Session II: Roles of the Institutional Biosafety Committee

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Outline

- University of Washington overview
- IBC organization and composition
- Project review process
- Examples of BMBL and Guideline application
- Philosophy of the IBC

University of Washington

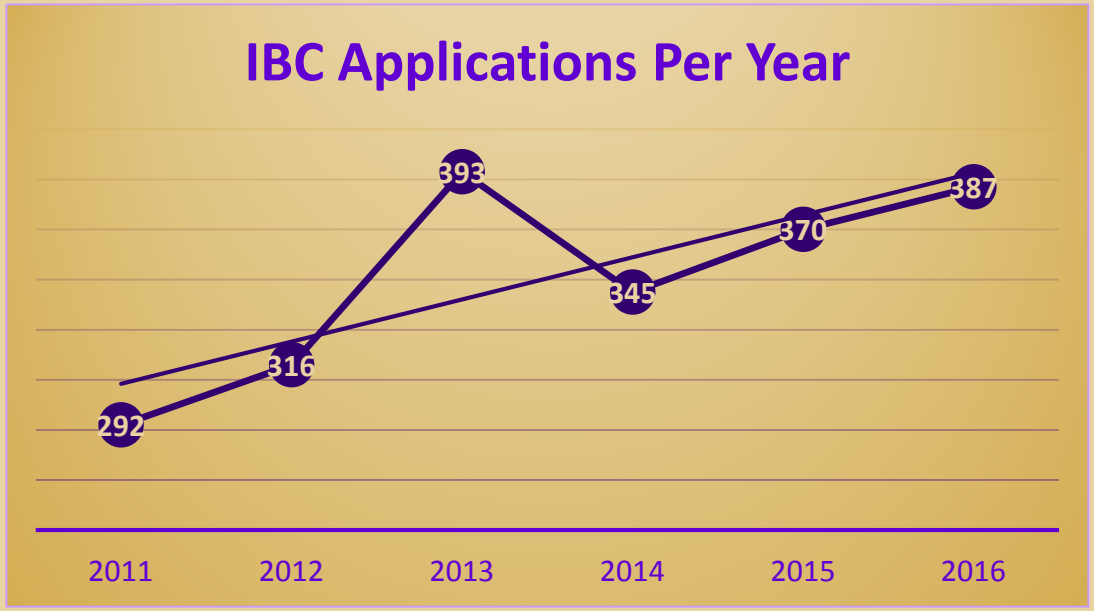
Funding and Research

- **$1.4 billion in federal research funds (2016)**
- **Three main campus locations and additional off campus research:**
  - Seattle (main campus), Bothell, Tacoma
- **Two medical centers**
- **Large University**
  - 4,703 faculty
  - 28,910 faculty and staff
  - Over 50,000 students (undergrad and graduate)

University of Washington

Biosafety program

- **1,813 of 4,100 total (44%) of lab spaces are biohazard labs**
- **539 of 970 total (56%) lab Principal Investigators (PI) are registered with IBC**
- **681 projects are registered with the IBC**
- **387 IBC applications reviewed in 2016**
  - 40% of IBC applications that have a registered IACUC protocol
  - 50% involve viral vectors
- **Non-human primate regional research center**
- **Select Agent Program and Biosafety level 3 (BSL-3**
  - **Responsible Officials/Alternate Responsible Officials in EH&S- Senior Director, Asst. Director, BSOs.**



*IBC application submissions have increased steadily within last five years
*2013 had increased submissions due to new school of medicine facility and lab relocations

Application of the Guidelines

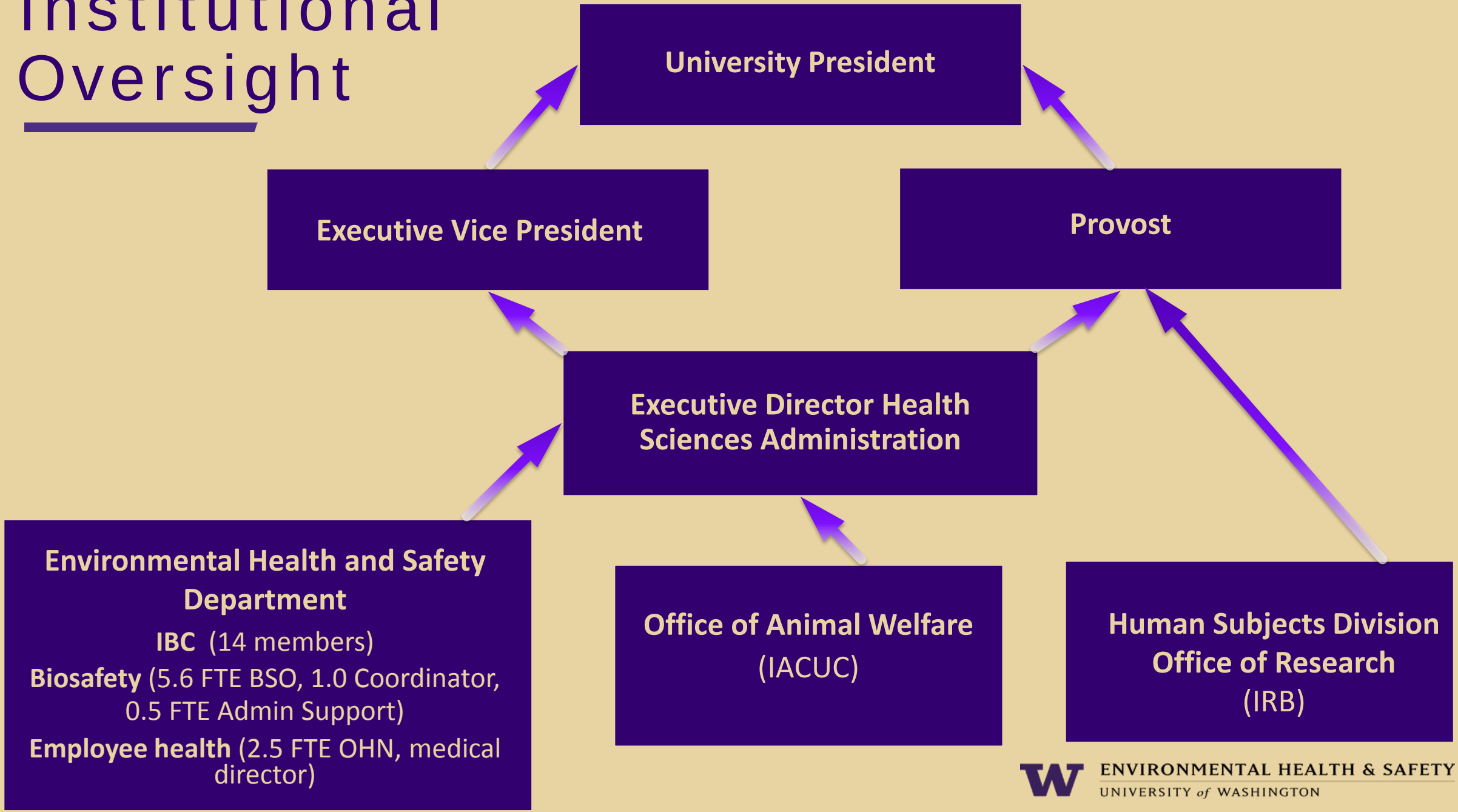
Research review

- Reviews, approves, and oversees research involving recombinant/synthetic DNA/RNA and also other biohazardous agents
  - IBC carries out these functions set forth by the NIH Guidelines, CDC select agent regulations, WA OSHA, BMBL, University policy, University Biosafety Manual, federal, state, and local regulations
  - Initial Project Review, Three Year Renewal Review, Research Change Review (e.g., new room, new agent, new animal model)
  - Monthly convened meetings, minutes posted online

Application of the Guidelines

- Advise, review, and approve policies and procedures related to procurement, use, storage, transportation, and disposal of biohazardous materials
  - Research practices
  - Facilities
  - Waste disposal
  - Training programs
  - Reviews incident reports

Institutional Oversight



IBC Composition and Structure

Faculty (11)	• PhD, MD, DVM • Comparative Medicine, Biology, Microbiology, Laboratory Medicine, Global Health, Infectious Disease, Environmental Science, Northwest Primate Center • Expertise: human gene transfer, plant, animal containment
Community Members (2)	• Public health, science writing, science backgrounds
Biosafety Officer (1)	• Senior biosafety officer (BSO)
Ad hoc Reviewers	• Subject matter experts in specialty field

Project Review Process

PI submits a “Biological Use Authorization” application

IBC Coordinator screens the application

BSO and IBC primary reviewer review applications

(subcommittee may be assigned e.g., BSL-3, human gene transfer)

Laboratory inspection is performed by BSO

IBC full committee review and vote (except for non-recombinant applications, administrative updates)

Biological Use Application

Robust application

- 96 questions to assess risk, review research, determine safety requirements
- Captures and reviews the diverse research at the UW
  - Recombinant DNA, viral vectors, biohazards, cells lines and/or tissues, animals, facilities, disposal methods, toxins, gene transfer, select agent
  - BSL/ABSL 1, 2, and 3 facilities
- Training records are verified (bloodborne pathogens and biosafety)
- Roles and responsibilities of PI
  - Ask PI to classify work with recombinant DNA according to NIH guidelines
  - PI signs a statement of responsibility to ensure research and laboratory operates in a safe manner
  - Re-review after three years, if changes to protocol

IBC Role on Review

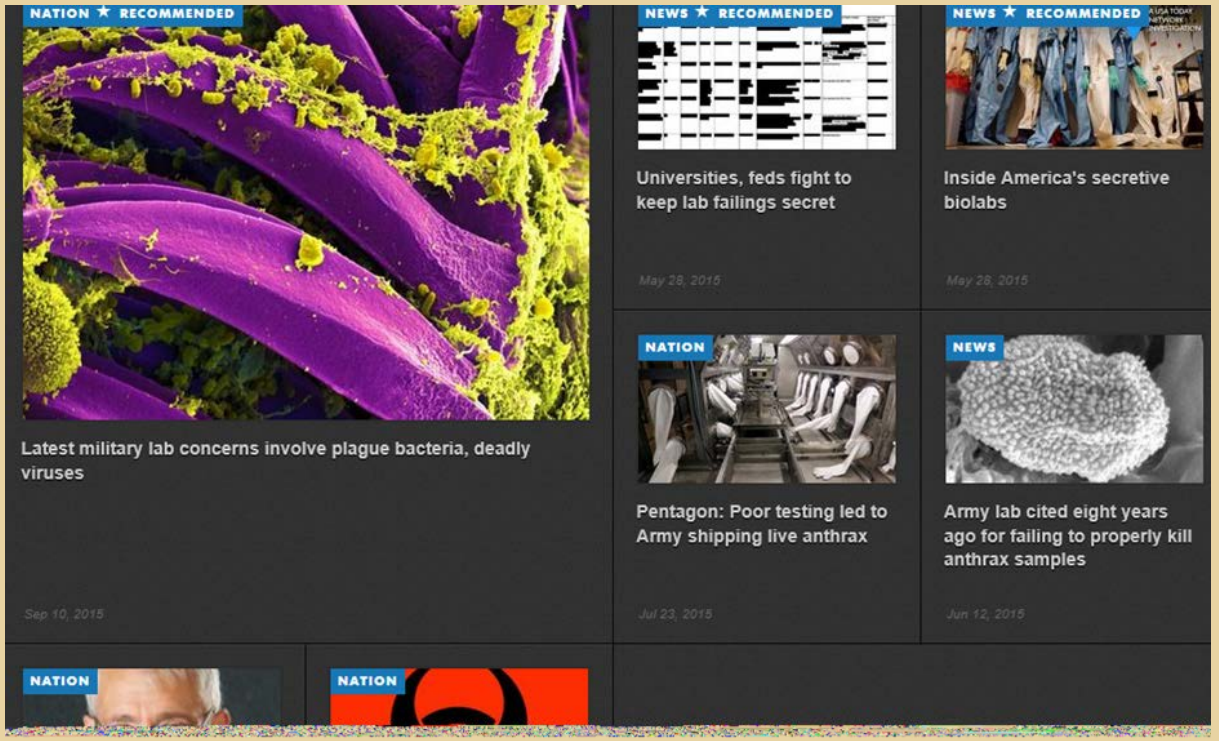
- Example 1 - New PI requested growth of up to 9 liters of *Vibrio cholerae* for protein purification. IBC recommended a cholerae toxin mutant for these studies, and to keep the production volume to less than 10 liters.

- Example 2 - Several PIs study *Plasmodium sp* in mice. Guidelines stated that "*Plasmodium sp* infected mice shall be house at ABSL2." Investigates were using murine-specific strains *Plasmodium yoelli* that do not infect humans. IBC assisted investigators to petition the NIH for an exemption to house animals at ABSL1, which was granted.

- Example 3 - How to inactivate recombinant viral vectors that may be in primate waste in order to sewer. IBC member with expertise devised testing method to inactivate DNA and RNA viruses with disinfection products. Worked with King County Water and UW EH&S. Result-method caused less stress on animals and humans and complied with NIH Guidelines for inactivation of recombinant material.

IBCs Today

- **Public trust is critical to continued scientific progress**
- **IBCs are an increasing component for public trust in recombinant DNA research**
- **Current issues:**
  - Public Trust: Lapses in oversight in federal labs
  - Changes in leadership at NIH and CDC
  - Public concern and negative media attention
- **Gain of function research, emerging technologies (CRISPR), dual use research of concern, inventory, biosecurity, biosafety stewardship**



Benefits and Challenges of Regulatory Guidelines

- **Benefits of an IBC**
  - Public trust
  - Safety of lab workers and the public
  - Environmental protection
  - Institutional Compliance
  - Helps researchers evaluate their research

- **Challenges**
  - Committee recruitment
  - Resources (personnel, facility maintenance, administrative process improvements)
  - Complex and emerging science
  - Adapting quickly to frequent regulatory changes (e.g., select agent)

UW IBC Philosophy

1. The role of the IBC is to ensure compliance to the NIH Guidelines.
2. The overall goal is a culture of safety and compliance.
3. Compliance is a team effort: Institutional support, compliance assistance and tools, training, compliance monitoring, and with the cooperation of the PI and research staff.
4. The IBC and EHS are there to provide guidance to facilitate research safely and in compliance. Without PIs, there would be no IBC.
5. The IBC partners with the IACUC and IRB to ensure safe research with animals and human research participants.

People who make this all work

Health Science Executive Director

David Anderson, DVM

IBC Members

Stephen Libby, PhD (Chair)
Thea Brabb, DVM, PhD
Toby Bradshaw, PhD
Lesley Colby, MS, DVM, DACLAM
Richard Grant, PhD
Garry Hamilton
Kevin Hybiske, PhD
David Koelle, MD
J Scott Meschke, JD, PhD
Matthew Parsek, PhD
David Scarsella, MS
Jason Smith, PhD
Eric Stefansson, MS
Paul Swenson, PhD

Environmental Health and Safety

Jude Van Buren, Dr.PH, MPH
Senior Director
Katia Harb, MS
Asst. Director for Research Safety

Biosafety

Zara Llewellyn, PhD, Manager
Eric Stefansson, MS, BSO
Linda Arnesen, BS, BSO
Priya Kumar, PhD, BSO
Tony Han, BS, BSL-3 BSO
Lesley Leggett, MS, BSO
Andrea Badger, BS, IBC Coordinator
Kao Nomura, BA, Admin Support

Employee Health

- Geoff Gottlieb, MD, PhD
- Judy Cashman, RN
- Patty Clayton, RN
- Becky Stenberg, COHN, MSN, RN

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