Animal Research and IACUC
Conduct of Research

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ANIMAL RESEARCH
- Importance
- Ethics
- Regulations
- Need to knows for PIs

IMPORTANCE
- Significant contribution to advancement of scientific knowledge in general and biomedical progress specifically
- Basic Research
- Animal Models of Human Disease
- Translational Research – “bench to bedside”
- GLP
THE ETHICAL DILEMMA

Summed up in four claims:
1. Live animal research is the only effective way of bringing certain important benefits to mankind, particularly in the prevention and therapeutic treatment of serious human diseases.
2. It is morally imperative to find new ways to prevent or treat serious human disease.

ETHICS CONCERNING ANIMAL RESEARCH

- Important for researchers to know:
  - Quality of animal studies ultimately depends on the welfare of animal subjects. (Elizabeth Heitman)
  - Working with animals in research, teaching, and testing is a PRIVILEGE.
  - It can be revoked at any time.

Regulatory Mandate

Each institution governed by the AWA and/or receiving PHS support for activities involving vertebrate animals must operate an animal care and use program with clear lines of authority and responsibility. This program must include:
- an IACUC
- procedures for self monitoring
- an adequate veterinary care program
- an occupational health and safety program
- a personnel training program
- an environment, housing and management program for animals
- appropriately maintained facilities for housing and support.
Institutional Animal Care and Use Committee (IACUC)

**Authority:**
- THE regulatory body in animal research, teaching, and testing
- IACUC reports to a senior administrator of the organization, the so-called Institutional Official (IO)
- The IACUC has an advisory role to the IO
  - recommendations to the IO regarding any aspect of the institution’s animal program, facilities, and personnel training
- The IACUC’s authority to review and approve protocols is independent of the IO.

**Functions:**
- Semi-annual program review
- Semi-annual site inspections of all housing facilities and satellites as well as laboratories where work with live animals occurs
- Submits reports of the IACUC evaluations to the IO and prepares plans for correction of deficiencies and programmatic suggestions

IACUC

**Functions:**
- The IACUC has to review concerns regarding the care and use of animals at the institution.
- Reviews and approves IACUC protocols and modifications/amendments to protocols
- Investigates non-compliance and requests corrective actions from the research staff, can suspend personnel and protocols
- Implements and directs Training Program
IACUC Committee Approves Protocol is submitted To IACUC Committee

Post-Approval Monitoring

The submitted protocol

Compliance Monitoring Research begins

Responsibilities of the PI

Everything done on a live animal needs to be described in an IACUC protocol

- Involve veterinarian in design/review of experiments that have potential or cause pain/distress
- Work with IACUC re pain category E protocols
- Changes in research – submit modification/amendment
- Stick to what is described in the protocol = be compliant
- How surgical/non-surgical procedures are performed
- Post-operative care and administration of analgesia
- Humane end-points

Principles for the Design of Animal Research Studies

- Goal is fruitful result for the good of society
- Good knowledge of the problem under study
- Careful study design
- Knowledge of the animal species chosen
Principles for the Design of Animal Research Studies

Claude Bernard 1865, often referred as founder of experimental medicine

“...it is proper to choose certain animals which offer favorable anatomical arrangements or special susceptibility to certain influences. For each kind of investigation we shall be careful to point out the proper choice of animals. This is so important that the solution of a physiological or pathological problem often depends solely on the appropriate choice of the animal for the experiment so as to make the result clear and searching.

Responsibilities of the PI

- Assure that personnel is enrolled in Health and Safety Program
  - Occupational health
  - Biosafety, hazardous chemicals, radioactivity
- Assure that personnel is properly trained
  - Regulations and ethics in governing animal research
  - Handling animals
  - Knowing the biology and signs of pain of the particular species
  - Proper experimental technique including surgical/aseptic technique

Principles for the Design of Animal Research Studies

- Consideration of possible alternatives
- Minimized numbers of animals
- Well-being of animals highest priority
- Alleviation of pain/distress whenever possible

Responsibilities of the PI

- Frequent observation of your animals – frequency depending on study and expected adverse effects
- Informing veterinarians in a timely manner when animals appear sick, working with veterinary personnel to provide appropriate palliative care
- Abiding to health program of the facilities to keep certain pathogenic agents out of facilities
- Educating care personnel re specific expected adverse events associated with particular animal model
Responsibilities of the PI

- Document:
  - Not only scientific data
  - Medical records for all USDA covered species
  - Surgical/anesthesia monitoring records
  - Post-operative monitoring including analgesia administration
  - Certain humane end-point monitoring, e.g. weight logs, tumor size, body scores
  - Controlled substance logs

Good Science and Animal Welfare

Goal of All Parties Involved in Research

- Get scientifically sound research done
- Obtain best possible research data
- Ensure animal well-being
- Ensure regulatory compliance
- Protect the Institution
- Advance science
- Keep public trust

Thank you for your attention.