

INTRODUCTION

Researchers working with biological samples taken from human donors require certainty that the material they are working with has been obtained legally, ethically and with due consideration for the well-being, privacy and dignity of the donor. The ethics of cell line generation has witnessed a profound transformation in standards and practices since the introduction of the Human Tissue Act (2004). The European Collection of Authenticated Cell Cultures (ECACC) has since evaluated its catalogue to apply contemporary ethical principles to cell lines generated before this modern legislation came into force. Further, ECACC complies with legislation regarding animal cell line including the Convention on International Trade in Endangered Species of Wild Fauna and Flora (CITES) and the Nagoya Protocol.

METHODS

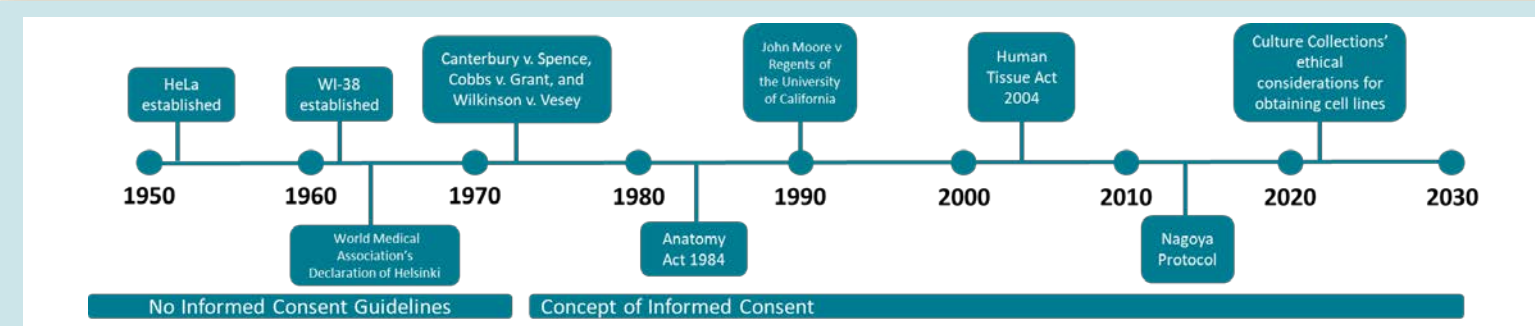
ECACC, as a custodian of cell lines developed before the implementation of modern ethical standards, recognised the importance of applying these standards to all products within its catalogue. A new ethical framework was established by a cross-team focus group, to ensure the transparency, accountability, and ethical integrity of the ECACC collection. Members of the Culture Collections' business development, external communications, technical and operational teams, with assistance from the UKHSA legal department, were tasked with reviewing the relevant guidance and legislation and preparing a policy statement. "Culture Collections' ethical considerations for obtaining cell lines" was published on the Culture Collections website in 2022. This document stated publicly for the first time ECACC's stance on human cell lines generated before 2004, and our commitment to legislation on animal cell lines. For human cell lines, should it be proven that the primary tissue was taken without the prior consent of the donor or the donor's immediate family, then ECACC will endeavour to acquire consent to continue the supply and distribution of the cell line.

THE CHANGING ETHICS OF HUMAN CELL LINE GENERATION

Previously, the ethical landscape surrounding cell line generation was characterised by a limited emphasis on informed consent and patient autonomy. Patients were often unaware that their tissues were used for research purposes, and consent procedures were less rigorous. Privacy and confidentiality concerns were also not given the same level of importance as they are today, potentially compromising patient identities. This is exemplified by the HeLa cell line, established in 1951 and WI-38 established in 1961. These cell lines were created using tissue obtained from patients without their or their families' consent or knowledge. In 1972, three





landmark cases *Canterbury v. Spence*, *Cobbs v. Grant*, and *Wilkinson v. Vesey* solidified informed consent into medical and scientific doctrine, paving the way for global reform.

During the 1970s, 1980s and 1990s political and social attitudes changed. In 2004, the UK Government passed the Human Tissue Act, providing a legislative framework for the taking, storing and using human organs and tissues. Modern human cell lines cannot be created without the informed consent of the patient or their family. ECACC ensures this is in place before accessioning any new product into its collection.



Policy Summary

Ethical considerations for obtaining cell lines

		Legislation	Summary	Our Commitment
	Human	(Prior to 2004)	No legal requirement for informed consent	<p>Proof of informed consent is required. ECACC is licensed for research blood sample storage and human tissue/cell handling.</p>
	Human	(2004)	Human Tissue Act	
	Animal	(1975)	CITES *	<p>Export/Re-Export licenses are required for all cell lines derived from animal species listed under CITES.UK researchers must follow MRC guidance when depositing animal cell lines.</p>
	Animal	(2014)	Nagoya Protocol – Access & Benefit sharing	<p>The Nagoya Protocol complements the Convention on Biological Diversity, ensuring fair benefits from genetic resource utilization.</p>

CITES* - (Convention on International Trade in Endangered Species of Wild Fauna and Flora)

NAGOYA PROTOCOL

The Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity came into force in October 2014. The Nagoya Protocol is an international agreement which provides a framework for the fair and equitable sharing of benefits arising from the utilisation of genetic resources.

ECACC has well-established accessioning protocols to ensure due diligence is performed regarding access and benefit sharing involving those resources covered by the Nagoya Protocol. If this is shown to be missing, then ECACC will establish Prior Informed Consent (PIC) or negotiate Mutually Agreed Terms (MAT) for the utilisation of those genetic resources.



The Nagoya CoP10 logo

CONCLUSIONS

The ethical landscape of cell line generation has undergone a substantial transformation since the 1960s. From limited consent procedures, privacy concerns, and undefined ownership, the scientific and medical professions have evolved to prioritise informed consent, privacy protection, equitable distribution, and responsible use. ECACC's commitment to evaluating its catalogue and applying modern ethics signifies a progressive and proactive approach to upholding the highest ethical standards in cell line generation, distribution and research.

REFERENCES

- Human Tissue Act (2004). [online] Available at: <https://www.legislation.gov.uk/ukpga/2004/30/contents>
- CITES. [online] Available at: <https://cites.org/eng>
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- The Nagoya Protocol on Access and Benefit-sharing. [online] Available at: <https://www.cbd.int/abs/>