



LEGAL HELPDESK

Q&A NO. 016

Can Human Biological
Samples be sold?

By University of Vienna



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Subject: **selling human biological samples; human tissues and cells**

1. International, European Union and Austrian Law

COMMENT

Biobanks, as custodians of samples and data of participants in research projects, must comply with general principles that govern scientific research in the European Union (EU). For example, the Charter of Fundamental Rights of the European Union (CFREU), specifically article 3(2)(c), sets out the prohibition on making the human body and its parts a source of financial gain. Other legally binding international treaties such as the Oviedo Convention¹ – namely article 21 of this international treaty – also sets out a prohibition of financial gain from the human body and its parts. Despite Austria not being a signatory State of the Convention – thus making it unapplicable in this country – the document helps set the scene for the global context of the permissibility of selling human biological samples.

Other EU legislation, such as the Tissues and Cells Directive² “[...] does *not* cover research using human tissues and cells, such as when used for purposes other than application to the human body” (recital 11, emphasis added). Nevertheless, for biobanks who store tissues and cells intended for human application, it is worth noting that article 12(2) of the Directive defines, as one of its principles governing tissue and cell donation, that “[...] Member States shall endeavour to ensure that the procurement of tissues and cells as such is carried out on a *non-profit basis*.” (emphasis added).

The SoHO Regulation³ (due to repeal the Tissues and Cells Directive, in accordance with article 85 of the act) is in line with this general principle. It maintains that the SoHO Regulation “[...] is *not* meant to cover research using SoHO when that research does not involve human application [...]” (recital 60, emphasis added). Nevertheless, “[...] the donation of SoHO that will be exclusively for use in research without any human application should also comply with the standards concerning voluntary and unpaid donation set out in this Regulation” (recital 60, *in fine*). This is reinforced within the body of the legal act, specifically in article 54(6).

However, these provisions (both EU and international) are only applicable “[...] between the first transferor (donor) and the first transferee [...]”⁴, i.e., the prohibition of financial gain “[...] only concerns the human body and its parts, ‘as such’, which, according to the established interpretation, is an expression that refers to the human body and its

¹ COUNCIL OF EUROPE. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine, 1997.

² Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

³ Regulation (EU) 2024/1938 of the European Parliament and of the Council of 13 June 2024 on standards of quality and safety for substances of human origin intended for human application and repealing Directives 2002/98/EC and 2004/23/EC

⁴ SANTAMARÍA, E. (2017). Contracts on Human Biological Samples: the European Prohibition of Financial Gain from the Human Body and its Parts. *European Review of Contract Law*, 13(2), pp. 195-214, p. 200.



parts when they have not been object of transformation”⁵. The prohibition of financial gain would not apply if a biobank transformed or processed a human biological sample and transferred it to another biobank or research institution⁶.

As for the selling of samples between donors and biobanks (or other first transferees, for research purposes or commercial purposes thereof), there are legal arguments – namely based in the right to exercise private autonomy – to sustain the interpretation that a financial gain benefiting the donors would not be untoward⁷.

Disclaimer: *this commentary aims to provide a summary of the main ethical and legal issues related to the questions put by interested stakeholders and to direct them to the relevant legal provisions that are applicable. It does not, however, preclude from reading the official sources of legislation relating to the subject matters of this document as well as those quoted by the authors and does not constitute legal advice.*

⁵ *Ibidem.*

⁶ See §132 of the COUNCIL OF EUROPE. Explanatory Report to the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine. Oviedo, 4.IV.1997, p. 20.

⁷ SANTAMARÍA, E., Op. Cit., pp. 211 and ff.