

Manuscript title: Ethical issues associated with the use of infant donors of biological material for establishing induced pluripotent stem cell banks

Authors: Joel C. Glover¹, Deborah Mascalzoni², Heidi Beate Bentzen³

1. Dept of Molecular Medicine, Institute of Basic Medical Sciences, University of Oslo; Norwegian Center for Stem Cell Research, Oslo University Hospital

2. Centre for Research Ethics and Bioethics (CRB), Uppsala University, Uppsala, Sweden

3. Centre for Medical Ethics, Faculty of Medicine, University of Oslo, Oslo, Norway and Cancer Registry of Norway, Norwegian Institute of Public Health, Oslo, Norway.

Abstract

National and international initiatives have been mounted to generate HLA-haplotyped biobanks of induced pluripotent stem cells (iPSCs) for use in regenerative medicine. In many instances the starting biological material is obtained from umbilical cord blood banks, which are derived from infant donors. In this case, consent is provided not by the donor, but by the donor's parent(s) or guardian(s). This presents an ethical issue related to a donor's right to withdraw (or modify) consent, which for an infant donor necessarily is delayed until the infant reaches adulthood. Since iPSCs can be maintained indefinitely, could be utilized for research and clinical applications in the interim, including commercialization and future uses that are difficult to predict, protecting the rights of infant donors until they are able to make their own decisions about the use of their biological material becomes a pivotal concern. Here we review existing guidelines and legislation, explore current practices and suggest potential solutions to this challenging issue.

This review was motivated by discussions held at the Training School in GDPR and iPSC haplobanking, held in Oslo, Norway, September 18-19, 2026, sponsored and supported by EU COST Action 21151: Generation of Human Induced Pluripotent Stem Cells from Haplo-selected Cord Blood Samples (HAPLO-iPS).