

- understanding of the legislation;
- collaborated with AHEC in finalising the ART guidelines 2004 with respect to protocols for obtaining proper consent;
- issued nine licences and administered the operation of these licences; and
- considered a number of requests for variations to licences already issued.

The Prohibition of Human Cloning Act 2002

The scope of the PHCA was decided by COAG in April 2002 following wide consultation. It was passed by the Federal Parliament in December 2002, following extensive parliamentary debate and a Senate inquiry.

Since December 2002, there have been a number of significant developments in science and technology, including the cloning of human embryos using nuclear transfer technologies, progress towards developing embryonic stem cells of suitable quality to use in clinical treatments, and the identification of adult stem cells in an increasing number of tissues.

A key prohibition in the PHCA is the ban on the cloning of human embryos for any purpose. The cloning of human embryos for research purposes, also called “*somatic cell nuclear transfer*” (SCNT)¹, is legal in the UK (subject to strict regulation) and not regulated by government in a number of other countries including Korea and the United States. The NHMRC notes that there is still a wide diversity of opinion on this matter within the research and wider community, and this is reflected across the membership of Council and its Principal Committees.

For example:

RC ([Appendix 1](#), page 20) states:

RC suggests that it is appropriate to open a full and wide-ranging debate amongst the relevant stakeholders in Australia to determine whether our legislation should be also changed.

AHEC ([Appendix 2](#), page 36) states:

In publishing the list at pages 10-11 in the ART guidelines 2004, both CREGART and AHEC intended to make clear that, regardless of other outcomes of the legislation review, all the practices listed were regarded as unethical².

The list of prohibited practices in the PHCA was included in its entirety in Chapter 4 of the ART guidelines 2004, as endorsed by the Council. Thus the ART guidelines 2004 represent the Council’s endorsed position on prohibited practices. However, Council considers that there should be regular community and parliamentary debate on these matters.

The Research Involving Human Embryos Act 2002

The RIHEA establishes a strong regulatory framework that permits research to be undertaken utilising excess ART embryos. It should be noted that prior to the RIHEA and corresponding State and Territory legislation there was no regulation of such research in the majority of States and Territories.

¹ Cloning for research purposes or *somatic cell nuclear transfer* is sometimes referred to as “therapeutic cloning”. The NHMRC does not use this terminology.

² The list referred to in this statement is the list of prohibited practices in Chapter 4 of the ART guidelines, which is the same as in the PHCA. CREGART was the Committee to Review the Ethical Guidelines on ART.