

# Ethical decision-making in clinical and field studies

Dr. Lisa Moses  
Valerie Benka



# The Ethics of Using Dogs and Cats as Research Subjects

**IMPLICATIONS FOR OWNED AND COMMUNITY ANIMALS**

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Massachusetts Society for the Prevention of  
Cruelty to Animals-Angell Animal Medical Center

Yale Center for Interdisciplinary Bioethics

# Why is a discussion on ethics part of the symposium?

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## Ethical Decision-Making in Innovation for Animal Welfare

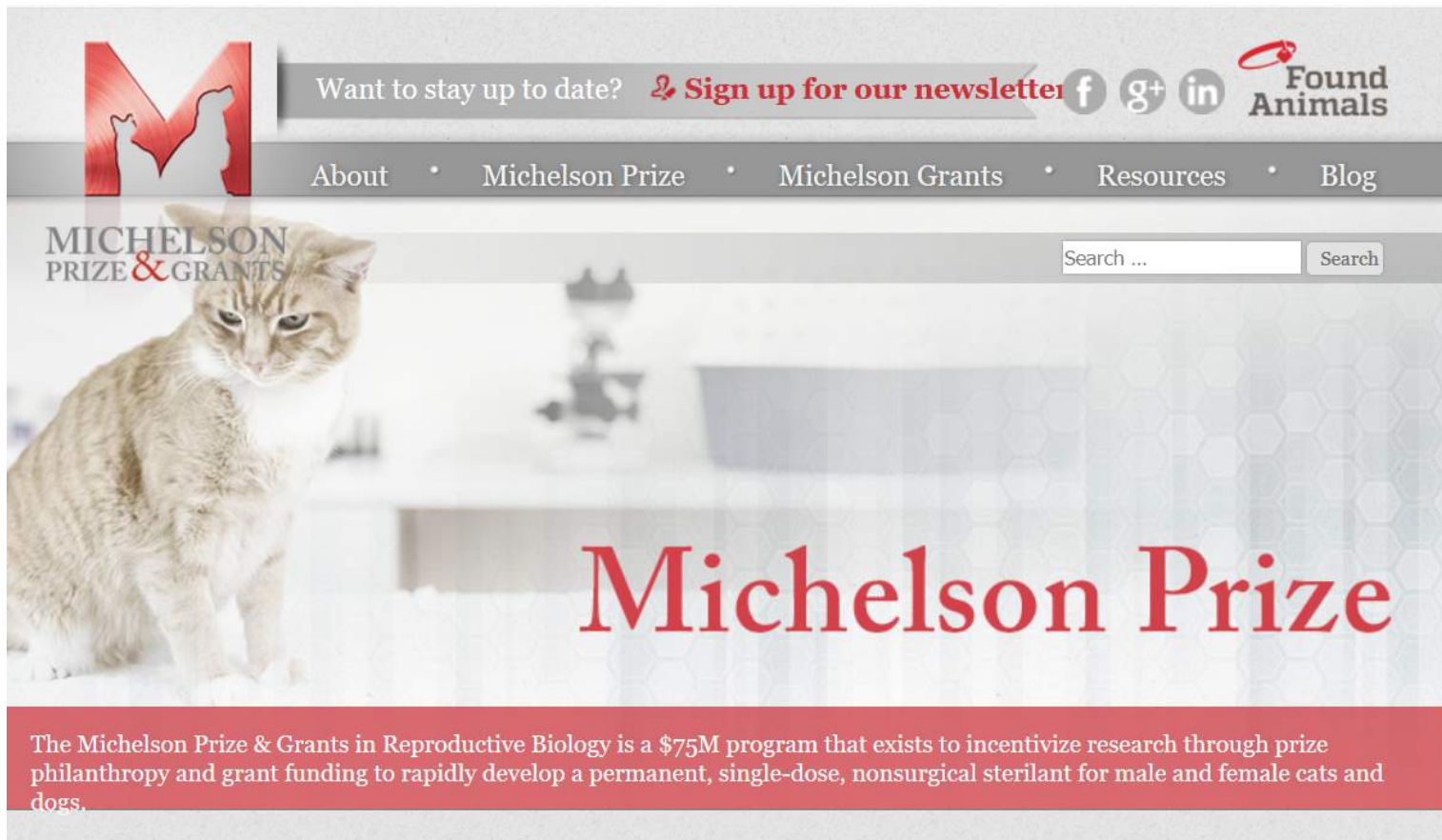
Think Tank  
February 15-17, 2017  
Denver, CO





**How do we incorporate reasonable protections for the animals used in contraceptive research?**



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# Do we need ethical guidelines for dog and cat contraceptive research?



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## Michelson Prize

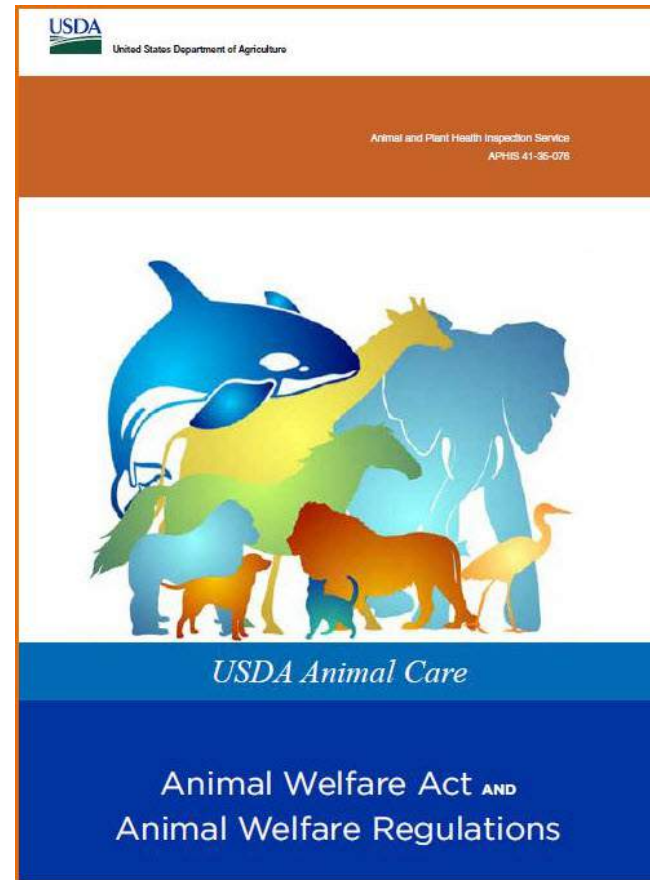
The Michelson Prize & Grants in Reproductive Biology is a \$75M program that exists to incentivize research through prize philanthropy and grant funding to rapidly develop a permanent, single-dose, nonsurgical sterilant for male and female cats and dogs.



# The U.S. Animal Welfare Act:

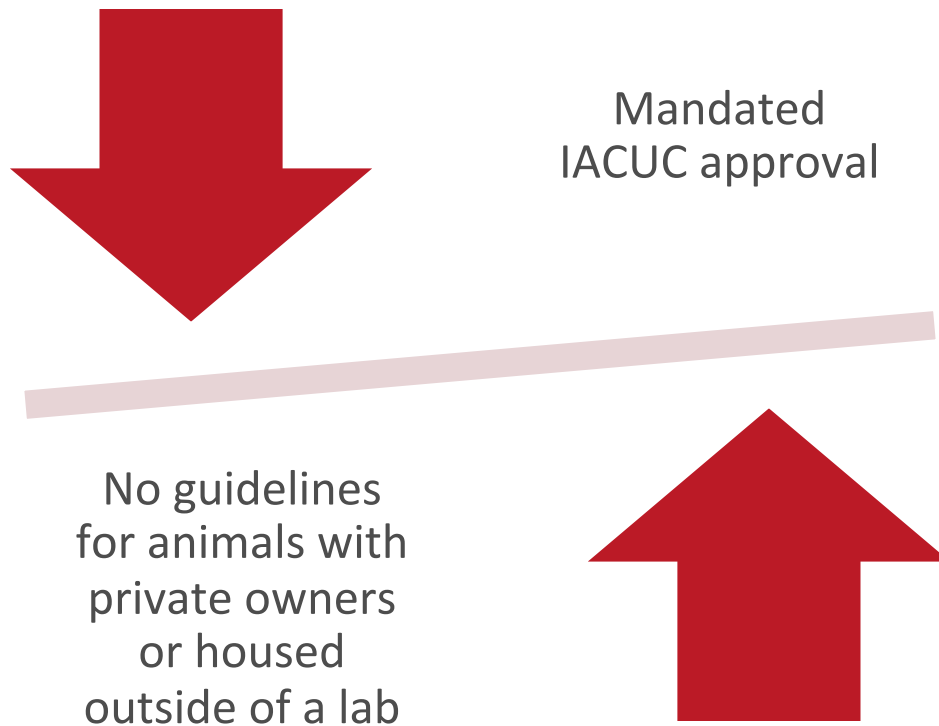
## Legal protection for animals used in research

- Regulates sourcing for use in research and commercial businesses
- Sets minimum standards for care and housing in these settings *only*
- Doesn't supersede pet owner's property rights



# Does the AWA protect owned pets?

That depends upon your definition of protection



**My OPINION: our current structure of IACUC review is inappropriate to address ethical concerns about companion animals, especially those not in the lab**



# Using Pets in Clinical Research

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- Owned pets fall through an oversight gap when enrolled in clinical research
- Also gap in protections for international field trials on healthy owned or community cats and dogs
- Research on owned pets can bypasses costs, limitations, and regulations that govern the use of laboratory animals, even when they are the same species.



# Companion animals occupy a complex and conflicted place in society.....



Family members?

Working partners?



Powerless victims?

which supports the claim that they deserve more protection, not less





# Pet are in legal limbo but have a high social value:

- Large majority consider pets family, not property
- Legally “property”
- Protected from neglect/cruelty and in some states from “pound seizure”
- Termed “kinship” relationship



# Ethical Concerns About Using Pets in Research

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- How do we obtain “consent”???
- Similar to children, we actually obtain *permission*, not consent
- Should we and how do we begin to respect the autonomy of pets as research subjects?



# Ethical Concerns About Using Pets in Research

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- Is the “Therapeutic Misconception” easily exploited when pets are research subjects?

“...patients—and investigators—may sometimes not clearly understand that research has purposes distinct from clinical care. Such a lack of understanding can compromise the objectives of informed agreement to participation in research.”

Ethical Conduct of Clinical Research Involving Children.

Institute of Medicine (US) Committee on Clinical Research Involving Children; Field MJ, Behrman RE, editors. Washington (DC): National Academies Press (US); 2004.



# Ethical Concerns About Using Pets in Research

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- Consider the convoluted role of money in veterinary medicine:
  - Are financial incentives for pet owners and veterinarians appropriate?
  - What are the conflicts of interest?
  - Are financial constraints to care tantamount to coercion?



# Specific Ethical Concerns About Community Animals

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- Are there local, cultural definitions about whether these animals have an owner or caretaker? How do you find that out? Who gets to speak for the community?
- What if those definitions of a caretaker are in conflict with the researcher's definition? Should local custom take precedent or those of the research interest?
- What should the relationship between the community and the researcher be? Financial?



# The Ethical Implications of Using Pets in Research: Solutions and Considerations for Debate

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## Create and Mandate Minimal Ethical Guidelines

- Some examples of minimum standards to consider:
  - specify how/when/who provides and pays for care in the event of adverse events
  - PI should be a different person than primary veterinarian so there is no conflict in enrollment or provision of care
  - Set pre-determined humane end points



# The Ethical Implications of Using Pets in Research: Solutions and Considerations for Debate

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- Consider pets a “vulnerable population” as research subjects
  - Enrollment of pets in research should be similar to enrollment of other vulnerable populations
- Would a hybrid IACUC/IRB that focuses on ethical protocol serve the purpose of protecting pets?



# Current Efforts to Create Ethical Guidelines for Pets in Clinical Trials

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- Creation of a few, hybrid IRB-IACUC committees
  - Academic centers of veterinary medicine
  - Pharmaceutical industry
- Ethics consults during project design
  - Few large research projects with NIH grants
- ACC&D's Efforts to create tools to navigate ethical decision making





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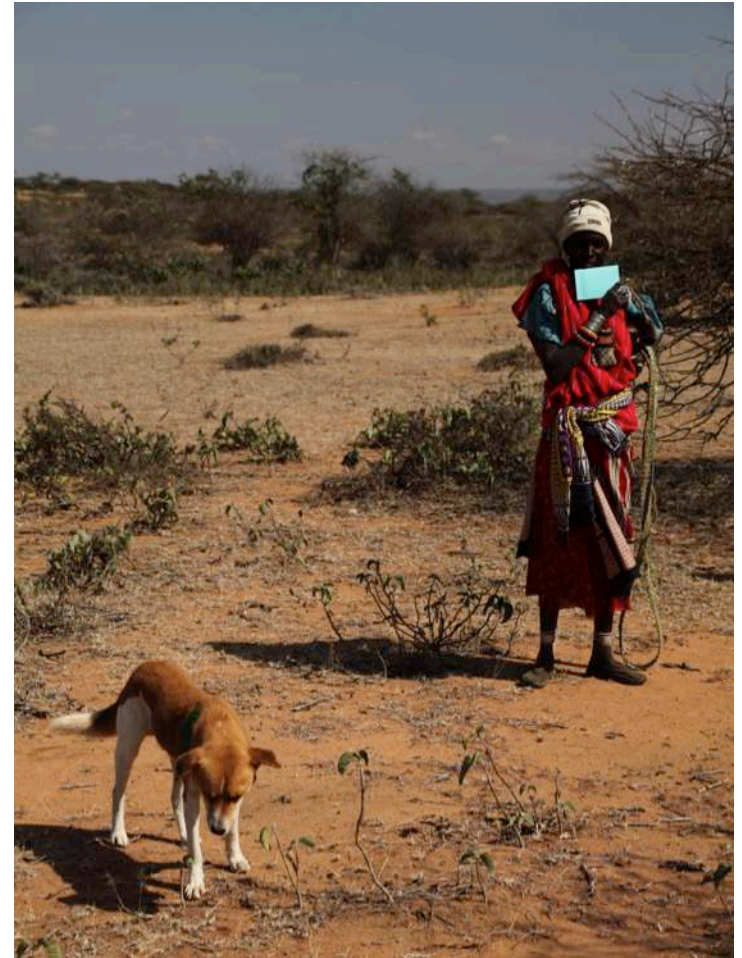


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# Ethical decision-making in clinical and field studies



# TWO of ACC&D's Ethical Dilemmas



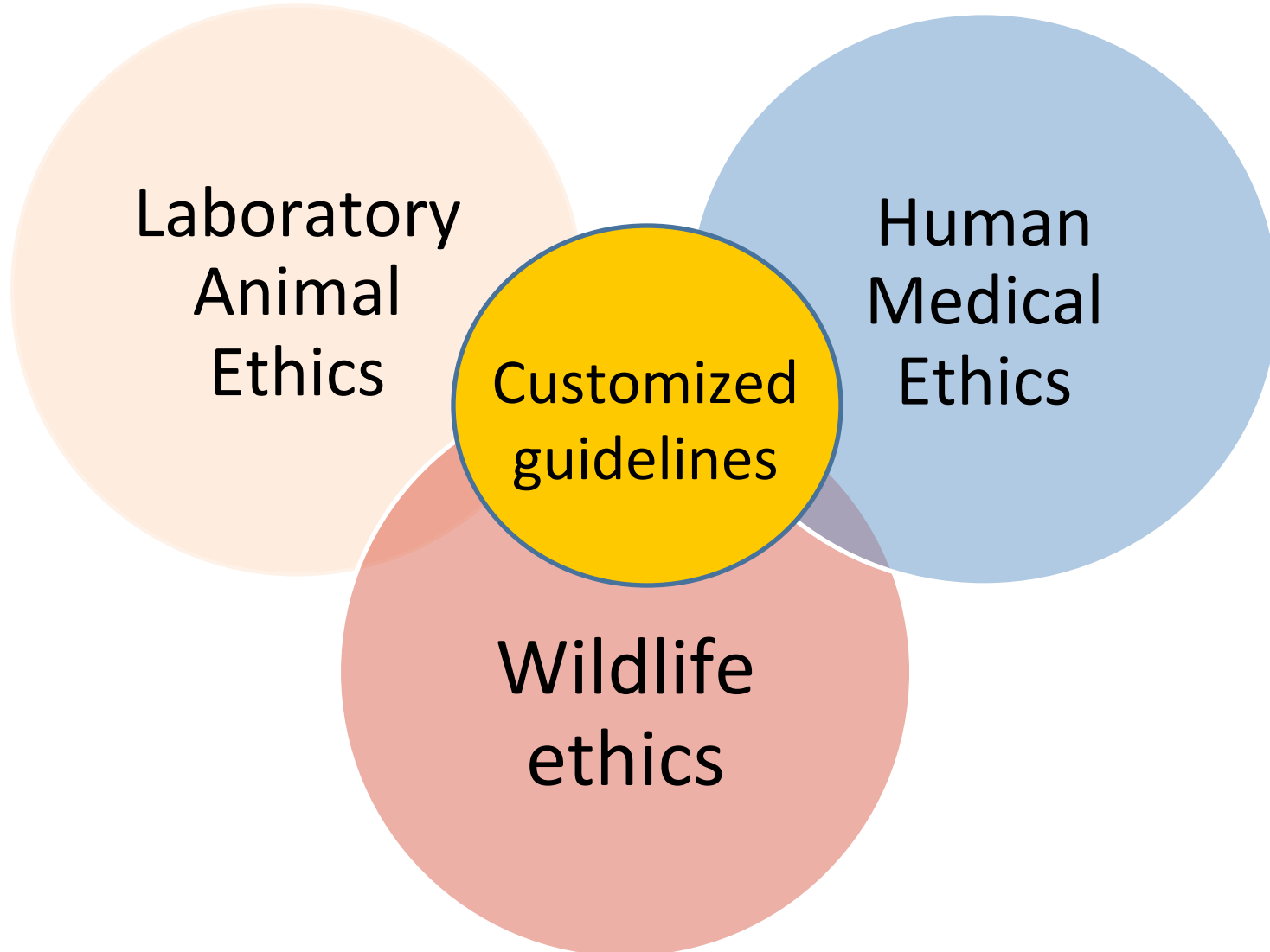
# Guidance Document & Online Interactive Tool: Ethical Decision-Making for field innovations in animal welfare



## Select Think tank leadership:

- **Kate Atema**, Director, Global Community Animal Welfare Program, IFAW
- **Dr. Lisa Moses**, Center for Bioethics, Harvard Medical School; Yale Center for Interdisciplinary Bioethics, MSPCA-Angell Animal Medical Center
- **Dr. Peter Sandøe**, Professor of Bioethics, University of Copenhagen
- **Dr. Vic Spain**, Epidemiologist; former Senior Director, Research & Development, ASPCA
- **Dr. James Yeates**, Chief Veterinary Officer, RSPCA

# Filling the Gap




# Project Funding and Leadership

Project Consultant: Dr. Lou Tasker

ACC&D Director of Programs: Valerie Benka

Seed funding from :

The William and Charlotte Parks Foundation  
Supporting Animal Welfare and Protection



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**The 2017 Grant  
Application Process  
is now CLOSED.**

# Audience

- Involved in field research or innovation involving dogs and/or cats
- Animal welfare, scientific & veterinary communities, governmental, nongovernmental, intergovernmental organisations
- Resource for consultation by
  - ethical review bodies
  - project funders
  - journals



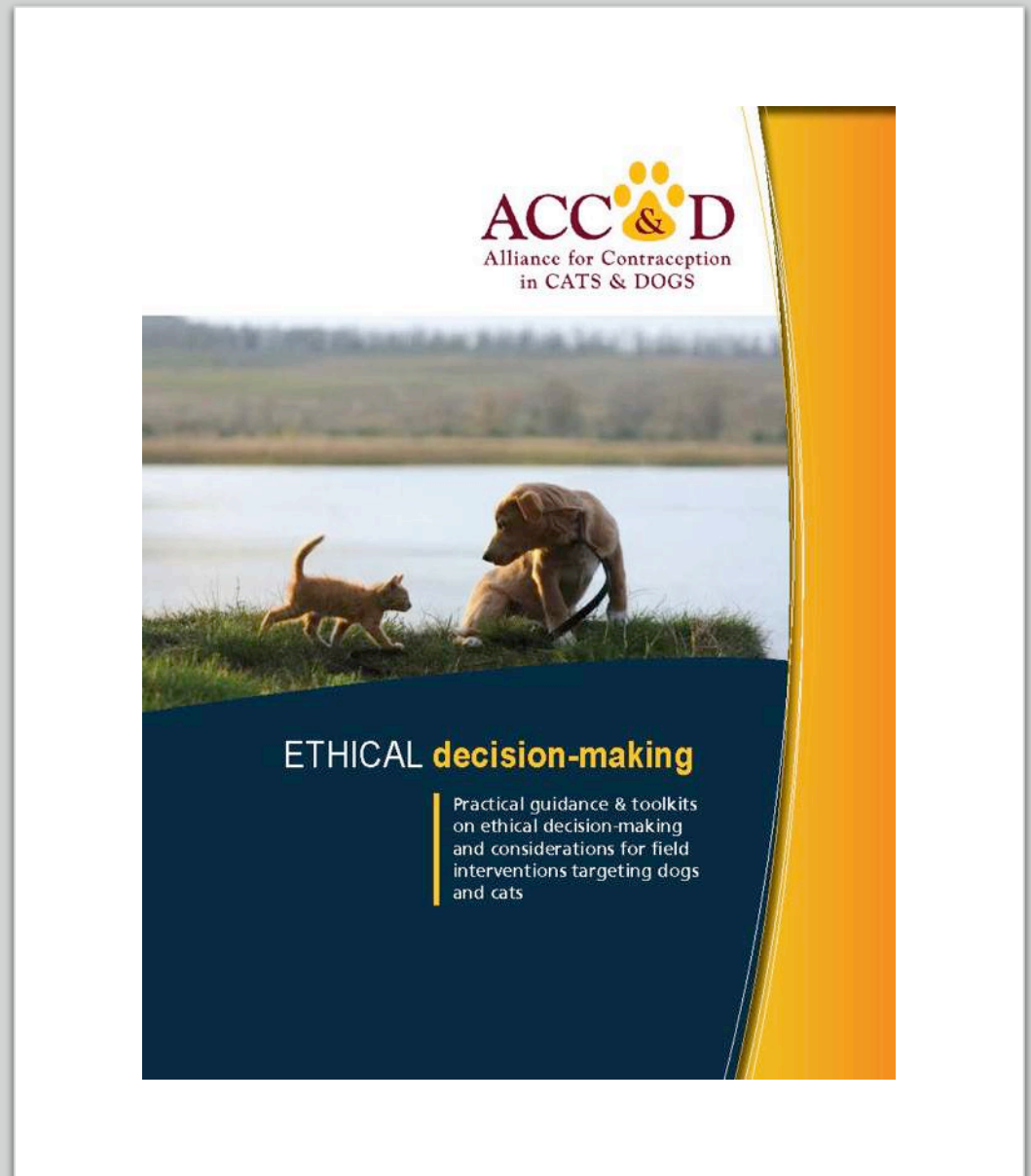
# Resource Structure





# Guidance document

- Dr. Lou Tasker lead
- ACC&D Staff
- Under review by Think Tank Committee members



# Contents



GUIDANCE DOCUMENT

LIST OF ETHICAL CONSIDERATIONS

## Guidance Document

### Introduction

- a) The inspiration for this resource
- b) Who this resource is for
- c) How to use this resource
- d) The framework for this resource

### Why do an ethical review?

#### Ethics

- a) What is ethics?
- b) Ethical theories
- c) Ethical Principles
- d) Animal Ethics

### Ethical considerations when planning, implement

- a) Ethical considerations when planning an intervention
  - 1. The necessity of the intervention
  - 2. Advance research
  - 3. Identifying external (legal, regulatory)
  - 4. Identifying stakeholders and risks
  - 5. Consent
  - 6. Conflicts of interest
  - 7. Exit
- b) Ethical considerations while implementing
- c) Ethical considerations upon completing a

### Summary

### References

### Further Information

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ETHICAL DECISION-MAKING GUIDANCE FOR FIELD

## GUIDANCE DOCUMENT

### Introduction

Domestic dogs and cats are found throughout the world, their global estimates at 700 and 500 million, respectively. Though the contexts in which cats and dogs live vary widely, there is a common thread of nongovernmental and intergovernmental organisations, veterinarians, and government agencies intervening in the lives of dogs and cats, and the communities in which they live. This is done to address concerns about perceived overpopulation, zoonoses, public health nuisances, animal welfare, impacts on wildlife, and impacts on people.

Although interventions are commonly undertaken with the admirable intention that animals (individuals, the target population, or future populations) benefit, there is the potential to cause harm. This harm can manifest not only for the cats and dogs who are targets of the interventions, but also for other stakeholders, both human and non. Those in charge of interventions therefore have an ethical responsibility to ensure that all actions are justified, to guarantee that work is humane for dogs or cats, and to consider the broader communities in which the animals live.

The purpose of this resource is to aid organisations and individuals seeking to improve the welfare of dogs and cats through field interventions by providing an overview of the ethical considerations associated with such work. We define "field" as outside a laboratory; it can range from clinical studies in a local veterinary office to projects in a local neighbourhood to projects in another country. "Interventions" can be as common as trap-neuter-vaccinate-return (TNVR) and animal birth control (ABC) programs, or as novel as research and testing of non-surgical fertility control technologies.

### The inspiration for this resource

This project was inspired by two research initiatives led by the Alliance for Contraception in Cats & Dogs (ACCS&D). One involved a promising non-surgical contraceptive vaccine for free-roaming cats, and the other involved a novel method to identify free-roaming animals who are non-surgically sterilized or vaccinated against rabies. The former project took place in a facility custom designed to simulate a "real-world" environment for free-roaming cats, and the latter in conjunction with a rabies vaccination campaign for owned and community dogs in rural Kenya.

The process of developing and implementing these studies raised some ethical questions, yet resources focused on conducting ethical research with and on animals outside a laboratory were noticeably lacking. In short, the projects went beyond the scope of an Institutional Animal Care and Use Committee (IACUC), a framework for compliance with federal policies, guidelines and principles related to the use of animals in research, teaching and testing. They went beyond this scope because some of the animals were owned, and the research took place within the context of communities, adding a clear human element to ethical decision-making. Meanwhile, an Institutional Review Board (IRB) is responsible for protecting the rights and welfare of human research subjects, with no application to animals. Components of each ethical review framework were relevant to ACCS&D's research, but neither was wholly applicable. These limitations hold true for some other countries'

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ETHICAL DECISION-MAKING GUIDANCE FOR FIELD INTERVENTIONS TARGETING DOGS AND CATS

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CROSS-CUTTING THEMES

KEY STAKEHOLDERS



# Stakeholders



GUIDANCE DOCUMENT

## Key Stakeholders

Contributed by: Lou Tasker & Kate Atema

*This brief toolkit introduces the topic of stakeholders in an intervention. It begins by describing stakeholders you might encounter when an intervention is implemented. It then discusses and benefits that stakeholders may experience during the intervention. It concludes with a discussion of how to effectively and ethically engage owners, and communities.*

**Stakeholders** include any animals and human communities, populations, or organisations that are affected by a particular innovation or intervention in a particular area. Specifically, some individuals are more affected than others (e.g. animals of different ages, animals in poor vs. acceptable welfare, underserved vs. advantaged communities).

Common stakeholders in a field-based animal welfare intervention include:

- The dogs or cats that are targeted by the intervention
- The dogs and cats (individuals and populations) that are not targeted by the intervention but could come into contact with the intervention by virtue of being part of the same community. For example, other animals owned by the same caretaker or guardian, other animals in the same area, or other animals that could be affected by the intervention or innovation.
- Other domestic animals (e.g., livestock, equine, etc.) that could come into contact with either direct or indirect effects of the intervention.

### KEY STAKEHOLDERS

- Owners, guardians, keepers, and caretakers that provide some form of care to dogs and cats.
- The community that comes into physical contact or shares the same environment with dogs or cats.
- Your organisation, specific individuals in that organisation and wider colleagues
- Your donors.
- Organisational collaborators (e.g., local authorities, local nongovernmental and/or intergovernmental organisations, research organisations or institutions, academic partners)
- Veterinarians, veterinary technicians, animal welfare officers, and animal care staff.
- Research participants included in any monitoring and evaluation plans.

Wider community of organisations or individuals that have an interest in the findings of the innovation or the effectiveness or impact of the intervention, as identified through stakeholder analysis. Each innovation or intervention will have different stakeholders, and each of those stakeholders will be affected differently and at different stages (initial planning through final evaluation and reporting or publication). Details on conducting stakeholder analysis are below.

#### Harms and Benefits

Any intervention has the potential to harm and/or benefit stakeholders, which contributes to the ethical questions around implementation. It is important to attempt to identify whether harms are mild, moderate, or severe.

	Animal	Human
<b>Mild</b>	Short-term mild pain, suffering, or distress. Annoyance or irritation.	Annoyance or irritation.
<b>Moderate</b>	Short-term moderate pain, suffering, or distress, or long-lasting mild pain, suffering, or distress.	Personal standing or reputation.
<b>Severe</b>	Severe pain, suffering, or distress, or long-lasting moderate pain, suffering, or distress.	Physical or psychological harms, impacts on livelihoods.

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### KEY STAKEHOLDERS

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# Stakeholder Analysis

<b>Stakeholder</b>	<b>Interest</b>	<b>Effect</b>	<b>Who is affected</b>	<b>Risk severity</b>	<b>Action steps</b>
Stakeholder	Stakeholder's specific interests in the intervention or study	How stakeholder affects (positively or negatively) the innovation or intervention	How stakeholder is affected positively or negatively by intervention	Are the risks/ negative effects on the stakeholder, mild, moderate or severe?	Steps to avoid or mitigate negative effects, and to maximize benefit positive effects.

# Case Studies

Worked examples to analyze stakeholder needs/issues, as well as other ethical considerations

## KEY STAKEHOLDERS

### CASE STUDIES AND EXAMPLE STAKEHOLDER GRIDS

There are three case studies and associated completed grids below. The examples are not intended to be exhaustive, but rather to provide inspiration to use the approach to identify and mitigate harms to stakeholders:

Example 1: Community-based dog population management and associated monitoring, evaluation for impact assessment  
 Example 2: Cat trap-neuter-return  
 Example 3: Clinical trial in veterinary practice

**Case study 1:**  
**Community-based dog population management and associated monitoring, evaluation for impact assessment (Oxley et al., 2019)**

Following decades of culling (strychnine poisoning) a municipality agrees to work with local and animal welfare organisations to establish a managed humane dog population management programme is devolved to the smallest unit and established through an animal manager by community volunteers (animal manager dogs). Volunteers are empowered to provide help select the most appropriate dogs for capture, often with the help of volunteers, members, consent is obtained for neutering dogs are transported short distances to a facility for anaesthesia, aseptic techniques, humane handling and evaluation of animal welfare etc.) When return home, they are transported back to community members or volunteers take responsibility for aftercare.

The project is designed following a baseline survey:

- Household questionnaires delivered on door-to-door visits about their knowledge, attitudes owned and/or cared for in the community
- A street survey that recorded the number of dogs, females, lactating, animal welfare indicators and route to monitor changes in dog density and

## KEY STAKEHOLDERS

intervention (e.g. ICAM 2015)

c) A community participatory exercise that 'mapped' the presence of dogs and dog-related issues (positive and negative) on a local map created by the group to help visualise and guide the discussion between participants and to form a stakeholder group that can help with conducting the intervention (e.g. ICAM 2015). The results of the baseline monitoring are presented to community representatives who are involved in the design and conduct of the intervention. Results are also reported to the municipality and NGOs, and they may be subsequently published in further reports or peer-reviewed literature.

A table for identifying positive and negative impacts on stakeholders for a community-based dog population management programme

Stakeholder	Interest	Effect	Effect achieved	Risk avoided	Adverse impact
Dog owners	Welfare of their dogs	Improved welfare of dogs	Improved welfare of dogs	Reduced risk of dog-related issues	None
Volunteers	Community welfare	Improved community welfare	Improved community welfare	Reduced risk of dog-related issues	None
Municipality	Public health and safety	Improved public health and safety	Improved public health and safety	Reduced risk of dog-related issues	None
Non-governmental organisations	Animal welfare	Improved animal welfare	Improved animal welfare	Reduced risk of dog-related issues	None

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ETHICAL DECISION-MAKING GUIDANCE FOR FIELD INTERVENTIONS TARGETING DOGS AND CATS

## KEY STAKEHOLDERS

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# The Online Tool

[Online Tool](#)



# A final word...

- We'd love your feedback!
  - Is these helpful?
  - Have we left out important details?
  - Do you have case studies?
- Valerie Benka: [valerie@acc-d.org](mailto:valerie@acc-d.org)

6TH INTERNATIONAL SYMPOSIUM  
on Non-Surgical Contraceptive  
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Questions,  
Comments,  
Challenges?