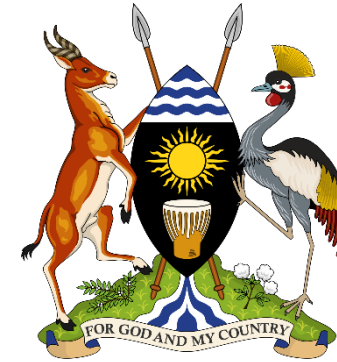




Agricultural Animals in Research: Special Issues and Ethical Considerations

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Introduction

- Agricultural animals are increasingly used in biomedical, translational, and comparative research leading to better understanding of various disease processes, and subsequent development of new products, medicines and treatments
- However, there is growing ethical and societal scrutiny resulting in demand for transparent, humane, and community-inclusive research
 - ✓ Animal welfare, rights, and the broader impact of the food system
 - ✓ Need for clear ethical frameworks
 - ✓ Community engagement
- Ethical soundness enhances scientific credibility and public trust



Agricultural animals in research

- Agricultural animals are domesticated animal species commonly kept with a primary role of production or utility in agriculture (food, value added products, labour or income)
- Some animals are classified differently depending on context
- For example, buffaloes and crocodiles are regarded as wild animals in Uganda, yet considered agricultural animals in other countries where they are farmed

Examples of agricultural animals

- Cattle
- Goats and sheep
- Pigs
- Poultry
- Fish
- Rabbits
- Horses, donkeys, and camels
- Beneficial insects
 - Bees
 - Black Soldier Flies





Why use agricultural animals in research?

- Their physiology and organ systems are usually closer to humans than laboratory animals → better translational models
 - Share diseases/ zoonotics with humans, helping in comparative medicine research
 - Appropriate size for surgical training & medical-device testing
 - Provide understanding into areas (nutrition, metabolism, reproduction, & growth) relevant to both human & veterinary health
 - Can be genetically engineered to produce medicines, vaccines, or organs for transplantation
 - They help improve livestock productivity, food security, and animal welfare through agricultural research
 - Enable production of biopharmaceuticals (e.g., human proteins in milk)
- There are clear benefits to society including;
 - Improved human and animal health
 - Advances in veterinary medicine
 - Food security and agricultural innovation



Key areas of use

- **Translational biomedical research**
(From basic understanding to real-world impact)
 - Pre-clinical studies (Developing promising discoveries into potential therapies or diagnostic tools)
 - Clinical Trials (Evaluating the safety and effectiveness of new treatments or diagnostics)
- **Comparative medicine**
 - Observing and treating diseases in a number of animal species to gain knowledge applicable to human and other animal health
 - Using animal models (e.g. rodents, non-human primates) to study human diseases



Key areas of use cont'd

- Nutrition, physiology and metabolic studies
 - Dietary manipulations
 - Surgical procedures such as rumen fistulation used in cattle and sheep to study rumen fermentation and nutrient utilization
 - Selective breeding for extreme traits
- Genetic engineering and biotechnology
 - Engineering of animals for organ transplantation
 - Manipulating animals to express foreign genes (e.g., human proteins in milk)
 - Use of techniques like cloning, embryo transfer, or gene editing



Considerations for research involving animals in translational biomedical research

- These studies can be **invasive** – Need for strict standards for anesthesia, analgesia, and post-operative care to minimize pain, suffering and distress
- Agricultural animals may also be **food sources** – Need for ethical clarity on whether research animals can enter the food chain and under what conditions
- Translational trials can last be **long-lasting** – Need for management practices thru adequate housing, nutrition, and enrichment to support both welfare and scientific validity
- **Close contact** between researchers and large animals increases the risk of disease transfer. – Need for ethical responsibility includes protecting both human animal handlers and animals
- Using large, familiar production animals in biomedical research can raise stronger **ethical and societal concerns** than rodent use – Need for clear communication and justification



Considerations for research involving animals in Genetic engineering and biotechnology

- Some genetic changes may cause unintended suffering, deformities, reduced fertility, or impaired immunity
- Manipulating animals to express foreign genes (for example, producing human proteins in milk) raises ethical concerns about maintaining the integrity and natural identity of the species
- Genetically engineered animals often require lifelong monitoring for health and welfare issues - Commitment needed
- Engineering pigs or cattle for organ transplantation introduces risks of **zoonotic disease** transfer; ethical debates about creating animals as organ sources
- **Escape or release** of genetically modified animals could disrupt ecosystems or spread altered genes into wild populations – Containment necessary
- Genetic engineering of food animals may **conflict with cultural, religious, or consumer values** - Transparency and engagement with stakeholders required



Considerations for research involving agricultural animals in comparative medicine

- Many comparative studies focus on **diseases shared between humans and animals** (e.g., tuberculosis, brucellosis, influenza) - Need for efforts to prevent cross-infection are imperative
- Agricultural animals used in comparative studies are often **part of food systems** - Ethical clarity is needed on whether such animals can re-enter the food chain after experimental use
- Some comparative studies (especially in rare diseases) require many animals to track disease spread or treatment responses - Need to consider 3Rs framework
- Animals must be housed in secure, species-appropriate environments that prevent pathogen escape and protect welfare during infectious disease trials
- Comparative studies often track disease progression over time – the need to balance longitudinal study requirements with minimizing pain, stress, or reduced quality of life
- Using production animals for human-related disease studies may raise public concern – Need for clear communication and transparency



Considerations for research involving fish

- Fish perceive pain and stress, so procedures must minimize suffering where possible thru proper anesthesia, analgesia, and humane endpoints. Sneddon, L. U. (2020) - *The welfare of fish*, 229-249
- Fish welfare depends directly on water conditions. Vital parameters such as temperature, oxygen, pH, and stocking density must be closely controlled
- Fish are highly sensitive to rough handling, crowding, or exposure to air
- Fish are extremely diverse with different biological needs. Ethical care must be custom-made to the species under study
- Euthanasia must be rapid and humane, often requiring specific approaches (like overdose of anesthetic agents), since standard methods for mammals may not be appropriate
- Escape of laboratory or genetically modified fish into natural ecosystems can have major ecological consequences, so containment is a key ethical issue



Considerations for research involving insects

Research using insects has fewer ethical restrictions compared to vertebrate animals, but there are still important considerations researchers must take into account:

- Evidence suggests certain insects may feel pain or stress thus, researchers should minimize unnecessary harm
- Insects are often used in very large numbers. Ethical review should ensure the scale of use is justified
- Many insects are pests or disease vectors. Preventing escape into the environment, which could cause ecological or public health risks is imperative
- Studies involving genetically engineered insects, long-term ecological effects, community acceptance, and regulatory compliance must be addressed
- Insects are important in food, culture, and livelihoods – Need for researchers to respect societal values when collecting, studying, and/or releasing insects
- Collecting large proportions of wild insects or releasing laboratory-reared insects can disturb the balance of ecosystems - Need to balance scientific goals with conservation obligations



Considerations for research involving animals in nutritional, physiological and metabolic studies

- Trials often require **controlled feeding or restricted** diets – Need that restrictions do not cause prolonged hunger, weakness, or suffering beyond what is scientifically necessary
- In ruminant studies, surgical access to the rumen (**Rumen fistulation and cannulation**) is sometimes used – Need for strict justification, proper surgical technique, pain management, and lifelong monitoring of the animal's welfare
- Nutritional and metabolic studies routinely involve frequent blood, tissue, or rumen fluid collection – Need to minimize invasiveness, should use trained personnel, and apply of anesthesia or analgesia
- Many studies run for months or years – Need for animals to be kept in environments that support natural behaviors, reduce stress, and prevent chronic discomfort
- Close monitoring of growth, weight loss, or metabolic stress, should have clear humane endpoints, if animals lose condition
- When studying **restricted or manipulated diets**, animals should still receive adequate nutrients to maintain basic health and welfare
- With advancements in science and technology, **alternative options** such as simulation, *in silico* models should be explored first



Research clearance and regulatory approval

(A) Administrative clearance

(1) The Commissioner for

Animal Health and or other relevant agencies and organizations

- Application submission
- Assessment of animal health implications.
- Veterinary approval
- Inter-agency consultation if more info is required
- Issuance of formal clearance

(2) The National Animal Genetic Resources Centre and Data Bank (NAGRC&DB) as per sections 4, 5, 7 and 8 of the Animal Breeding Act (2001)

- Interrogate if proposed research aligns with the mandate of conserving, regulating, and improving animal genetic resources
- Evaluate whether the study requires use, import, or export of genetic materials (semen, embryos, live animals)
- Researchers may need to register and obtain a license to access or use genetic resources in their work
- If breeding related, ensure adherence to established breeding standards, record-keeping, and proper reporting of genetic data generated by the study
- Approval is granted if the project meets breeding and conservation standards, with monitoring mechanisms in place



Compliance

(B) Scientific, ethical review and approval

1) Clearance from the Scientific Committees

- A complete research protocol. Assess the scientific merit, feasibility, and methodological soundness of submitted studies
- Ensure research involving animals meets ethical standards and follows established guidelines
- Examine potential benefits of the research against risks to animals, humans, or the environment
- Monitor whether researchers adhere to approved protocols, reporting, and data integrity
- Provide guidance to researchers on best practices, responsible conduct of research, and emerging scientific issues



Compliance cont'd

2) Clearance from IACUC

- A complete research protocol with a protocol version number and date
- Evidence/plan for acquisition of animals, husbandry and end point procedures
- Study instruments e.g. questionnaires, case report forms, and other data collection tools/forms
- Samples of trial drugs/devices and or other appropriate interventions
- Informed consent documents
- Evidence that the researcher is appropriately qualified, experienced and, where applicable, licensed, and has adequate facilities for safe and efficient conduct of research
- Evidence/plan of GCP training for the researcher and study team
- A plan for community engagement and dissemination of research findings to the relevant stakeholders
- Monitor whether researchers adhere to approved protocols, reporting, and data integrity



Compliance cont'd

3) Clearance from the Institutional Biosafety Committees

- Submission of a completed research protocol
- Risk assessment associated with handling biological materials
- Regulatory compliance to national and international biosafety laws, standards, and guidelines
- Approval of research protocols for safety and containment
- Implementation, monitoring and enforcement of corrective actions where necessary
- Training and capacity building of researchers and staff on biosafety practices, emergency response, and safe disposal of biological waste



Compliance cont'd

4) Clearance from the UNCST, registration of study and research permit.

1. A completed research protocol
2. Informed consent
3. Scientific merit (methodologies, data management plan, data collection tools)
4. Capacity and competence of research
5. Safety issues (to animal, environment, humans)
6. Ethical compliance
7. Risk management plan
8. Stakeholder engagement plan, public interest and benefits
9. Transparency and reporting (annual reports, periodic monitoring reviews)
10. Animal welfare and humane treatment
11. Regulatory and institutional approvals including clearance from the other relevant authorities and committees before submission and evidence of IACUC and Scientific committee review.

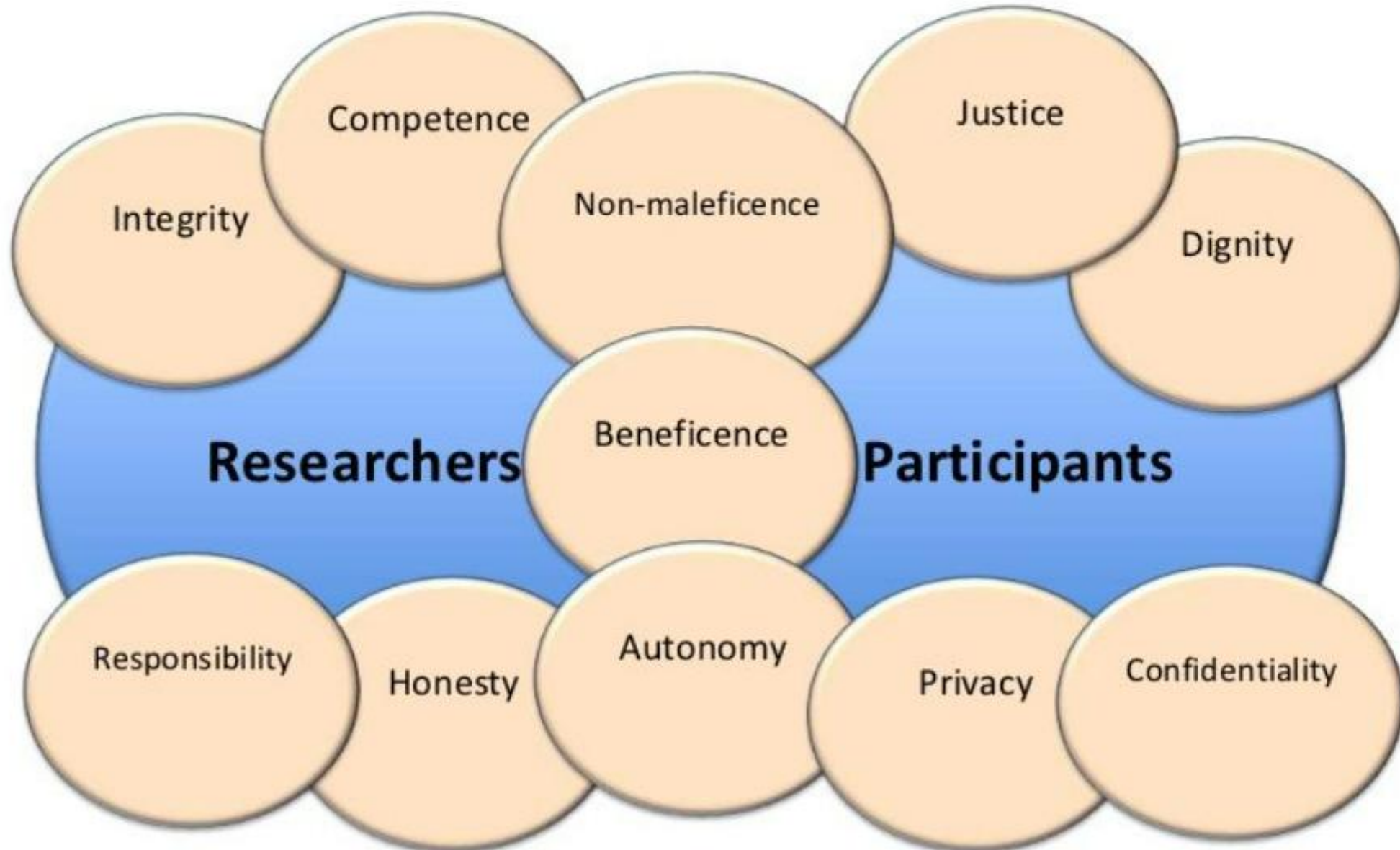
5) Clearance from NDA (If intending to conduct a clinical trial obtain a field trial certificate): On-station and Field trials



General/Universal ethical considerations

- Persons planning to use animals in research and teaching should ensure their proper care and use in consideration of the following general guiding principles:
 - Scientific sound
 - Animal welfare
 - Replacement, Reduction and Refinement (the 3Rs) in research protocol design and implementation
 - Responsibility
 - Responsiveness to community needs

Ethical Principles of Research





Legal frameworks and Institutional Alignment

- **National:** UNCST Guidelines (2021), Animals (Prevention of Cruelty) Act, 1957 (Cap 39, and Animal Breeding Act (2001)
- **International:**
 - World Organisation for Animal Health (WOAH) Animal Welfare Standards
 - Organisation for Economic Co-operation and Development (OECD) test guidelines, good laboratory practice (GLP) standards, and biosafety principles
 - European Union (EU) Directive 2010/63
 - Association for Assessment and Accreditation of Laboratory Animal Care (AAALAC) voluntary accreditation and assessment programs
- Alignment ensures credibility, publication eligibility, and global collaboration

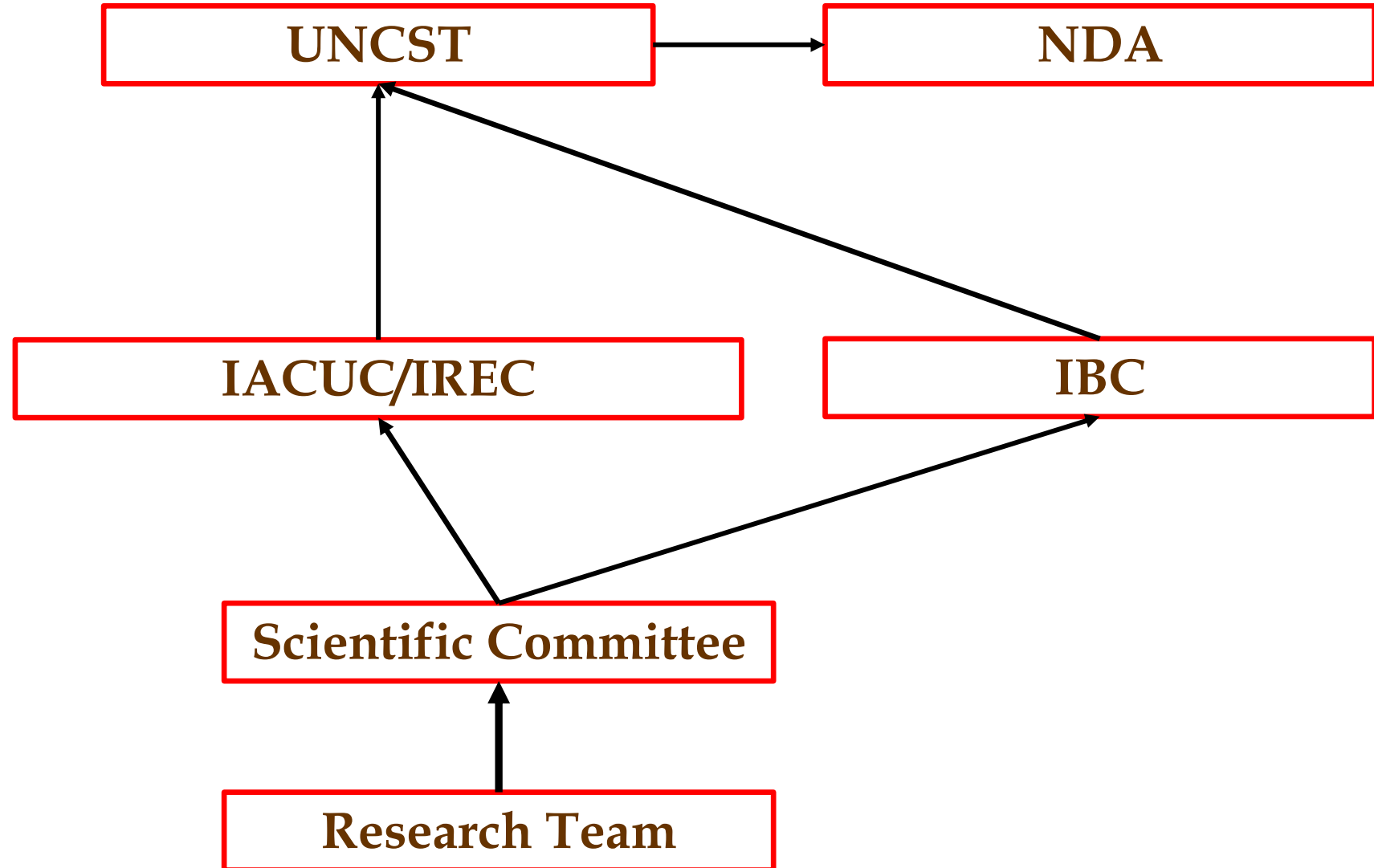


Community engagement in animal research

- Communities as owners, custodians, and beneficiaries of animals
- Transparency builds acceptance & trust
- Engage in:
 - Dialogue before, during, after trials
 - Feedback mechanisms for local concerns
 - Respect for cultural and religious values
- Community input helps shape ethical acceptability and sustainability

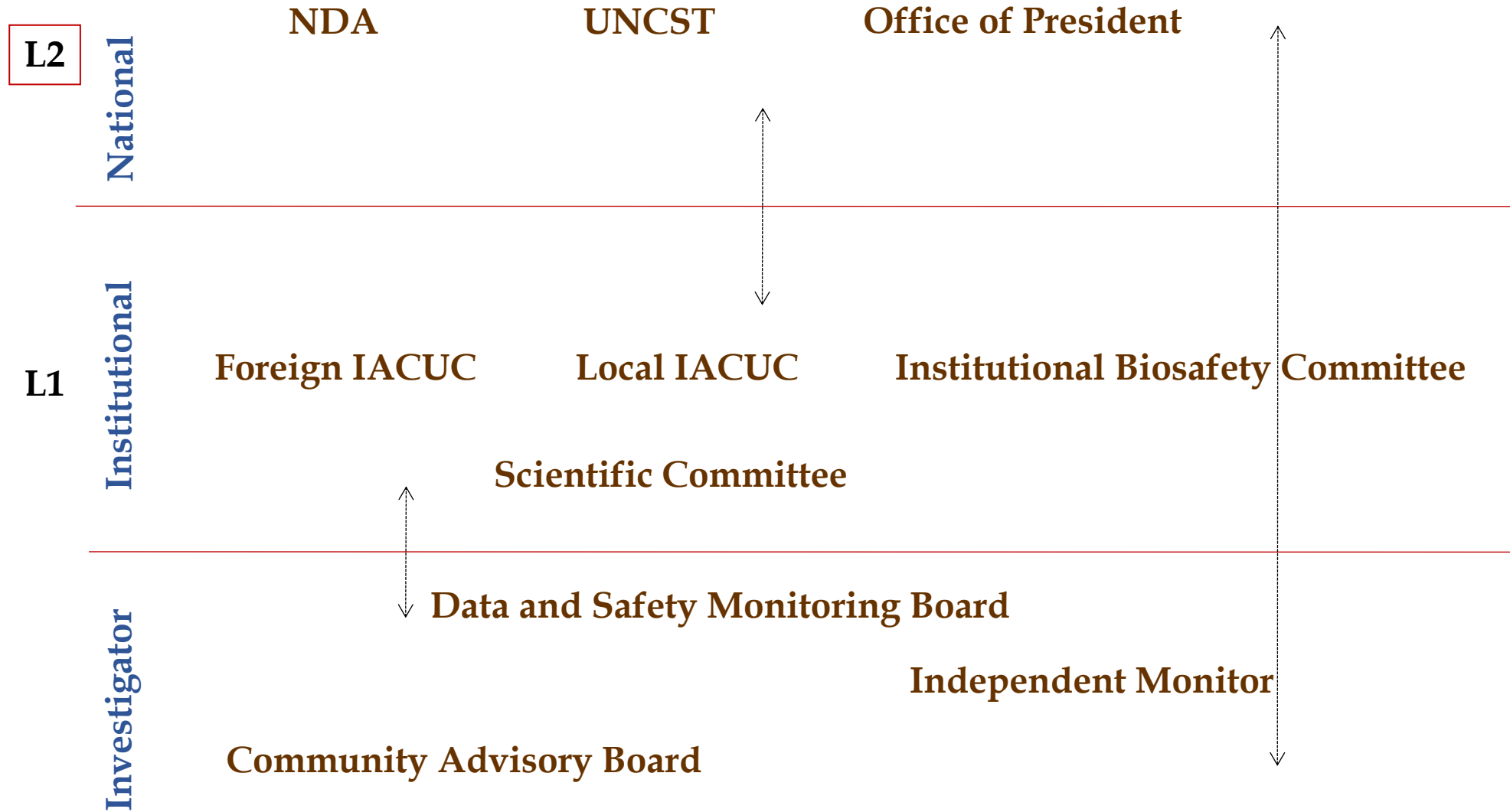
Protocol processing

National Level
Institutional Level
Investigator Level





Outline of the research implementation structure





Key take home messages

- Agricultural animals play an important role in research
- The use of agricultural animals in research should be guided by ethical considerations that can be unique for each animal category
- Regulatory approval and compliance are essential to ensure that research is conducted transparently and with integrity
- Compliance with national and global frameworks safeguards both animals and science
- Community engagement transforms ethics from regulation to shared responsibility



**Thank you so much for your
kind attention**