

# ETHICS AND IACUC RESPONSIBILITIES “THE INTERSECTION”

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**What is ethics “as applied to research with animals” ?**

# Ethics defined

Webster defines “Ethics” as a branch of philosophy that seeks to address questions about morality; that is, about concepts such as good and bad, the noble and the ignoble, right and wrong, justice and virtue.

# Opposing Ethical Based Viewpoints

- ◆ The animal rights movement opposes animal research on moral grounds and believes that the use of animals in research is fundamentally wrong and, therefore, unethical .

VS

- ◆ The biomedical research community and the public at large support animal research and believe we have a moral obligation to treat animals humanely and ensure their use is justified.

# What is a “right”?

- ◆ Legal Right: Incorporated into law and has legal status.

VS

- ◆ Moral Right: Not incorporated into law, but is characterized by a universality of entitlement.

**What does “humane” mean?**



Public Health Service  
Policy on Humane  
Care and Use of  
Laboratory Animals

Office of Laboratory  
Animal Welfare

National Institutes  
of Health

Guide for  
the Care  
and Use of  
Laboratory  
Animals

NATIONAL RESEARCH COUNCIL

Animal Welfare Act  
and Animal Welfare  
Regulations



# “SCIENTIFIC MERIT”

Webster defines “merit” as the “state of having worth, value or excellence.” When the noun “merit” is combined with the adjective “scientific,” it means “of scientific worth, value or scientific excellence.”



## MORE ON SCIENTIFIC MERIT

“In order for research to have scientific merit, the research should be based on a significant hypothesis and, if possible, oriented towards uncovering an important biological mechanism. The hypothesis should be testable...by the proposed experiment.”

*Gordon, S.J.; Ortho. Res. 7:138-141, 1989*

# PHS Policy on “Scientific Merit”



## Public Health Service Policy on Humane Care and Use of Laboratory Animals

Office of Laboratory  
Animal Welfare

National Institutes  
of Health

# PHS POLICY ON “SCIENTIFIC MERIT”

- ◆ “Procedures involving animals should be designed and performed with due consideration of their **relevance** to human or animal health, the advancement of knowledge, or the good of society.” *USGP II*
- ◆ Avoidance of “...**unnecessary duplication** of experiments....” *The Guide*
- ◆ “The animals selected...for a procedure should be of an appropriate species and quality... required to obtain **valid results**.” *USGP III*

## PHS POLICY ON “SCIENTIFIC MERIT” cont’d

- ◆ The number of animals selected... should be...“ the minimum number required to obtain **valid results.**” *USGP III*
- ◆ “Procedures with animals will avoid or minimize discomfort, distress, and pain to the animals, consistent with **sound research design.**” *PHS Policy at IV.C.1.a.*

# PHS POLICY ON SCIENTIFIC MERIT cont'd

- ◆ “Applications and proposals...shall contain...a description of procedures designed to assure that discomfort and injury to animals will be limited to that which is unavoidable for the conduct of **scientifically valuable research....**” *PHS Policy at IV.D.1.d.*
- ◆ “Proper use of animals, including the avoidance or minimization of discomfort, distress, and pain when consistent with **sound scientific practices,** is imperative....” *USGP IV*

## PHS POLICY ON SCIENTIFIC MERIT cont'd

- ◆ “Procedures that may cause more than momentary or slight pain or distress to the animals will be performed with appropriate sedation, analgesic, or anesthesia, unless the procedure is justified for **scientific reasons**....”  
*PHS Policy at IV.C.1.b.*
- ◆ “Personnel conducting procedures on the species being maintained or studied will be appropriately **qualified and trained** in those procedures.”  
*PHS Policy at IV.C.1.f.*

Sound Research Design and  
Scientific Practices



Valid Results Not  
Unnecessarily Duplicative



Relevance



Scientifically Valuable  
Research

**“Scientific  
Merit”**

## OPRR (OLAW) on “Scientific Merit”

“The primary focus of the IRG is scientific merit whereas the primary focus of the IACUC is animal welfare. It is evident, however, that there is... overlap of function between the two bodies... The IACUC is expected to... consider in its review the general scientific relevance of the proposal.”

*ILAR News 33 (4), 68-70 (1991)*



**Can the IACUC defer the assessment of the potential relevance and scientific value or merit of the research to other peer review bodies ?**

*The IACUC Can't Pass the  
Buck!*

# The PHS Policy

“... in no way is a peer review intended to supersede or serve as a replacement for IACUC approval.”

*Revised PHS Policy FR 67 (152)  
51289 – 51290 (7 August 2002)*

# ETHICAL COST BENEFIT ASSESSMENT



An acceptable ethical cost-benefit relationship ensures that the research is “ethical”.

# ETHICAL COSTS

**Procedure-specific**

**Animal-specific**

- Pain
- Discomfort
- Distress
- Morbidity
- Mortality

# PRINCIPLE I

Using an intervention applied to a less sentient animal subject that causes the least possible pain, discomfort, distress, morbidity and mortality reduces the ethical costs of the research.

## PRINCIPLE II

The same intervention which causes pain, discomfort, distress, morbidity and mortality applied to a more sentient animal versus a less sentient animal increases the ethical costs of the research.

## PRINCIPLE III

The greater the scientific value of the research, the higher the level of pain, discomfort, distress, morbidity and mortality (that is, the ethical costs) that are acceptable.



## PRINCIPLE IV

Investigators and the IACUC should strive to achieve the most favorable ethical cost-benefit relationship possible.

- ◆ The ethical costs are as low as possible .
- ◆ The potential scientific value clearly outweighs the ethical costs of the research.

# ETHICAL COST-BENEFIT RELATIONSHIP

(ACCEPTABLE)

Scientific  
Value

To humans  
To animals  
To science  
To society

Ethical  
Cost

Pain  
Discomfort  
Distress  
Morbidity  
Mortality



# OUR OBLIGATION

When we use any animal in research, be it rodent or non-human primate, we must do so with compassion, humility, sound ethics, and humaneness.