



CATHOLIC WOMEN'S LEAGUE AUSTRALIA INC.

Member Organisation of the World Union of Catholic Women's Organisations (WUCWO)
NGO in consultative (Roster) status with the Economic and Social Council of the United Nations

Thursday, 18 October 2012

Project Officer – Human Biospecimens
Ethics and Genetics Section
Research Translation Group
National Health and Medical Research Council
GPO Box 1421
Canberra ACT 2601

Dear Sir/Madam

Re: Proposed Revisions to the *National Statement on Ethical Conduct in Human Research 2007*, Chapter 3.4 – Human biospecimens

1. Catholic Women's League Australia Inc. (CWLA) is the national peak body representing the League's seven member organisations located throughout Australia. We are a Non-Government Organisation and have consultative (Roster) status with the Economic and Social Council of the United Nations. We are also a member organisation of the World Union of Catholic Women's Organisations.

One of CWLA's four principle aims is to engage with legislative and administrative bodies at all levels of government to advocate respect for the inherent dignity of the human person. This leads us to have an active interest in biomedical ethics.

2.1 CWLA's principle concern with the Proposed Revisions to the *National Statement on Ethical Conduct in Human Research 2007*, Chapter 3.4 – Human biospecimens (the *Proposed Revisions*)¹ is the withdrawal of the current prohibition on trade in human tissue.

Section 3.4.10 of the current *National Statement* reads: "There should be no trade in human tissue for research purposes." The *Proposed Revisions* do not include an equivalent statement.

Furthermore, Section 3.4.4 (i) of the *Proposed Revisions* assumes that there may be "foreseeable commercial outcomes arising from research involving (their) biospecimens".

¹ National Health and Medical Research Council, *Proposed Revisions to the National Statement on Ethical Conduct in Human Research 2007, Chapter 3.4 – Human Biospecimens*, 2012.



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This represents a major change in position which is inconsistent with relevant guidelines and laws, and not reflective of the dominant public perceptions and values associated with organ and tissue donation.

2.2 The NHMRC's *Organ and Tissue Donation after Death, for Transplantation: Guidelines for Ethical Practice for Health Professionals*, released in 2007, restrict trade in human tissue and support altruism in the donation of human organs or tissue for the purposes of transplantation.

Submissions received during two rounds of targeted consultation for these 2007 guidelines indicated neither a desire to alter the altruistic basis of organ and tissue donation in Australia, nor support for allowing human tissue to be used or disposed of as though it were property.²

2.3 Submissions received during public consultation on the NHMRC issues paper, *Ethics and the exchange and commercialisation of products derived from human tissue – Background and issues 2011*, also showed overwhelming support for the current practice of organ and tissue donation in Australia. Most of the submissions expressed the view that commercial use of human tissue would undermine the social capital in the existing, altruism-based system of organ and tissue donation.³

The Working Committee behind the issues paper accepted the premise that property or ownership should not be applied to human tissue, and did not revisit the issue of payment of material incentives for donation of human organs or tissue for the purposes of research or transplantation.⁴

2.4 Under common law property principles, human tissue cannot be “owned” by the person from whom it was derived. All Human Tissue Acts and Coroners Acts in Australian jurisdictions generally prohibit the sale or exchange of human tissue and govern its use.⁵

3.1 Along with many other members of the Australian community, Catholic Christians view any trade in human tissue and organs, either before or after death, as inconsistent with respect for human dignity and persons. This position is already well explained in *Ethics and the exchange and commercialisation of products derived from human tissue*.

² National Health and Medical Research Council, *Ethics and the exchange and commercialization of products derived from human tissue: Background and issues*, 2011, 1.3, p.4.

³ *ibid*, 1.3, p.4-5.

⁴ *ibid*, 1.3, p.5.

⁵ *ibid*, 2.5.2, p.15.



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Respect for the human person explicitly extends this concept to include the human body, whether living or after death. Many members of the community hold the view that selling human organs or tissues involves treating the human body as an object separate from the person whose body it is. This is thus inherently disrespectful of the body of a living person or the memory of a deceased person. Respect for the human person involves respecting the human body because the latter is intimate to the person and constitutive of the human identity.⁶

3.2 Catholic Health Australia's *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia* clearly states the principle:

Parts of the human body are not to be treated as commodities. Trade in human body parts is unacceptable, as is any other disrespectful use of the organs or tissues of a living or deceased person.⁷

4.1 There are also important practical reasons for maintaining the ban on trade in human tissue for research.

Australia's system of organ and tissue donation relies upon altruism. Allowing profit to be made from trade in human tissue for research purposes could erode the general spirit of altruism and diminish 'donations' for organ and tissue *transplantation*, including blood and bone marrow donation. This could lead to loss of equity in access to organ and tissue transplantation and related treatments.

4.2 Another potentially harmful consequence of opening the door to trade in human tissue is the 'creation of perverse incentives'. *Ethics and the exchange and commercialisation of products derived from human tissue* defines 'perverse incentives' and explains their potential for harm:

Incentives may be offered to donors and their families either to elicit consent or to engage them directly in the sale of their tissue (by-passing the consent process). These incentives are perverse if they may cause people to behave in ways that they would not otherwise behave, or to take undue risks....This may compromise not only the person's own health but also that of others if the potential donor withholds information that would be relevant to recipients. Thus payment to the donor may compromise product safety and community health.⁸

⁶ *ibid*, 3.1, p.23.

⁷ Catholic Health Australia, *Code of Ethical Standards for Catholic Health and Aged Care Services in Australia*, 2001, section 3.16.

⁸ NHMRC, *Ethics and the exchange and commercialization of products derived from human tissue*, 4.6, p.34.



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5. The *Proposed Revisions* do not distinguish between *human biospecimens* and *products derived from human biospecimens*, much less provide guidance about the commercialisation of human tissue *products* in research.

Only last year, however, *Ethics and the exchange and commercialisation of products derived from human tissue - background and issues*, carefully dealt with this issue and proposed that while the existing ban on for-profit commercialisation of human tissue for transplantation should be retained, *products* derived from human tissue may be used commercially in some circumstances, within a context of ethical guidelines. Five decision-making criteria, (community benefit, genomic significance, commodification, unique properties and perverse incentives) were suggested for use by a Human Research Ethics Committee (HREC) to determine whether commercialisation of human tissue products is ethically permissible.⁹

Regrettably, the distinction between human tissue and human tissue products, and the ethical guidance provided by this comprehensive issue paper has not been included in the *Proposed Revisions*.

6. Recommendations

Catholic Women's League Australia recommends that proposed revisions to the *National Statement on Ethical Conduct in Human Research 2007*:

- (i) retain the prohibition on trade in human tissue (human biospecimens) for research
- (ii) include guidance on how to deal ethically with commercialisation of human tissue products (products derived from human biospecimens) in research situations.

Thank you for the opportunity to make this submission.

Authorised by:

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⁹ *ibid*, 4.1, p.27.