

2023

**THE LEGISLATIVE ASSEMBLY FOR THE
AUSTRALIAN CAPITAL TERRITORY**

ASSISTED REPRODUCTIVE TECHNOLOGY BILL 2023

**EXPLANATORY STATEMENT
and
HUMAN RIGHTS COMPATIBILITY STATEMENT
(*Human Rights Act 2004, s 37*)**

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ASSISTED REPRODUCTIVE TECHNOLOGY BILL 2023

The Bill is a Significant Bill. Significant Bills are bills that have been assessed as likely to have significant engagement of human rights and require more detailed reasoning in relation to compatibility with the *Human Rights Act 2004*.

OVERVIEW OF THE BILL

The Bill contains two main aspects, as set out below.

- To introduce regulatory requirements for the clinical practice of assisted reproductive technology (**ART**) by ART providers, including registration requirements, requirements around provision of clinical services and requirements for gamete retrieval, embryo creation, storage and disposal, and limitations on multiple uses of gametes from the same donor.
- To provide for the establishment of a register of information in relation to donors (the person/s donating sperm, eggs or an embryo), intended parent(s) who use the donation for ART treatment, and the donor-conceived person born as a result of the donation.

Summary of Regulatory Requirements

The regulatory requirements to apply to ACT ART providers have been designed to largely mirror the regulatory requirements applying to ART providers in New South Wales (**NSW**), as set out in the *Assisted Reproductive Technology Act 2007 (NSW) (NSW Act)*. The ACT sits wholly within NSW and there are existing connections between the delivery of health services across the ACT/NSW border. Ensuring that the regulatory requirements align broadly with NSW promotes consistency in the delivery of ART treatment between people accessing ART treatment on either side of the border.

Similar to the NSW Act, the Bill establishes regulatory requirements for clinical practice by ART providers. These regulatory requirements are designed to broadly align with the National Health and Medical Research Council (NHMRC) *Ethical guidelines on the use of assisted reproductive technology in clinical practice and research (NHMRC Guidelines)* which govern the accreditation requirements, for ART providers, of the Reproductive Technology Accreditation Committee of the Fertility Society of Australia and New Zealand (**Fertility Society**). A summary of the regulatory requirements in the Bill follows.

Registration of ART providers	ART providers must hold ART accreditation and be registered to provide ART services. Registration can be cancelled if, for example, the ART provider ceases to be accredited.
Provision of ART services	The ART services must be performed or supervised by a doctor, and counselling must be offered.

	The ART provider must inform clients that are donating their gametes and/or embryos about the collection and storage of their information, and about the existence of and access to the donor register.
Use of gametes	<p>A gamete may be used in ART treatment (or for research) only in accordance with the consent of the gamete provider.</p> <p>Gametes cannot be used from deceased gamete providers (posthumous use) without their prior consent to the posthumous use of their gametes except in limited circumstances with court authority.</p> <p>Gametes should not be used after 15 years without formal authorisation.</p> <p>There is a limit on the use of gametes in an ART treatment where use of gametes from a single donor, would result in more than five families in the ACT created by ART treatment or ten families created by ART treatment Australia-wide.</p>
Records and Donor register	The ART provider must collect and keep records on gametes, donors and clients, and retain pre-commencement records. ART providers must provide all relevant records to the donor register, including live births as they occur.
Enforcement	The legislation provides for powers necessary for the enforcement of the regulatory provisions of the Bill including issuing improvement and prohibition notices, processes for obtaining information, entering premises, and warrants as well as matters relating to activity such as falsifying records.

Some key adaptations from the regulatory model in place in NSW have been made to ensure that the regulatory model is appropriate to the ACT. In making these changes, the aim is to provide legislation that is clear and possible to regulate; prevent unintended consequences for those accessing donor-assisted ART treatment stemming from family limits that are too restrictive; and provide legislation that is compatible with the *Human Rights Act 2004*.

Key adaptations to the NSW Act included in the Bill are as follows, with further information below.

- Mechanisms for consent of donors have been updated so that a gamete provider may not utilise consent as a vehicle to discriminate in relation to groups of persons who may utilise gametes.
- The maximum number of families that can be created via ART treatment from a single donor will be five within the ACT and a total of ten Australia-wide.

- The use of gametes following the death of the gamete provider (**posthumous use**) will be permitted with consent of the gamete provider or in certain exceptional circumstances with authority of the Court.

Donor Consent

An ART provider must only provide ART treatment consistently with the consent of the gamete provider (except in relation to authorised posthumous use) (see ss 28 and 29). The requirements for consent of the gamete provider, provide that the gamete provider's consent must (amongst other things) state the number of people to whom ART treatment may be provided, and the kinds of ART treatment for which the gamete may be used (s 29). As set out at s 29(3) of the Bill, a gamete provider will not be able to specify the classes of people who may receive ART treatment for which the gamete may be used, or to otherwise discriminate in respect of who may use the gametes.

Family Limits

Family limits are an accepted part of ART regulation across Australia as they help protect donor-conceived people from the risk of consanguineous relationships and from the psychosocial impacts of having many genetic siblings.

However, there is no nationally consistent approach to family limits in Australia, with Victoria maintaining a limit of ten women, Western Australia a limit of five families, and NSW five women, for example. There is also little clarity provided in other jurisdictions about the geographical parameters that limits are applied to, creating inconsistencies in interpretation in practice. In setting the policy position, three aims were considered important:

- Protecting the interests of donor-conceived people by limiting the total number of families that can be created within the ACT from a single donor;
- Preventing unintended consequences for those accessing donor-assisted ART treatment, stemming from family limits that are too restrictive; and
- Providing legislation that is clear and possible to regulate.

The overall finding of epidemiological analysis undertaken by ACT Health indicated that irrespective of the assumptions (which only affect the overall risk of siblings meeting each other) the risk of a chance meeting between genetic siblings increases 3.5 times when the family limit is raised from five to ten.

The Bill therefore sets the following policy positions for the ACT:

- A limit of five families created through ACT-based ART from a single donor;
- A limit of ten families created through ART in Australia from a single donor; and
- These limits may be lower if determined by the donor's consent.

Posthumous use of gametes

The Bill provides that it is an offence for an ART provider to provide ART treatment using a gamete or embryo from a person who is deceased unless the deceased person had specifically consented to the use of the gamete or embryo after their death. However, there may be some very limited circumstances under which the domestic partner of the deceased person could be permitted to use the gametes of their deceased partner to conceive a child without the deceased person's specific consent.

To ensure the Bill responds to such tragic circumstances, it is intended to permit posthumous use of gametes for ART treatment of the domestic partner of the deceased person where the use of gametes have been authorised by the court (s 37). The Bill includes a list of factors that the court should consider in making such a decision, which is proposed to include the following factors:

- whether the domestic partner has capacity to consent to the provision of the treatment;
- whether the domestic partner has undergone appropriate counselling;
- the best interests of the child to be born as a result of the treatment;
- that the gamete provider did not expressly object to posthumous use of their gametes or embryos;
- whether there is evidence the gamete provider would have supported posthumous use of their gametes or embryos by their partner; and
- any other matter the court considers appropriate.

Summary of Donor Register

As with the regulatory requirements, the requirements relating to the donor register are based off those of NSW. The donor register is designed to ensure that identifying information is collected and available to be disclosed to all people who are conceived from ART treatment after the commencement of the Bill. For a donor-conceived person, the release of identifying information of their donor is relevant to the donor-conceived person's own identity and helps them to understand their own genetic heritage. Provision of information about donors to donor-conceived people is also important to protect donor-conceived people by ensuring they can access the relevant medical history of the donor, as well as to manage the fear of, and risk of, unknowingly forming consanguineous relationships.

Key aspects of the donor register include:

Provision of information to the donor register	Within two months of the birth of a child resulting from ART, the ART provider must provide information about the donor, donor-conceived person and parents to the donor register.
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	<p>People participating in informal ART (for example, self-insemination not involving an ART clinic), may voluntarily provide information to the donor register.</p> <p>Donor-conceived people and pre-commencement/historic donors may voluntarily provide information to the register.</p> <p>Any donor or donor-conceived person may voluntarily provide information about their personal characteristics, as well as record their contact preferences.</p>
When information may be accessed	<p>Donor-conceived people over the age of 16, or who are younger but have been assessed by a counsellor to be of sufficient maturity, may access identifying information about their donors from the donor register.</p> <p>Donor information may be accessed by the parents of a donor-conceived person, soon after the birth of the donor-conceived person, except where gametes donated prior to commencement are used. This upholds the best interests of donor-conceived people to readily access available information about their genetic identity and equips families to self-determine the integration of this information into family narratives and systems.</p>
Type of information	<p>For donors - identifying information such as name, date of birth, address, donor code, physical characteristics, ethnicity, relevant medical history and any other donor-conceived offspring.</p> <p>For a person undergoing ART - information such as name, date of birth, address, and name date of birth and sex of any children resulting from the treatment.</p>
Disclosure of information from the donor register	<p>From the donor register: any person with information in the donor register can access any information about themselves; parents can access information kept for the benefit of their donor-conceived child or young person (including identifying information and various personal characteristics of their donor, except where gametes donated prior to commencement are used); mature donor-conceived people may access identifying information about their donors (in the same way that information is available to parents); and donors can access limited non-identifying information about their donor-conceived children.</p>

Some of the key changes from the NSW donor register include:

- The rights of access to information for donor-conceived people born from treatment prior to commencement of the Bill.
- The age upon which information can be accessed from the donor register by donor-conceived people, and parental access to information.

Access to information for donor-conceived people born prior to commencement

- Information about donor-conceived people born prior to commencement or their donors will not be included in the donor register unless placed there voluntarily.
- Stage 2 of the donor register (which is not included in the Bill) will review the legislation to consider options to make the donor register retrospective, which would allow the donor register to be expanded to include information related to donor-conceived people born prior to the date of commencement and their donors (this is explained in more detail below).
- Although not included in the donor register, under the Bill, donor-conceived people born prior to commencement may also access accessible information about their donor directly from the ART provider (s 76), which reflects the existing practices under the NHMRC Guidelines.
- The accessible information which may be accessed directly from the ART provider includes:
 - The donor's ethnicity and physical characteristics;
 - The donor's relevant medical history;
 - The sex and year of birth of each person born as a result of ART treatment using a donated gamete of the donor;
 - Any other information about the donor (including identifying information) if the donor has consented to its disclosure, and subject to any restrictions on disclosure stated by the donor.

Age of access to the donor register

Across Australia, there is an inconsistent approach to age of access to donor information. The NHMRC Guidelines recommend that where minors are assessed as sufficiently mature, that they be provided non-identifying and identifying information about their donors. Victoria follows this approach and includes that a less mature child can apply with the consent of a parent or guardian. Western Australia currently sets the age of access at 16 years for all donor-conceived people, with younger people granted access through the support of a parent or guardian.

Representatives of the government of Western Australia advised that Western Australia is considering reforms to release identifying donor information to recipient

parents soon after the birth of the donor-conceived person.¹ This approach upholds the best interests of donor-conceived people to readily access available information about their genetic identity and equips families to self-determine the integration of this information into family narratives and systems. Additionally, it offers a supported approach to managing this information, in place of families seeking this information independently through third-party DNA testing and social media.

It is also worth noting that people aged under 18 years are afforded many opportunities under the law, such as to work, drive a vehicle and consent to sexual relationships. Some of these will require establishing an independent identity with Government agencies, such as applying for a tax file number and paying income tax, applying for and holding a Working with Vulnerable People registration, or a learner's and provisional driver's license, and being held responsible for parking and traffic infringements, for example. In the case of sexual relationships, it may be important for them to understand their genetic identity to reduce the risk of consanguineous relationship. Many of these examples could have significant implications for the future of a young person and, for the purposes of the law, maturity has been determined at age 16 (or younger).

The Bill therefore sets the following policy positions for the ACT.

- Access to identifying information about donors who have donated following commencement of the Bill will be made available to recipient parents soon after the birth of a donor-conceived person, as this allows a donor-conceived child to be raised in knowledge of their genetic identity.
- For the release of information directly to the donor-conceived person, it is intended that identifying information of their donor be available from the age of 16 years (in line with other laws which determine that maturity has been reached at age 16).
- For donor-conceived people aged younger than 16 years, information of any donor may be accessed where the child or young person is assessed as sufficiently mature by a suitably qualified counsellor or with the support of a parent or guardian.

Commencement

The commencement of this Bill will occur in a staged manner. Part 1 (Preliminary), Part 2 (Objects and important concepts), Division 4.5 (Record keeping requirements), Division 6.1 (Preliminary), Division 6.2 (Retention of pre-commencement records), Part 11 (Miscellaneous), Part 12 (Transitional), and the dictionary will commence on the day after the Bill's notification day. This will allow the requirement for an ART provider to retain all 'pre-commencement' records for 75 years after the provision of the ART services to begin immediately, alongside the new obligations of ACT providers in relation to the collection of records. This will ensure that historic records relating to donor conceptions are not destroyed and that ART providers maintain their

¹ Department of Health, 'Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy – Final Report' *Government of Western Australia*, <Ministerial Expert Panel on Assisted Reproductive Technology and Surrogacy (health.wa.gov.au)>.

current records. Commencement of Divisions 6.1 and 6.2 on the day after notification will maximise the information which is available to donor-conceived persons born prior to commencement under Division 6.3 and ensure those records are retained whilst consideration of the policy approach to a retrospective register is underway as part of Stage 2.

Part 5 (Donor register), which establishes the donor register, will automatically commence on the first day after 12 months of the notification day, or earlier on a day fixed by the Minister by written notice. This displaces s 79 of the *Legislation Act 2001*, which provides for commencement to occur at most six months after notification. It is necessary to allow further time for the commencement of Part 5 as the design and functionality of the donor register is still being planned and will require significant ICT and security considerations prior to becoming operational. Given the sensitive and personal information forming the donor register, it will need to be designed to ensure that privacy, storage, access, and security are protected. Therefore, an extended timeframe in the commencement of the donor register is required to allow for these necessary controls and safeguards to be established.

The remaining provisions automatically commence 6 months after the Bill's notification date or will commence earlier on a day fixed by the Minister by written notice. Commencing these provisions at 6 months (or earlier by written notice) supports a phase-in period for the ART industry which will enable the industry to become familiar with the new requirements before they commence. In particular, the Bill introduces a new registration scheme that ART providers must apply for to continue providing ART services in the ACT, and as such, a delay to allow businesses to adjust is required. The Bill also provides for a number of offences against ART providers, including that an ART provider must be registered to provide ART services. The practical implication of commencing these provisions on notification instead of at 6 months would mean that ART providers would be committing an offence if not registered from that time - even if the registration scheme is not operational. A communications package will be required in the lead up to the commencement of the Bill to inform the community and support the ART providers in understanding their responsibilities under the new legislation.

CONSULTATION ON THE PROPOSED APPROACH

The ACT Health Directorate (**ACTHD**) conducted targeted consultations with key stakeholders during the development of this Bill. The targeted consultations included meetings, the dissemination of a discussion paper with opportunities for feedback, analysis of similar existing legislation in other Australian jurisdictions, and discussions with government counterparts in other jurisdictions about the development of their legislation and processes, and lessons learned.

There are currently four jurisdictions that have existing ART legislation: Victoria, NSW, Western Australia and South Australia. ACTHD has met with all four jurisdictions to gather key insights into what might work well for the ACT.

The University of NSW (**UNSW**) has provided data on donor-conceived people that will inform the development and establishment of the donor register.

Engagement with Donor Conceived Australia has provided a connection to donor-conceived people and their families, providing insight into the issues affecting this cohort that have been considered during policy development.

Key stakeholders that have been consulted include:

External stakeholders

Donor Conceived Australia; Women's Health Matters; IVF Australia; Compass Fertility; Genea; Fertility Society of Australia and New Zealand (FSANZ); Meridian; A Gender Agenda; Health Care Consumers' Association ACT; and Professor Sonia Allan OAM, University of New England.

State-based Government Agencies

The Victorian Assisted Reproductive Treatment Authority (VARTA); NSW Ministry of Health; SA Health; the WA Department of Health ART Legislative Review Clinical Excellence Division; and the QLD Department of Health.

ACT Government Agencies

- The Human Rights Commission
- Justice and Community Safety
- Canberra Health Services
- Chief Minister, Treasury and Economic Development
- Office of LGBTIQ+ Affairs,
- Access Canberra Register of Births, Deaths and Marriages
- Community Services Directorate (CSD) Office for Women

In relation to the regulatory requirements to be applied to ART providers, consultation focused on the appropriateness of adopting analogous regulatory requirements to those applicable in NSW. In response to stakeholder feedback, the Bill departs from the regulatory requirements of the NSW Act in a number of important ways, which are detailed above, but in summary include: changes to donor consent, family limits and the posthumous use of gametes.

In relation to the donor register, a significant issue which arose in consultation related to whether, and to what extent the reform will allow access for donor-conceived people who were born prior to commencement of the legislation, to identifying information of their gamete provider.

As detailed in the testimonials of donor-conceived people, the ACT Government Response, and cross-jurisdictional inquiries, the ACT Government acknowledges that

the historic practice of anonymous donation has caused considerable trauma in the lives of many donor-conceived people. However, where a gamete provider donated gametes prior to the commencement of the legislation, particularly in the circumstance where the gamete provider made that donation on the expectation of maintaining anonymity, complex human rights issues arise with respect of the impact upon such a donor's right to privacy.

In order to balance the needs of various stakeholders elucidated during consultation, such as the need for access to a donor register as soon as practicable whilst allowing for adequate consultation and provision of information to those affected, the legislation will be developed and implemented in two stages.

- Stage 1 (the Bill) involves the initial establishment of a prospective donor register which will contain the information about donors for ART treatments after commencement of the legislation. However, to maximise the information which will be available to donor-conceived people, the Bill will allow for the following.
 - A donor-conceived person to receive identifying information about their donor has been updated so that a mature donor-conceived person (that is a donor-conceived person who is over 16 years old, or if they are younger, was assessed as sufficiently mature by a suitably qualified counsellor) can access the information. Further, for any person conceived from gametes donated after commencement, parents of a donor-conceived child or young person may access the same information after the child's birth, so that the child can be raised in knowledge of their genetic heritage (ss 66 and 67).
 - For voluntary information to be provided by any donor or donor-conceived person for inclusion in the donor register so as to maximise the opportunity to permit voluntary exchanges of information (ss 54, 55 and 57).
 - Although the donor register will not be immediately retrospective, mature donor-conceived people born prior to commencement will have rights to require an ART provider under Division 6.3 to provide them with various categories of information in relation to their donor. This includes non-identifying information of the donor such as their physical characteristics, medical history and the sex and year of birth of each person born as a result of ART treatment using a donated gamete of the donor, as well as any other information (including identifying information) for which the ART provider has the consent of a donor for that disclosure. As current accreditation requirements of ART providers set by the NHRMC Guidelines, which have been in place since 2004, require that gametes are only donated where the donor consents to the release of identifying information to a person conceived from that donation, it is expected that this will provide a legal avenue to access information for any donor-conceived person born from ART treatment in the ACT from 2004.

- Stage 2 (future process) will involve consideration of the best legislative solution for expanding the register to be retrospective. For the future process, consideration will be given to how the donor register might be expanded to include information about donors irrespective of when they donated (where records have been kept), including those who originally donated under conditions of anonymity. Consideration of the best approach for Stage 2 will be undertaken through broad stakeholder and public consultation. This will be supported by a public information campaign. Research and consultation for Stage 2 is anticipated to commence in 2024.

CONSISTENCY WITH HUMAN RIGHTS

The proposed Bill has been carefully considered in the context of the objects of the *Human Rights Act 2004 (HR Act)*. Any limitations on human rights are justifiable as reasonable limits set by laws in a free and democratic society, as required by s 28 of the HR Act. Importantly, the Bill also supports and strengthens protection of several rights under the HR Act. The human rights limitations that this Bill creates are proportionate to and the least restrictive approach to achieve the overall policy objective of this Bill.

Rights engaged

This Bill engages the following rights under the HR Act:

- Section 8 – Right to equality and non-discrimination (promoted and limited)
- Section 9 – Right to life (promoted)
- Section 10 – Protection from torture and cruel, inhuman or degrading treatment etc (promoted)
- Section 11 – Protection of the family and child (promoted and limited)
- Section 12 – Right to privacy and reputation (limited)
- Section 16 – Right to freedom of expression (limited)
- Section 18 – Right to liberty and security of person (limited)
- Section 21 – Right to a fair trial (promoted)
- Section 22 – Rights in criminal proceedings (limited)
- Section 27(1) – Rights of minorities to culture (promoted)
- Section 27B – Right to work and other work-related rights (limited)

Rights Promoted

This Bill promotes the following rights under the HR Act:

- Section 8 – Right to equality and non-discrimination
- Section 9 – Right to life
- Section 10 – Protection from torture and cruel, inhuman or degrading treatment etc

- Section 11 – Protection of the family and child
- Section 21 – Right to a fair trial
- Section 27(1) – Rights of minorities to culture

Section 8 – Right to equality and non-discrimination

Section 8 of the HR Act provides that everyone is entitled to enjoy their rights without discrimination of any kind and that everyone is equal before the law and entitled to the equal protection of the law without discrimination. The donor register seeks to improve accessibility to identifying information through a consistent and centralised approach (Part 5). Prior to the proposed Bill, donor-conceived people would approach their respective ART providers for this information, but procedures around release of information varied between ART providers. A centralised approach seeks to reduce discrimination around access of information, particularly in relation to any stigmas faced by people identifying as LGBTQI+ by ensuring that donor-conceived people in the ACT have a universal experience when requesting for information. Furthermore, s 29 outlines that a gamete provider's consent must not limit use of a gamete in relation to a person's protected attribute. A person's protected attributes are outlined in s 7 of the *Discrimination Act 1991*.

Section 9 – Right to life

Section 9(1) of the HR Act recognises that everyone has the right to life and that no-one may be arbitrarily deprived of life. The right to life requires the ACT Government to safeguard life where there may be a real and immediate direct or indirect risk to life. The Bill acknowledges that without a regulated approach to ART treatment, there may be outcomes that pose a risk to the health, safety and wellbeing of people seeking ART treatment, donor-conceived people, donors, and the broader community. The Bill's regulatory framework for ART promotes the right to life on the basis of improving consistency in ethical and health standards of ART providers in the ACT and preventing any adverse incidents that might occur without proper oversight. The Bill requires ART providers to be appropriately qualified and registered (Part 3). The regulatory framework will generally increase the attainable standard of health of children who are born from ART procedures, as well as anyone undergoing such procedures and will reduce any risk to life that may otherwise occur in a legally unregulated setting.

The Bill addresses the risk of a donor-conceived person unknowingly forming a consanguineous relationship with a half-sibling or donor through provisions for access to information (Part 5), a provision limiting the maximum number of families created through a donated gamete (s 40), and a provision prohibiting the use of a gamete to create an embryo with a close family member (s 42). These provisions promote the right to life in addressing a significant public and social risk of unknowing consanguineous relationships, especially in circumstances where a consanguineous

relationship would bear children, leading to the risk of the birth of children with genetic or chromosomal abnormalities, which can cause a threat to life.

A right to life is also promoted where the Bill provides authority for ART providers and the director-general to release personal health information that may prevent or reduce a serious and imminent risk to anyone's life or physical, mental or emotional health or that may result in that person or the person's descendants preventing, or limiting the effect of, life-threatening genetic or hereditary conditions (ss 25 & 68). Given that there is a threat to a person's life, or other medical consequence to the person, these provisions will apply irrespective of when the donor-conceived person was born, or whether the donor has consented to release of information in such circumstances.

Members of the public can also access a register of registered ART providers (s 20) to be able to easily identify whether services are compliant with the regulatory scheme. This public register will increase visibility and prevent a person unknowingly receiving ART services from an unqualified provider which poses a direct risk to the health, safety and wellbeing of that person.

Section 10 – Protection from torture and cruel, inhuman or degrading treatment etc

Section 10 of the HR Act provides that everyone is entitled to protection from torture and cruel, inhuman, or degrading treatment. Section 10(2) provides that no-one may be subjected to medical or scientific experimentation or treatment without their free consent. The Bill promotes the right to not being subject to medical treatment without consent, by requiring an ART provider to inform a person seeking ART services about a list of matters and confirm that the person has understood those matters (s 24).

The right to not be subject to medical treatment without consent, is also promoted as the Bill requires that a gamete be used only in accordance with the consent of the gamete provider and sets out when that consent may be modified or withdrawn (ss 28, 29 & 30). These provisions will ensure that a person's gametes can only be used in accordance with their explicit instructions and consent. For example, if a person dies their gametes can only be used if that person consented to their posthumous use or in other very limited and exceptional circumstances (ss 36 & 37). There is also a positive obligation on the ART provider to confirm consent in certain circumstances (s 32). The right not to be subject to medical treatment without consent is also supported by the mandatory obligation on ART providers to ensure that counselling services are available for gamete providers and people receiving treatment prior to ART treatment being provided (s 23), to ensure the implications of the ART treatment are fully understood by the relevant parties involved.

Section 11 – Protection of the family and child

Section 11 of the HR Act provides that the family is the natural and basic group unit of society and is entitled to be protected by society. Section 11(2) provides that every

child has the right to the protection needed by the child because of being a child, without distinction or discrimination of any kind.

The Bill will interact with the right to protection of the family and child. The establishment of the donor register seeks to promote the right of donor-conceived children to know their genetic identity. The right for a child to know their identity is promoted by Article 8 of the United Nations Convention on the Rights of the Child:

Article 8

- 1. States Parties undertake to respect the right of the child to preserve his or her identity, including nationality, name and family relations as recognized by law without unlawful interference.*
- 2. Where a child is illegally deprived of some or all of the elements of his or her identity, States Parties shall provide appropriate assistance and protection, with a view to re-establishing speedily his or her identity.*

A lack of information around heritage can cause significant distress among donor-conceived people, and within families. The rights of the child are interpreted by reference to the rights contained in the Convention on the Rights of the Child, which requires that the best interests of the child must be a primary consideration in any decision that affects the child. 'Best interest' encompasses requirements of health, education, cultural and kinship relations, and opportunities for social and personal development.

Allowing for identifying information of donors who donated post-commencement to be shared with the parents of a donor-conceived child or young person will allow that child to be raised in the context of their genetic heritage and mitigate the distress such a child suffers because of uncertainty around genetic identity.

The Bill promotes the best interests of the child by ensuring a centralised source of heritage information through the donor register for donor-conceived people, which will enhance access to cultural and kinship identity information. The central storage of information through the donor register will also improve access to medical information (including access to medical information about children), which promotes this right by improving the health outcomes and wellbeing of children.

The protection of the family may extend to a person knowing the identity of their biological parent where they are born as a result of donor conception. This is supported by the United Kingdom case of *Re T (a child)* [2001] 2 FLR 1190 in which the court ordered DNA testing despite the mother's objection. The court relied on the right to family life in Article 8 of the European Convention on Human Rights and stated that any interference with the rights of the mother and father was 'proportionate to the legitimate aim of providing the child with the possibility of certainty as to his real paternity'. The Bill therefore promotes both the protection of families and children by

providing all persons born as a result of donor conception with the right to know their genetic parentage.

The proposed Bill also engages in the right to the protection of family and children by seeking to reduce the risk of unknowing consanguineous relationships. Such a risk may be significant within the Territory, given the proportionally smaller population and the higher number of donor-conceived people in existence. The proposed Bill seeks to promote the long-term wellbeing of donor-conceived people and their families by introducing safeguards such as limiting the number of families created from a gamete to reduce unknowing consanguineous relationships (s 40).

The Bill requires ART providers to obtain from donors and provide for inclusion in the register, mandatory information, including identifying information about the donor, and non-identifying information about the donor, such as relevant medical history (ss 46 & 53). This Bill does not require ART providers and donors to provide the relevant information in relation to gametes used for ART treatment before commencement of the Bill. Whilst Stage 2 will consider access to mandatory information in respect of ART services which occurred prior to commencement, the fact that the Bill does not require ART providers to provide retrospective information for inclusion in the donor register, will mean that information relating to donor-conceived people born prior to commencement is not available from the donor register. Due to the lack of retrospective application of the Bill, donor-conceived people born before commencement of the legislation will only be able to access information in the donor register where that information has been voluntarily provided.

However, mechanisms are built into the Bill to maximise the information available for donor-conceived people born after commencement of the Bill, and to safeguard existing records of ART providers whilst consideration of a donor register with retrospective effect is underway for Stage 2.

These include the ability for donor-conceived people and donors to voluntarily provide certain information to the donor register (ss 54, 55 and 57) and to require the release of information that is contained in the register to a mature donor-conceived person, or their parent (ss 66 and 67).

Further, a mature donor-conceived person born prior to commencement will have rights under Division 6.3 to require an ART provider to provide them with various categories of information in relation to their donor. This includes non-identifying information of the donor such as their ethnicity and physical characteristics, medical history and the sex and year of birth of each person born as a result of ART treatment using a donated gamete of the donor, as well as any other information (including identifying information) for which the ART provider has the consent from a donor for that disclosure. As current accreditation requirements of ART providers, which have been in place since 2004, require that gametes are only donated where the donor consents to the release of identifying information to a person conceived from that

donation, Division 6.3 will in effect provide a legal avenue to access information for any donor-conceived person born from ART treatment in the ACT after 2004.

To ensure that existing ART providers maintain their current records and maximise the information which is available to donor-conceived persons born prior to commencement, Division 6.2 requires ART providers to retain pre-commencement records for the period of 75 years from the date an ART service was last provided. These provisions are intended to safeguard existing records to allow donor-conceived people born prior to commencement to exercise their rights under Division 6.3, and to ensure those records are retained whilst consideration of the policy approach to a retrospective register is underway as part of Stage 2.

Section 21 – Right to a fair trial

Section 21 of the HR Act provides a right to fair trial, encompassing the right to fair hearing which is concerned with procedural fairness, and equal access to proceedings.

This right is promoted in the Bill through the protection for officials from liability when engaging honestly and without recklessness in the exercise of their functions under the Bill (s 121).

Section 27(1) – Rights of minorities to culture

Section 27(1) of the HR Act protects the right for anyone who belongs to an ethnic, religious or linguistic minority to enjoy their culture, to practice their religion, or to use their language. The Bill promotes this right by providing donor-conceived persons with the right to access information about their donor and their heritage. This in turn grants a donor-conceived person the opportunity to understand and explore the culture related to that heritage. The difficulties that donor-conceived persons may experience in relation to accessing information about their donors due to systems of anonymity mean that many do not know the identity of their biological father, mother, or parents, and they may also be deprived of non-identifying information such as the cultural extraction of their forebears, leading to a sense of "lost culture" for some donor-conceived people. The proposed Bill will provide a centralised source of information through the donor register for donor-conceived people, which will enhance access to heritage information. This in turn then promotes a greater opportunity for a donor-conceived person to explore their cultural background and kinship if they so wish. Donors, irrespective of whether they donated their gametes before or after commencement of the Bill, can also voluntarily submit information about their personal characteristics, such as religious affiliations or languages spoken to the donor register (s 57).

Rights Limited

This Bill limits the following rights under the HR Act:

- Section 8 – Right to equality and non-discrimination
- Section 11 – Protection of the family and child
- Section 12 – Right to privacy and reputation
- Section 16 – Right to freedom of expression
- Section 18 – Right to liberty and security of person
- Section 22 – Rights in criminal proceedings
- Section 27B – Right to work and other work-related rights

Section 8 – Right to equality and non-discrimination

1. Nature of the right and limitation (ss 28(2)(a) and (c))

Section 8 of the HR Act provides that everyone is entitled to enjoy their rights without discrimination of any kind and that everyone is equal before the law and entitled to the equal protection of the law without discrimination. The Bill engages this right as it may have a more significant impact upon the LGBTIQ+ community than other sectors of the community, given the necessary role of ART treatment in conceiving children for a significant portion of this community. In a similar way, the Bill may have disproportionate impact on single women, and given that relationship status is a protected attribute under the *Discrimination Act 1991*, this will also limit the right to equality and non-discrimination.

Overall, the increased regulation and requirements on ART providers may impact the ease of access to donated gametes, which may make ART treatment less accessible. The obligations imposed on ART providers under Part 3 of the Bill may increase the costs of ART businesses because of the increased compliance requirements, and this may flow through to increased costs for consumers.

In particular, an issue raised in consultation was that the limitation of the use of a single donor's gametes where an ART provider becomes aware that it may result in more than five families with children born from ART treatment in the ACT and 10 families with children born from ART treatment Australia-wide (s 40), may result in fewer donor alternatives for people seeking ART treatment.

The resulting impact on cost or accessibility of the service by reason of the new regulatory requirements, including the family limitation, will have a more significant impact on single women, and those portions of the LGBTIQ+ community for whom ART treatment is necessary for conception of children.

2. Legitimate purpose (s 28(2)(b))

The overall objective of the regulatory regime is designed to promote and protect the health and well-being of donor-conceived people and people undergoing ART treatment and to ensure that the rights of donor-conceived people to know their genetic heritage are protected.

Additionally, the objective for the provision limiting ART treatments to create children from donors above the specified limits is to address and prevent a significant public and social risk of unknowing consanguineous relationships, and to address the psychosocial impacts of consanguineous relationships for donor-conceived people.

3. Rational connection between the limitation and the purpose (s 28(2)(d))

While the new regulatory requirements, including the family limitation, will have a more significant impact on single women and the LGBTIQ+ community than other sectors of the community, the scheme is ultimately aimed at protecting the health and safety of the same people whose rights have been limited. Without introduction of a regulatory regime for ART providers, there is no way to achieve legal protection to promote the health and well-being of donor-conceived people and people undergoing ART treatment and ensure the rights of donor-conceived people to know their genetic heritage are protected. Therefore, any limitations on the right to equality and non-discrimination are balanced and rationally connected to protecting the health and wellbeing of the same people whose rights may be limited.

The limitation contemplated in s 40 is necessary to ensure that ART providers exercise due diligence in ensuring that a donated gamete is not used past prescribed limits. A limit on the maximum use of a gamete reduces the risk of half siblings incidentally meeting within a given population, without knowing that they are related. Therefore, this limitation on the right to equality and non-discrimination is directly linked to the policy objective of reducing the likelihood of individuals forming an unknowing consanguineous relationship.

4. Proportionality (s 28(2)(e))

Family limits

In relation to the per family limit specifically (s 40), this limitation is fixed (no more than five families with children born from ART treatment within ACT and no more than 10 families with children born from ART treatment Australia-wide) by the Bill, with no flexibility available.

Family limits are considered a means through which to reduce the likelihood of inadvertent intimate relationships between genetic siblings and other close relatives (consanguinity) and to limit the psychosocial impacts on donor-conceived people by having a large number of genetic siblings. There is no nationally consistent approach

to family limits in Australia and population sizes between Australian jurisdictions also differ significantly, which affects the determination of a reasonable limitation. Research conducted by ACTHD Epidemiology demonstrated the higher risk of incidental meeting between genetic siblings at a ten-family limit when compared to a five-family limit. This is further outlined above in the covering overview of the Bill. Conversely, stakeholder feedback demonstrates that overly restrictive family limits (such as a blanket five-family limit in all locations, not just the ACT) can lead to reduced accessibility and affordability of donor-assisted ART treatment. One further unintended consequence of imposing unduly restrictive family limits that disrupt supply of donor gametes, is to drive interest in the unregulated online gamete trade. This unregulated online trade presents several health, legal and psychological risks for recipient parents, donor-conceived people and donors, including unknown sperm quality; risk of genetic and infectious disease; lack of legal contracts between parties; lack of clarity regarding parentage; and lack of regulation of the number of families being created by a single donor.

The two-pronged proposed limitation in the Bill serves as the least restrictive means to balance between effectively reducing donor alternatives and preventing unknowing consanguineous relationships. A five-family limit within the ACT reduces the risk of chance meetings between siblings from a single donor, and a ten-family limit Australia-wide dilutes the risk of chance meetings across greater geographical distances, while ensuring that supply of donor gametes is not unduly disrupted.

The limit on “families” instead of “women” that can access a single donor’s gametes ensures that lesbian and female queer partnerships where both partners may wish to carry a pregnancy assisted by the same donor are not inadvertently disadvantaged by this provision. For example, a limit on the number of “women” instead of “families” would mean that if each woman in a queer partnership were to access the same donor’s gametes, it would count as twice used. A family limit, conversely, ensures that as both partners are within the one family, the gametes would only be counted as once used.

Regulation of ART treatment

In relation to the disproportionate impact of the regulatory regime more generally on single women, and those portions of the LGBTIQ+ community for whom ART treatment is necessary for conception, the regulatory aspects of the regime have been designed to reflect the requirements of the NHMRC Guidelines. As all existing ART providers in the Territory are accredited by the Fertility Society, and as a requirement of that accreditation are required to comply with the NHMRC Guidelines, the additional regulatory burden on ACT providers is minimised.

Minimising the increased burden on ART providers in turn minimises the disproportionate impact on single women and the LGBTIQ+ community, as impacts on cost and accessibility are minimised. ART is regulated in other Australian

jurisdictions including Victoria, NSW, Western Australia and South Australia and the regulatory requirements are relatively similar across all Australian jurisdictions that have introduced them. In Australia, there is currently no national legislation specifically regulating ART services as legislative responsibility lies with the states and territories.

Given the lack of legislation governing ART in the ACT prior to this Bill, there are no robust enforcement mechanisms in place if an ART provider did not comply with the NHMRC Guidelines or other accreditation requirements. Providers in the ACT have self-regulated to date, and this arrangement leaves no legal recourse should a provider fail to meet these requirements. The current lack of regulation poses a risk to the safety, health and wellbeing of donor-conceived persons and persons seeking ART treatment. The proposed regulatory scheme is the least restrictive means to address this risk.

The Bill is unlikely to result in major changes to current services and practices for ART clients and providers in the ACT as it was designed to complement the NHMRC Guidelines and will enshrine in law the clinical and ethical requirements and social expectations for all ART providers operating in the ACT.

The limitation on the right to equality and non-discrimination is therefore reasonable and justifiable in accordance with s 28 of the HR Act.

Section 11 – Protection of the family and child

1. Nature of the right and limitation (ss 28(2)(a) and (c))

The right to protection of the family and children is outlined in s 11 of the HR Act and provides that, “the family is the natural and basic group unit of society and is entitled to be protected by society”. This right has its origins in Article 23(1) of the International Covenant on Civil and Political Rights, which recognises that families should not be “subjected to arbitrary or unlawful interference with [their] privacy, family, home or correspondence...” by public authorities. The definition of “arbitrary” in this context is broader than its ordinary meaning: the UN Human Rights Committee describes it extending to actions consistent with laws:

“...arbitrary interference can also extend to interference provided for under the law. The introduction of the concept of arbitrariness is intended to guarantee that even interference provided for by law should be in accordance with the provisions, aims and objectives of the Covenant.”

The Bill may engage with and may limit the rights of the gamete provider to family as the gamete provider can only modify or withdraw their consent up until a certain point (s 30). This interferes with a gamete provider’s ability to make decisions around who can genetically consist of their family. Gamete providers may not modify or withdraw consent once the gamete or embryo is placed in a person’s body or if an embryo has been created using the gamete (s 30).

The rights to family may also be limited in the case of a person conceived from a gamete after the death of the gamete provider. Where posthumous use by the domestic partner is authorised by the court (s 36), the right to family of the child born as a result will be limited as they will not have the opportunity to be raised with their father. Where a person is born from gametes donated by a deceased donor (with that donor's consent), there is some engagement with the right to family, as the donor-conceived person would be entitled to information about their genetic identity but will not have the opportunity to contact their donor should they wish.

2. *Legitimate purpose (s 28(2)(b))*

The overall objective of the regulatory regime is designed to promote and protect the health and wellbeing of people undergoing ART treatment and donor-conceived people. The legitimate purpose for allowing the posthumous use of a gamete without the explicit consent of the gamete provider is to ensure that the wishes of the deceased gamete provider to create a family and the wishes of the surviving domestic partner to achieve that may be given effect, or if the Court has otherwise considered it is appropriate to authorise the use (s 37).

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

It is necessary that the legislative framework regulating ART in the ACT include provisions regarding when consent for the use of donated gametes can and cannot be withdrawn. Once the gamete has been placed in a person's body, that person's right to make autonomous decisions about their own body and reproductive functions is engaged. Modification or withdrawal of consent by the gamete provider at that point in time would (if the treatment were successful) involve a termination of pregnancy.

When an embryo is created from multiple persons' genetic material, any withdrawal or modification of consent would mean that the embryo could no longer be used. This would impact the rights of the other parties to family and may breach their consent.

The limitation of the rights of the gamete provider caused by the threshold upon which a gamete provider is no longer able to withdraw consent is in each case, a direct consequence of the threshold being necessary for the legitimate purpose of protecting the rights of the person undergoing ART treatment.

Where posthumous use of gametes is authorised by the court (s 36), the limitation on the right to family of the person conceived from a gamete after the death of the gamete provider is a direct consequence of the legitimate purpose of ensuring that the wishes of the deceased gamete provider to create a family and the wishes of the surviving domestic partner to achieve that may be given effect as the intention of the posthumous use of a gamete is to conceive a child.

4. Proportionality (s 28(2)(e))

The interference with a gamete provider's ability to choose the composition of their genetic family once withdrawal or modification of consent is no longer permitted under the Bill, is necessary to protect the bodily autonomy of the person to which the gamete or embryo is being implanted in. In the case where an embryo has been created using a gamete provider's gamete, a gamete provider will also not be able to withdraw or modify their consent once the gamete has been created. This is because that embryo will consist of genetic material from multiple people, each with rights to family that must be balanced.

The threshold upon which a gamete provider can withdraw consent in respect of the use of their gametes, offers the maximum possible flexibility of a gamete provider to withdraw consent, until the withdrawal of that consent would pose a significant limitation of the rights of someone else.

Further, the Bill provides for several safeguards to ensure that a gamete provider's right to family is not unreasonably limited. The points in time where consent is no longer able to be modified or withdrawn are set out clearly in the Bill and no discretion is permitted. Gamete providers donating with an ART provider regulated by the Bill will be notified as to the points in time when they can no longer withdraw or modify consent as part of a package of information provided to them prior to an ART provider obtaining their gametes (s 24). Counselling services will be offered to gamete providers before undergoing any ART treatment to ensure that the consent obtained is fully informed and to ensure that the gamete provider has capacity to understand and make decisions in relation to the treatment (s 23).

Therefore, the provisions which limit the modification or withdrawal of a gamete provider's consent, and consequently their right to family are reasonable and proportionate to the legitimate purpose of balancing the rights to the other parties involved in the ART treatment.

Strict parameters are provided for when posthumous use of gametes is permitted. Ordinarily, posthumous use is only permitted if the gamete provider had consented to the use of their gametes posthumously and if the person undergoing ART treatment has also consented to the treatment. Without the deceased person's consent, posthumous use is only permitted by the domestic partner of the deceased with the authorisation of the court (s 37). The Bill provides for a list of factors which the court must consider in their decision making, including whether the domestic partner has capacity to consent to the provision of treatment, whether the domestic partner has undergone appropriate counselling, the best interests of the child to be born, that the gamete provider did not expressly object to the posthumous use, whether the gamete provider would likely have supported the posthumous use of their gametes, and any other matters the court considers appropriate (s 37). The right to enjoy family life for a person conceived from ART treatment authorised by the court is therefore not arbitrarily limited as the framework has been carefully framed to ensure that

posthumous use is only permitted without consent in very exceptional circumstances, and subject to appropriate safeguards (s 37).

To the extent that all posthumous use of gametes limits the right of a donor conceived person to be able to contact their donor, the limitation on a person conceived from a deceased person's gametes is not fundamentally different to other circumstances outside of ART where a child may be born whose donor has passed away after conception, or who is uncontactable or has expressed a preference for no contact. Such an individual will retain all their rights to access information about their genetic heritage.

Section 12 – Right to privacy and reputation

Nature of the right (s 28(2)(a))

Section 12 of the HR Act protects individuals from unlawful or arbitrary interference with privacy, family, home, or correspondence.

Right to privacy impacted by donor register

1. *Nature of the limitation (s 28(2)(c))*

The Bill engages with the right to privacy as it provides for the collection, storage, use, and disclosure of personal information and personal health information of donors, donor-conceived people, and their broader family and biological relations.

Disclosure to a mature donor-conceived child

The right to privacy of information of donors is limited in a balance with the right of donor-conceived people to know their heritage. The Bill enables donor-conceived people to obtain identifying information about their donor from the donor register without the consent of the donor. The Bill provides that an ART provider must provide mandatory information about the donor to the director-general for inclusion into the donor register within 2 months after becoming aware that a child has been born alive as a result of the treatment (s 53). The director-general is required to disclose any mandatory information provided under s 53 to a mature donor-conceived person who requests it (s 66).

However, all donors who donate gametes with an ART provider regulated by the Bill, will have donated in knowledge of information sharing requirements of the Bill and have understood those requirements (s 24). Donors who have not donated via a regulated ART provider, such as international donors, or donors who donated prior to the commencement of the Bill, may not be explicitly aware that information will be shared via the donor register, but would have donated in the general knowledge that their identifying information would become available to a child born from the donated gametes. This is because the accreditation requirements for ART providers, require

that donated gametes must not be used unless the donor has consented to the release of their identifying information to any donor conceived person born from that donation.

Accordingly, donors would have an expectation and understanding that identifying information about themselves may be released to a person conceived from that donation. However, a limitation arises as where a donor has donated gametes, they will not be entitled to withdraw their consent for identifying information to be disclosed to a person conceived from the donated gametes, or the parents of such a child. The consent of a gamete provider can only be withdrawn where the donor also withdraws consent for their gametes to be used entirely - and this may only occur for gametes that have not already been used in an ART treatment (s 30).

The Bill may interfere with the families of donors and donor-conceived persons. Although the Bill does not alter the legal status of familial relationships, the disclosure process of a donor's identifying information may impact a donor and donor-conceived person's family relationships. Some donors may not have told their families about their donor status and may have some trepidation that the release of identifying information could impact adversely on their family relationships.

Disclosure of identifying information through the donor register is also likely to lead to identification of persons other than the donor, including the donor's relatives and any donor-conceived siblings, and so the impact of the Bill on the right to privacy is not insignificant.

Whilst a donor or a donor-conceived person may have consented to or donated in awareness of the requirements for the disclosure of their identifying information, any of the donor's or donor-conceived person's relatives who can be subsequently identified, would not have provided their consent.

Disclosure to parents of a donor conceived child

Section 67 of the Bill allows disclosure of the identifying information of a donor who donated after commencement of the Bill to the parent of a donor-conceived child born as a result. Specific privacy issues arise in relation to the disclosure of mandatory information to the parents of a donor-conceived child. Any donor within the jurisdiction of the Bill will be made explicitly aware of the disclosure obligations in relation to the donor register, including that disclosure of their identifying information may be made to the parents of a donor-conceived person after the birth of the child (s 24).

However, as the ACT is the first jurisdiction in Australia to introduce mandatory disclosure of information to the parents of a donor-conceived child, donors who donated outside the protections of the Bill, may not have had an expectation that identifying information would be released to the child's parents after the birth of a child.

Other privacy impacts

The Bill also allows a mature donor-conceived person, or the parent of a donor conceived child or young person to voluntarily include the donor code of the donor (s 55). This limits the donor's right to privacy as a donor code is usually linked to the donor's identifying information in a record-keeping system.

Section 59 of the Bill may also limit a person's right to privacy as it provides for the director-general to enter information into the donor register on their own initiative in limited circumstances, and where consent is not necessary. Section 68(1) of the Bill allows the director-general to, on their own initiative, disclose information entered under ss 59 or 60 to a person who would be entitled to be given the information under Part 5.

2. *Legitimate purpose (s 28(2)(b))*

The overall objective of the regulatory regime is designed to promote and protect the health and wellbeing of donor-conceived people and people undergoing ART treatment and to ensure that the rights of donor-conceived people to know their genetic heritage are protected.

The limitation of the right to privacy is intended to address the legitimate purpose of allowing any donor-conceived person of sufficient maturity, or parents of a donor-conceived child, to understand their genetic heritage by obtaining identifiable information about the donor. Allowing a donor-conceived person to obtain this information promotes the rights of the child to know about their identity and heritage. Providing access to information to the parents of a donor conceived child will allow those parents to raise their donor conceived child in the knowledge of that child's genetic heritage.

The right to privacy of a donor's other donor-conceived children is limited to serve a legitimate purpose in addressing a significant public and social risk of unknowing consanguineous relationships.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

The limitation of a donor's right to privacy occurs as a direct result of disclosure and use of their information to enable donor-conceived people to understand their genetic heritage.

The donor register will consist of several kinds of information – information mandatorily provided by ART providers, and voluntary provisions of information by donor-conceived persons or donors (ss 53-58). The kinds of information that are mandatorily provided by an ART provider include identifying information about the donor including their full name, address, date of birth and non-identifying information including the donor's place of birth, ethnicity, physical characteristics, medical history,

and the sex and year of birth of each donor-conceived offspring born as a result of ART treatment using a donated gamete of the donor (s 53).

For a donor-conceived person, the release of identifying information of their donor is relevant to the donor-conceived person's ability to understand their own genetic identity. The disclosure of the donor's name, address and date of birth is necessary to ensure that the donor may be identified by the donor-conceived person, which in turn allows the donor-conceived person to better understand their own identity, and to provide a pathway for contact to be made should both parties wish. The provision of the donor's ethnicity and physical characteristics further allow the donor-conceived person to understand their genetic heritage, and also explore the cultural background and kinship associated with their genetic heritage if they so wish. The provision of medical history, and information about the sex and year of birth of other donor siblings is necessary to ensure that risks to the health of a donor-conceived person by reason of their genetic parent, and risks in relation to unknowing consanguineous relationships can be managed by the donor-conceived person. This information about the donor as well as any voluntary information, must be disclosed to a mature donor-conceived person upon application.

Disclosure of both identifying information and non-identifying information of a donor is necessary to achieve the legitimate purpose of allowing a donor-conceived person to obtain a full understanding of their genetic heritage.

A donor may voluntarily include their donor code in the donor register and a mature donor-conceived person or the parent of a donor-conceived child or young person may voluntarily include the donor code of the gamete donor (ss 54 & 55). The voluntary sharing of donor codes is necessary to establish linking of donors and donor-conceived people, especially in circumstances where historical donor anonymity has resulted in the donor code being the only information about their donor available to a donor-conceived person.

Stakeholder feedback has demonstrated that for some donor-conceived people, there is substantial distress associated with an inability to obtain information about their donor. Feedback demonstrated that there was a clear desire for donor-conceived people to have access to both identifying and non-identifying information about their donor, and the associated stress experienced when this information is unable to be accessed. Parents of donor-conceived people spoke about being discouraged from telling their children that they were donor-conceived, due to the inability to access information about their donor. This has flow-on effects for the wellbeing of donor-conceived person who learn about the nature of their birth later in life. The inclusion of a fulsome set of information in the donor register allows for increased accessibility of that information which is managed through a central point. This would decrease the risk of any lost or missing records and ensure that all future donor-conceived people in the ACT have a universal experience when requesting for information about their heritage.

Sections 59 and 68(1) are intended to ensure the accuracy of the information in the donor register which is necessary to achieve the legitimate purpose of ensuring that the rights of donor-conceived people to know their genetic heritage are protected. Sections 59 and 68(1) allow the director-general to fill in any gaps in the donor register where that information is part of the kind of information which must be provided to the director-general by an ART provider under s 53, and subsequently disclose that information. In other words, the information to be provided under s 59 would be information which in the usual course would have been provided by the ART provider. Under s 59, the director-general can only enter information into the donor register which was sourced from an ART provider (for example where they provide the information, there is an irregularity in how it is provided), a donor about themselves (for example where the information should have been provided by the ART provider, but was not), by a donor-conceived person about themselves (for example where the ART provider was not able to contact the person who received treatment to confirm a live birth), by parents of a donor-conceived person, or from the register-general via the information sharing provisions under s 62, or by a direction to a health services provider under s 61. For ss 59 and 68(1), the power for the director-general to enter and disclose this information on their own initiative relates to the overall purposes of establishing the donor register, as it will enable quality control of the donor register and ensure that accurate and current information is provided to an applicant. It is necessary to the efficacy of the donor register to provide for a mechanism for the director-general to fill in the gaps in the donor register, as this will improve the accuracy and completeness of information which is available to donor-conceived people, and mitigate risks of a donor-conceived person not being able to access the information to which they are entitled to under the Bill.

4. Proportionality (s 28(2)(e))

Disclosure to mature donor conceived people generally

As set out above, all donors who donate gametes with an ART provider regulated by the Bill, will have donated in knowledge of the information sharing requirements of the Bill and have understood those requirements (s 24). Donors who have not donated via a regulated ART provider, such as international donors, or donors who donated prior to the commencement of the Bill, may not be explicitly aware that information will be shared via the donor register, but would have donated in the general knowledge of and consent to their identifying information becoming available to child born from the donated gametes once they were sufficiently mature.

Although it is unlikely that all donors not subject to the protections of the Bill were or will be aware of the specific mechanism of disclosing personal information to a donor-conceived person via a donor register at time of donation, these donors will have donated their gametes on the basis that the donor-conceived person will have access to their information. International and domestic trends for ART have moved away from donor anonymity and towards open and transparent disclosure, and donors

will have been aware of this and will have chosen to donate in this context. All other Australian jurisdictions with ART legislation in place, have facilitated the keeping of donor registers, and so it is likely that domestic donors and international donors donating to Australia, would have the expectation that the mechanism for disclosure could include a central register.

The most significant impost on the privacy of a donor comes from the inability of the donor to withdraw consent to their details being included in the donor register, and the associated risk that persons other than the donor may become identifiable. However, all donors will have knowledge or expectation of this prior to donating gametes and so will be able to make an informed decision about whether to become a donor.

Although the Bill does not provide for disclosure of information to a donor-conceived person of anyone's information other than their donor and very limited non-identifying information of their donor-conceived half siblings, a donor-conceived person could potentially identify a donor's other family members through social media and the internet.

As set out above in relation to the rational connection, disclosure of the types of information available to donor-conceived people from the register is limited to only information necessary to mitigate the harm that might be suffered by a donor-conceived person from not understanding their genetic heritage.

The Bill provides for a number of safeguards in order to not unduly limit a donor and their family's right to privacy. Protections include that the donor register must not be made publicly available, and only very limited and specific people can apply to obtain information. Therefore, although the release of information may lead to the possibility that persons other than the donor are able to be identified, the pool of applicants that such information is released to remains tightly controlled. This will limit the impact on any associated persons, such as the donor's family, becoming incidentally identifiable in the course of releasing identifying information about the donor.

Access to identifying information is limited to the parents of donor-conceived people, or donor-conceived people above the age of sixteen, or donor-conceived people who are assessed as sufficiently mature.

The test for sufficient maturity includes the ability to understand and comply with contact preferences and understand that the donor has no parental rights or responsibilities (s 51). Although a donor-conceived person will be able to obtain identifying information about a donor without the donor's consent, the donor will have the option of specifying their contact preferences and regulate the contact they wish to have (if any) (s 58). This is also relevant to the limitation on a donor's privacy by allowing a donor-conceived person (or their parents) to voluntarily provide their donor's donor code in the register. The provision of the donor code is a necessary limitation as the donor code may be the only source of information a donor-conceived person has about their donor. Allowing for both the donor and the donor-conceived person to

submit the donor code into the donor register will allow for linkages and identification of donors, where it previously may not have been possible. The limitation on the right to a donor's privacy is safeguarded as the director-general will only be able to disclose this information to the donor (s 65) and the donor may still specify their contact preferences (s 58).

The information on the donor register would also not be available under the *Freedom of Information Act 2016*. To safeguard the privacy of donors, s 58 of the Bill provides that donors and donor-conceived people may specify their preferred contact arrangements. For example, a donor may specify that they only wish contact to be made via electronic mail. Although, the regime does not provide for penalties for breach of contact preferences, the inclusion of an ability to specify the manner of contact allows appropriate expectations to be set in relation to the mechanics of contact between the donor and the donor-conceived person, which is intended to minimise the impact on families of donors.

The Bill does not collect or disclose information about a donor's family. Incidental identification of a donor's family through social media is safeguarded by the tightly controlled pool of applicants for this information and the Bill provides for provisions which will allow a donor to specify their preferred contact arrangements. The approach taken represents the least restrictive means to achieve the legitimate purpose of enabling a donor-conceived person to access information about their identity.

Specific issues in relation to donor conceived children

Section 67 provides that identifying information about the donor must be provided on application of a parent of a donor-conceived child or young person, in the same way as it would to a mature donor-conceived person. This promotes the best interests of the child as it will allow the person with parental responsibility for a donor-conceived child to raise their child in knowledge of their child's genetic heritage without altering the legal familial relationship. Section 67 also balances the impact on the donor's family by ensuring that the information is provided to an adult with capacity understand and abide by the contact preferences of a donor.

However, current consent processes at international and domestic donor banks for disclosure of a donor's information, generally do not contemplate a donor's information being shared with the parents of the donor-conceived child or young person. The ACT is the first jurisdiction in Australia to facilitate disclosure of a donor's information to the parents of a donor-conceived child or young person, so that the child can be raised with full knowledge of their genetic identity.

Therefore, donors who at the time of donation lacked the specific awareness of the donor register, may not have contemplated that their information might be disclosed to a donor-conceived person's parent, or would be expecting to be contacted by those parents. In order to safeguard these donors' rights to privacy, the access of parents to a donor's information will only be in relation to the donation of gametes post-

commencement (s 67). Donors donating post-commencement will be informed of the donor register and obligations to disclose to parents of donor-conceived children under the Bill at the time of their donation (s 24). Applying this requirement to donors following commencement will also provide the opportunity for gametes to be sourced following commencement in a manner consistent with updated donor consents to reflect the access to be provided to the parents of donor conceived people.

Other privacy impacts

Sections 59 and 68(1), which provide a mechanism for the director-general to fill gaps in the register, are reasonably justifiable to ensure the accuracy of the donor register. As outlined in the 'rational connection' element, the director-general may only enter and disclose information where that information would in the usual course have been provided by the ART provider under s 53 and in some other limited circumstances. This limits the impact on a donor's privacy as they would have consented to such a provision of information to the donor register in the first instance under s 24, prior to donating their gametes. Other information that the director-general may enter into the donor register and disclose under ss 59 and 68(1) are sourced from the person about themselves or from the parent of the person about the person and so consent is implicit in the provision of that information to the director-general.

Information can also be sourced from the register general under s 62 or by a direction to a health services provider under s 61. This is justified to ensure the accuracy of the donor register and is sufficiently limited. Section 61 only applies to information that would have been registrable in the ordinary course. The justification for the director-general in entering information obtained under s 61 into the donor register is to prevent a donor-conceived person born as a result of ART treatment provided by an unregistered ART provider from being disadvantaged in their right to genetic information. That is, the conduct of the health services provider should not preclude a donor-conceived person from their right to identity. In relation to information obtained from s 62, the registrar-general will have information relating to the births, deaths and marriages of donor-conceived people, donors, and people who give birth to donor-conceived people. There are other avenues where the appropriate persons can obtain this information and the sharing of the information is limited only to ensuring the accuracy of the donor register. The limitation to privacy will only arise in the rare circumstance when there is an inconsistency between the information in the donor register and the information kept by the registrar general. The type of information that the registrar general has knowledge of is the same kind of information that would ordinarily have been provided by the ART provider under s 53, and so there is a limited impact on a donor's privacy as they would have consented to the provision of the same kind of information prior to donating their gametes.

The very limited information disclosed about a donor-conceived person's donor siblings under s 66 represents the least restrictive approach on the other donor-conceived siblings' right to privacy. The information disclosed is non-identifying

and minimal given that consent is not required before disclosure. The sex and year of birth of donor siblings represents the minimum amount of information necessary so that a donor-conceived person can ensure that their potential partner is not genetically related. The imposition on a donor-conceived sibling's right to privacy is therefore extremely limited and proportionate to the legitimate purpose of minimising the risk of consanguineous relationships.

Personal health information

1. Nature of the limitation (s 28(2)(c))

The Bill also allows the disclosure of personal health information about a donor or a donor-conceived person by an ART provider (or the director-general) where a doctor certifies that (or the director-general reasonably believes) it is necessary to prevent or reduce a serious and imminent risk to anyone's life or physical, mental or emotional health or to warn the person to whom the information is disclosed about the existence of a genetic or hereditary medical condition that may be harmful to that person or the person's descendants in the future, without the person's consent (ss 25 and 68).

Section 68 also allows the director-general to disclose information kept in the donor register on their own initiative to an affected person or the parent of the affected child or young person, where they believe on reasonable grounds that a donor or donor-conceived person is involved in a consanguineous relationship or another serious risk to the safety or welfare of a donor or donor-conceived person exists.

The disclosure of information enabled by ss 25 and 68 affects the right to privacy of the person about whom that information is to be disclosed, and possibly some family members of that person incidentally, particularly as the information can be disclosed without the consent of the person to whom the information relates.

2. Legitimate purpose (s 28(2)(b))

The limitation on the donor or donor-conceived person's right to privacy in this circumstance is for the legitimate purpose of warning a person of the existence of a genetic medical condition, a consanguineous relationship or another serious risk to the safety or welfare of a donor or donor-conceived person. This in turn promotes the right to life as set out in s 9 of the HR Act.

3. Rational connection between the limitation and the purpose (s 28(2)(d))

The personal health information of a donor or donor-conceived person is necessarily provided to inform a person of the specific details of the genetic medical condition. The information provided will need to be sufficient to allow for the receiving person to undergo further medical tests to assess whether the condition is also present in the person receiving the information.

Section 68 ensures that in exceptional circumstances, that there is an avenue to disclose relevant information from the donor register that would assist in protecting the health, wellbeing or safety of donors and donor-conceived people. The types of information that s 68 will allow the director-general to release include a donor or donor-conceived person's information kept in the donor register relating to the identification of a consanguineous relationship or because of another serious risk to the welfare or safety of a donor or donor-conceived person. The information disclosed will need to be sufficient to allow for the receiving person to undergo further medical tests, or to identify a consanguineous relationship, or to prevent any harm for the receiving person. There is a direct connection between the types of information released and the legitimate purpose of protecting the health, wellbeing or safety of donors and donor-conceived people.

4. Proportionality (s 28(2)(e))

The Bill allows for early notification of medical conditions. In one significant case in Victoria, a donor-conceived woman, Narelle Grech, died from heritable bowel cancer.² It was speculated that her death could have been prevented had Grech been appropriately informed about her genetic background. Early screening that would have saved her life depended on knowledge that was withheld or unrecorded. Being informed about heritable conditions and the background of biological relatives has a bearing on quality of life, and ultimately, life expectancy. For example, information about biological family history, including allergic reactions, predisposition to diseases (such as certain types of cancer), predisposition to addiction, or reactions to medications are relevant to health care.³ Both Victoria and NSW legislation have very similar provisions in place to ensure that a person can be forewarned about any genetic medical conditions.

Under ss 25 and 68(2) information can only be disclosed to a very limited pool of people, including the personal health information of a donor to a mature donor-conceived person, a parent of a donor-conceived child or young person, and a person who is pregnant using that donor's gametes. A donor-conceived person's personal health information can only be disclosed to their donor or donor sibling.

The Bill includes certain safeguards, particularly that the disclosure must be made by a doctor on the ART provider's behalf (s 25). The disclosure can also only be made if a doctor certifies that the disclosure is necessary to prevent or reduce a serious and imminent risk to anyone's life or physical, mental or emotional health or to warn the

² Sonia Allen, 'Donor identification: Victorian legislation gives rights to all donor-conceived people', *Family Matters. Australia: Australian Institute of Family Studies*, 2019, Report no: 98 <<https://aifs.gov.au/research/family-matters/no-98/donor-identification>>.

³ Damian H. Adams, 'Gamete donor medical records: whose information is it?' *Med Journal of Australia*, 2012 Vol 197(10), p. 543.

person to whom the information is disclosed about the existence of a genetic or hereditary condition that may be harmful to that person or the person's descendants in future (s 25). ART providers and doctors have access to specialist counsellors and expert training and have experience in sensitively managing these disclosures, including in circumstances where an individual is unaware of their donor-conceived status. Therefore, the disclosure of health information in this circumstance is not an arbitrary interference with privacy as there is a high threshold before disclosure can occur, the circumstances of any disclosure are circumscribed and are not unreasonable or unproportionate.

Section 68(2) of the Bill allows the director-general to release information from the donor register that would facilitate early notification of medical conditions. Information can only be disclosed to a very limited pool of people, in the same way as s 25. Section 68(2) includes certain safeguards, including that the director-general believes on reasonable grounds that the disclosure is necessary to prevent or reduce a serious and imminent risk to anyone's life or physical, mental or emotional health or to warn the person to whom the information is disclosed about the existence of a genetic or hereditary condition that may be harmful to that person or the person's descendants in future. The director-general will have the ability to delegate and has access to specialist medical staff and counsellors who will have the appropriate training to sensitively managing these disclosures. Therefore, the disclosure of personal health information in this circumstance is not an arbitrary interference with privacy as there is a high threshold before disclosure can occur.

Section 68(3) also allows for the disclosure of information relevant to identifying a consanguineous relationship or because there is another serious risk to the welfare or safety of a donor or donor-conceived person. For a risk to the safety or welfare of a donor or donor-conceived person that is less 'serious', the director-general must first contact the mature donor-conceived person and ask the person whether they wish to consent to the disclosure of information (s 69). This operates as a safeguard to s 68(3) as it means that when the risk to safety and welfare threshold is less than a serious risk, the director-general must first obtain consent (s 69). The limited pool of persons able to receive the information, the serious risk threshold, and the separate process to obtain consent for a lower risk threshold under s 69 means that the limitation on the right to privacy of the donor or donor-conceived person whose information is getting released under s 68(3) is minimised to the extent necessary to achieve the policy objective of protecting the welfare and safety of the applicant.

Privacy limitations relating to registration and enforcement

1. Nature of the limitation (s 28(2)(c))

The Bill limits the privacy of various people connected with the ART provider. Sections 13, 14 and 19 may limit the right to privacy of the connected people as the names of various people involved in delivery the services are required to be provided as part of

the registration process for an ART provider. Section 20 also limits the right to privacy of those individuals, as the director-general must make the details at s 20(2) (which includes the name of each doctor who performs or supervises ART services, and the name of each person providing counselling services) available to the public. These sections will also limit the privacy of an ART provider in the unlikely circumstance that provider is a sole trader (see further detail in relation to this under the heading *Specific issues in relation to sole traders*).

The following sections of the Bill limit the right to privacy by providing for powers of entry to premises, seizure, compelling of information, and inspection:

s 94 Direction to give information	Provides for an authorised person to direct a person to give information or a document within a reasonable timeframe.
s 95 Direction to give name and address	Provides for an authorised person on reasonable grounds to request name and address of a person who has committed or is committing or is about to commit an offence under the Bill or may be able to assist in the investigation of an offence against the Bill.
s 96 Powers of authorised person to enter premises	The power to enter premises that are only used for residential purposes can only be done with consent or with a warrant.
s 98 General powers on entry to premises	Specifies the scope of actions an authorised person can do under the Bill in relation to the premises or anything at the premises, upon entering a premises under this part. It also authorises an authorised person to direct a person to give information, a document, or other thing, answer a question, and to give assistance to exercise a power under this part.
s 107 Authorised person may seize things at premises	An authorised person who is satisfied that a thing is connected with an offence under the Act and that the seizure is necessary for listed reasons, may seize the thing at the premises, in specific circumstances.
s 108 Moving things to another place for examination or processing under warrant	If a premises was entered under a warrant, a thing found at those premises may be moved to another place for examination or processing in listed circumstances.

s 116 Court to notify director-general of offence	Limits the privacy of any person who is convicted of an offence under the Bill, where that offence is committed by an individual.
s 135 Court to notify director-general of offence	Limits the privacy of any person who is convicted of an offence under the <i>Human Cloning and Embryo Research Act 2004</i> , where that offence is committed by an individual.

These provisions serve as enforcement measures for the Bill, and necessarily limit the affected person's right to information privacy, physical privacy and potentially interferes with a person's home. Sections 116 and 135 allow the director-general to receive information which is necessary and relevant to the exercise of the director-general's functions to manage the registration of ART providers.

2. Legitimate purpose (s 28(2)(b))

The legitimate purposes of these provisions are to ensure the effective regulation of ART services to protect the safety, health and wellbeing of people undergoing ART treatment and manage risks to public health and safety which may arise if an ART provider is committing an offence under the Bill.

3. Rational connection between the limitation and the purpose (s 28(2)(d))

Where the right to privacy of ART providers, and persons associated with them, is limited by reason of the registration requirements for ART providers, this is connected with the purpose of the Bill as it enables the director-general to have adequate information to be able to regulate the delivery of ART services, which will protect the health and wellbeing of people receiving ART services and donor-conceived people. Publishing names of the relevant people providing services on a public register is for the purpose of promoting public awareness of which providers and individuals are appropriately registered, and thereby reduces the risk that members of the public will seek services from unregulated providers.

The provisions in the Bill providing powers relating to enforcement which may impact the right to privacy of a person are directly linked to ensuring the safety, health and wellbeing of people undergoing ART treatment and risk management activities related to the function of the Bill.

For the purposes of ART legislation, it is important that officers have adequate powers in relation to entry, search and seizure to ensure that risks to the health of people undergoing ART treatment can be appropriately managed in a timely and efficient manner. For this reason, the following powers are authorised under the Bill.

Authorised persons are given powers to compel information because, if a health risk is present at the premises, individual persons associated with the health risk may be

the only source of information or may be best placed to provide information that authorised persons may need to investigate and respond to such an event (ss 94 & 95).

The power to enter premises is required as the provision of ART treatment must take place on a physical premise. Therefore, in order to ensure that ART services are being carried out by or under the supervision of a doctor, or that the premises are the approved premises upon application, or that counselling services are being offered before treatment, it is necessary for the authorised person to physically enter, inspect, seize or request information (s 96).

An authorised person undertaking functions under this Bill when responding to a health event relating to ART services needs to be able to assess the risk including its intensity, scale and scope. For example, whether ART services are being provided to a child or close family member. To obtain this information and then to be able to appropriately respond to the risk, it is necessary for an authorised person to have recourse to a suite of measures to gather the necessary details about the ART health risk. Typical actions they may be required to undertake in such an event include for example, being able to inspect premises for any violations of infection control standards, or to take images of the premises and equipment, or to request evidence of ART accreditation or to request evidence that counselling services are being offered before ART treatment. In addition, copies of documents may also be required, for example for traceability and reporting purposes (s 98).

The power for an authorised person to seize things at premises and the power to move things to another place for examination or processing under warrant is required to ensure that an ART provider is not storing gametes for longer than the donor's consent or legislated maximum time. An authorised person may also need to seize something to prevent it being used to repeat an offence. For example, a donated gamete that had been used to create more than five families using ART treatment in the ACT. The power to move things to another place for examination is necessary to access specialist equipment for examination or analysis. For example, a donated gamete or embryo being moved to a laboratory for examination (ss 107 & 108).

The obligation of the court to notify the director-general at ss 116 and 135 is necessary to allow the director-general to properly exercise their powers under ss 18, 79 and 84 so that the regulation of ART services is conducted effectively.

4. *Proportionality (s 28(2)(e))*

Registration functions

The information provided to the director-general by an ART provider, and which is then published by the director-general, is necessary so as to allow consumers to identify whether or not the provider they are receiving ART services from is registered.

This is necessary to protect consumer safety by ensuring that consumers are alert to the provision of services by unregistered providers. The provision of the names of relevant doctors and persons providing counselling services is necessary to ensure that consumers can identify the clinicians who are responsible for their care, and ensure they have the appropriate qualifications. It is noted that similar information about ART providers is already published as a part of the accreditation of providers by the Fertility Society.

Enforcement functions

Any imposition on a person's right to privacy is subject to the specific circumstances of an investigation of a matter under the Bill. The Bill requires an adequate range of powers to be available to authorised persons so they can respond effectively under a broad spectrum of plausible risk management scenarios.

Measures required to appropriately manage breaches of provisions under this Bill are highly situationally specific. While Part 8 of the Bill provides for the necessary powers for authorised persons to undertake required functions under the Bill appropriate to enforcement, the Bill also provides for safeguards to ensure that the enforcement provisions are commensurate with need, powers are not misused, and a person's right to privacy is impacted to the least extent possible.

The right to privacy is only engaged with respect of entering a person's residential property and does not extend to commercial property. The power to enter residential premises is limited under the Bill so that it is permitted only with consent, or with a warrant. The authorised person must follow a set of prescribed steps when obtaining consent (s 97) which limits any discretion from the authorised person. Section 97 stipulates the manner in which an authorised person may seek consent to entry from an occupier, and requires that an authorised person must produce proof of identity for themselves and any persons accompanying the authorised person to the occupier, inform the occupier of the purpose of the entry and that anything found and seized under this part may be used as evidence in court, and that consent may be refused. Therefore, the limitation to a right to privacy created by the powers of entry to premises is managed by appropriate safeguards and is proportionate.

The Bill further sets out the limited circumstances under which an authorised person may enter non-residential premises, including that they must believe that an offence under the Bill is or is likely to be, or has been committed on the premises, or that the risk to a person, the environment, or public health is so serious and urgent that immediate entry without a warrant is necessary (s 96). The power to enter is therefore appropriately limited to specific circumstances pertaining to the function of the Bill as it relates to managing any ART health risks.

Other safeguards to ensure that a person's right to privacy is not arbitrarily or disproportionately limited includes s 92, which provides that before exercising any of the enforcement powers, the authorised person must show their identity card to the

affected person, tell the affected person the reason for exercising the power, and tell the affected person about any relevant offence in relation to the power. Section 114 also requires that an authorised person causes as little inconvenience, detriment and damage as possible.

In relation to ss 116 and 135, an ART provider has an obligation to notify the director-general in relation to any contravention of any ART legislation. Accordingly, in the event of a conviction, the ART provider would be obliged to notify the director-general in any case. The requirement for direct information to be provided will help to circumvent any failure of the ART provider to comply with its obligations under s 19(1), and ensure the effective regulation of ART services.

Section 16 – Right to freedom of expression

1. *Nature of the right and the limitation (ss 28(2)(a) and (c))*

Section 16(2) of the HR Act recognises that everyone has the right to freedom of expression, which includes the freedom to seek, receive and impart information. This right is relevant to obligations of public authorities to provide access to government held information and is relevant when considering ACT freedom of information laws.

The Bill limits the right to freedom of expression as it excludes information in the donor register from the *Freedom of Information Act 2016* (FOI Act) (s 134). The effect of this exclusion means that government information held in the donor register is not accessible by members of the public.

2. *Legitimate purpose (s 28(2)(b))*

The legitimate purpose of this provision is to protect the right to privacy of persons whose information forms part of the donor register, including donors and donor-conceived people.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

Excluding information in the donor register from the FOI Act means that members of the public cannot request and seek that information. Alongside other provisions in the Bill that specify who can receive this information, a controlled and limited pool of people is formed. The information in the donor register is of a personal and identifying nature and significantly impacts the right to privacy of the people whose information is disclosed. Excluding donor register information from the FOI Act would provide an additional layer of assurance to those people that their information is not being distributed in an ad hoc manner, and is rationally connected to protecting the right to privacy of people whose information is held in the donor register.

4. *Proportionality (s 28(2)(e))*

The exclusion from the FOI Act is necessary for the purposes of this Bill to protect the privacy of those people whose information is on the donor register. The limitation of a member of the public's ability to seek government information is not a significant

limitation and is proportionate in light of the legitimate purpose. The exclusion to the FOI Act only applies to one specific database of information and no discretion is conferred as to what is or is not excluded. Most of the information in the donor register pertains to people’s personal information, including identifying information and information about the person’s medical conditions. These types of information would ordinarily not be disclosable under the FOI Act in any case or would be provided in a significantly redacted format as disclosure would prejudice an individual’s right to privacy (see sch 2 FOI Act – 2.2 outlines factors favouring nondisclosure in the public interest).

Information on the donor register will be available to donor-conceived persons and donors and appropriately regulated by the Bill.

Section 18 – Right to liberty and security of person

1. Nature of the right and the limitation (ss 28(2)(a) and (c))

Section 18 (1) of the HR Act recognises that everyone has the right to liberty and security of person. In particular, no-one may be arbitrarily arrested or detained.

Provisions in the Bill which may limit the right to liberty include those listed in the table below. Although each of the offences will apply to an ART Provider, who would not usually be an individual, s 118 provides for the criminal liability of an executive officer of a company.

Imprisonment terms are included in these specific provisions of the Bill.

s 21 Requirement to be registered	An ART provider commits an offence if it provides an ART service and is not a registered ART provider. A person commits an offence if the person advertises or holds out that the person is a registered ART provider and is not a registered ART provider.
s 22 Performance and supervision of ART services	An ART provider commits an offence if the ART services it provides are not performed or supervised by a doctor.
s 26 Provision of ART treatment to a child or young person	An ART provider commits an offence if it provides ART treatment to a child or young person or if it obtains a gamete from a child or young person for use in ART treatment or for research in relation to ART treatment.
s 42 Use of gametes to create embryo with close family member	An ART provider commits an offence if it uses a gamete to create an embryo and knows that

	the gamete provider is a close family member of the other person whose gamete is used to create the embryo.
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The Bill may limit the right to liberty because these provisions create new offences which include penalties for imprisonment, and thus lead to a potential deprivation of liberty.

2. *Legitimate purpose (s 28(2)(b))*

Appropriate sentencing for offences under the Bill protects and promotes the health and wellbeing of donor-conceived people, donors, and people seeking ART treatment.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

These amendments support this purpose by putting in place measures to adequately address the behaviour of offenders and minimise the risk of further harm to victims. Imprisonment terms are included in specific provisions of the Bill to reflect the serious nature of this conduct, deter this conduct, and provide adequate regulatory powers in support of enforcement when regulating the ART industry in the ACT. Within the ART industry, the ACT's provisions need to be adequate to deter people from viewing the ACT as an attractive place for dealings in illegal ART services.

Setting penalties which includes an imprisonment term for specific offences provides guidance to the courts and the ACT community about the seriousness of the particular offences when compared to other offences. By doing so, the imprisonment penalties will help to protect the community and persons seeking ART treatment.

4. *Proportionality (s 28(2)(e))*

A maximum penalty of imprisonment for an unregistered ART provider to provide an ART service is necessary as a deterrent and relays the seriousness of the offence. As ART treatment can often be an invasive procedure, and in many cases require anaesthesia, it is important to ensure that the bodies and individuals providing these services are highly trained, accredited, and are operating in a regulated environment. The offence promotes public health and specifically protects the safety and wellbeing of donor-conceived people and people seeking ART treatment, by requiring any persons or bodies seeking to provide these services to be registered (s 21).

There is also a maximum penalty of imprisonment attached to an ART provider providing ART services not performed or supervised by a doctor. As above, it is public expectation and medical necessity that ART services are being provided by highly trained and qualified people, given the specialist nature of the procedure. This offence serves as a deterrent against ART providers using underqualified staff members to perform these procedures, as a way to cut costs or for any other reason (s 22).

The maximum penalty of imprisonment attached to the offence of an ART provider providing ART treatment to a child or young person demonstrates the seriousness of this offence. From a perspective of public policy, children should be protected from harm, and providing an ART treatment to a child would be a serious breach of that child's right to protection, which could not be justified (s 26).

A maximum penalty of imprisonment is attached to the offence an ART provider creating an embryo with the gametes of close family members. Children born from the gametes of close family members have a high risk of genetic or chromosomal abnormalities, which can cause a threat to life. The imprisonment penalty acts as a deterrent and outlines the seriousness of the offence (s 42).

Any limitation on rights is the least restrictive means to achieve the aim of ensuring that offenders are appropriately sentenced. These provisions do not create a mandatory sentencing regime and judicial sentencing discretion is retained to ensure that justice is done in each individual case.

In addition, any limitations to the right to liberty are lawful and not arbitrary. The maximum imprisonment penalty for each offence is set out in the provision for each relevant offence, ensuring that there is transparency in relation to the alleged offence and maximum penalty at the charge stage. Moreover, the maximum penalties proposed for the offences are not excessive and are determined with reference to the ACT Guide to Framing Offences. Offence provisions in the Bill are notably lower than equivalent provisions in those of other jurisdictions. The Bill has sought to include penalties which can be applied proportionate to risk and impact and provide adequate deterrence to non-compliance, without arbitrarily depriving an individual's right to liberty.

Section 22 – Rights in criminal proceedings

1. Nature of the right and the limitation (ss 28(2)(a) and (c))

Section 22(1) of the HR Act recognises that everyone charged with a criminal offence has the right to be presumed innocent until proven guilty according to law. Section 22(2) provides that a person must not be compelled to testify against themselves or to confess guilt.

The Bill includes provisions which limit the right to be presumed innocent. There are a number of offences in the Bill which either reverse the evidential burden to the accused or provide for strict liability of the offence. Also, ss 61 and 93 (detailed below) limits the right of an individual not to be compelled to testify against themselves, or to confess guilt. Each of these provisions is outlined below.

s 26 Provision of ART treatment to a child or young person	Prohibits the provision of ART to a child or young person.
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	<p>An accused ART provider has the evidential burden to show that a doctor has certified there is a reasonable risk of the child or young person becoming infertile before becoming an adult, and the gamete was obtained for the purpose of storing the gamete for the child or young person's future benefit.</p>
<p>s 32 Requirement to confirm consent in certain cases</p>	<p>Creates an offence where an ART provider has not confirmed consent of a gamete provider in certain circumstances.</p> <p>An accused ART provider has the evidential burden to prove it knew or believed on reasonable grounds that the gamete provider was deceased and therefore did not confirm consent under the provision.</p>
<p>s 33 Use of gamete to create embryo outside body; and s 34 Use of gametes or embryos in ART treatment</p>	<p>Provides for offences in relation to the creation of embryos and the provision of ART treatment, otherwise than in accordance with the consent of the gamete provider.</p> <p>An accused ART provider has the evidential burden to prove that the use was authorised.</p>
<p>s 36 Posthumous use of gametes or embryos</p>	<p>Provides an offence for the posthumous use of gametes or embryos.</p> <p>An accused ART provider has the evidential burden to prove that the person is the gamete provider's domestic partner and that the use was authorised, or that the use has been undertaken in accordance with the consent of the gamete provider and the person receiving ART treatment.</p>
<p>s 38 Use of gametes or embryos obtained more than 5 years ago</p>	<p>Provides for an offence for a failure of an ART provider to take reasonable steps to ascertain if a gamete provider has died if the gamete was obtained more than 5 years before the provision of ART treatment.</p> <p>An accused ART provider has the evidential burden to prove that it or another ART provider that supplied the gamete or embryo used in the ART treatment was contacted by the gamete provider less than 5 years before the provision of the ART</p>

	<p>treatment; or it knew or believed on reasonable grounds that the gamete provider was deceased.</p>
<p>s 43 Storage of gametes or embryos</p>	<p>Provides for an offence where gametes of a provider are stored inconsistently with the consent of a gamete provider.</p> <p>An accused ART provider has the evidential burden to prove that it was required to store a gamete of a child or young person under s 26(3); it had a reasonable excuse; or the gamete provider is deceased, and the gamete or embryo was stored for the purposes of its authorised use (including use authorised by s 37) or to allow a person to apply for a court order under s 37.</p>
<p>s 44 Supply of gametes or embryos to another person; and</p> <p>s 45 Export of gametes or embryos from ACT</p>	<p>Provides for an offence where gametes are supplied or exported from the ACT inconsistently with the gamete providers consent.</p> <p>An accused ART provider has the evidential burden to prove that the gamete provider is deceased, and the gamete or embryo was supplied or exported for the purpose of its authorised use (including authorised use under s 37).</p>
<p>s 46 Requirement to collect information about gamete provider</p>	<p>Provides a requirement on ART providers to collect various information about a gamete provider before obtaining a gamete and before using the gamete or an embryo created from the gamete for any purpose.</p> <p>This offence is a strict liability offence.</p>
<p>s 47 Requirement to collect information about person undergoing ART treatment</p>	<p>Provides a requirement on ART providers to collect various information about a person undergoing ART treatment.</p> <p>An accused ART provider has the evidential burden to prove that within 10 months after the treatment, it was informed by the person who received the treatment that a child was born as a result of the treatment and the full name, sex, date of birth of the child; or it knew that no children were born as a result of the treatment.</p>

	<p>The offence under s 47(1) which requires ART providers to collect certain information before using a gamete in the provision of ART treatment is a strict liability offence.</p>
s 61 Direction to provide information about donor conceived person	<p>Limits a person's right against self-incrimination by requiring compliance with a direction, notwithstanding whether doing so may tend to incriminate the person or expose the person to penalty. Where information is provided because of this section, that information is not admissible in evidence against the person in a civil or criminal proceeding.</p>
s 88 Direction to provide information about potential notice recipients	<p>Provides for a requirement for a company to provide information to support a prohibition or improvement order.</p> <p>An accused ART provider has the evidential burden to prove that it had a reasonable excuse for contravening the direction.</p>
s 91 Identity cards	<p>Provides for enforcement of the Bill where an authorised person fails to return their identity card.</p> <p>An accused person has the evidential burden to prove that their identity card was lost or stolen or destroyed by someone else.</p> <p>This offence is also a strict liability offence.</p>
s 93 Privilege against self-incrimination does not apply	<p>Limits a person's right against self-incrimination by requiring compliance with a direction, notwithstanding whether doing so may tend to incriminate the person or expose the person to penalty. Where information is provided because of this section, that information is not admissible in evidence against the person in a civil or criminal proceeding.</p>
s 94 Direction to give information	<p>Provides for enforcement of the Bill where a person fails to take reasonable steps to comply with a requirement to give information, a document or other thing.</p> <p>An accused person has the evidential burden to prove that the authorised person did not comply</p>

	<p>with s 92 (Requirements before certain powers can be exercised) and did not explain the effect of s 93 (Privilege against self-incrimination does not apply).</p>
<p>s 95 Direction to give name and address</p>	<p>Provides for an authorised person require the person to state the person's name and home address if the authorised person believes on reasonable grounds that the person has committed an offence under the Bill. A person must then comply with a direction of an authorised person to provide evidence of the correctness of the information if they believe on reasonable grounds the information is false and misleading.</p> <p>An accused person has the evidential burden to prove that the authorised person did not comply with s 92 (Requirements before certain powers can be exercised).</p> <p>This offence is also a strict liability offence.</p>
<p>s 98 General powers on entry to premises</p>	<p>Provides for enforcement of the Act where a person does not comply with a direction to give information, a document, or other thing, to produce a document or other thing, to answer a question, or to give the authorised person reasonable help.</p> <p>An accused person has the evidential burden to prove that the authorised person did not comply with s 92 (Requirements before certain powers can be exercised) and did not explain the effect of s 93 (Privilege against self-incrimination does not apply).</p>
<p>s 110 Person must not interfere with seized things</p>	<p>Provides for enforcement of the Bill where a person interferes with a seized thing without approval.</p> <p>This offence is a strict liability offence.</p>
<p>s 117 Destruction or falsification of records</p>	<p>Provides for an offence where an ART provider destroys or falsifies a pre-commencement record, or another record required to be kept under the Bill.</p> <p>An accused person has the evidential burden to prove that the destruction was authorised by the director-general or that the record is a hard copy version that has been converted to electronic format.</p>

s 118 Criminal liability of executive officer	<p>Provides for an offence by an executive officer of a corporation in circumstances where the corporation has committed an offence.</p> <p>An accused executive officer has the evidential burden to prove that the corporation would have a defence to a prosecution for the relevant offence.</p>
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2. *Legitimate purpose (s 28(2)(b))*

The potential limitation to the accused person's right to be presumed innocent serves a legitimate purpose to protect and promote the health and wellbeing of donor-conceived people, donors, and people seeking ART treatment.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

To ensure that the public health and safety benefits of the ART regulatory regime are achieved, it is necessary to provide adequate regulatory powers in support of enforcement when regulating the ART industry in the ACT.

The strict liability offences in the Bill engage the right to be presumed innocent by reversing the onus of proof from the prosecution onto a defendant. In instances in the Bill where there is a reverse onus of proof its purpose is to ensure the effective enforcement of and compliance with the requirements of the Bill by enabling the offences within it to be effectively prosecuted. The limitation on s 22 of the HR Act is aimed at promoting the regulatory framework to protect the health and safety of people receiving ART treatment, as well as the health and safety of donor conceived people, is effective and enforceable.

Section 61 which limits a health service provider's privilege against self-incrimination has been included to support the director-general to compel the provision of certain information about a donor-conceived person. This is necessary to support the inclusion of mandatory information in the donor register to protect the health and wellbeing of donor-conceived people and their right to their genetic identity. Similarly, s 93 has been included to support an authorised person's powers to compel information and require attendance to answer questions. These powers are deployed to support enforcement functions under the Bill and allow information to be provided to protect of the health and safety of people receiving ART treatment, and donor conceived people, even in circumstances where that information may incriminate the person giving it.

4. Proportionality (s 28(2)(e))

Strict Liability and Reverse Burden Offences

For those offences referenced above which involve the reversal of the burden of proof it is noted that once a person has adduced some relevant evidence, the burden shifts to the prosecution to prove the elements of the offence beyond reasonable doubt. This continues to operate as a safeguard to the rights of the individual.

Generally, where the burden of proof has been reversed in relation to a particular factor, this will be because the accused person is uniquely or better placed to produce evidence of the relevant thing. The elements the accused is being asked to prove in the above provisions are in relation to elements which in all the circumstances it would be unreasonable for the prosecution to be required to establish. Accordingly, for those offences with a reversed burden of proof, the limitation of a person's rights under s 22 of the HR Act are necessary to ensure that appropriate regulatory action can be taken.

Part 8 of the Bill, which provides a number of offences related to the enforcement functions of authorised persons under the Bill, also includes a number of strict liability offences which are necessary for the effective enforcement of the regulatory regime.

Strict liability offences typically arise in a regulatory context where, for reasons such as public safety and ensuring that regulatory schemes are complied with, criminal penalties are required. A defendant can reasonably be expected, because of their involvement with the regulated activity, to know what the requirements of the law are, and as such the mental, or fault, element can justifiably be excluded.

The strict liability offences in the Bill each relate to either obligations to collect information, or to specific aspects of the exercise of enforcement powers under Part 8 of the Bill.

The strict liability offences affect ART providers, or the people who are exercising enforcement powers. Each of the affected entities can be expected to have a high degree of awareness and understand of the regulatory framework. Therefore, in each case the relevant defendant can be reasonably expected to know what the requirements of the law are, and therefore the mental, or fault element can justifiably be excluded.

A less restrictive approach (namely, making the offences not strict liability) would still enable enforcement, but would not be as effective a deterrent given the nature of the strict liability offences, and the effect the prohibited conduct would have on the enforceability of the regulatory regime. A less restrictive approach would compromise the availability of information for the donor register, the ability to investigate and rely on evidence seized for enforcement purposes.

Outlined below is the rationale as to why the limitation is reasonable in each case:

<p>s 26 Provision of ART treatment to a child or young person</p> <p><i>Prohibits the provision of ART to a child or young person.</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused ART provider has the evidential burden to show that a doctor has certified there is a reasonable risk of the child or young person becoming infertile before becoming an adult, and the gamete was obtained for the purpose of storing the gamete for the child or young person’s future benefit.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>The ART provider is likely to be uniquely aware of and capable of establishing whether a doctor has been certified that there is a reasonable risk of the child being infertile. Ensuring appropriate records in relation to this would form part of the ordinary clinical care of a child in relation to this issue, and therefore it is reasonable to require the ART provider to provide evidence on this issue.</p>
<p>s 32 Requirement to confirm consent in certain cases</p> <p><i>Creates an offence where an ART provider has not confirmed consent of a gamete provider in certain circumstances.</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused ART provider has the evidential burden to prove it knew or believed on reasonable grounds that the gamete provider was deceased and therefore did not confirm consent under the provision.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>The exemption to this offence is included mitigate any overlap in relation to the posthumous use of gametes. Whether or not the ART provider knew or believed on reasonable grounds that a gamete provider was deceased will be a matter that the ART provider is uniquely aware of.</p>
<p>s 33 Use of gamete to create embryo outside body; and</p> <p>s 34 Use of gametes or embryos in ART treatment</p> <p><i>Provides for offences in relation to the creation of embryos and the provision of ART treatment, otherwise than in accordance with</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused ART provider has the evidential burden to prove that the use was authorised.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>The authorisation of posthumous use of gametes will only occur in very limited circumstances, which are set out in s 37. Given the limited scope for authorisation of posthumous use, and court authority is required, the application of this exception is likely to be very rare. The relevant court order permitting posthumous should be something which is retained by the ART provider, as a precondition to providing an ART treatment authorised under s 37. Given that authorisation of posthumous use</p>

<p><i>the consent of the gamete provider.</i></p>	<p>is likely to be very rare, and the ART provider will have evidence of such an order, the reversal of the burden is not an unreasonable limitation on the rights of the ART provider.</p>
<p>s 36 Posthumous use of gametes or embryos</p> <p><i>Provides an offence for the posthumous use of gametes, except where authorised.</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused ART provider has the evidential burden to prove that the person is the gamete provider’s domestic partner and that the use was authorised, or that the use has been undertaken in accordance with the consent of the donor and the person receiving ART treatment.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>Establishing whether the person proposing to posthumously use the gamete is the gamete provider’s domestic partner and that the use was authorised, or that the gamete provider has consented to the use of gametes posthumously, are expected and reasonable steps on the ART provider to have undertaken before providing ART treatment.</p> <p>Whether the gamete provider, and the person receiving treatment have each consented to the use of posthumous gametes will be a matter uniquely within the knowledge of the ART provider.</p> <p>The authorisation of posthumous use of gametes will only occur in very limited circumstances, which are set out in s 37. Given the limited scope for authorisation of posthumous use, and court authority is required, the application of this exception is likely to be very rare. The relevant court order permitting posthumous should be something which is retained by the ART provider, as a precondition to providing an ART treatment authorised under s 37. Given that authorisation of posthumous use is likely to be very rare, and the ART provider will have evidence of such an order, the reversal of the burden is not an unreasonable limitation on the ART provider.</p>
<p>s 38 Use of gametes or embryos provided more than 5 years ago</p> <p><i>Provides for an offence for a failure of an ART provider to take</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused ART provider has the evidential burden to prove that it (or another ART provider that supplied the gamete used in the ART treatment) was contacted by the gamete provider less than 5 years before the provision of the ART treatment; or it knew or believed on</p>

<p><i>reasonable steps to ascertain if a gamete provider has died, if the gamete was obtained more than 5 years before the provision of the ART treatment.</i></p>	<p>reasonable grounds that the gamete provider was deceased.</p> <p><i>Reason why the limitation is reasonable</i> Whether or not the ART provider was contacted by the gamete provider within the relevant period or whether they knew or believed on reasonable grounds that a gamete provider was deceased will be a matter that the ART provider is uniquely aware of and capable of demonstrating.</p>
<p>s 43 Storage of gametes or embryos</p> <p><i>Provides for an offence where gametes of a provider are stored inconsistently with the consent of a gamete provider.</i></p>	<p><i>Reverse burden relates to the following factor</i> An accused ART provider has the evidential burden to prove that it was required to store a gamete of a child or young person under s 26(3); it had a reasonable excuse; or the gamete provider is deceased, and the gamete or embryo was stored for the purposes of its authorised use or to allow a person to apply for a court order under s 37.</p> <p><i>Reason why the limitation is reasonable</i> For each of the matters identified in s 26(3), the ART provider will be best placed to introduce relevant evidence. The storage of gametes to allow fertility preservation for a child will be a matter which occurs in limited circumstances, and the ART provider will have unique knowledge of the circumstances of the storage of those gametes. The authorisation of posthumous use of gametes, or the proposed authorised use, will also only occur in very limited circumstances, and the ART provider will be best placed to adduce evidence in relation to these matters.</p> <p>Similarly, whether or not the ART provider has a reasonable excuse for failing to store gametes in accordance with consent, is likely to be the result of a technical or equipment issue which will be a matter the defendant is best placed to provide any evidential proof for.</p>
<p>s 44 Supply of gametes or embryos to another person; and</p>	<p><i>Reverse burden relates to the following factor</i> An accused ART provider has the evidential burden to prove that the gamete provider is deceased, and the gamete or embryo was supplied or exported for the purpose of its authorised use.</p>

<p>s 45 Export of gametes or embryos from ACT</p> <p><i>Provides for an offence where gametes are supplied or exported from the ACT inconsistently with the gamete providers consent.</i></p>	<p><i>Reason why the limitation is reasonable</i></p> <p>The authorisation of posthumous use of gametes, whether via s 37 or in another jurisdiction will only occur in very limited circumstances, and the ART provider will be best placed to adduce evidence in relation to these matters.</p>
<p>s 46 Requirement to collect information about gamete provider</p> <p><i>Provides that an ART provider must collect various information before obtaining or using a gamete</i></p>	<p><i>Limitation of section 22 rights</i></p> <p>This offence is a strict liability offence.</p> <p><i>Reasons the limitation is reasonable</i></p> <p>This offence is a strict liability offence as although an evidential onus would be less restrictive on the right to be presumed innocent found in section 22 of the HR Act, it would not serve the legitimate objective of the Bill as effectively.</p> <p>In the circumstances of this offence, the ART provider is required to collect key information which is necessary for the effectiveness of the donor register, and to achieve access to information of donor conceived people. Given the highly regulated nature of ART treatment, and the central nature of the collection of information by an ART provider for the operation of the donor register, ART providers can be expected to be clearly aware of their obligations under ss 46 and 47.</p> <p>If information is not collected by an ART provider under this section, then the ART provider would not be able to provide mandatory information under s 53, and as a consequence information would not be available to any donor conceived child born from the donation, which would undermine the effectiveness of the donor register. It is necessary for this offence to be a strict liability offence to address this risk as this will mean that the defendant's act alone should dictate the offence, rather than the reasons that the defendant acted in that way</p>
<p>s 47 Requirement to collect information about</p>	<p><i>Limitation of section 22 rights</i></p> <p>An accused ART provider has the evidential burden to prove that within 10 months after the treatment, it was informed by the person who received the treatment that</p>

person undergoing ART treatment

Provides a requirement on ART providers to collect various information about a person undergoing ART treatment.

a child was born as a result of the treatment and the full name, sex, date of birth of the child; or it knew that no children were born as a result of the treatment (s 47(5)).

The offence under s 47(1) which requires ART providers to collect certain information before using a gamete in the provision of ART treatment is a strict liability offence.

Reason why the limitation is reasonable

In relation to the reverse burden, whether the ART provider was informed by the person who received ART treatment if children were born as a result of the ART treatment will be a matter that the ART provider is uniquely aware of and capable of demonstrating.

The offence under s 47(1) is a strict liability offence. Although there are ways the offence could be framed to be less restrictive on the right to be presumed innocent found in section 22 of the HR Act, those alternatives would not serve the legitimate objective of the Bill as effectively.

As with s 46, this section requires the ART provider to collect key information which is necessary for the effectiveness of the donor register, and to achieve access to information for mature donor conceived people, and to generally ensure that information is available from the donor register for disclosure under Division 5.4. Given the highly regulated nature of ART treatment, and the central nature of the collection of information by an ART provider for the operation of the donor register, ART providers can be expected to be clearly aware of their obligations under s 47.

If information is not collected by an ART provider under this section, then the ART provider would not be able to provide mandatory information under s 53, and as a consequence information would not be available to any donor-conceived child born from the donation, which would undermine the effectiveness of the donor register. It is necessary for this offence to be a strict liability offence to address this risk as this will mean that the defendant's act alone should dictate the offence, rather than the reasons that the defendant acted in that way.

<p>s 88 Direction to provide information about potential notice recipients</p> <p><i>Provides for a requirement for a company to provide information to support a prohibition or improvement order.</i></p>	<p><i>Reverse burden relates to the following factor</i> An accused ART provider has the evidential burden to prove that it had a reasonable excuse for contravening the direction.</p> <p><i>Reason why the limitation is reasonable</i> Whether or not the ART provider has a reasonable excuse for contravening a direction to provide information will be a matter the defendant is best placed to provide any evidential proof for. It is further noted that this offence applies specifically to corporations, so the engagement with rights of individuals are limited.</p>
<p>s 91 Identity cards</p> <p><i>Provides for enforcement of the Bill where an authorised person fails to return their identity card.</i></p>	<p><i>Limitation of section 22 rights</i> An accused person has the evidential burden to prove that their identity card was lost or stolen or destroyed by someone else.</p> <p>This offence is also a strict liability offence.</p> <p><i>Reason why the limitation is reasonable</i> The accused person will be uniquely aware of, and able to provide evidential proof in relation to whether their identity card was lost or stolen. In relation to the offence being a strict liability offence, as an authorised person under s 89, the accused person will know, or ought to know, their legal obligation to return their identity card.</p> <p>Regarding identity cards, identification of authorised people is critical to the safeguards in the Bill in respect of the enforcement functions, such as exercise of warrants, entry to premises and seizing property. Accordingly, there is a high risk of harm to the community should an identification card be used to gain entry to premises or information, by a person fraudulently acting as an authorised person under the Bill. The strict liability offence in relation to return of identity cards is necessary in order to manage this risk.</p> <p>Given the importance of the security of identity cards, a less restrictive approach would not adequately protect the community from this risk.</p>
<p>s 94 Direction to give information.</p>	<p><i>Reverse burden relates to the following factor</i> An accused person has the evidential burden to prove that the authorised person did not comply with s 92 (Requirements before certain powers can be exercised)</p>

<p><i>Provides for enforcement of the Bill where a person fails to take reasonable steps to comply with a requirement to give information or provide a document.</i></p>	<p>and did not explain the effect of s 93 (Privilege against self-incrimination does not apply).</p> <p><i>Reason why the limitation is reasonable</i> This offence is an important feature of the investigation of breaches by ART providers of their obligations under the Bill, and therefore necessary for the effective enforcement of the regulatory regime. Given the nature of this offence, it would not be reasonable to expect the prosecution to demonstrate for each contravention of the offence that the authorised person complied with each of the requirements in s 92 and explained the effect of s 93. The defendant is better placed to provide evidence that one of those requirements was not met.</p>
<p>s 95 Direction to give name and address</p> <p><i>Provides for an authorised person to state the person’s name and home address if the authorised person believes on reasonable grounds that the person has committed an offence under the Act. A person must then comply with a direction of an authorised person to provide evidence of the correctness of the information if they believe on reasonable grounds the information is false and misleading.</i></p>	<p><i>Limitation of section 22 rights</i> An accused person has the evidential burden to prove that the authorised person did not comply with s 92 (Requirements before certain powers can be exercised).</p> <p>This offence is also a strict liability offence.</p> <p><i>Reason why the limitation is reasonable</i> This offence is an important feature of the investigation of breaches by ART providers of their obligations under the Bill, and therefore necessary for the effective enforcement of the regulatory regime. Given the nature of this offence, it would not be reasonable to expect the prosecution to demonstrate for each contravention of the offence that the authorised person complied with each of the requirements in s 92. The defendant is better placed to provide evidence that one of those requirements was not met.</p> <p>In relation to this offence being a strict liability offence, although an evidential onus would be less restrictive on the right to be presumed innocent found in section 22 of the HR Act, it would not serve the legitimate objective of the Bill as effectively.</p> <p>In the circumstances of this offence, the person is only required to provide identification showing their name and address. In the context, with the authorised person being required to comply with s 92, it should be expected that</p>

	<p>the individual would be aware of the obligation to comply with the request.</p> <p>An inability of an authorised person to be able to identify a particular individual who is believed to be involved in the commission of an offence, or is able to assist in the investigation of such an offence, would provide an avenue for individuals under investigation to undermine enforcement of the regulatory regime. It is necessary for this offence to be a strict liability offence to address this risk as this will mean that the defendant's act alone should dictate the offence, rather than the reasons that the defendant acted in that way.</p>
<p>s 98 General powers on entry to premises</p> <p><i>Provides for enforcement of the Bill where a person does not comply with a direction to give information, a document, or other thing, to produce a document or other thing, to answer a question, or to give the authorised person reasonable help.</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused person has the evidential burden to prove that the authorised person did not comply with s 92 (Requirements before certain powers can be exercised) and did not explain the effect of s 93 (Privilege against self-incrimination does not apply).</p> <p><i>Reason why the limitation is reasonable</i></p> <p>This offence is an important feature of the investigation of breaches by ART providers of their obligations under the Bill, and therefore necessary for the effective enforcement of the regulatory regime. Given the nature of this offence, it would not be reasonable to expect the prosecution to demonstrate for each contravention of the offence that the authorised person complied with each of the requirements in s 92 and explained the effect of s 93. The defendant is better placed to provide evidence that one of those requirements was not met.</p>
<p>s 110 Person must not interfere with seized things</p>	<p><i>Limitation of section 22 rights</i></p> <p>Provides for enforcement of the Bill where a person interferes with a seized thing without approval.</p> <p>This offence is a strict liability offence.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>This offence is an important feature of the investigation of breaches by ART providers of their obligations under the Act, and therefore necessary for the effective enforcement of the regulatory regime.</p>

	<p>In relation to the offence being a strict liability offence, although an evidential onus would be less restrictive on the right to be presumed innocent found in section 22 of the HR Act, it would not serve the legitimate objective of the Bill as effectively.</p> <p>In the circumstances of this offence, the person is only required not to interfere with seized things, as such interference would significantly compromise the enforceability of the regulatory regime. It is necessary for this offence to be a strict liability offence to address this risk as this will mean that the defendant's act alone should dictate the offence, rather than the reasons that the defendant acted in that way. A less restrictive alternative would not adequately deter the conduct of interference with seized things.</p>
<p>s 117 Destruction or falsification of ART records</p> <p><i>Provides for an offence where an ART provider destroys or falsifies a pre-commencement record, or another record required to be kept under the Bill.</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused person has the evidential burden to prove that the destruction was authorised by the director-general or that the record is a hard copy version that has been converted to electronic format.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>Ordinary, there are few reasons for the destruction of a record in relation to an ART provider. Accordingly, it is anticipated that any authorisation under this section will be rare. Given this, and that ART provider will have evidence of the relevant authorisation, the ART provider is likely best placed to provide evidence of whether the destruction of a record has been authorised by the director-general. An ART provider would also be best placed to show evidence that an electronic format of the record exists.</p>
<p>s 118 Criminal liability of executive officer</p> <p><i>Provides for an offence by an executive officer of a corporation in circumstances where the corporation has committed an offence.</i></p>	<p><i>Reverse burden relates to the following factor</i></p> <p>An accused executive officer has the evidential burden to prove that the corporation would have a defence to a prosecution for the relevant offence.</p> <p><i>Reason why the limitation is reasonable</i></p> <p>Whether or not the corporation has a defence for prosecution of an offence under the Bill will be a matter within the knowledge of an executive officer, who will have responsibility for management of the company. Therefore, the whether the corporation has a defence</p>

	will be a matter the defendant is best placed to provide any evidential proof for.
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Self-Incrimination

Sections 61 & 93 limit a person's right against self-incrimination by requiring compliance with a direction notwithstanding whether doing so may tend to incriminate the person or expose the person to penalty.

Section 61(5) ensures that a health services provider cannot refuse to comply with a direction for information under s 61(2) on the grounds that the information may result in self-incrimination. This will support the director-general to gather information about a donor-conceived person conceived after commencement of the Bill which would in an ordinary setting, be mandatorily provided for inclusion in the donor register by an ART provider. However, the power to mandate information under s 61 will allow the director-general to still obtain this information in circumstances where the ART treatment did not occur in the ordinary course, and where the mandatory information subsequently was not provided for inclusion in the donor register.

The right against self-incrimination under s 61 is only limited to the extent that information that would have been mandatorily registrable in the ordinary course. The justification for the director-general to be able to mandate information, including information which may self-incriminate an individual, is to prevent a donor-conceived person born as a result of ART treatment provided by an unregistered ART provider from being disadvantaged in their right to genetic information. That is, the conduct of the health services provider should not preclude a donor-conceived person from their right to identity.

Furthermore, the power to compel information under s 61 only applies to health service providers, as defined in the *Health Act 1993*. Individuals who are health service providers would be aware of their classification as health service providers and would be required to be aware and up to date on any legislative obligations and responsibilities they would need to meet in their capacity as health service providers. Without s 61(5), health service providers could refuse to disclose information at the request of the director-general, on the grounds that it would open them to penalties for failing to comply with ss 53 or 21.

A further safeguard to the effect of s 61(5) is that any information obtained because of the health service provider's compliance with the direction would not be admissible in evidence against the provider in a civil or criminal proceeding, other than a proceeding for an offence arising out of the false or misleading nature of the information or document.

Section 93 ensures that the information gathered under the Part 8 enforcement provisions are used primarily to support information gathering and questioning by

authorised persons in relation to information which is required for the Bill. This will ensure that authorised persons can obtain information which relates to health and safety risks posed to people who have received or are receiving ART treatment, or are born as a result of such treatment, as regulated by the Bill.

The Bill includes safeguards to ensure the s 93 limitation of the right against self-incrimination is reasonable and proportionate. This includes s 93(2), which provides for use immunity and prevents the admission as evidence in a civil or criminal proceeding of any information, document or other thing obtained, directly or indirectly, because of the giving of the answer or the production of the document or other thing. Further to s 93(2), information is only admissible as evidence in a proceeding for an offence arising out of the false or misleading nature of the answer, information, document or other thing.

A further safeguard is that the effect of s 93 must be explained to an individual upon a direction to give information (s 94) and prior to exercise of the general powers in respect of entry to premises (s 98).

Specific Issues in relation to ART providers who are sole traders

The regulatory requirements of the Bill focus on regulation of ART providers, rather than the regulation of the individuals who provide the particular ART services. In particular, s 11 provides that an ART provider does not include a person who provides an ART service for a registered ART provider, under a contract or employment arrangement with that registered ART provider.

Although there is nothing to explicitly prevent an ART provider being a sole trader, the requirements of ART accreditation (which in turn provides the eligibility for registration), mean that in nearly every case a registered ART provider will be a corporate or other entity, rather than an individual who operates as a sole trader.

To achieve ART accreditation, a provider is required to comply with numerous requirements including minimum staffing requirements (all ART units must have or ensure access to a Medical Director, a Scientific Director, a Nurse Manager and a Senior Counsellor), and requirements for laboratory and other facilities and equipment.

Given these requirements, ART providers are typically larger medical facilities that require significant infrastructure, specialised equipment, and a team of medical professionals to provide comprehensive fertility treatments, which are characteristics that do not generally lend themselves to operation as a sole trader. There are currently only three ART providers in the ACT, and none of those providers are a sole trader. Further, a review of all providers in NSW who are currently accredited by the Fertility Society, has not identified any provider who is currently accredited as a sole trader.

To the extent that ART providers are entities rather than individuals the regulation of those entities will not engage with any human right.

However, given it remains possible for an ART provider to be a sole trader, the relevant human rights impacts are addressed below.

Section 21 – Rights to Fair Trial

1. *Nature of the right and the limitation (ss 28(2)(a) and (c))*

Section 22 of the HR Act provides that everyone has the right to have criminal charges, and rights and obligations recognised by law, decided by a competent, independent and impartial court or tribunal after a fair and public hearing.

The Bill authorises the director-general to make various decisions which will impact a person's registration as an ART provider, including the decision to approve an application for registration (s 15), to place conditions on registration (s 16), cancel registration (s 18), to issue an improvement notice (s 79), revoke an improvement notice (s 82), give a prohibition notice (s 84) and end a prohibition notice (s 86) which will affect a person's entitlement to continue to deliver ART services should a prohibition notice be issued.

As above, where an ART provider is an entity, decisions in relation to that entity will not engage the right to fair trial. However, in the unlikely event that a prohibition notice is made in respect of an individual, such an individual's right to fair trial would be limited. This is because the decision maker in this instance will be the director-general, rather than a court or tribunal. It is noted that a prohibition notice is not the only remedy available to the director-general, and for less serious breaches, the director-general has alternatives to issue an improvement notice (s 79).

The mechanism for ending a prohibition notice is for the person to apply to the director-general to have the notice revoked (s 86). The Bill also includes an appropriate review process (s 122) for the more significant discretionary powers of the director-general, including a right to a review of a decision to issue or revoke an improvement notice (ss 79 & 82), issue or revoke a prohibition notice (s 84 & 86) and to place conditions on an ART provider's registration (s 16).

2. *Legitimate purpose (s 28(2)(b))*

The overall objective of the regulatory regime is designed to promote and protect the health and wellbeing of donor-conceived people and people undergoing ART treatment and to ensure that the rights of donor-conceived people to know their genetic heritage are protected.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

The ability to issue a prohibition notice quickly and efficiently is necessary to enable the effective enforcement of the regulatory regime, and therefore to promote the

health, safety and welfare of people who are receiving ART treatment, or who are born as a result of ART treatment.

The purpose of being able to issue a prohibition notice in respect of an individual who may be an associated entity of an ART provider is to ensure that associated legal entities are not utilised to undermine the operation of the regulatory framework.

Given the nature of the regulatory regime, it may be necessary to prohibit the operation of a business (or part thereof) with little notice, so as to avoid harm occurring to an individual as a result of ART treatment, or to prevent a contravention of the ART legislation.

4. Proportionality (s 28(2)(e))

The rights of an individual to a fair trial are only impacted by the regulatory regime to the extent that the person is either an ART provider who is a sole trader, or is an associated entity of such an ART provider.

In order to be an associated entity, an individual must be either an executive officer of a corporate ART provider (or related corporation) or a person with an interest in the corporation. This is directed to those likely to have a high degree of control over the corporate entity. Although the ability to issue a prohibition notice in relation to an associated entity who is an individual has been included to avoid ART providers adopting corporate structures to undermine the regime, issuing a prohibition notice in respect of an individual, is unlikely to have a significant impact on the rights of that individual. This is because any individual upon whom a prohibition notice is served is unlikely to themselves be registered ART provider who would otherwise be permitted to provide ART services under the Bill.

Further it is noted that a prohibition notice may only be issued by the director-general on reasonable grounds, which are tightly confined under s 84. A prohibition notice may only be issued where satisfied on reasonable grounds the ART provider has contravened or is likely to contravene the legislation, the ART provider's accreditation has been denied, suspended, cancelled or revoked, or to prevent or minimise a serious risk to another person's health, safety or welfare, or to public health or safety.

In some circumstances, it may be necessary for the director-general to issue a prohibition notice with little (if any) notice. For example, if the director-general reasonably suspected that an ART provider was fraudulently using their own gametes for ART treatment and altering records so that this was not identified. In such circumstances the director-general may wish to immediately stop ART treatments from continuing.

The Bill includes a procedure for a prohibition notice to be revoked. A prohibition notice must the period after which the person to whom it is given may apply to have the notice revoked (s 85). This offers an avenue for the ART provider to bring the prohibition notice to an end.

Importantly, the Bill also provides a process for review of a decision to issue a prohibition notice (s 122). This helps to safeguard the rights of an ART provider, to the extent they may be an individual.

The protections in the Bill in relation to the issuing of prohibition notices, are considered proportionate given that the power to issue a prohibition notice is unlikely to substantively affect the rights of an individual, that it is a reviewable decision, and given the impacts of conduct that does comply with the Bill on individuals accessing ART treatment.

Section 27B – Right to work

1. *Nature of the right and the limitation (ss 28(2)(a) and (c))*

Section 27B of the HR Act recognises that everyone has the right to work, including the right to choose their occupation or profession freely. The Bill includes provisions for registration (ss 12 & 13), conditions on registration (s 16), improvement and prohibition notices (Part 7) and cancellations of registration (s 18).

Requirements on ART providers in relation to registration, cancellation of or conditions on registration, and the ability to issue improvement orders and prohibition notices are most likely to affect a corporate or other body, rather than each individual employed and providing the services. Therefore, in most, if not all, cases the legislation will apply to ART providers who are entities and thus will not enliven the right to work.

However, in the unlikely case that an ART provider is a sole trader, issuing of a prohibition notice, or cancellation of registration would impact such a person's right to work. Also, a prohibition notice may be made to an associated entity of corporation who might include an executive officer of the corporation, or a person with a significant interest in the corporation, and further to s 12(d) this would mean that the individual could not be the executive officer any other registered ART provider whilst prohibited.

Therefore, it is possible (although unlikely) that the Bill will limit the right of an individual to themselves achieve or maintain registration as an ART provider (s 13), or to be an executive officer of a future ART provider.

However, it is important to note that this will not limit that person's ability to be employed in a profession relevant to ART services generally. Such a person would be restricted from operating as an ART provider themselves (with the regulatory responsibilities that entails) but would not be prohibited under the Bill from delivering those same services if under the employment of another ART provider.

2. *Legitimate purpose (s 28(2)(b))*

The purpose of these measures is to achieve the overarching goals of the regulatory framework to promote the health, safety and welfare of persons receiving and born from ART treatment.

3. *Rational connection between the limitation and the purpose (s 28(2)(d))*

Requiring that ART providers who operate in the ART industry to obtain the necessary registration and approvals is rationally connected to managing risks to persons receiving ART treatment and born from ART treatment, as it ensures that only those with the requisite skills, knowledge and experience under the Bill, are permitted to engage in the regulated behaviour.

The extension of the regulatory requirements to individuals (where they are a sole trader, executive officer or associated entity of a provider) is necessary to ensure that ART providers do not adopt a sole trader structure, or vary corporate structures, to avoid compliance with the regulatory requirements.

Within the ART industry, all jurisdictions operate and participate in a range of schemes including accreditation for additional safety nets within the system. This is supported by enforcement provisions and offence provisions within the Bill to deter non-compliance. ART services are regulated in most jurisdictions across Australia including NSW, Queensland, Victoria and Western Australia.

4. *Proportionality (s 28(2)(e))*

The work requirements for these roles within the ART industry are often technical and/or specialised. Given that ART services are regulated in most jurisdictions across Australia, and across Australia must meet detailed and specific parameters set by the Fertility Society so as to achieve accreditation, ART providers are expected to have a high level of engagement and awareness of the regulatory regime established by the Bill.

Unethical practices in these areas puts at risk people seeking ART treatment, and people born from ART treatment. For these reasons, the Bill specifies eligibility criteria for registration, including that an ART provider must hold ART accreditation. Professional and industry schemes of this nature are not unique to the ART sector. They exist in the ACT in other health sectors, for example in the form of professional accreditation bodies such as for dentists.

To the extent that the Bill limits the right of a person because that person is an executive officer of an ART provider, (in particular s 12(d)) this is reasonable and is not arbitrary as the limitation specifically relates to the conduct of the individual in the provision of ART services. Safeguards to ensure that a person's right to work is not unduly limited are incorporated in the Bill. The Bill requires that the director-general must give written notice of their decision (s 15). Similarly, if the director-general imposes conditions on a person's registration, they must also give the person written notice (s 16). The person has 28 days to provide a written response to the director-general, which the director-general must consider (s 16).

As with the right to fair trial, the Bill includes a procedure for a prohibition notice to be revoked. A prohibition notice must state the period after which the person to whom it

is given may apply to have the notice revoked (ss 85 & 86). This offers an avenue for the ART provider to bring the prohibition notice to an end.

Importantly, the Bill also provides a process for review of a decision to issue prohibition notices, improvement notices, revoking improvement notices, ending prohibition notices, or place conditions on registration (s 122). This helps to safeguard the rights of an ART provider, to the extent they may be an individual.

The protections in the Bill in relation to the issuing of prohibition notices, are considered proportionate given that the power to issue a prohibition notice will relate primarily to entities and is unlikely to substantively affect the rights of any individual.

ASSISTED REPRODUCTIVE TECHNOLOGY Bill 2023

Human Rights Act 2004 - Compatibility Statement

In accordance with section 37 of the *Human Rights Act 2004* I have examined the ***Assisted Reproductive Technology Bill 2023***. In my opinion, having regard to the Bill and the outline of the policy considerations and justification of any limitations on rights outlined in this explanatory statement, the Bill as presented to the Legislative Assembly is consistent with the *Human Rights Act 2004*.

.....

Shane Rattenbury MLA
Attorney-General

CLAUSE NOTES

PART 1 Preliminary

Part 1 deals with formal matters including commencement.

Clause 1 Name of Act

This clause provides that the title of the Act will be the *Assisted Reproductive Technology Act 2023* (the Act).

Clause 2 Commencement

This clause provides the commencement dates of the Act.

Part 1 (Preliminary), Part 2 (Objects and important concepts), Division 4.5 (Record keeping requirements), Division 6.1 (Preliminary), Division 6.2 (Retention of pre-commencement records), Part 11 (Miscellaneous), Part 12 (Transitional), and the dictionary commence on the day after this Act's notification day.

Section 79 of the *Legislation Act* (Automatic commencement of postponed law) does not apply to Part 5 (Donor register) and if Part 5 has not commenced within 12 months of the notification day, it automatically commences on the first day after that period.

The remaining provisions commence on a day fixed by the Minister by written notice. These provisions will automatically commence 6 months after the Act's notification date if not otherwise commenced.

Clause 3 Dictionary

This clause states that the dictionary at the end of the Act is part of the Act.

Clause 4 Notes

This clause states that a note included in the Act is explanatory and does not form part of the Act.

Clause 5 Offences against Act – application of Criminal Code etc

This clause provides that the Criminal Code, chapter 2 applies in relation to all offences against the Act. The *Legislation Act*, section 133 applies in relation to the meaning of penalty units expressed in the Act.

Clause 6 Application of Act

Clause 6 provides that the Act does not limit or otherwise affect the regulation of a public health risk activity under the *Public Health Act 1997*, or the operation of the *Human Cloning and Embryo Research Act 2004*; the *Mutual Recognition Act 1992* (Cwlth); the *Parentage Act 2004*; or the *Trans-Tasman Mutual Recognition Act 1997* (Cwlth).

PART 2 Objects and important concepts

Part 2 sets out the objects of the Act and defines key terms.

Clause 7 Objects of Act

This clause sets out the objects of the Act.

The objects recognise that there is a need to regulate assisted reproductive technology treatment within the ACT and ensure that access to information in relation to ART services is also regulated.

The objects will be achieved through:

- (a) establishing a registration scheme for the regulation of ART providers and ART treatments;
- (b) providing for the enforcement of the regulatory regime to ensure compliance with the Act;
- (c) the establishment of a donor register, including rights of access to various information for relevant individuals.

Clause 8 Principles of Act

This clause enumerates the general principles that must be given effect in the administration of the Act, or in the carrying out of an activity regulated by the Act.

It provides for: the protection of the welfare and interests of people born, or to be born as a result of assisted reproductive technology treatment; the protection of the reproductive capabilities of individuals, and children born as a result of ART treatment, from commercial exploitation; the right of donor conceived people to have access to information about their donors; and the protection of the health and wellbeing of people undergoing assisted reproductive technology treatment.

Clause 9 Meaning of *ART treatment*

This clause defines *ART treatment* (or *assisted reproductive technology treatment*) for the Act. Given that ART treatment is rapidly evolving and developing, this clause allows treatments or procedures to be prescribed by regulation to ensure that the regulatory regime can adapt to evolutions in ART treatment.

Clause 10 Meaning of *ART service*

This clause defines *ART service* for the Act.

Clause 11 Meaning of *ART provider*

This clause defines *ART provider* for the Act.

PART 3 Registration of ART providers

Part 3 establishes the registration process for ART providers.

Clause 12 Eligibility for registration

This clause provides that a person is eligible to be registered as an ART provider if the person holds ART accreditation, has not been convicted or found guilty of an offence against ART legislation, is not currently prohibited from carrying on a business that provides ART services, and for a corporation, that no executive officer is an executive officer of another corporation that is currently prohibited, or was an executive officer of another corporation that is currently prohibited when the prohibition took effect, or has been convicted or found guilty of an offence under the Act because of clause 118 (Criminal liability of executive officer).

Clause 13 Application for registration

This clause provides that a person may apply to the director-general for registration as an ART provider and enumerates information that is required in an application.

Clause 14 Application for renewal

This clause provides that a person may apply to the director-general for renewal of their registration as an ART provider and provides the timeframes for which a renewal application must be made as well as the information that is required in a renewal application.

Clause 15 Deciding applications

This clause provides that if the director-general is satisfied that a person is eligible for registration or renewal of registration and their application is made in accordance with clause 13 or 14, the director-general must approve the person's application for registration or application for renewal of registration. The director-general must also give written notice of the director general's decision to approve or refuse an application to the applicant.

Clause 16 Conditions on registration

This clause provides that a person's registration is subject to any conditions the director-general considers appropriate. The director-general must give the person written notice of the condition proposed to be imposed, the reasons for the proposed condition, and provide the person with 28 days to respond to the notice. The director-general must consider any response to the notice. Any condition imposed must not be inconsistent with a condition imposed on the person's ART accreditation and, to the extent of any inconsistency, is invalid.

Clause 17 Term of registration

This clause provides that the term of registration begins on the day the director-general gives the person notice of the decision to approve the person's application for registration under clause 15 (or for a renewed registration – on the day the director-general approves the person's application for renewal) and ends 5 years after the day the registration begins unless cancelled earlier under clause 18. If cancelled under clause 18, the term ends when it is cancelled. If a person applies for renewal of their registration in accordance with clause 14 before the registration ends, the registration will continue to be in force until the application is decided.

Clause 18 Cancellation of registration

This clause provides that the director-general must cancel a person's registration as an ART provider if the person gives the director-general notice of the person ceasing to provide ART services under clause 19, stops holding ART accreditation; or if the person is prohibited from carrying on a business that provides ART services for 12 months or longer under Division 7.3.

Clause 19 Requirement to notify director-general about certain events

This clause provides that a registered ART provider must notify the director-general of the following notification events within 7 days after the event happens:

- (d) the ART provider ceasing to provide ART services;
- (e) a change of premises at which the ART provider provides ART services;
- (f) a change to the doctors who perform or supervise ART services on the ART provider's behalf;
- (g) a change to the ART provider's ART accreditation;
- (h) the ART provider contravening any ART legislation;
- (i) if the ART provider is a corporation – a change to the address of its registered office or principal place of business;
- (j) a change to the people who provide counselling services in relation to ART services provided by the ART provider; and
- (k) any other event prescribed by regulation.

Failing to comply with clause 19 is an offence with a maximum penalty of 30 penalty units.

Clause 20 Register of ART providers

This clause requires the director-general to keep a register of registered ART providers. The register is required to contain certain information including the ART provider's name; the address of each premises at which the ART provider provides ART services; the name of each doctor who performs or supervises ART services provided by the ART provider; and the name of each person who provides counselling services in relation to ART services provided by the ART provider.

This information must be made available to the public unless the person to whom the information relates applies in writing for the information not to be made available to the public and the director-general is satisfied that the publication of the information would or could reasonably be expected to endanger anyone's life or physical safety.

The register established under this clause may contain any other information the director-general considers appropriate.

PART 4 Provision of ART services

Part 4 regulates the provision of ART services.

Clause 21 Requirement to be registered

This clause provides for two separate offences. First, that it is an offence for an ART provider who provides an ART service to not be registered. Second, that a person commits an offence if they advertise or hold out that the person is a registered ART provider when they are not registered. The maximum penalty for each of these offences are 200 penalty units, imprisonment for 2 years or both.

Clause 22 Performance and supervision of ART services

This clause provides that an ART provider commits an offence if they provide ART services that are not performed or supervised by a doctor. The maximum penalty for this offence is 200 penalty units, imprisonment for 2 years or both.

Clause 23 Requirement to offer counselling before providing ART service

This clause provides for three points in time, before which an ART provider must offer counselling services to certain individuals. An ART provider must offer counselling services to a person seeking to undergo ART treatment as well as the person's domestic partner before providing ART treatment. ART providers must offer counselling services to a person proposing to provide a gamete to the ART provider before obtaining a gamete. Finally, an ART provider must offer counselling services to a gamete provider where the gamete was not originally obtained as a donated gamete and the gamete provider proposes to donate the gamete or embryo for use by someone other than the gamete provider or their domestic partner before the ART provider uses the gamete or embryo.

The counselling services offered must be provided by a qualified person as detailed in the regulations. The counselling services offered must be available in the ACT, either in person or remotely.

It is an offence for an ART provider to not offer counselling services in accordance with this clause with a maximum penalty of 15 penalty units.

This clause does not prevent a person providing such counselling services from charging a reasonable fee for the service; nor does it require a person to use a counselling service.

Clause 24 Requirement to provide certain information before providing ART service

This clause provides that an ART provider must tell and confirm understanding from a person mentioned in an item in table 24, column 2, about the matters mentioned in the relevant item in column 3, before providing the relevant ART service mentioned in column 4. The information provided to the person in this clause are either basic matters or extended matters.

Basic matters mean:

- (a) the availability of counselling services under clause 23;
- (b) the effect of a gamete provider's consent under clause 29, including how and when consent may be modified or withdrawn under clause 30; and
- (c) any other matter prescribed by regulation.

Extended matters mean:

- (a) basic matters;
- (b) the ART provider's obligations in relation to collecting information about the person and the person's children;
- (c) the application of the Criminal Code, part 3.4 (False or misleading statements, information and documents) to the person, including in relation to information given to the ART provider by the person;
- (d) the existence of the donor register and the information to be kept in the register about the person and their donor conceived offspring;
- (e) the person's right to obtain information in the donor register about themselves;
- (f) the person's right, and the right of their donor conceived offspring, to obtain information in the donor register about other people;
- (g) the right of other people to obtain information in the donor register about the person and their donor conceived offspring; and
- (h) any other matter prescribed by regulation.

A person seeking to undergo ART treatment which does not use donated gametes and a person providing a gamete (other than as a donated gamete) need only be provided with basic matters before the relevant ART service occurs. However, a person who is seeking to undergo ART treatment using donated gametes or a person proposing to provide a donated gamete, or a gamete provider from whom the gamete was not originally obtained as a donated gamete, must be provided with information in relation to the extended matters.

An ART provider commits an offence if it fails to tell a person about the relevant information under table 24 or fails to confirm that a person understands that

information. The maximum penalty in relation to a matter, that is either a basic or extended matter is 200 penalty units, unless it is a basic matter prescribed by regulation or an extended matter prescribed by regulation, which has a maximum penalty of 30 penalty units.

Clause 25 Disclosure of personal health information by ART provider

This clause provides for the circumstances in which personal health information may be disclosed.

An ART provider may disclose personal health information if a doctor certifies that the disclosure is necessary to either prevent or reduce a serious and imminent risk to anyone's life or physical, mental or emotional health or to warn the person to whom the information is disclosed about the existence of a medical condition that may be harmful to the person or the person's children (including future children).

In relation to personal health information about a donor, an ART provider may disclose such information to the following people:

- (a) a person born as a result of ART treatment using the donor's donated gamete if the person is at least 16 years old or the ART provider is satisfied that the person is sufficiently mature to access the information;
- (b) a parent of a child or young person born as a result of ART treatment using the donor's donated gamete;
- (c) a person who is pregnant as a result of ART treatment using the donor's donated gamete.

An ART provider may disclose personal health information about a donor conceived person to their donor or donor sibling.

Disclosures made under this clause must be made by a doctor on the ART provider's behalf and may also be made to a doctor treating the person to whom it is made.

This clause does not require an ART provider to disclose information to any person.

Clause 26 Provision of ART treatment to child or young person

This clause provides that an ART provider commits an offence if it provides ART treatment to a child or young person; or obtains a gamete from a child or young person for use in ART treatment or for research in relation to ART treatment. The maximum penalty is 200 penalty units, imprisonment for 2 years or both.

This offence does not apply to an ART provider if:

- (a) a doctor has certified there is a reasonable risk of the child or young person becoming infertile before becoming an adult; and
- (b) the gamete obtained from the child or young person is for the purpose of storing the gamete for the child or young person's future benefit.

An ART provider that has obtained a gamete from a child or young person in accordance with subsection (2) of this clause must, store the gamete until the person becomes an adult and provides instructions, and take reasonable steps to obtain the person's consent to storage of the gamete when the person becomes an adult, unless the person gives consent sooner.

Clause 27 Infection control standards

This clause provides that a regulation may prescribe requirements for controlling infection in the provision of ART services. These standards are referred to as *infection control standards*. An ART provider must comply with the infection control standards.

Clause 28 Requirement to obtain consent of gamete provider

This clause provides that a gamete may be used in ART treatment only in accordance with the consent of the gamete provider. Similarly, an embryo may be used only in accordance with the consent of both gamete providers.

This clause does not apply to a gamete or embryo used in accordance with a court order under clause 37.

Clause 29 Form and content of consent

This clause provides that a gamete provider's consent must be in writing, be given to an ART provider obtaining or proposing to obtain a gamete from the gamete provider, state the number of families to which the gametes may be used in the provision of ART treatment, state the kinds of ART treatment for which the gamete may be used, and the period for which the gametes may be stored. A gamete provider's consent must not limit use of a gamete in the provision of ART treatment to a person because of any protected attribute of the person.

A regulation may prescribe other requirements in relation to the consent of gamete providers.

Clause 30 Modification or withdrawal of consent

This clause provides that a gamete provider may modify or withdraw their consent at any time until:

- (a) for a donated gamete – the gamete is placed in a person's body, or an embryo is created from the gamete; or
- (b) for a gamete used to create a donated embryo – the embryo is implanted in a person's body; or
- (c) in any other case – the gamete, or an embryo created from the gamete, is placed or implanted in a person's body.

A gamete provider may modify or withdraw consent by written notice given to an ART provider that is, or has been, in possession of the gamete or embryo to which the consent relates.

Accordingly, if an ART provider receives a notice of modification or withdrawal of consent in relation to a gamete or embryo it has supplied to another ART provider, it must give the other ART provider written notice of the modification or withdrawal as soon as practicable. The withdrawal or modification takes effect as soon as the ART provider is given written notice of the modification or withdrawal in accordance with this clause.

Regulations may prescribe other requirements for modification or withdrawal of consent.

Clause 31 Requirement to verify identity of gamete provider

This clause provides that an ART provider after receiving a document under clause 29 or 30, commits an offence if it fails to take the steps prescribed by regulation to verify the identity of a person who purports to give, modify or withdraw their consent as a gamete provider. The maximum penalty is 30 penalty units.

Clause 32 Requirement to confirm consent in certain cases

This clause provides that it is an offence for an ART provider to carry out certain activities in relation to a gamete or embryo that is not a donated gamete or embryo without confirming the gamete provider's consent in relation to the activity, or if the ART provider carries out the activity more than 12 months after the ART provider is given the gamete provider's consent to the activity or more than 12 months after the ART provider confirms the gamete provider's consent to the activity. The activities include:

- (a) using the gamete to create an embryo outside a person's body;
- (b) providing ART treatment to a person using the gamete or embryo;
- (c) supplying the gamete or embryo to another person (including an ART provider);
- (d) exporting the gamete or embryo, or causing the gamete or embryo to be exported, from the ACT.

The maximum penalty for this offence is 200 penalty units.

This offence does not apply to an ART provider if it knows or believes on reasonable grounds that the gamete provider is deceased.

Clause 33 Use of gamete to create embryo outside body

This clause provides that an ART provider commits an offence if it uses a gamete to create an embryo outside a person's body without the gamete provider's consent or in a way that is inconsistent with the gamete provider's consent. The maximum penalty for this offence is 200 penalty units. This offence does not apply if the ART provider uses the gamete in accordance with a court order under clause 37 (Authorisation of posthumous use).

Clause 34 Use of gametes or embryos in ART treatment

This clause provides that an ART provider commits an offence if it provides ART treatment to a person using a gamete or embryo without the gamete provider's consent or in a way that is inconsistent with the gamete provider's consent. The maximum penalty for this offence is 200 penalty units. This offence does not apply if the ART provider uses the gamete or embryo in accordance with a court order under clause 37 (Authorisation of posthumous use).

Clause 35 Use of gametes or embryos for research

This clause provides that an ART provider commits an offence if it uses a gamete or an embryo for research without the gamete provider's consent, or in way that is inconsistent with the gamete provider's consent. The maximum penalty for this offence is 200 penalty units.

Clause 36 Posthumous use of gametes or embryos

This clause provides that an ART provider commits an offence if it provides ART treatment to a person using a gamete or embryo from a gamete provider whom the ART provider knows or reasonably ought to have known is deceased. The maximum penalty for this offence is 100 penalty units.

This offence does not apply if:

- (a) the gamete provider had consented to the use of the gamete in the circumstances and the person undergoing the treatment has consented to the treatment in writing, having been notified of the gamete provider's death and date of death (if known); or
- (b) the ART provider provides the treatment to the gamete provider's domestic partner in accordance with a court order under clause 37.

Clause 37 Authorisation of posthumous use

This clause provides that a domestic partner of a deceased gamete provider may apply to the Supreme Court for authorisation for the posthumous use of the gamete in the provision of ART treatment to the partner and storage of the gamete for authorised use. This clause also provides a list of factors for which the court must consider in deciding whether to authorise the use or storage of a deceased gamete provider's gamete:

- (a) whether the domestic partner has capacity to consent to the provision of the treatment;
- (b) whether the domestic partner has undergone appropriate counselling;
- (c) the best interests of any children to be born as a result of the treatment including whether the domestic partner has capacity to provide for the child's emotional, intellectual, and other needs and whether the child is likely to have safe and stable living arrangements;
- (d) whether the gamete provider expressly objected to posthumous use of their gamete;
- (e) whether the gamete provider is likely to have supported posthumous use of their gamete in the provision of ART treatment to their domestic partner;
- (f) any other matter the court considers appropriate.

Clause 38 Use of gametes obtained more than 5 years ago

This clause provides that it is an offence for an ART provider to provide ART treatment using a gamete, or an embryo created from a gamete, obtained from a gamete provider more than 5 years before the provision of the ART treatment and the ART provider fails to take reasonable steps to find out whether the gamete provider is alive. Reasonable steps is defined in this clause to include obtaining a certificate under section 45 of the *Births, Deaths and Marriages Registration Act 1997* about whether the gamete provider's death has been recorded in the register and completing any other inquiries prescribed by regulation. The maximum penalty for this offence is 100 penalty units.

This offence does not apply if the ART provider or another ART provider that supplied the gamete or embryo has been contacted by the gamete provider less than 5 years before the provision of the ART treatment; or it knows or believes on reasonable grounds that the gamete provider is deceased.

Clause 39 Donated gametes or embryos – time limits on use

This clause provides that an ART provider must not provide ART treatment using a donated gamete or embryo if the gamete was obtained, or embryo was created more than 15 years before the provision of the ART treatment unless the director-general has given written authorisation. Maximum penalty is 100 penalty units.

The director-general may give an authorisation only if satisfied there are reasonable grounds for doing so. The director-general may also make guidelines in relation to the giving of an authorisation. A guideline made under this clause is a notifiable instrument.

Clause 40 Donated gametes or embryos – limits on number of families

This clause provides that an ART provider commits an offence if it provides ART treatment using a donated gamete or embryo, the donor has donated gametes or embryos used in ART treatment previously, and either the number of families that

include a child born as a result of ART treatment provided in the ACT is not less than 5, or the number of families that include a child born as a result of ART treatment provided Australia-wide is not less than 10. Maximum penalty is 200 penalty units. The ART provider does not commit an offence under this clause if it proves that it exercised due diligence to prevent the contravention, which includes searching its records, making reasonable inquiries of the donor, and requesting information from another ART provider if it has reason to believe another ART provider has obtained or been supplied with a gamete or embryo of the donor.

Clause 41 Requirement to provide information about number of families

This clause provides that if an ART provider receives a request for information from another ART provider under clause 40, it must provide certain information, and failure to do so would constitute an offence with a maximum penalty of 30 penalty units.

Clause 42 Use of gametes to create embryo with close family member

This clause provides that it is an offence for an ART provider to use a gamete to create an embryo if the ART provider knows that the gamete provider is a close family member of the other person whose gamete is to be used to create the embryo. Maximum penalty is 200 penalty units, imprisonment for 2 years or both.

Clause 43 Storage of gametes or embryos

This clause provides that it is an offence for an ART provider to store a gamete or embryo without the consent of the gamete provider, or in a way that is inconsistent with the gamete provider's consent. Maximum penalty is 200 penalty units.

This clause also provides for the maximum period that such a gamete or an embryo may be stored. Maximum penalty is 30 penalty units if an ART provider stores a gamete or embryo for longer than the listed periods.

The offences under this clause do not apply if the ART provider is required to store a gamete under clause 26 (Provision of ART treatment to a child or young person) or if it has a reasonable excuse for contravening a storage requirement, or a gamete provider is deceased and the ART provider is storing the deceased gamete provider's gametes or embryo for the purpose of its authorised use (including use authorised by a court order under section 37) or to allow a person to apply for a court order under clause 37.

Clause 44 Supply of gametes or embryos to another person

This clause provides that it is an offence for an ART provider to supply a gamete or embryo to another person (including another ART provider) without the consent of the gamete provider or in a way that is inconsistent with the gamete provider's consent. Maximum penalty is 200 penalty units.

This clause does not apply if the gamete provider is deceased, and the ART provider supplies the gamete or embryo for the purpose of its authorised use (including use authorised by a court order under clause 37).

Clause 45 Export of gametes or embryos from ACT

This clause provides that it is an offence for an ART provider to export a gamete or embryo from the Territory without the consent of the gamete provider or in a way that is inconsistent with the gamete provider's consent. The maximum penalty is 100 penalty units.

This clause does not apply if the gamete provider is deceased, and the ART provider exports the gamete or embryo for the purpose of its authorised use (including use authorised by a court order under clause 37).

Clause 46 Requirement to collect information about gamete provider

This clause requires an ART provider to obtain certain information before obtaining a gamete from a gamete provider. An ART provider must have collected the information mentioned in this clause in relation to a gamete before using the gamete, or an embryo created using the gamete, for any purpose. An ART provider commits an offence if it contravenes this section with a maximum penalty of 50 units.

This offence is a strict liability offence.

Clause 47 Requirement to collect information about person undergoing ART treatment

This clause specifies the information to be collected about a person undergoing ART treatment before and after the treatment, and provides for two offences. An ART provider commits an offence if it fails to collect certain information a person before using a gamete in the provision of ART treatment to the person with a maximum penalty of 50 penalty units. This offence is a strict liability offence.

The ART provider also commits an offence if an ART provider uses a donated gamete in the provision of ART treatment to a person and fails to take reasonable steps to find out where the person becomes pregnant, or a child was born within certain timeframes. The maximum penalty for this offence is 50 penalty units.

Clause 48 – Requirement to keep records

This clause requires an ART provider to keep and retain for 50 years after the record is made, certain records. It is an offence for an ART provider to not keep such records with a maximum penalty of 30 penalty units. It is a separate offence to not retain the records for 50 years with a maximum penalty of 100 penalty units.

Clause 49 Information sharing between ART providers

This clause provides that an ART provider that supplies a gamete or embryo to another ART provider must give the other ART provider a copy of the gamete provider's consent, and may give the other ART provider a copy of any other information required to be collected under the Act, in relation to the gamete or embryo.

PART 5 Donor Register

This part provides for provisions relating to the donor register including the information contained within the donor register and when such information may be disclosed.

Clause 50 Definitions – Part 5

This clause defines the following terms for this Part: *commencement day, donor, donor code, donor conceived, donor sibling, and mature donor conceived person.*

Clause 51 Meaning of *mature donor conceived person* – Part 5

This clause provides that a mature donor conceived person is a donor conceived person who is at least 16 years old or has received appropriate counselling services from a suitably qualified and experienced counsellor who is satisfied the person is able to understand and comply with the donor's contact preferences under clause 58 and understand that the donor has no parental rights or responsibilities.

Clause 52 Donor register

This clause provides that the director-general must keep a donor register, that the register may be kept in any form the director-general decides and that the director-general may correct any mistake, error or omission in the register.

Clause 53 Mandatory information

This clause sets out the mandatory information which an ART provider must provide to the director-general within 2 months after becoming aware that a person has been born alive as a result of ART treatment and applies to an ART provider that provides ART treatment using a donated gamete. Failure to provide such information is an offence with a maximum penalty of 100 penalty units.

The director-general must enter information it was given under this clause into the donor register.

Clause 54 Voluntary information about donors

This clause provides that a donor who donated a gamete before the commencement day, or a donor who donated a gamete for use in an informal donor arrangement, or an ART provider acting on behalf of a donor under subparagraphs (a) or (b) with the donor's consent may give the director-general the following information about the donor for inclusion in the donor register:

- (a) full name;
- (b) home address;
- (c) date and place of birth;
- (d) donor code;
- (e) relevant medical history;
- (f) the sex and year of birth of each of their donor conceived offspring; and
- (g) the name of each ART provider that has previously obtained a donated gamete from the donor and the date on which the gamete was obtained.

Clause 55 Voluntary information about donor conceived people

This clause provides that a mature donor conceived person whether born before or after the commencement day of this Act may provide the following information for inclusion in the donor register:

- (a) their full name;
- (b) their sex;
- (c) their home address;
- (d) their date and place of birth;
- (e) their donor's donor code;
- (f) the full name of the person who gave birth to them.

A parent of a donor conceived child or young person may provide the following information about the child or young person for inclusion in the donor register.

- (a) full name;
- (b) sex;
- (c) date of birth;
- (d) donor's donor code;
- (e) full name of the person who gave birth to the child or young person.

Clause 56 Voluntary information about informal donor arrangements

This clause provides that a parent of a donor conceived person born as a result of self-insemination using a donated gamete or ART treatment that is not provided for fee or reward or in carrying on a business, may provide the following information for inclusion in the donor register:

- (a) the parent's full name;
- (b) the donor conceived person's full name, sex and date of birth;
- (c) if the donor consents in writing—the donor's full name and date of birth;
- (d) whether the donor conceived person was born as a result of ART treatment or self-insemination.

Clause 57 Voluntary information about personal characteristics

This clause provides that a donor who donated a gamete, whether before or after the commencement day, or a mature donor conceived person, whether born before or

after the commencement day, may give the director-general information about their personal characteristics for inclusion in the donor register.

Clause 58 Voluntary information about contact preferences

This clause provides that a donor who donated a gamete, whether before or after the commencement day, or a mature donor conceived person, whether born before or after the commencement day, may give the director-general their contact details and preferred way to be contacted about matters in relation to the donor register, or that they do not wish to be contacted about matters in relation to the donor register. The director-general must enter this information into the donor register.

Clause 59 Information entered on director-general's own initiative

This clause provides that the director-general may, of their own initiative enter into the donor register certain information provided that the director-general is satisfied that certain requirements are met.

Clause 60 Requirement to ensure accuracy

This clause provides that the director-general must ensure, as far as is practicable, that the information in the register is accurate and not misleading. The director-general may refuse to enter, revise, or remove information, retain historical information, add any notes the director-general considers appropriate, or ask an ART provider to give information to verify information provided voluntarily for inclusion in the donor register under Division 5.2. The director-general must remove information provided voluntarily by a person if that person asks the director-general to remove such information and the director-general is satisfied the information is not required to be on the donor register. A person may ask the director-general to revise incorrect or outdated information about themselves in the donor register.

Clause 61 Direction to provide information about donor conceived person

This clause provides that the director-general may give a written direction to a health service provider to answer stated questions or provide certain information where the director-general believes on reasonable grounds that a health service provider has mandatory information in relation to a donor conceived person, which has not been provided in accordance with clause 53. A health service provider commits an offence if the provider contravenes the direction with a maximum penalty of 30 penalty units.

The health service provider is not excused from complying with this clause on the ground that doing so may tend to incriminate the provider or expose the provider to a penalty. However, any information obtained from compliance with a direction issued in accordance with this clause is not admissible as evidence against the health service provider in a civil or criminal proceeding, other than a proceeding for an offence arising out of the false or misleading nature of the information.

Clause 62 Information sharing between director-general and registrar-general

This clause provides that the director-general and registrar-general may share information in relation to certain people to ensure the accuracy of the donor register.

Clause 63 Disclosure of information in donor register generally

This clause provides that the director-general may disclose information kept in the donor register only in accordance with this part.

The director-general may assume that information provided to the director-general and kept in the donor-register is accurate, for the purposes of disclosure.

Clause 64 Disclosure to subject of information

This clause provides that the director-general must, on application by certain people, give the applicant a copy of any information about the applicant that is kept in the donor register, or if the parent is applying on behalf of a donor conceived child or young person, any information about the donor conceived child or young person that is kept in the donor register.

This clause does not authorise the disclosure of information about anyone other than the applicant, or if a parent is applying on behalf of a donor conceived child or young person, anyone other than the child or young person.

Clause 65 Disclosure to donor

This clause provides that the director-general must, on application by a donor, give the donor a copy of the sex and year of birth and any other voluntary information kept in the donor register about a person born as a result of ART treatment or self-insemination using the donor's donated gamete.

Clause 66 Disclosure to donor conceived person

This clause provides that the director-general must, on application by a mature donor conceived person, give the person a copy of the following information kept in the donor register:

- (a) Mandatory information about the person's donor, if the person was born as a result of ART treatment provided on or after the commencement day.
- (b) Information provided voluntarily by the person's donor under Division 5.2;
- (c) Information about the person's donor sibling provided voluntarily under Division 5.2; and
- (d) The sex and year of birth of the person's donor siblings.

Clause 67 Disclosure to parent of donor conceived child or young person

This clause provides that the director-general must, on application by a parent of a donor conceived child or young person, give the parent a copy of the information to which the child or young person would be entitled to as a mature donor conceived person under clause 66.

However, the director-general must not give the parent information about the child or young person's donor if the child or young person was born as a result of ART treatment or self-insemination using a gamete donated before the commencement day, and the donor has not otherwise provided the mandatory information voluntarily under Division 5.2.

If the parent is unwilling or unable to seek information on the child or young person's behalf and the information cannot reasonably be obtained by the person in any other way, the director-general must on application by a suitable person, give the suitable person a copy of the information that may be given to a parent under this clause.

Clause 68 Disclosure of information included on director-general's initiative

This clause provides that the director-general may on their own initiative, disclose information kept in the donor register that has been entered or revised under section 59 or 60 provided that the person to whom the information is disclosed would otherwise be entitled to be given the information under this part.

This clause provides that the director-general may on their own initiative, disclose personal health information kept in the donor register if the director-general believes on reasonable grounds that the disclosure is necessary to prevent or reduce a serious and imminent risk to anyone's life or physical, mental or emotional health or warn the person to whom the information is disclosed about the existence of a medical condition that may be harmful to the person or the person's children (including future children). The director-general may disclose personal health information to:

- a mature donor conceived person or a parent of a donor conceived child or young person about the donor conceived person's donor;
- a person who is pregnant as a result of ART treatment or self-insemination using a donor's donated gamete if the information is about the donor;
- a donor if the information is about a person born as a result of ART treatment or self-insemination using the donor's donated gamete; and
- a donor conceived person if the information is about their donor sibling.

The director-general may also, on their own initiative, disclose information kept in the donor register to an affected person or a parent of an affected child or young person, if the director-general believes on reasonable grounds that a donor or donor conceived person is involved in a consanguineous relationship or another serious risk to the safety or welfare of a donor or donor conceived person exists. The information disclosed should only be to the extent necessary to allow the affected person or their parent to understand the risk.

Nothing in this section requires the director-general to disclose information to any person.

Clause 69 Contacting donor conceived person for consent to disclosure

This clause provides that the director-general may at the request of certain people or on their own initiative, contact a mature donor conceived person and ask the person whether they wish to consent to the disclosure of information under this division.

The director-general may only contact a mature donor conceived person if in their opinion, the contact is justified to promote the safety or welfare of at least 1 of the people concerned.

Clause 70 Consent to disclosure generally

This clause provides that a person whose information is kept in the donor register, may consent to the disclosure of their information in circumstances not otherwise allowed under this part and that the consent must be in writing.

PART 6 Pre-commencement records

Clause 71 Definitions Pt 6

This clause defines *ART provider*, *commencement day*, *pre-commencement record*, and *retention period* for this part.

Clause 72 Requirement to retain records

This clause provides that an ART provider (which in the proposed Part includes a former ART provider) must retain a pre-commencement record it has control of during the retention period for the record (which is 75 years after the provision of the ART service to which the record relates) in a readily accessible form. Failure to do so is an offence with a maximum penalty of 50 penalty units.

Clause 73 Transfer of records

This clause provides that a person (including an ART provider) who has a pre-commencement record in the person's control may transfer the record to a registered ART provider. A person who transfers a record under the proposed section and the registered ART provider to whom the record is transferred must both notify the director-general of the transfer in writing as soon as practicable. A person or ART provider who fails to comply with this clause is guilty of an offence with a maximum penalty of 30 penalty units.

Clause 74 Director-general may authorise destruction of records

This clause permits a person to destroy a pre-commencement record with the written authorisation of the director-general. The director-general must not give any such

authorisation unless satisfied that no person will be adversely affected by the destruction of the record.

Clause 75 Meaning of *accessible information* - Division 6.3

This clause sets out the meaning of *accessible information* about a donor (being the information that can be disclosed under this Division) which is certain non-identifying information about the donor and persons born as a result of ART treatment using a donated gamete of the donor, and any other information about the donor if the donor has consented to its disclosure.

Accessible information is intended to include identifying information held by an ART provider in relation to a donor where disclosure of the information would be consistent with the consent provided by the donor upon donation of their gametes, consistently with the requirements of the NHMRC Guidelines. Accessible information does not include information that can be obtained under clause 66 or 67.

Clause 76 Application for accessible information about donor

This clause permits a person who was born as a result of ART treatment using the donor's donated gamete (if the person is at least 16 years old or the ART provider to whom the application is made is satisfied the person is sufficiently mature to access the information), or a parent of a child or young person born as a result of ART treatment using the donor's donated gamete to apply to certain ART providers for accessible information about the donor of the gamete.

Clause 77 Disclosure of accessible information by ART provider

This clause requires an ART provider to, within 28 days after receiving an application under clause 76, to give any accessible information that the ART provider has about the donor to the applicant, or a statement stating that the ART provider has no accessible information, or details of another ART provider which may have accessible information. Any failure of an ART provider to comply with this section is an offence with a maximum penalty of 50 penalty units.

PART 7 Regulatory action

Clause 78 Definitions – Part 7

This clause sets out the meaning of *associated entity*, *recipient*, and *related corporation* in this Part.

Clause 79 Giving improvement notice

This clause provides that if the director-general is satisfied on reasonable grounds that a person has contravened, is contravening, or is likely to contravene ART legislation, or it is otherwise necessary to require a person to rectify a matter or activity to prevent or minimise a risk to another person's health, safety or welfare, or to public health or

safety, they may give an improvement notice to the person requiring the person to rectify the matter or activity to which the notice relates.

Clause 80 Contents of improvement notice

This clause sets out the contents of an improvement notice.

Clause 81 Extension of compliance period

This clause provides that the compliance period of the improvement notice may be extended on application by the recipient of the notice or on the director-general's own initiative, and that the director-general must give written notice of their decision. If the extension is refused, the written notice about the decision relating to the extension must state the reasons for refusal.

Clause 82 Revoking improvement notice

This clause provides that an improvement notice remains in force until the day it is revoked. The director-general, if satisfied that the improvement notice has been complied with, may, on application by the recipient of the notice or on their own initiative, revoke the notice, and must give written notice of their decision. If the revocation is refused, the written notice about the decision relating to the revocation must state the reasons for refusal and set a further period after which an application for revocation can be made.

Clause 83 Contravention of improvement notice

This clause provides that it is an offence to contravene an improvement notice. The maximum penalty for a first offence is 150 penalty units and the maximum penalty for a second or subsequent offence is 300 penalty units. For each day after the first day of contravention for which the contravention continues, there is a maximum penalty of 20 penalty units per day.

Clause 84 Giving prohibition notice

This clause provides that if the director-general is satisfied on reasonable grounds that a person has contravened, is contravening, or is likely to contravene ART legislation, or a person has been refused ART accreditation or had their accreditation suspended, cancelled or revoked, or it is otherwise necessary to prohibit a person from carrying on a business, or part of a business that provides ART services to prevent or minimise a serious risk to another person's health, safety or welfare or to public health or safety, the director-general may prohibit a person from carrying on a business or part of a business that provides ART services and prohibit a person from offering to provide ART services in the form of a prohibition notice, if the director-general is satisfied that there are reasonable grounds to do so.

Clause 85 Contents of prohibition notice

This clause sets out the information that a prohibition notice must contain.

Clause 86 Ending prohibition

This clause sets out that a prohibition notice remains in force until the earliest of either the day the prohibition ends as stated in the notice or the day the notice is revoked and provides that a person may apply to the director-general to have their notice revoked in accordance with the notice. The director-general may also on their own initiative revoke the notice if satisfied the grounds on which it was given no longer apply.

Clause 87 Contravention of prohibition notice

This clause creates an offence for contravening a prohibition notice. The maximum penalty for a 1st offence is 250 penalty units and for a 2nd or subsequent offence - 500 penalty units. For each day after the first day of contravention for which the contravention continues, there is a maximum penalty of 30 penalty units per day.

Clause 88 Direction to provide information about potential notice recipients

This clause provides that the director-general may require a corporation to provide specified information if a corporation is the subject of a prohibition or improvement notice.

If a person fails to comply with a direction for information under this clause, the maximum penalty is 100 penalty units for a 1st offence or 200 penalty units for a 2nd or subsequent offence.

A person does not commit an offence under this clause if that person has a reasonable excuse for failing to comply with the direction.

PART 8 Enforcement

Clause 89 Definitions – Part 8

This clause defines the following terms for this Part: *authorised person*, *connected*, *occupier*, *offence*, *premises*, and *warrant*.

Clause 90 Appointment of authorised people

This clause provides for the director-general to appoint a public servant as an authorised person for this Act.

Clause 91 Identity Cards

This clause requires that the director-general give an authorised person an identity card and specifies the format and information required for the identity card.

It is an offence under the Act for a person who stops being an authorised person to not return their identity card within 7 days. The maximum penalty for this offence is 1 penalty unit. If the card has been lost, stolen or destroyed by someone else, this offence does not apply.

An offence under this section is a strict liability offence.

Clause 92 Requirements before certain powers can be exercised

This clause provides that before an authorised person exercises their powers under certain clauses in this part, the authorised person must show their identity card to the affected person, provide reasons for exercising the relevant power to the affected person, and tell the affected person about any relevant offence in relation to the power being exercised.

Clause 93 Privilege against self-incrimination does not apply

This clause provides that a person is not excused from complying with a direction to provide information, a document or other thing under this part, on the ground that doing so may tend to incriminate the person or expose the person to a penalty.

Any information, document or thing obtained, directly or indirectly, under this part is not admissible in evidence against the person in a civil or criminal proceeding, other than a proceeding for an offence arising out of the false or misleading nature of the information, document or thing.

Clause 94 Direction to give information

This clause provides that an authorised person may, in writing, direct a person to give the authorised person information, a document or other thing that is required by the authorised person for this Act within a stated reasonable period. It is an offence for a person to not take reasonable steps to comply with a direction with a maximum penalty of 50 penalty units.

Clause 95 Direction to give name and address

This clause provides for an authorised person to direct a person to state their name and address if the authorised person believes on reasonable grounds that the person has, is or is about to commit an offence against this Act, or who may be able to assist in the investigation of an offence against this Act. Failure to comply with a direction under this clause is a strict liability offence with a maximum penalty of 5 penalty units.

Clause 96 Powers of authorised person to enter premises

This clause provides for an authorised person to enter premises and prescribes the circumstances under which it is reasonable to do so and the way it may be done. An authorised person may only enter premises or a part of the premises that is being used

only for residential purposes with the occupier's consent or in accordance with a warrant.

Clause 97 Obtaining consent to entry

This clause requires that an authorised person when seeking to enter premises under clause 96 must tell the occupier the purpose for the entry, the reason for and identity of any other person accompanying the authorised person, and that anything found and seized under this part may be used in evidence in court and that the person has the right to refuse entry.

If the occupier consents to entry, the authorised person must give the occupier a written record confirming matters in relation to consent.

Clause 98 General powers on entry to premises

This clause stipulates what an authorised person who enters premises may do in relation to the premises or anything at the premises. Among other things an authorised officer may direct the occupier of the premises to do certain prescribed things. Failure to comply with such a direction is an offence with a maximum penalty of 50 penalty units.

Clause 99 Definitions – Division 8.5

This clause defines the following terms for this division: *remote application*, *warrant form*, and *warrant terms*.

Clause 100 Application for warrant

This clause provides for an authorised person to apply to a magistrate for a warrant to enter premises and states the requirements for an application.

Clause 101 Magistrate may refuse to consider application for warrant until authorised person gives relevant information

This clause provides that a magistrate may refuse to consider an application under clause 100 until that authorised person provides the necessary information the magistrate requires.

Clause 102 Decision on application for warrant

This clause provides for the matters a magistrate must be reasonably satisfied of before issuing a warrant under clause 100 and provides for the information that must be contained in the warrant terms.

Clause 103 Warrant issued on remote application

This clause provides the method by which a magistrate may issue a warrant on a remote application. It requires the authorised person to swear the remote application and give the sworn application to the magistrate.

Clause 104 Announcement before entry under warrant

This clause specifies what an authorised person must do before anyone enters premises under a warrant.

Clause 105 Warrant etc to be given to occupier

This clause requires that an authorised person must give the occupier present at the time a warrant is being executed, a copy of the warrant or equivalent, and a document setting out the rights and obligations of the person.

Clause 106 Occupier entitled to watch search etc

This clause provides for the occupier of the premises being searched to observe the search being conducted, unless this would impede the search, or the person is under arrest.

Clause 107 Authorised person may seize things at premises

This clause provides for an authorised person who enters premises with the occupier's consent to seize anything at the premises if seizure of the thing is necessary to prevent the thing from being concealed, lost or destroyed, or necessary to prevent the thing from being used to commit, continue or repeat the offence, or the thing is connected with an offence against the Act. If the authorised person enters premises under a warrant, the authorised person may seize anything that the warrant authorises. This clause also provides for a seized thing to be removed from the place of seizure or to have access to it restricted.

Clause 108 Moving things to another place for examination or processing under warrant

This clause provides for an authorised person acting under a warrant to move things seized under said warrant for examination or processing and specifies conditions for when and how this function may be executed.

Clause 109 Owner etc may access seized things

This clause provides for a person entitled to inspect a thing seized to be able to inspect the thing, make a visual recording of the thing, and if the thing is a document, take extracts from or make copies of the thing.

Clause 110 Person must not interfere with seized things

This clause provides that a person commits an offence if a person interferes with a seized thing, or anything containing a seized thing, where the person does not have the approval of an authorised person to interfere with the thing. Failure to comply is an offence under this clause. The maximum penalty for this offence is 50 penalty units.

An offence against this clause is a strict liability offence.

Clause 111 Authorised person must give receipt for seized things

This clause requires an authorised person to provide a receipt to the owner of things seized and specifies what information must be included in the receipt.

Clause 112 Return of seized things

This clause provides for a thing seized to be returned to its owner or subject to specified conditions, for reasonable compensation paid to the owner by the Territory for the loss of the thing.

Clause 113 Order disallowing seizure

This clause provides that a person claiming to be entitled to a thing seized under this division may apply to the Magistrates Court for an order disallowing the seizure and sets out the process for such an application to be made.

Clause 114 Damage etc to be minimised

This clause requires an authorised person in executing functions under this part to take all reasonable steps to ensure that as little inconvenience, detriment and damage as is practicable is caused.

Clause 115 Compensation for exercise of enforcement powers

This clause provides that a person who has suffered loss or expense because of the exercise of a function under this part by an authorised person or a person assisting an authorised person may make a claim for compensation to a court of competent jurisdiction.

PART 9 Procedural and evidentiary provisions

Clause 116 Court to notify director-general of offence

This clause requires a court to notify the director-general if a person is found guilty or convicted of an offence under the Act.

Clause 117 Destruction of falsification of records

This clause provides that it is an offence for a person to knowingly falsify or destroy a pre-commencement record or another record required to be kept under the Act with a maximum penalty of 100 penalty units. This offence does not apply if the destruction of the record is authorised by the director-general, or the record is a hard copy version that has been converted to electronic format.

Clause 118 Criminal liability of executive officer

This clause provides the circumstances for which an executive officer of a corporation may be held personally liable, if the corporation contravenes a provision of the Act. The maximum penalty is the maximum penalty that may be imposed for the commission of the offence by an individual.

Clause 119 Evidentiary certificates

This clause provides that in a proceeding for an offence against the Act, a certificate that appears to be signed by the director-general or other person prescribed by regulation, relating to certain matters is evidence of the matters contained in the certificate.

Clause 120 Disclosure of information by ART providers and others

This clause provides that a requirement to disclose information under the Act has effect despite any duty of confidentiality or other restriction on disclosure (including under the *Health Records (Privacy and Access) Act 1997*) and if a person discloses information in accordance with the Act, the disclosure is not a breach of confidence, or a breach of professional etiquette or ethics, or a breach of a rule of professional conduct. The person disclosing information in accordance with the Act does not incur civil or criminal liability only because of the disclosure.

Clause 121 Protection of public officials from liability

This clause provides that a public official is not civilly liable for conduct engaged in honestly and without recklessness in the exercise of or in the reasonable belief that the conduct was in the exercise of a function under this Act or another territory law, and that any liability attaches instead to the Territory.

PART 10 Notification and review of decisions

Clause 122 Meaning of *reviewable decision* – Part 10

This clause defines *reviewable decision* for this part and includes a decision by the director-general to impose conditions on registration under clause 16, give an improvement notice under clause 79, revoke an improvement notice under clause 82, give a prohibition notice under clause 84, or end a prohibition notice under clause 86.

Clause 123 Reviewable decision notices

This clause provides that the director-general must give a reviewable decision notice to the ART provider if the director-general makes a reviewable decision in relation to an ART provider.

Clause 124 Applications for review

This clause sets out who may apply to the ACAT for review of a reviewable decision.

PART 11 Miscellaneous

Clause 125 Determination of fees

This clause provides that the Minister may determine fees for the Act and that the determination is a disallowable instrument.

Clause 126 Incorporating, applying or adopting documents in regulations

This clause provides that a regulation may incorporate, apply or adopt a law as in force from time to time; or another instrument as in force from time to time, with or without change or modification. The director-general must ensure that an instrument incorporated, applied or adopted under this clause is accessible in certain formats.

Clause 127 Regulation-making power

This clause provides that the Executive may make regulations for the Act and that the regulations may create offences and fix maximum penalties of not more than 30 penalty units.

PART 12 Transitional

Clause 128 Meaning of *transitional period* – Part 12

This clause defines transitional period for this part.

Clause 129 Use, supply and export of gametes and embryos

This clause provides that a provision under the Act relating to the use, supply or export of a gamete or embryo applies to a gamete or embryo obtained or created before the end of the transitional period.

Clause 130 Storage of gametes and embryos

This clause provides that clause 43 does not apply to a gamete or embryo obtained or created before the end of the transitional period.

Clause 131 Completion of family – gametes donated before end of transitional period

This clause allows for completion of a family using the same donated gametes, where a child has been conceived by a person or their spouse from ART treatment before the end of the transitional period. The gamete must have been donated for use in the provision of ART treatment and a first child was conceived from ART treatment using another donated gamete of the same donor as a result of ART treatment before the end of the transitional period.

An ART provider may use the same donor's gametes to provide future ART treatment to the person who gave birth to the child or their domestic partner, or to create an embryo outside the body of a person for use in providing ART treatment to the person who gave birth to the child or their domestic partner. The consent of the donor for the use is taken to have been provided and may be modified or withdrawn in accordance with clause 30.

The clause then outlines a list of provisions which do not apply to the ART provider, where the first child conceived from the relevant donated gametes was conceived from ART treatment provided before the transitional period.

This clause also outlines a list of provisions which do not apply to the ART provider in relation to the gamete or an embryo created from the gamete, where the first child conceived from the relevant donated gametes was conceived from ART treatment within the transitional period.

Clause 132 Completion of family – embryos created before end of transitional period

This clause allows for completion of a family using an embryo created using a donated gamete before the end of the transitional period, for use in providing ART treatment to a particular person. An ART provider may use the embryo to provide ART treatment to the person or their domestic partner. The consent of each gamete provider for the use is taken to have been provided and may be modified or withdrawn in accordance with clause 30.

This clause outlines a list of provisions which do not apply to the ART provider in relation to the embryo, if the embryo is created before the transitional period.

This clause also outlines a list of provisions which do not apply to the ART provider in relation to the embryo, if the embryo is created during the transitional period.

Clause 133 Expiry – Part 12

This clause provides that Part 12 of the Act expires **15 years** after the day it commences.

PART 13 Consequential amendments

Clause 134 Freedom of Information Act 2016 - New section 11A

This clause amends the Freedom of Information Act 2016 (FOI Act) to exclude the FOI Act from applying to information in the donor register.

Clause 135 Human Cloning and Embryo Research Act 2004 - New section 49A

This clause amends the Human Cloning and Embryo Research Act 2004 (Human Cloning Act) so that the court must notify the director-general in writing if a person is found guilty or convicted of an offence against the Human Cloning Act.

Dictionary

The Dictionary sets out the definitions for this Act.