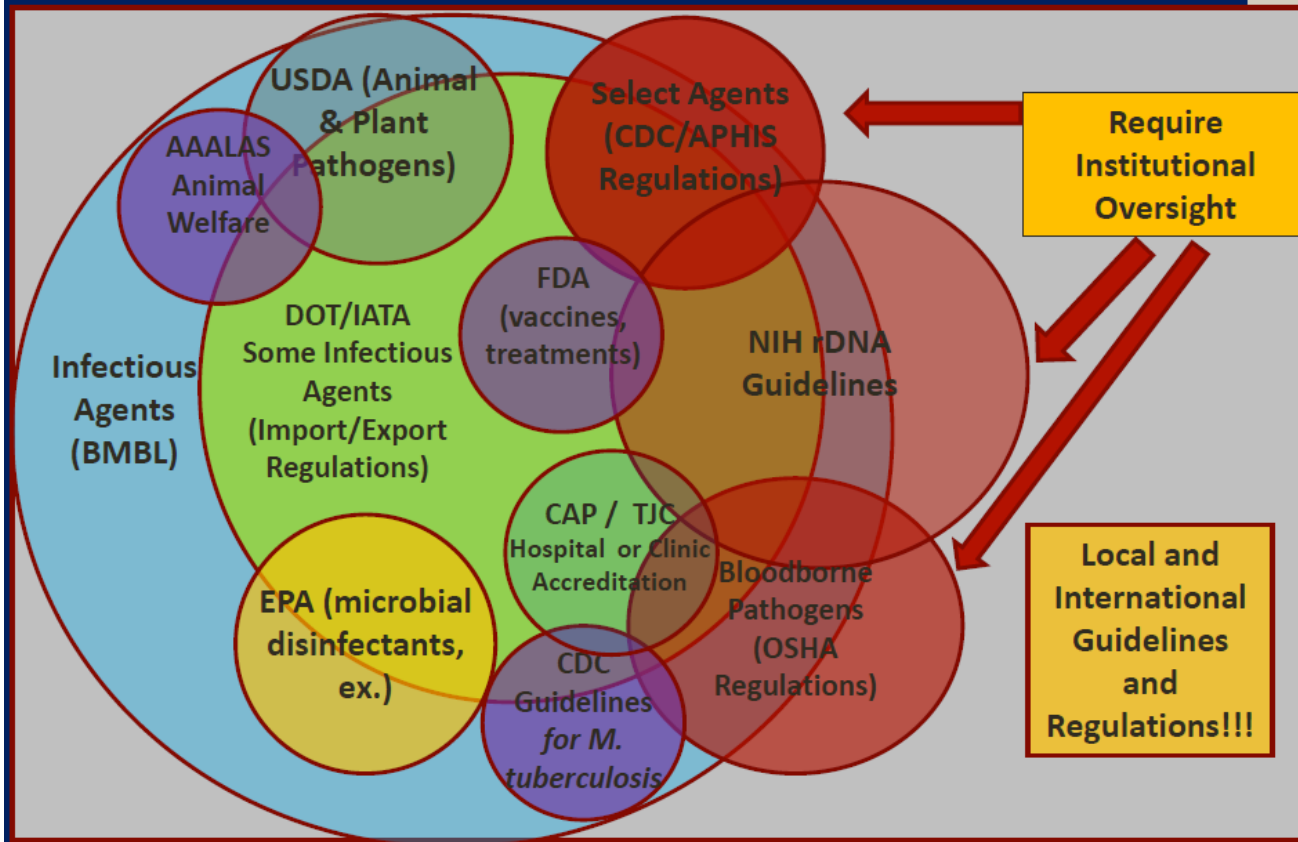
# Where Would You Expect A Biological Safety Program?

- ▶ Universities
- ▶ Hospitals
- ▶ Research facilities
- ▶ Pharmaceutical companies
- ▶ Military and government agencies
- ▶ Biotechnology industry



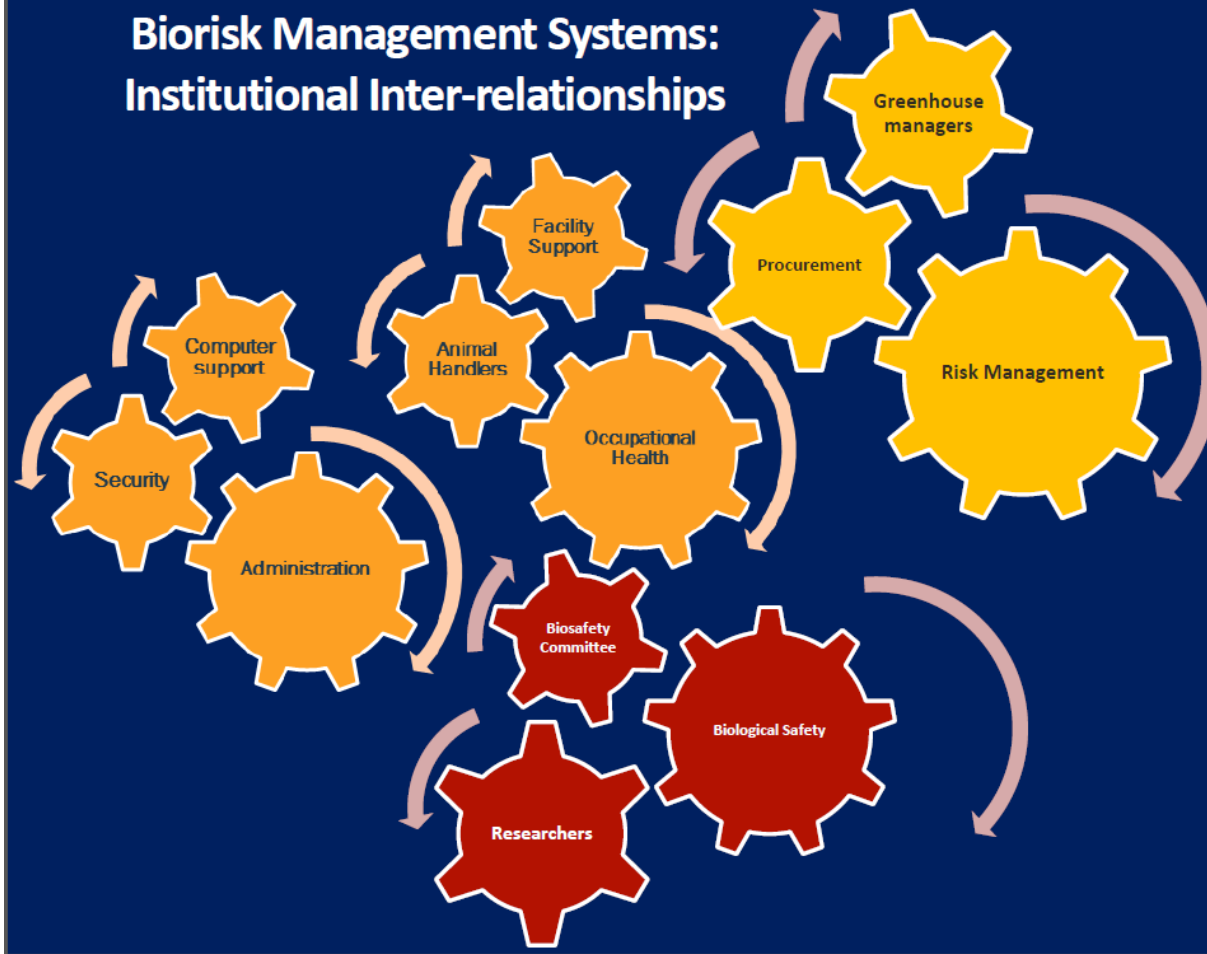


## Seek Relevant US Federal Standards for Biological Research/Issues in Your Institution



Taken from presentation by Debra Hunt

## Biorisk Management Systems: Institutional Inter-relationships



Taken from presentation by Debra Hunt



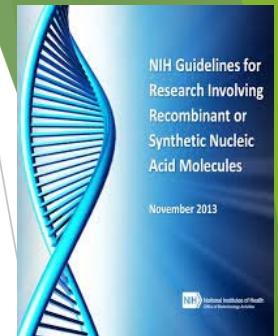
# What Is A Biosafety Professional?

- ▶ ABSA International (Association for Biosafety and Biosecurity):

A biosafety professional develops and participates in programs to promote safe microbiological practices, procedures, and proper use of containment equipment and facilities; stimulates responsible activities among workers; and provides advice on laboratory design

# NIH Guidelines

- ▶ Biosafety is required when institution
  - ▶ engages in large-scale research or production activities involving viable organisms containing recombinant or synthetic nucleic acid molecules
  - ▶ engages in recombinant or synthetic nucleic acid molecule research at BL3 or BL4
- ▶ Duties:
  - ▶ Periodic inspections
  - ▶ Report non-compliance and significant research-related accidents or illnesses
  - ▶ Develop emergency plans for accidental spills and personnel contamination
  - ▶ Provide advice on lab security
  - ▶ Provide technical advice to PI and IBC on safety procedures





# Biosafety Officer Job Description

- ▶ Develops, implements, and coordinates a biosafety program
- ▶ Coordinates, quality controls, and monitors the delivery of biosafety education and training
- ▶ Monitors all teaching and research activities involving biological materials and recombinant DNA molecules
- ▶ Reviews research grant applications, proposals, and activities involving biological materials and recombinant DNA,
- ▶ Oversees select agent transfers to and from University laboratories; monitors use of toxins covered by the Select Agent regulation.
- ▶ Inspects research and teaching facilities
- ▶ Coordinates the review and investigation of all biosafety accidents and develops corrective action plans.
- ▶ Develops and implements emergency response procedures
- ▶ Advises regarding appropriate equipment, facilities, and work practices for protecting personnel and the environment from contamination
- ▶ Provides technical
- ▶ Participates in and provides leadership to various internal committees, such as IBC and IACUC
- ▶ Supervises biosafety staff

# Who Conducts Biosafety?

- ▶ Microbiologists
- ▶ Industrial Hygienists
- ▶ Biologists
- ▶ Engineers
- ▶ Molecular Biologists
- ▶ Veterinarians
- ▶ Occupational Health Professionals
- ▶ Environmental Health Professionals
- ▶ Clinical Health Care Professionals
- ▶ Biosecurity Professionals

# How Do I Prepare For A Career In Biological Safety?

- ▶ Take microbiology courses at an accredited university, which may include courses in virology, medical or pathogenic microbiology, plant microbiology, and mycology
- ▶ Take additional courses in other areas such as molecular biology, biotechnology, regulatory law
- ▶ Shadow a biosafety professional
- ▶ Join an IBC committee
- ▶ Join ABSA International (ABSA)
- ▶ Participate fully in ABSA sponsored seminars
- ▶ Join local affiliates for networking opportunities

# Biosafety Officer Professional Credential

- ▶ *Registered Biosafety Professional (RBP)*
  - ▶ is an individual with a documented university education or specialized training in relevant biological safety disciplines and been found to be eligible for registration by the ABSA Credentialing Evaluation Board
- ▶ *Certified Biological Safety Professional (CBSP)*
  - ▶ passes a written exam and meet experience and educational criteria set by ABSA.

# Lab Rules - Dua Lipa





# Responsible Official for a Select Agent Program

- ▶ Usually not its own position - often collateral duty
- ▶ Go-to-jail official
- ▶ Makes sure Select Agent regulations are followed



# Fundamental Responsibilities of the Responsible Official

- ▶ Pass a security risk assessment (SRA)
- ▶ Be familiar with the select agent regulations to the extent that the RO can ensure that the entity is compliant
- ▶ Foster open lines of communication with upper management, facility directors, principal investigators (PIs), veterinarians, contractors, local authorities and institutional oversight committees
- ▶ Ensure that annual internal inspections are conducted
- ▶ Have a physical (and not merely a telephonic or audio/visual) presence within the principal duty station
- ▶ Have the authority to speak and act on behalf of the entity.
- ▶ Ensure that individuals listed on the entity's select agent registration are provided the contact information for the HHS OIG Hotline and USDA OIG Hotline so that they may anonymously report any safety or security concerns related to select agents and toxins.
- ▶ For entities registered to possess, store, or use Tier 1 select agents and toxins, the RO must coordinate their efforts with the entity's safety and security professionals to ensure security of Tier 1 select agents and toxins and share, as appropriate, relevant information.
- ▶ Ensure limited access to select agents and toxins to SRA approved personnel only. Conduct initial and annual refresher training, and provide performance oversight and disciplinary action for employees engaged in work with select agents and toxins.

# Making the transition

- ▶ Be realistic about your job prospects and don't aim too high or too low.
- ▶ Be aware that you may not be treated differently than colleagues who have "lower" qualifications. They may have more relevant experience.
- ▶ Know the keywords and buzz words of the sector you want to go into.
- ▶ You might not be paid more because you have a PhD.
- ▶ Moving from research is a transition and while you may have had a lot of freedom to organize your days and weeks when you were doing research, in other sectors things might be more structured.
- ▶ You may miss research!
- ▶ You'll probably have to work on other people's priorities but you can shape the job you're in thanks to your experience.



Dr Nathalie Mather-L'Huillier  
UK



Cheri Hildreth

Clarissa Cowan

Rachel Cary

Tim Mulliger

