Australian Government
National Health and Medical Research Council

Question and Answer: *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017*

The 2017 ART guidelines

Do the 2017 guidelines replace the 2007 guidelines?

Yes – the CEO of the National Health and Medical Research Council (NHMRC) revoked the 2007 guidelines on 20 April 2017, upon release of the 2017 guidelines.

Why were the ART guidelines under review?

NHMRC, through the work of its principal committee, the Australian Health Ethics Committee (AHEC), periodically reviews all its ethical guidelines for currency. AHEC has reviewed the clinical practice component (Part B) of the ART guidelines to ensure the provision of contemporary ethical guidelines to support the clinical practice of ART in Australian clinics.

Why weren't the ethical guidelines for research (Part C) under review?

Part C of the ART guidelines was updated in 2007 to reflect changes to the *Prohibition of Human Cloning for Reproduction Act 2002* (PHCR Act) and the *Research Involving Human Embryos Act 2002* (RIHE Act).

Minor editorial changes have been made to Part C, to ensure consistency throughout the document. Part C of the ART guidelines will not be reviewed until required by further changes in the legislation.

What's changed?

A summary of the major revisions is available on the NHMRC website.

How do the ART guidelines fit in the regulation of ART practice?

There is a robust framework in Australia for the conduct of ART (both in clinical practice and in research). This framework consists of:

Commonwealth legislation

- *Prohibition of Human Cloning for Reproduction Act 2002*

- *Research Involving Human Embryos Act 2002*

State and territory legislation

- Legislation to regulate ART exists in four states:
    - Victoria
    - New South Wales
    - South Australia
    - Western Australia

NHMRC guidelines

- *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research, 2017.*
- *National statement on ethical conduct in human research, 2007.*
- *Australian code for the responsible conduct of research, 2007.*

Accreditation

- Accreditation of ART clinics is the responsibility of the Reproductive Technology Accreditation Committee (RTAC), established by the Fertility Society of Australia (FSA).
    - RTAC accreditation requires ART clinics to comply with government laws and guidelines concerning the practice of ART, including NHMRC's ART guidelines.
    - RTAC accreditation is required for services provided by clinics to be eligible for Medicare funding.

The review process

How does NHMRC develop ethical guidelines?

AHEC advises NHMRC on ethical issues relating to health and the development of guidelines for the conduct of medical research involving humans.

The functions of AHEC, as set out in subsection 35(3) of the *National Health and Medical Research Council Act 1992 (*NHMRC Act), are:

- to advise the Council on the ethical issues relating to health; and
- to develop and give the Council human research guidelines under subsection 10(2) of the NHMRC Act; and
- any other functions conferred on the Committee in writing by the Minister after consulting the CEO; and
- any other functions conferred on the Committee by the NHMRC Act, the regulations or any other law.

In the course of its activities, AHEC consults extensively with individuals, community organisations, health professionals and governments, and undertakes formal public consultation when developing guidelines.

To inform the development of the 2017 ART guidelines, NHMRC conducted two public consultations:

- 11 March – 30 April 2014
- 23 July – 17 September 2015.

How does AHEC make decisions?

AHEC may recommend the establishment of working committees for select projects, under section 39 of the NHMRC Act. Working committees are established to address contemporary issues in health and medical research.

In the event that a section 39 working committee is established, the reports and/or findings of this committee are considered by AHEC. AHEC is responsible for making the final recommendation to NHMRC's Council. In turn, Council then provides its recommendation to the NHMRC CEO. See also section 10 of the NHMRC Act.

Why has the review taken this long?

A review of NHMRC ethical guidelines typically takes between 2.5 – 3 years and includes at least one round of public consultation. Due to the complex and sensitive issues addressed by the 2017 ART guidelines, two public consultations were necessary and this naturally increased the review timeframe.

What was the approval process for the 2017 ART guidelines?

In accordance with section 10 of the NHMRC Act, draft ethical guidelines developed by AHEC must be provided to the Council of NHMRC before being issued by the NHMRC CEO.

Who was told about the public consultations?

NHMRC's requirements for public consultation are set out in the NHMRC Act and the *National Health and Medical Research Council Regulations, 2006* (the Regulations).

Section 13 of the NHMRC Act states that:

Before:

a) the Council provides guidelines (other than human research guidelines) to the CEO for the purposes of subsection 9(1); or
b) the Australian Health Ethics Committee provides human research guidelines to the Council for the purposes of subsection 10(2);

the Council or Committee must:

c) prepare a draft of the guidelines; and
d) publish a notice, in the manner and form specified in the regulations:
   i) containing a summary of the draft guidelines; and
   ii) stating where copies of the draft guidelines can be obtained; and
   iii) inviting persons or bodies to make submissions relating to the draft guidelines in accordance with the procedures, and within the period, specified in the notice; and
e) have regard to any submissions received as a result of the invitation referred to in subparagraph (d)(iii).

In accordance with section 6 of the NHMRC Regulations, both public consultations were advertised in *The Australian*, on the NHMRC website, and via the *NHMRC Tracker*. Key stakeholders, as identified by AHEC, were also notified via email.

The NHMRC has developed a public consultation portal to facilitate public consultation. A link to this portal can be found here.

What issues were raised during public consultation?

The main issues raised in submissions to the public consultations included:

- the information needs of individuals and access to appropriate counselling services
- the information and counselling needs of all people involved in the donation of gametes and embryos
- sex selection for non-medical purposes
- commercial surrogacy
- preimplantation genetic testing.

Are the submissions from the public consultations publically available?

Submissions to the 2014 and 2015 public consultations are available from the NHMRC public consultation website.

NHMRC seeks permission from the respondents before making the submissions publically available. NHMRC will not publish submissions when this permission has not been granted.

I provided a submission to public consultation – was my opinion considered?

In accordance with section 13 of the NHMRC Act, AHEC must have regard to any submissions received as a result of the invitation referred to in subparagraph (d)(iii).

The ART Working Committee

What is a Working Committee?

Under section 39 of the NHMRC Act the CEO (or CEO approved delegate) is authorised to establish any working committee deemed necessary to assist the functions of the CEO, Council, or a Principal Committee.

The CEO establishes working committees when required to seek advice, support, research or expertise from outside NHMRC in order to achieve a specific NHMRC outcome.

The ART Working Committee was established on 16 April 2013 to advise AHEC on the review of Part B of the ART guidelines. Appointments to the ART Working Committee conclude on 31 December 2017.

Who was on the (ART) Working Committee?

The ART Working Committee was made up 10 members and a Chair. Membership included persons with expertise and experience in:

- health ethics
- the regulation of ART
- the clinical practice of ART
- religion
- consumer issues related to ART
- consumer issues related to disability and/or genetic conditions.

Details of the membership of the ART Working Committee can be found here.

How were members of the ART Working Committee chosen?

Nominations to the ART Working Committee were sought from a range of organisations with an interest in ART. These organisations included provider groups and key industry bodies, ethics organisations and consumer advocacy groups.

All nominations to the ART Working Committee were considered in relation to:

- suitability against the identified expertise required to undertake the review
- achieving a balance of gender
- state representation
- the nominees known interests.

Further information regarding the appointment process and the management of disclosed interests can be found in Appendix 4 of the 2017 ART guidelines.

Some of the ART Working Committee members are employed by, or own, ART clinics – isn't this a conflict of interest?

Members of the ART Working Committee were appointed in accordance with NHMRC policy.[1] NHMRC recognises that many experts, who bring experience and ideas to guideline development, will also often have interests. These interests must be transparent and appropriately managed to maintain the integrity of NHMRC guidelines.

What is the role of the ART Working Committee?

The terms of reference for the ART Working Committee was to review Part B of the *Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research, 2007* and provide draft ethical guidelines for consideration by AHEC.

The ART guidelines

Who uses the ART guidelines?

The ART guidelines are used by professional organisations to set standards for the practice of ART. The ART guidelines are primarily intended for ART clinicians, clinic nurses, embryologists, counsellors and administrators, researchers, Human Research Ethics Committees, and governments.

Do all ART clinics have to follow the ART guidelines?

The ART guidelines underpin the regulation of ART practice within Australia. The Reproductive Technology Accreditation Committee (RTAC) is responsible for the accreditation of ART clinics. RTAC accreditation is the basis of a nationally consistent approach for overseeing ART clinical practice and requires ART treatment centres to comply with government laws and guidelines concerning the practice of ART. The ART guidelines are included in this requirement.

RTAC accreditation is required for services provided by clinics to be eligible for Medicare funding.
See also '*How do the ART guidelines fit in the regulation of ART practice?*' on page 2.

Do the ART guidelines affect Medicare funding?

The funding for ART is outside the scope of the ART guidelines. Questions regarding Medicare funding for ART should be directed to the Commonwealth Department of Health.

[1] Guideline Development and Conflicts of Interest: Identifying and Managing Conflicts of Interest of Prospective Members and Members of NHMRC Committees and Working Groups Developing Guidelines

Specific issues

Age limits

Is there an age limit for ART?

AHEC agreed that it was not appropriate in an ethical framework to set an upper age limit for access to ART services. AHEC concluded that it was important for clinics to provide individuals with information about risks and success rates, taking into account the age of the individual. There may be clinical reasons to restrict access to ART services, and these decisions are guided by separate clinical guidelines.

Sex selection for non-medical purposes

Has the position on sex selection for non-medical purposes changed?

The 2017 ART guidelines do not support the use of sex selection for non-medical purposes.

In recent years, there have been many public and professional discussions on whether intended parents should be permitted to make an autonomous decision on sex selection for non-medical purposes. However, a significant voice against the practice remains. To date, sex selection for non-medical purposes has generated the most interest from the public, health professionals and the media in relation to these guidelines.

Throughout the development of the 2017 ART guidelines, there has been significant debate on this issue within the expert working committee and AHEC. AHEC concluded that the motivations of the intended parent(s) were a significant consideration in determining the ethical acceptability of the practice. The majority view of AHEC was that there is an ethical difference between a desire to introduce variety to the existing sex ratio of a family and the desire to select a child of a particular sex due to an individual's or a couple's cultural or personal bias, influences or desires. AHEC saw merit in permitting access to ART activities to select the sex of a human embryo prior to embryo transfer to introduce variety to the sex ratio of offspring within a family, where:

- the intended parent(s) have (collectively) two or more offspring of the one sex and no offspring of the opposite sex
- the intended parent(s) have been provided with relevant information and counselling
- the decision to permit access is made on a case-by case basis, following consideration of the guiding principles in Chapter 2 of the 2017 ART guidelines in the context of the individual family.

However, AHEC acknowledged that the motivations of those seeking to use sex selection for non-medical purposes cannot be easily identified and AHEC does not endorse, nor wish to perpetuate, gender stereotyping, or cultural or personal biases based on biological sex.

AHEC also recognised that many of the issues surrounding ART are as much social and political as they are ethical and that further discussions needed to take place before any change to the availability of sex selection for non-medical purposes could eventuate.

How many couples go overseas for sex selection?

NHMRC does not collect data on this, and so is unable to provide any information.

Donor conception

Why isn't 'unknown but directed donation' permitted?

The 2017 ART guidelines acknowledge that the criteria for unknown but directed donation can be discriminatory and inequitable, and now state that this type of donation is considered unethical.

Can I be paid to donate my eggs/sperm?

In accordance with Commonwealth legislation, payment for gametes is not permitted in Australia. The reimbursement of reasonable expenses however, is permitted. Paragraph 5.4 of the 2017 ART guidelines provides guidance on the reimbursement of verifiable out-of-pocket expenses *directly* associated with the donation.

AHEC considered compensation for gamete donors and a summary of the issues considered is available in Appendix 5 of the 2017 ART guidelines.

Can I use donated eggs/sperm/embryos from overseas?

See paragraph 5.5 of the 2017 ART guidelines for guidance on the use of imported gametes.

Anyone who wishes to import donated eggs/sperms/embryos from overseas should seek the advice of an Australian ART clinic, and their own independent legal advice.

Surrogacy

Can I be paid to be a surrogate?

There is legislation governing surrogacy in all Australian states and in the Australian Capital Territory.

AHEC considers commercial surrogacy to be ethically unacceptable because it raises concerns about the commodification and exploitation of the surrogate, the commissioning parent(s) and any person born as a result of the surrogacy arrangement.

Australian surrogates may be reimbursed for verifiable out-of-pocket expenses *directly* associated with the surrogacy procedure, pregnancy or birth. See Chapter 8 of the 2017 ART guidelines.