

Interconnectedness of Animal and Human Research

Jeremiah Dunlap – IACUC Analyst Lead

Mila DeMarte – IRB Analyst

Northwestern

Introductions

Jeremiah Dunlap



- Lead analyst on the IACUC Office Protocol Review Team
- BA in Biology from Washington University in St. Louis, MPPA from Northwestern University
- Previously worked in QA and training for CCM and in the IACUC's PAM program

Mila DeMarte

- IRB analyst on the biomedical team
- Background in public health research, psychosis research, and IBD clinical trials
- B.S. Health Science, Boston University



Overview

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Regulatory origins & historical context

Key functions of IACUCs and IRBs

Insulin: from animal discovery to human medical advancement

NU IACUC and NU IRB overview

Q&A

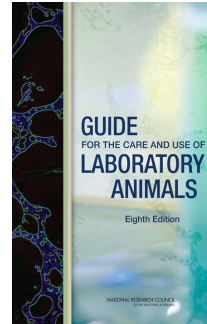
Regulatory origins & historical context

History of Animal Care and Use

Animal Care Panel (ACP) formed to ensure professional and standardize animal research.

1967 renamed AALAS

1950



1963

Originally published as the Guide for Laboratory Animal Facilities and Care by the ACP, revised and currently under the 8th edition (2011)

Primary reference document on animal care and use.

AAALAC incorporated, voluntary accreditation to promote high standards of animal care and use.

NU has maintained accreditation since 1985, demonstrating our high standards

Although voluntary, some funding sources require accreditation to be eligible

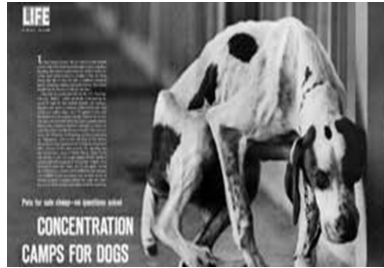
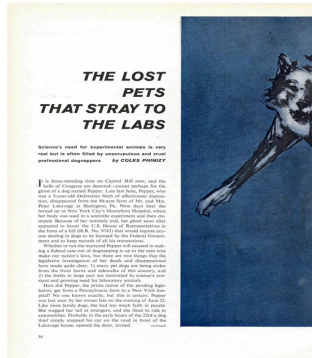
1965



Regulations – The Beginning

Sports Illustrated ran an article about a family pet that was discovered in a hospital laboratory .

1965



1966

Life Magazine ran a different article about another family pet found at a biomedical auction.

Due to Public outcry congress creates the Animal Welfare Act (AWA).

Doesn't apply to: farm animals used for food or fiber; coldblooded species; horses not used for research purposes; fish; invertebrates (crustaceans, insects, etc.); or birds, rats of the genus *Rattus*, and mice of the genus *Mus* that are bred for use in research.

1966



Regulations – Public Health and Services (PHS Policy)

Health Research Extension Act (HREA) was enacted due to concerns raised for other vertebrates not covered by the AWA.

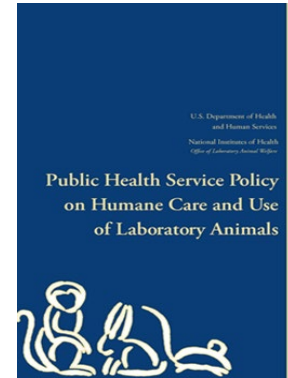
U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

Covers vertebrates such as mice, rats, fish and birds

1985



1986



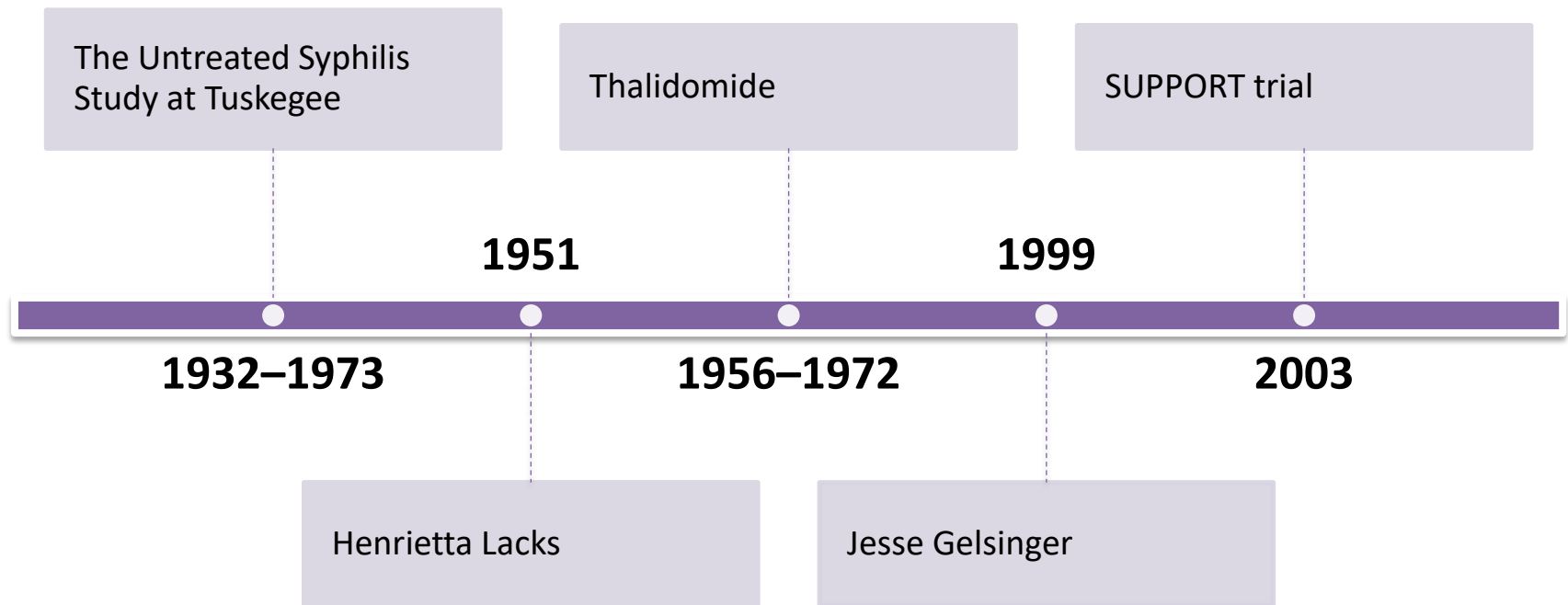
Revised Public Health and Service Policy (1973) on the Human Care and Use of Laboratory Animals to include HREA

Requires institutions receiving PHS funds to have an assurance.

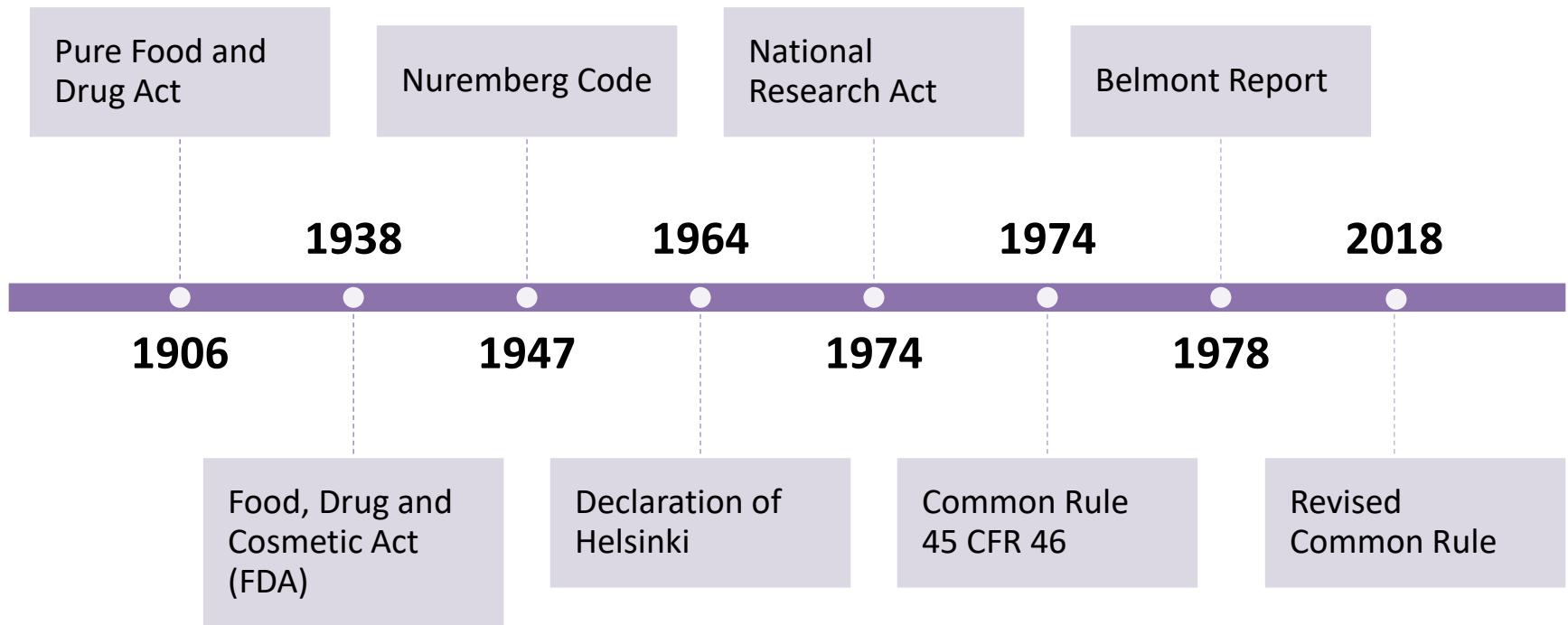
Why is there an IACUC?

- To regulate the use of animals in research and ensure that they are afforded humane care and that ethical standards of research are maintained.
- The law **requires** research institutions to have an IACUC
 - Mandated by the Health Research Extension Act (HREA), the Animal Welfare Act (AWA), and Public Health Service (PHS) Policy.
 - Regulatory agencies ensure humane care and use of animals in research:
 - The [United States Department of Agriculture](#) (USDA)
 - The [Office of Laboratory Animal Welfare](#) (OLAW)
- Prior to the signing of the FDA Modernization Act 2.0 in December 2022, new medical treatments were required by law to be tested on animals before entering human clinical trials.

Unethical Human Research in the US



History of Research Regulation



Key functions of IACUCs and IRBs

Research: Basic vs. Applied

- Humans and animals have many comparable physiological processes. Genetically modified animals, usually mice, can be bred to increase these similarities with humans.
- Basic research (compared to applied research) provides the underpinnings for development of new medical and veterinary treatments.
 - **Basic** research seeks to expand our knowledge
 - **Applied** research seeks to answer a specific question or need (e.g., create a new device)

Components of an Animal Care and Use Program



Our Mission

The IACUC balances the possible harm to an animal against the potential benefit of the research involving each animal.

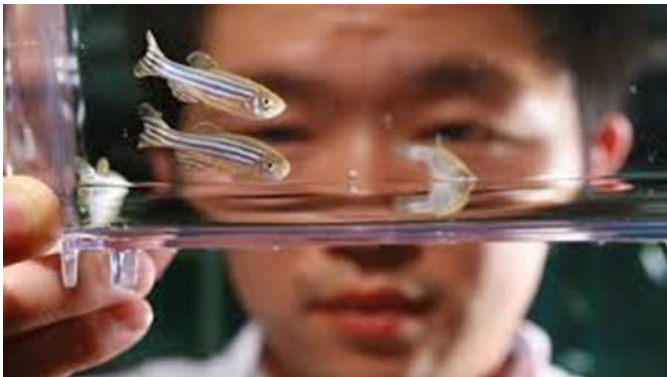
The IACUC makes recommendations to improve animal welfare. *Better standards of animal welfare produce better quality research.*



Our Mission

The IACUC encourages investigators to consider **alternative methods** by:

- Replacing** animals with other research methods
- Refining** procedures to minimize potential pain/distress
- Reducing** animal numbers



Key Functions of the IACUC



Purpose of IRBs



Conduct ethical review



Follow ethical principles, policies and guidelines



Minimize research related risks

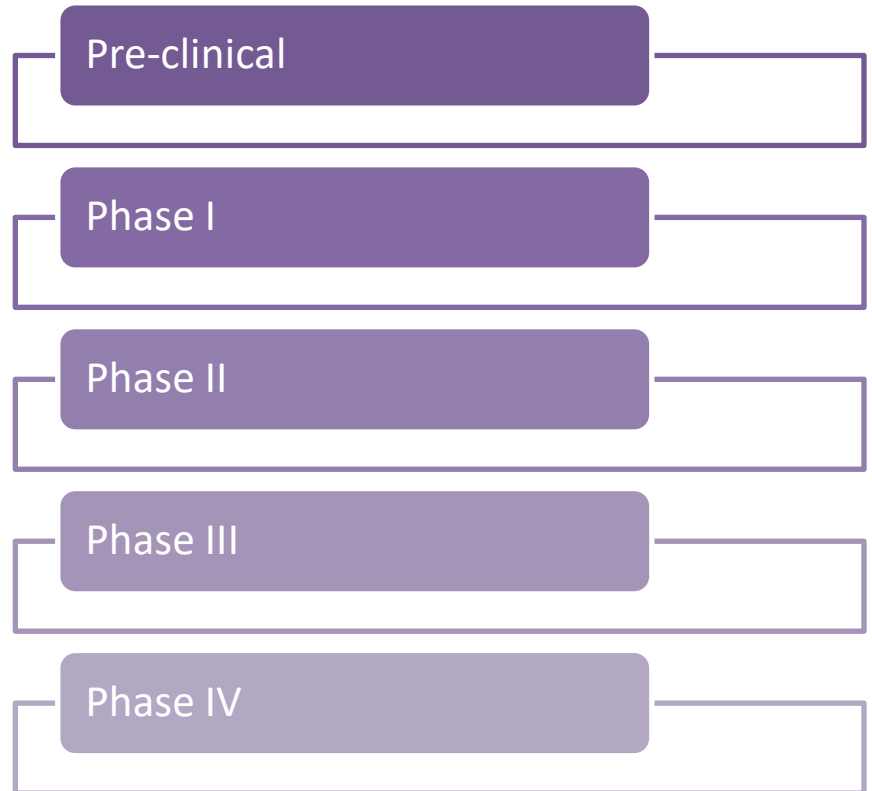
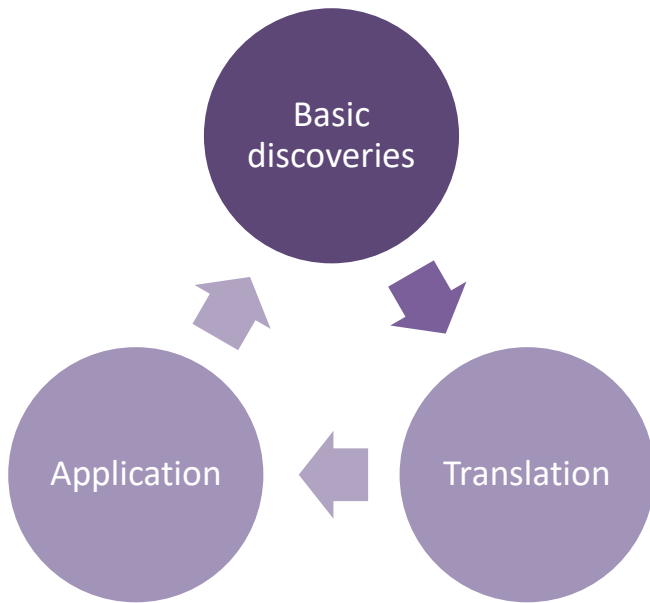


Build and maintain public trust

Ethical regulation for human research includes animals

- 1906: Pure Food and Drug Act
 - “... treatments, devices, and drugs are evaluated for **safety and efficacy in 2 types of animals** prior to approval for clinical trials in humans”
- 1948: Nuremberg Code
 - “experiment should be so designed and based on the results of **animal experimentation...**”
- 1964: Declaration of Helsinki
 - “Research with humans should be based on the results from laboratory and **animal experimentation...**”

Human Discoveries Depend on Iterative Research



Insulin: From animal discovery to human medical advancement

The Discovery of Insulin

1889

Importance of the pancreas established through research in dogs



1921

Extracted insulin prolongs a severely diabetic dog's life

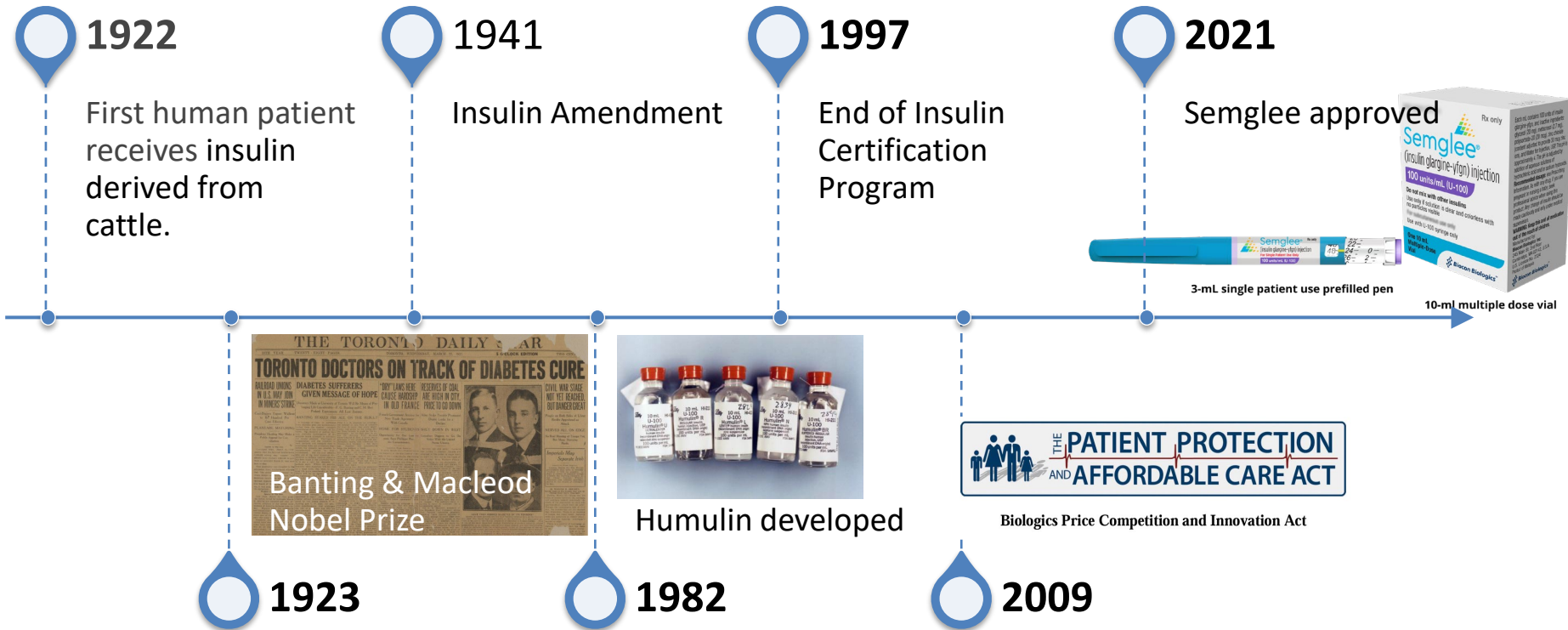


Sir Edward Sharpey-Shafer suggests that diabetics lack a single pancreatic substance – insulin

1910



Human Origin of Insulin



Additional examples of advancements based on animal studies

COVID-19 vaccine

Polio

Insulin

Treatment for
HIV/AIDS

Artificial spinal
cord and spinal
implants

Neural prosthetic
device for
amputees to be
able to feel

Cochlear implants

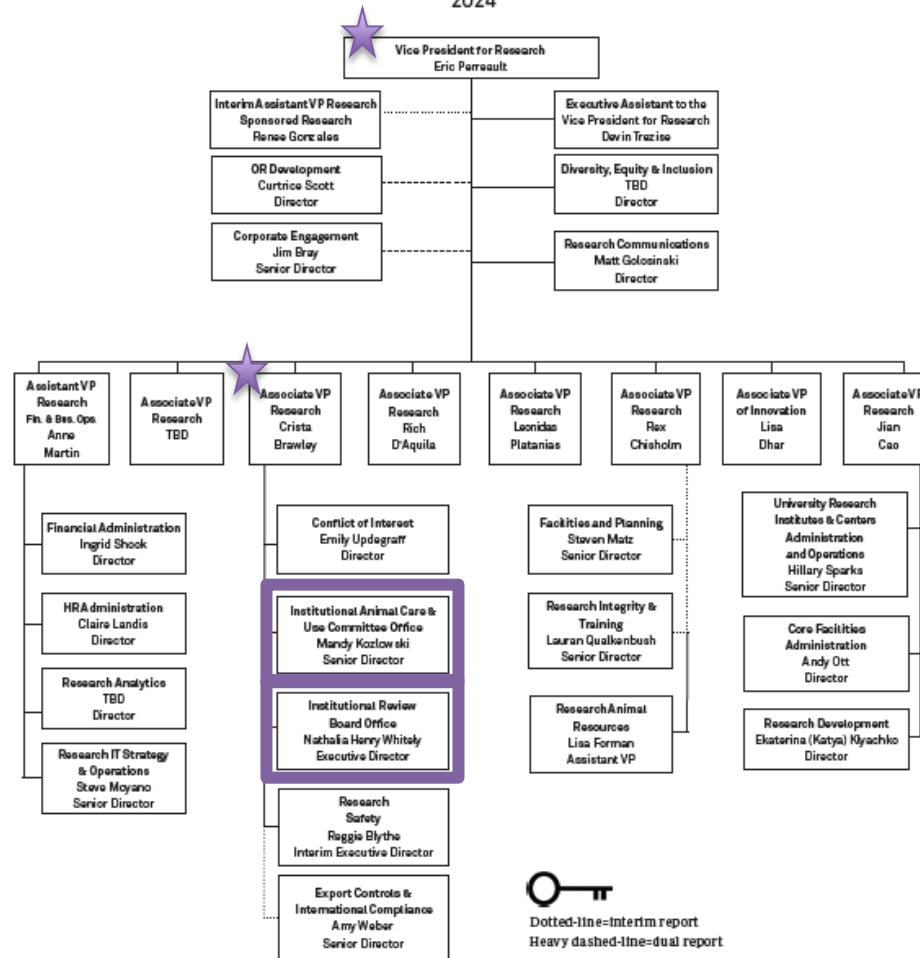
Parkinson's
disease treatments

Treatments for
schizophrenia and
mental health

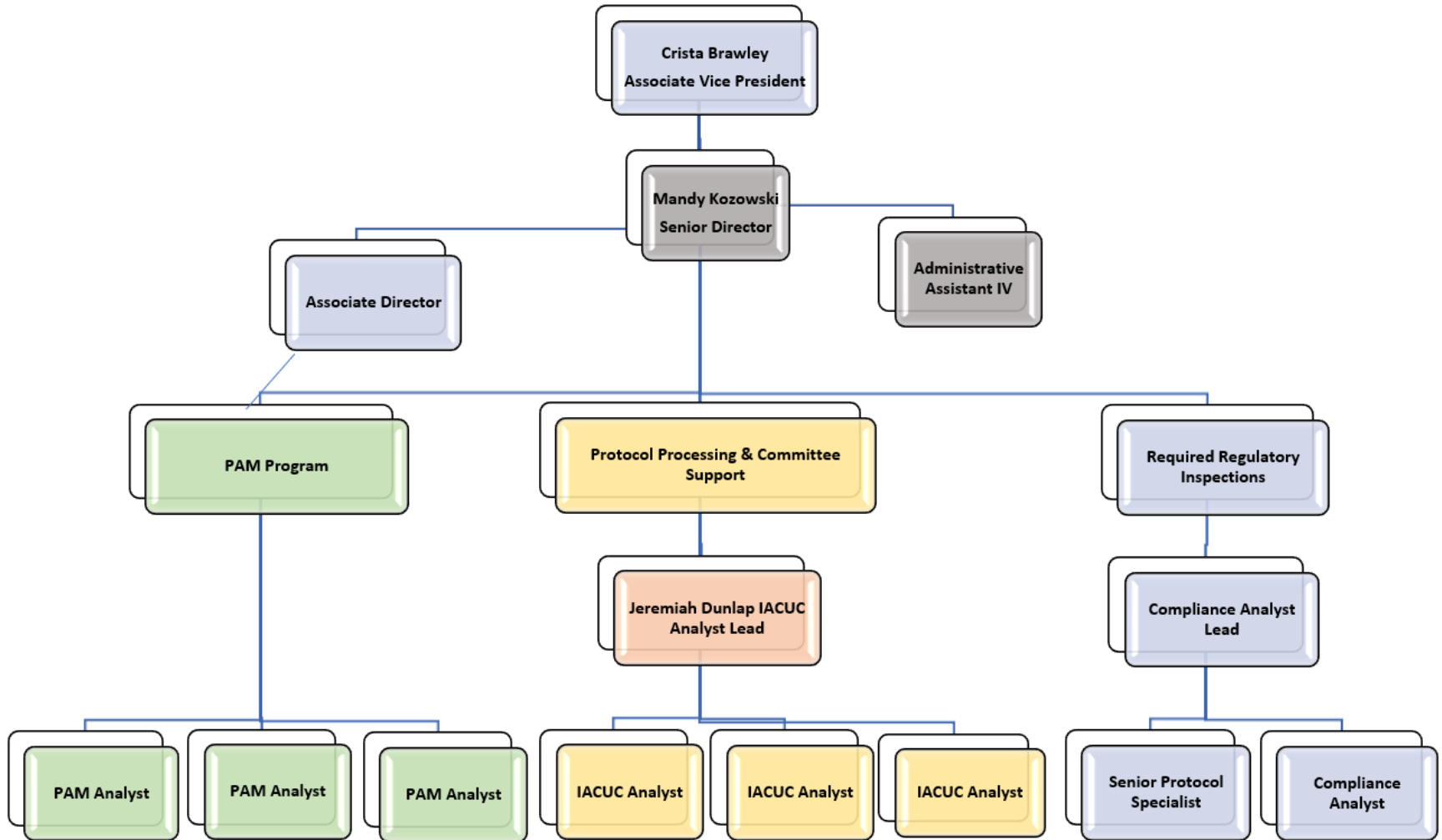
Studies of other
animals that help
us understand
animal cognition

NU Office for Research NU IACUC and NU IRB Overview

Office for Research Organization Chart 2024



Our IACUC Office



Northwestern's HRPP



<https://irb.northwestern.edu/about/>

IRB Panels

Biomedical:

- A, B, C, D
- Q

Social Behavioral:

- E

References and Resources

NU Specific Information

- <https://research.northwestern.edu/about/leadership/or-organization-chart.html>
- <https://irb.northwestern.edu/about/irb-information/panels-rosters.html>
- <https://iacuc.northwestern.edu/> (NetID and password required for some pages)
- Ethical Treatment of Animals links from IACUC
 - <https://iacuc.northwestern.edu/resources/links-regarding-the-ethical-treatment-of-animals.html>
- <https://irb.northwestern.edu/submitting-to-the-irb/getting-started/research-ethics.html>

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Questions

Thank you!