

Ethical Framework **OUTLINE** for **One Medicine**

Definitions:

ETHICAL FRAMEWORK - a set of principles (beliefs or ideas) which are used to guide how we make decisions.

ONE MEDICINE - a concept that recognises the interconnection between human and animal health, and fosters sustainable and equitable improvements in healthcare and medicines for both human and animal patients - without the expense of an animal's life.

Purpose and Scope

This framework outline has been co-designed with Humanimal Trust's PGIE group. It begins to:

- Provide ethical guidance for collaborative research and clinical practice involving both human and non-human patients.
- Support fair decision-making about the availability of medicines and treatments, ensuring that choices are based on disease and clinical need rather than species.
- Make sure that both humans and animals can benefit equally from the newest and most effective medicines and treatments.
- Promote approaches that reduce reliance on animal experimentation and supports the long-term goal of replacing animal experiments wherever possible.

Background and Rationale

- Human clinical research ethics are well established; equivalent frameworks for veterinary clinical research are still limited.
- Existing animal research guidance focuses largely on experimental models, not clinical patients.
- One Medicine offers an ethical alternative by studying naturally occurring disease in real patients.
- Ethical alignment improves translational relevance, welfare outcomes and public trust.

Core principles

Overarching Principles

We hope in the future the framework will:

- Provide ethical guidance for collaborative research and clinical practice involving human and non-human patients.
- Support innovation in One Medicine while safeguarding welfare, dignity and rights across species.
- Apply to academic, clinical and industry research, including veterinary clinical trials with client-owned animals.
- Aim to align ethical standards across human and veterinary medicine where appropriate.

Operational Principles

We hope the framework will ultimately help to support:

- **Autonomy:** animals will be represented through informed guardians who understand personality, behaviour and quality of life.
- **Non-maleficence:** any potential risk of harm will be minimised, and must be justified by potential benefit.
- **Beneficence:** research will maximise benefit for animal patients.
- **Justice:** risks and benefits will be balanced fairly across species, avoiding human benefit at animal cost.

Responsibilities: Future aims for a full framework



Researchers

will need to:

- Design studies that align with Fair Deal principles.
- Prioritise welfare, minimise risk and ensure scientific integrity.



Guardians

will:

- Act as surrogate decision-makers for animal patients.
- Consider natural behaviours, species-specific needs and quality of life impacts.
- Use structured tools to guide decisions.



Institutions

will need to:

- Provide ethical governance, training and oversight.
- Support cross-disciplinary collaboration.



Regulators and Funders

will need to:

- Harmonise standards across human and veterinary research where possible.
- Enable ethical innovation while enforcing core One Medicine principles.

Ethical Framework OUTLINE for One Medicine

Ethical Review and Oversight

Aim for an ethical approach that ensures:

- Independent ethical review for all projects involving human or non-human participants.
- Risk-benefit assessment to explicitly consider animal patients as participants.
- Ongoing monitoring to ensure continued compliance with welfare and ethical standards.

Public Guardian Involvement & Engagement (PGIE)

Aim for a PGIE approach that:

- Involves animal guardians, public members and professionals in ethical design and evaluation.
- Supports transparent, consensus-based decision-making.
- Helps operationalise guardian representation in practice.

What standards will need to be met?

Welfare Standards

There will be a requirement to:

- Uphold the highest standards of care.
- Minimise suffering and avoid unnecessary or excessive intervention.

Informed Consent/Guardian Representation

The framework will make sure that:

- Humans retain the current standard informed consent processes.
- Non-humans have guardian representation informed by behaviour, personality and quality of life.

Data Integrity

This will be retained through:

- Transparent reporting of all outcomes.
- Compliance with FAIR data principles.



Public Engagement

Aim for:

- Ongoing consultation with guardians, patient advocates and the public.
- Clear communication of risks, benefits and uncertainties.



Education and Training

It will need:

- Cross-disciplinary training in human and veterinary ethics.
- Embedding ethical reasoning into professional education.
- Promoting shared ethical responsibility within One Medicine.



Implementation

Implementation of an ethical framework will need:

- Phased adoption across sectors.
- Integration with existing policies (e.g. GCP, Animal Welfare legislation).
- Regular review to ensure relevance and ethical robustness.

Accountability and Transparency

We will need to develop:

- Public registers of research projects.
- Reporting of harms, benefits and compliance issues.
- Clear sanctions for non-compliance.

Future directions A One Medicine Framework can help us to:



- Adapt to evolving scientific, ethical and societal expectations.
- Support global harmonisation of ethical standards.
- Encourage innovation that prioritises participant welfare.



Registered charity numbers:
1156927 & SC048960

Human Animal Trust, Eashing Barns, Halfway Lane, Eashing, GU7 2QQ

+44(0)1483 791725

info@humananimaltrust.org.uk

www.humananimaltrust.org.uk