

# Ethical issues in Use of Animals in Science

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# PURPOSE OF USE OF ANIMALS

- 1. Fundamental biological & biomedical research
- 2. Developing new treatment for diseases
- 3. Safety testing of chemicals & drugs
- 4. Developing new diagnostics
- 5. Preparation of animal products
- 6. Biology & Medical education

# EXTENT OF USE OF ANIMALS

- Biomedical research----- 40%
- Drug testing ----- 26%
- Product safety testing ----- 20%
- Teaching ----- 7%
- Others ----- 7%
  - Animal products
    - Sera, vaccine, Immuno diagnostics, drugs
  - Space research, Testing of arms/ammunitions

# The Importance of Animals in Biomedical Research

"Virtually every major medical advance for both humans and animals has been achieved through biomedical research using animal models to study and find a cure for a disease and through animal testing to prove the safety and efficacy of a new treatment."

C. Everett Koop, M.D.  
Former U.S. Surgeon General

# Without animal research

- Most of the nation's one million insulin-dependent diabetics would be dead.
- More than 60 million would risk death from heart attacks, strokes or kidney failure – because there would be no medicine to combat high blood pressure.
- Chemotherapy wouldn't exist – and couldn't save 70 percent of children who now survive acute lymphocytic leukemia.
- People disabled by strokes or spinal cord injuries could not benefit from rehabilitation techniques.
- More than 1 million would be blind in at least one eye – there would be no surgery to correct cataracts.
- Newborns who develop jaundice each year would contract cerebral palsy, now preventable through phototherapy.
- There would be no kidney dialysis.
- Surgery of any type would be rare – and extremely painful – because there would be no anesthesia.
- Smallpox, which has been eradicated, would continue unchecked.
  
- Millions of dogs, cats, other pets and farm animals would have died from anthrax, distemper, canine parvovirus, feline leukemia, rabies and more than 200 other diseases now preventable.
- Polio would kill or cripple thousands of unvaccinated adults and children each year.

# Major concerns

- Pain and suffering- avoidable
- Degree of infringement on other animal interests/ animal rights- sensitivity
- Sentience level as per phylogenetic scale
- Endangered species
- Purpose of experiment/Purposeless Expts.
- Competence of the investigators-inadequate training
- Adequacy of animal care facilities & animal husbandry issues

# Legislation on Animal experiments

- 1876 - Prevention of cruelty to animals Act-United Kingdom( anti-vivisectionists )
  - Sanctioned animal experiments
    - prescribed limits on pain to animals
    - Use of anaesthetics
    - Registration of designated places
    - Maintenance of records
- Prevention of Cruelty to Animals Act- India 1960 –
- France 1963 , USA 1966

# Institutional Animal Care & Use

## Committee

Became mandatory in 1985

- Mandated by the Animal Welfare Act
  - Public Health Service and AAALAC International

An amendment must be submitted if significant changes are planned after a protocol has been approved by the Committee

# The 3 + Rs of Animal Experimentation

- Reduction
  - Number
  - Species
- Refinement
- Replacement
  - Alternate method
- Reuse
- **Rehabilitation**

**Russell and Burch**

**The Principles of Humane Experimental Technique, 1959**



• **Replacement**

• **Reduction**

• **Refinement**

**RESPONSIBLE USE OF QUALITY ANIMALS**

# Strategies

- **Reduction** can be attempted on several ways like animal sharing, changes in research strategy, use of proper statistical design to minimise the number, proper use of strains, mutants, transgenics etc. (Quality and Quantity)
- **Refinement** encompass all the methods (good housing, professionally qualified keepers and users) and include use of new techniques aimed at decreased invasiveness of bodies, improved instrumentation for monitoring animals and analysis of body fluids and better management of pain and distress in animals.
- **Replacement** is the ultimate in animal welfare measures, where a given purpose is achieved without conducting experiments or other scientific procedures on protected live animals. The replacement can be absolute or relative, direct or indirect, total or partial.
- **Rehabilitation** is the moral obligation to feel responsible for the welfare of the large animals after their use for scientific pursuit.

# National Centre for Laboratory Animal Sciences(NCLAS)NIN,Hyderabad



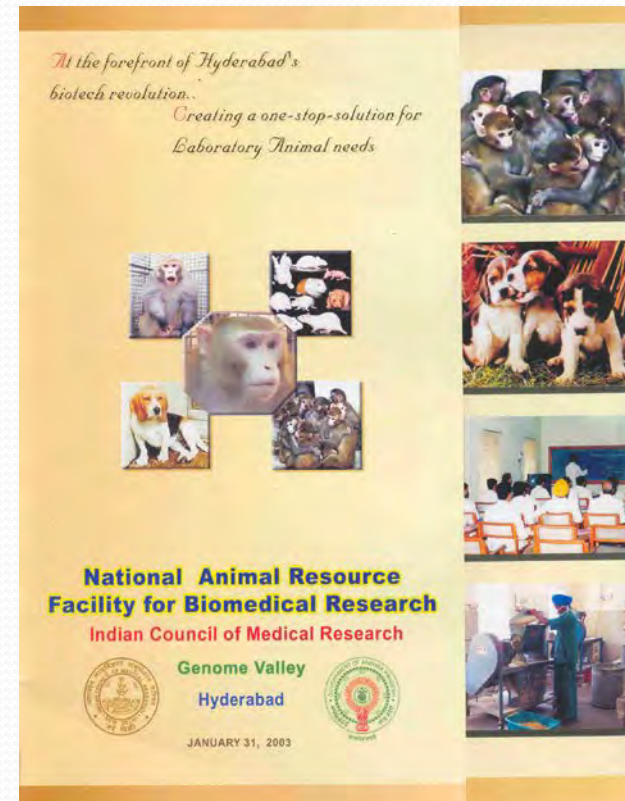
# National Centre for Non-human Primate Breeding & Research, Susnavgarh



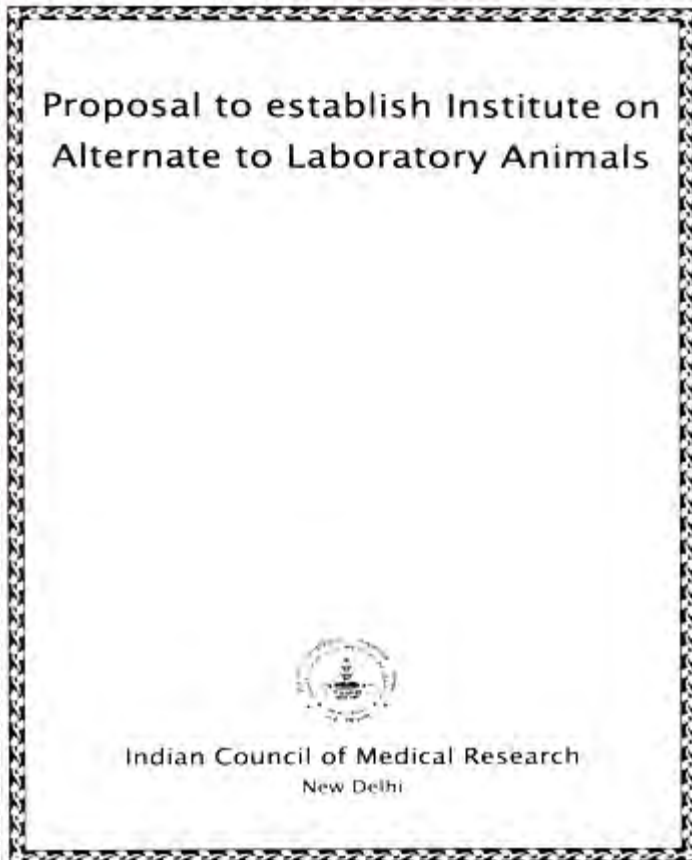
A state-of-the art NHP breeding facility in the natural habitat conditions for pursuing biomedical research to resolve the human diseases and also develop models in NHP

# National Animal Resource Facility for Biomedical Research Genome Valley, Hyderabad

- World class facility for providing biological resources especially large animals to cater to the needs of the R&D Institutions, Pharma and Biotech companies in the country
- As a joint venture proposition being coordinated through ICMR's institute at NIN, Hyderabad



# Establishment of Institute on Alternate to Laboratory Animals



## Objectives

- To standardize, practice and publicize the established methods and systems
- To develop newer methods and systems to replace use of laboratory animal systems for Research and Pharmaceutical work.
- To develop new sensitive and specific methods for screening, assaying, quality control, toxicity tests etc.
- To impart training in the above aspects and to render guidance to R&D and commercial organization.

# Guidelines Prepared



DELHI  
USE OF ANIMALS IN  
SCIENTIFIC RESEARCH

GUIDELINES

FOR CARE

AND USE OF

ANIMALS

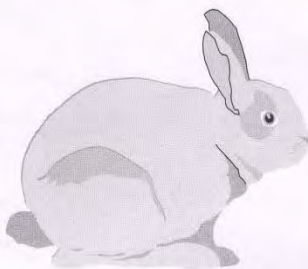
IN SCIENTIFIC

RESEARCH *H*

INDIAN NATIONAL  
SCIENCE ACADEMY  
NEW DELHI

9/15/2011

## Guidelines for use of Laboratory Animals in Medical Colleges



Indian Council of Medical Research  
New Delhi  
2001

## CPCSEA GUIDELINES FOR LABORATORY ANIMAL FACILITY

**CPCSEA**

COMMITTEE FOR THE PURPOSE OF  
CONTROL AND SUPERVISION ON EXPERIMENTS ON ANIMALS

No.13/1, 3<sup>rd</sup> Seaward Road, Valmiki Nagar,  
Thiruvanniyur, Chennai - 600 041, Tamil Nadu, India.  
Tel : 044 - 2441 6914 Tel/Fax : 044-2440 3551  
E-mail : [cpcsea@eth.net](mailto:cpcsea@eth.net) Website: [www.cpcsea.com](http://www.cpcsea.com)

# International Documents

- Ethical principles in animal experimentation, Lyons, 1979
- CIOMS International Guiding Principles for Biomedical research involving animals
- US NIH Guide for Care and Use of Laboratory animals, 1985
- Canadian council on Animal care and use of lab. animals, 1984
- FRAME news, founded in 1969 (Funds for Replacement of Animals in Medical Research)
- Veterinary public health report -breeding and care of lab. animals-WHO/FAO/ISS-CC/12.5Te/94.3

# INSA(Indian National Science Academy) Guidelines 1992/2000

- Housing
- Environment
- Feed
- Anaesthesia
- Euthanasia
- Care of the injured
- disposal of the dead
- Supervision of Expts.
- Constitution and Responsibilities of IAECs
- Number and species of animals to be used
- Drugs for analgesia and anaesthesia
- Training of personnel
- **Genetically modified animals**

# CPCSEA Guidelines for Animal Facilities - 2001

- (f) **Physical facilities**
  - (i) Building materials
  - (ii) Corridor(s)
  - (iii) Utilities
  - (iv) Animal Room Doors
  - (v) Exterior windows
  - (vi) Floors
  - (vii) Drains
  - (viii) Walls and ceilings
  - (ix) Storage areas
  - (x) Facilities for sanitizing equipment and supplies
  - (xi) Experimental Area
  - (xii) Environment
  - (xiii) Temperature and Humidity control
  - (xiv) Ventilation
  - (xv) Power and lighting
  - (xvi) Noise control
- g) **Animal Husbandry**
  - (i) Caging or housing system
  - (ii) Sheltered or outdoor housing
  - (iii) Social environment
  - (h) Food
  - (i) Bedding
  - (j) Water
  - (k) Sanitation and Cleanliness
  - (l) Waste Disposal
  - (m) Pest Control
  - (n) Emergency, weekend and holiday care
  - (o) Record keeping
  - (p) Personnel and Training
  - (q) No. of technical staff, supporting staff, details of the training of the supporting staff
  - ® Transport of laboratory animals
  - (s) Anaesthesia and Euthanasia
  - (t) **Laboratory animal ethics**
  - (u) Transgenic animals
  - (v) Maintenance
  - (w) Disposal
  - (x) **Details of rehabilitation facilities**
  - (y) Overall assessment
  - (z) Recommendation

## Salient features of the 1998 Breeding & Experimentation Rules notified by CPCSEA amended in 2001 & 2006

- Registration of all establishments breeding or Using animals for research/experiment
- Clearence of all experiments with smaller animals by IAEC
- Experiments involving larger animals to be evaluated by a sub-committee of CPCSEA(LASC) & CPCSEA after IAEC clearence
- Specified Formats for all records

# IAEC(Institutional Animal Ethics Committee)s

- Composition
  - Representative of the Department
  - Scientists with knowledge of animal experiments
  - Expert veterenarian
  - Member from community - Nominee of CPCSEA
  - Incharge Animal facility

# IAECs

- Responsibilities
  - Review and approve research projects
  - Prevent unnecessary suffering to animals during experimentation
  - Proper accommodation /veterinary care
  - Humane disposal after termination of study
  - Mid term termination if unnecessary suffering
  - Adequately skilled personnel to do the expts.

# Recent Developments

- Operational guidelines for CPCSEA
- Scrapping of LASC – referral to main CPCSEA
- Reconstitution of CPCSEA with balanced membership
- **Rehabilitation guidelines**
- **SOP for IECs**

# Action Points

- Increase awareness amongst scientists for rational use of animals
- Popularise the components of 3+Rs
- Registration of all establishments
- Adequate training of animal handlers
- Setting up appropriate IAECs
- Establishing Rehabilitation facilities
- Maintain a transparent system for humane use of animals

# Suggestions

- Functioning IAECs
- Increasing research on Alternatives
- Appropriate Legislations
- Develop mechanism for checking Humane treatment to animals
- Editorial responsibilities
- Ethical discussion in mainstream scientific literature
- Teaching ethics of animal expts. at every level

# Suggestions ( contd.)

- Training courses for different personnel
- Adequate funds for animal houses
- Detailed guidelines for animal houses
- **National body for Lab. animal care & supervision**
- Breeding programmes for quality genetically defined animals
- Ongoing professional training for upholding the 4 Rs.

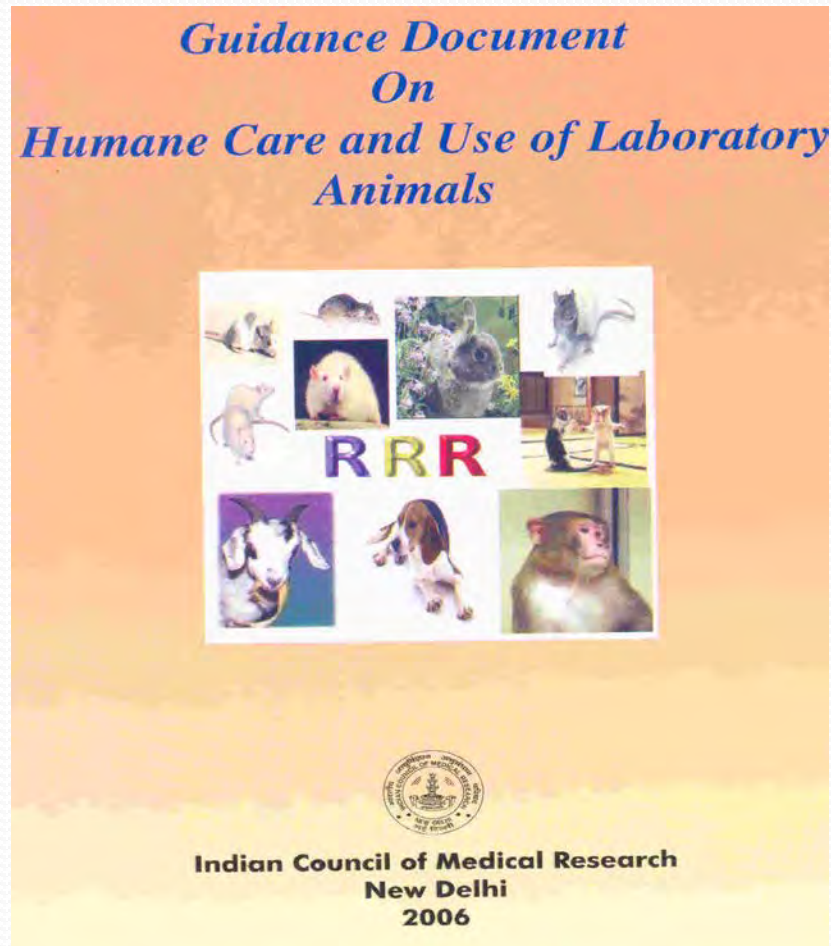
# Bio-Medical Ethics

*Laboratory  
Animal  
Welfare*

*Ethics  
in  
Human  
Experimentation*



# *Guidance document on guidelines on humane care and use of laboratory animals including national and international regulation of animal research*





# Conclusions

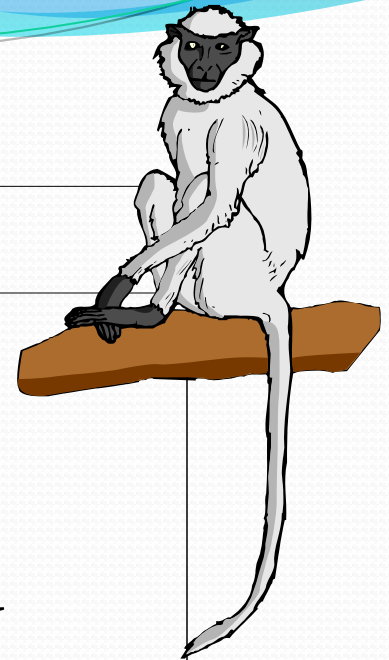
- **Use of animals in research is inevitable at the current level of knowledge in the interest of human and animal welfare.**
- **There are mandatory statutory requirements for developing new drugs, testing chemicals etc.,**
- **National and international laws and guidelines to be strictly followed for Humane treatment of animals**
- **Developing specific animal models for rational animal use**
- **Efforts to develop alternates should be taken up on priority basis.**
- **Formulate appropriate Rehabilitation programmes/facilities**
- **Teaching of animal ethics at every level of education as well as public awareness in conjunction with NGOs.**

# GOOD ANIMAL CARE PROMOTES GOOD SCIENCE



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**THANK YOU**

