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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Why is a discussion on ethics part of the symposium?

How do we incorporate reasonable protections for the animals used in contraceptive research?
Do we need ethical guidelines for dog and cat contraceptive research?
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

Mandated IACUC approval

No guidelines for animals with private owners or housed outside of a lab

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

- 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

- 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

- 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.
Ethical Concerns About Using Pets in Research

- 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

- 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

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

- 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

• 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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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

Customized guidelines

Laboratory Animal Ethics

Human Medical Ethics

Wildlife ethics
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

The 2017 Grant Application Process is now CLOSED.

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William and Charlotte Parks Foundation
700 Professional Drive
Gaithersburg, MD 20879
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

Practical Guide to Ethical Decision-Making for Field Interventions Targeting Dogs & Cats

GUIDANCE DOCUMENT

ADDITIONAL RESOURCES

ETHICS TOOL KITS

Foundations for Decision-Making
  Ethical Principles
  Ethical Review

Cross-Cutting Themes
  Conflicts of Interest
  Consent
  Monitoring

Key Stakeholders
  Owners
  Animals
  Community
Guidance document

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

Guidance Document

Introduction
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

Ethical considerations when planning, implementing
a) Ethical considerations when planning an intervention
 b) Ethical considerations while implementing
 c) Ethical considerations upon completing a

Summary
References
Further Information
Stakeholders

Key Stakeholders

Contributed by LouClicked & Kate Attena

This brief toolkit introduces the topic of stakeholders as an intervention. It begins by describing stakeholders you might encounter who have an interest in the outcomes of a project. Stakeholder analysis should be performed in advance of starting a project. Initial discussion of how to effectively and ethically engage owners and communities.

Stakeholders include: any animals and their communities, populations, or organizations; a particular innovation or intervention in an animal community. Specifically, some individuals or groups (e.g., animals of different ages, animals in poor or acceptable welfare, or advantaged communities)

Common stakeholders in a field-based animal welfare project:

- 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 and cats.
- Your organization, specific individuals in that organization and wider colleagues.
- Board members.
- Organizational collaborators (e.g., local authorities, local government and community organizations).
- Research organization and institutions.
- Veterinarians, veterinary technicians, animal welfare officers, and animal carers.
- Research participants included in any monitoring and evaluation plans.
- Dog owners of organizations or individuals that have an interest in the findings of the innovation or the effectiveness or impact of the intervention, as described through stakeholder analysis. Stakeholders may include different stakeholders and needs of these stakeholders will be affected differently at different stages of the planning through the evaluation and reporting of data.

Harms and Benefits

Any intervention has the potential to harm and/or benefit stakeholders, which contribute to ethical questions around implementation. It is important to identify whether harms are real, moderate, or minor.

<table>
<thead>
<tr>
<th>Animal</th>
<th>Human</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild</td>
<td>Arthritis or irritation</td>
</tr>
<tr>
<td>Moderate</td>
<td>Arthritis or irritation</td>
</tr>
<tr>
<td>Severe</td>
<td>Physical or psychological harms, impact on livelihoods</td>
</tr>
</tbody>
</table>
## Stakeholder Analysis

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

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

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Questions, Comments, Challenges?