

General Scheme of the Assisted Human Reproduction Bill 2017

**GENERAL SCHEME OF THE
ASSISTED HUMAN REPRODUCTION BILL 2017**

A Bill to provide for:

- 1) The regulation of assisted human reproduction
- 2) Gamete and embryo donation for use in assisted human reproduction treatment and research
- 3) Posthumous assisted reproduction involving the gametes or embryos of a deceased person under certain conditions.
- 4) Pre-implantation genetic diagnosis and sex selection
- 5) Surrogacy
- 6) Embryo and stem cell research
- 7) Independent regulatory authority for assisted human reproduction

General Scheme of the AHR Bill 2017

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Introduction to the General Scheme

The number of people accessing assisted human reproduction (AHR) treatments and services in Ireland is increasing. However, the provision of these services remains largely unregulated, which means that individuals are availing of often complex and sometimes risky procedures in a legal vacuum. This legal vacuum has significant consequences not only for couples and individuals using AHR treatments and services, but also for the fertility clinics themselves and for the general public who have a legitimate expectation that all AHR practices and related research is regulated and carefully monitored.

Background

Given the ethical, legal and social concerns arising in relation to AHR and associated research, the need for a specific regulatory framework in these areas has been highlighted in a number of expert reports, and high-profile Irish court cases.

On 17 February 2015, the Government approved the drafting of a General Scheme of a Bill for AHR and associated research. This Government decision included provision for the following policy areas in the General Scheme: gamete and embryo donation for use in AHR treatment and research; surrogacy; posthumous assisted reproduction; pre-implantation genetic diagnosis and sex selection; embryonic and induced pluripotent stem cell research; and to provide for an independent regulatory authority for AHR.

Overview of Key Provisions

The proposed legislation has a number of objectives, most importantly, protecting and promoting the health and safety of children born through AHR, their parents and others involved in the process such as donors and surrogates.

The General Scheme encompasses the following key elements:

General principles that apply in the context of all AHR treatments and procedures, including requirements regarding informed consent and counselling, conditions regarding embryo transfer, and welfare of the child considerations.

The conditions and restrictions relating to an individual or couple donating his/her or their gametes and embryos for use in AHR treatment by others and/or for use in research and relating to people accessing AHR treatment involving donated material.

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Providing for posthumous assisted reproduction (PAR) in certain circumstances, whereby gametes provided by a deceased person, or embryos created using those gametes, may be used in AHR treatment for that person's surviving spouse, civil partner or cohabitant.

Permitting pre-implantation genetic diagnosis (PGD), sex selection (for medical purposes) and human leucocyte antigen (HLA) matching in the context of AHR treatment, provided certain eligibility criteria are fulfilled.

Outlining the specific conditions under which surrogacy will be permitted, including a requirement for all surrogacy agreements to be pre-authorised by the Regulatory Authority. These provisions also put in place a court-based mechanism through which the parentage of a child born through surrogacy may be transferred from the surrogate (and her husband, if applicable) to the intending parent(s).

Stipulating the conditions under which research involving embryos, embryonic stem cells and induced pluripotent stem cells may be permitted, subject to licence, as well as prohibiting specific associated practices, such as reproductive cloning.

Providing for the establishment of the Assisted Human Reproduction Regulatory Authority and detailing its functions in the context of the oversight and regulation of compliance with the proposed legislation, including the issuing of licences to AHR treatment providers and researchers.

entitled

Assisted Human Reproduction Bill 2017

AN ACT TO PROVIDE FOR THE REGULATION OF ASSISTED HUMAN REPRODUCTION (AHR) INCLUDING GAMETE AND EMBRYO DONATION FOR USE IN AHR AND RESEARCH; POSTHUMOUS ASSISTED REPRODUCTION; PRE-IMPLANTATION GENETIC DIAGNOSIS AND SEX SELECTION; SURROGACY; EMBRYO AND STEM CELL RESEARCH; AND TO PROVIDE FOR THE ESTABLISHMENT OF A BODY TO BE KNOWN AN TÚDARÁS RIALÁLA UM ATÁIRGEADH DAONNA CUIDITHE OR IN THE ENGLISH LANGUAGE AS THE ASSISTED HUMAN REPRODUCTION REGULATORY AUTHORITY (AHRRA) TO PERFORM THE FUNCTIONS OF THE THIS ACT AND SECTIONS 33-42 OF THE CHILDREN AND FAMILY RELATIONSHIPS ACT 2015 AND TO PROVIDE FOR RELATED MATTERS.

BE IT ENACTED BY THE OIREACHTAS AS FOLLOWS:

PART 1 PRELIMINARY AND GENERAL

Head 1 – Short title and commencement

This Head provides that:

(1) This Act may be cited as the Assisted Human Reproduction Act 2017.

(2) This Act comes into operation on such day or days as the Minister may appoint by order or orders either generally or with reference to any particular purpose or provision, and different days may be so appointed for different purposes and different provisions.

Explanatory Note

This is a standard provision containing the title and commencement date. **Subhead (2)** is included on the assumption that not all provisions of the Act will not come into force on enactment.

Head 2 – Interpretation

This Head provides that:

(1) In this Act, unless the context otherwise requires-

"Act of 1987" means the Status of Children Act, 1987;

"Act of 2010" means the Civil Partnership and Certain Rights and Obligations of Cohabitants Act 2010;

"Act of 2015" means the Children and Family Relationships Act 2015;

"AHR treatment provider" means a person licenced by the Assisted Human Reproduction Regulatory Authority to perform AHR treatment procedures;

"assisted human reproduction (AHR)" means all treatment or procedures that involve the handling of gametes and embryos for the purposes of establishing a pregnancy;

"birth certificate" means a document issued under section 13(4) of the Civil Registration Act 2004 in respect of an entry in the register of births;

"child" means a person who is under 18 years of age;

"civil partner" shall be construed in accordance with section 3 of the Act of 2010;

"cohabitant" shall be construed in accordance with section 172(1) of the Act of 2010;

"court" means the Circuit Court;

"donor" means a person who provided a gamete or embryo -

(a) for use in providing AHR treatment to one or more other people and who does not intend to be the legal parent of a child born as a result of that treatment, or

(b) for use in research,

in accordance with the provisions of Part 3;

"embryo" means a human embryo formed by the fertilisation of a human egg by a human sperm;

"gamete" means,

- (a) a human sperm, which is formed in the body of and provided by a man, or
- (b) a human egg, which is formed in the body of and provided by a woman.

"human leukocyte antigen (HLA) matching" refers to the use of PGD for the purpose of testing and selecting embryos that would result in a child whose tissue was compatible with that of an existing, sick child;

"intending parent" means, in relation to an AHR treatment procedure, a person who intends to be the parent of any child born as a result of that procedure;

"licence holder" means an AHR treatment provider or a researcher who has been issued with a licence by the Regulatory Authority in accordance with this Act;

"Minister" means the Minister for Health;

"partner" means spouse, civil partner or cohabitant;

"pre-implantation genetic diagnosis (PGD)" means a procedure for genetically testing embryos for specific genetic or chromosomal mutations prior to transfer involving the biopsy of embryos to remove one or more cells, and selection of embryos for transfer on the basis of the results from the analysis;

"sex selection" refers to any procedure carried out in order to increase the probability, or ensure that a human embryo will be of a particular sex;

"S.I. No. 158 of 2006" means S.I. No. 158 of 2006 - European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006;

"supernumerary embryo" means an embryo that was created and stored for use as part of a person's own AHR treatment (whether as an individual or as part of a couple), but which remains unused following the completion of that treatment;

"surrogate" means a woman who carries a pregnancy in pursuance of a surrogacy agreement and who is the legal mother of any child born under a surrogacy agreement;

"writing" includes voice and video recording and speech recognition technologies.

Explanatory Note

This Head defines key words and terms used in this Act.

Head 3 – Expenses

This Head provides that:

(1) The expenses incurred by the Minister in the administration of this Act shall, to such extent as may be sanctioned by the Minister for Public Expenditure and Reform, be paid out of moneys provided by the Oireachtas.

Explanatory Note

This is a standard provision in regard to the cost of the administration of the Act.

Head 4 - Regulations

This Head provides that:

(1) The Minister may by regulation provide -

- (a) for any matter referred to in this Act as prescribed or to be prescribed, or
- (b) for any matter that appears to the Minister to be necessary or expedient for bringing this Act into operation.

(2) Without prejudice to any provision of this Act, regulations under this head may contain such incidental, supplementary and consequential provisions as appear to the Minister to be necessary or expedient for the purposes of the regulations.

(3) Every regulation under this Act shall be laid by the Minister before each House of the Oireachtas as soon as may be after it is made and, if a resolution annulling the order or regulation is passed by either such House within the next 21 days on which that House sits after the order or regulation is laid before it, the order or regulation shall be annulled accordingly but without prejudice to the validity of anything previously done thereunder.

Explanatory Note

This is a standard provision in regard to Ministerial powers to make regulations.

PART 2 GENERAL PRINCIPLES

Head 5 - General principles

This Head provides that:

(1) In all decisions regarding the provision of assisted human reproduction (hereafter referred to as AHR) treatment, due regard shall be given to the health and wellbeing of children born as a result of such treatments and to women who receive such treatments.

(2) The benefits of AHR technologies and associated research, for children, intending parents, donors, surrogates and society will be promoted by the taking of appropriate measures, as provided for herein, for the protection and promotion of human health, safety, dignity and rights in the use of such technologies and associated research.

Explanatory Note

Subhead (1) acknowledges that children are the most vulnerable parties in the AHR process as they lack any control over the circumstances of their conception and birth. Considerations in relation to the health and wellbeing of children born through AHR underpin these legislative provisions. The intention here is that, as far as practicable, children born as a result of AHR should not be exposed to greater medical or psychosocial risk than children who are conceived without AHR treatment. Subhead (1) also provides that the wellbeing of women involved in AHR procedures also requires special attention, as women are the main recipients of interventions due to their biological role in pregnancy and childbirth. AHR interventions are not without potential complications, such as in the case of ovarian hyperstimulation syndrome, which can be fatal. Moreover, AHR treatments can extract a heavy psychological toll and can cause anxiety and stress.

Subhead (2) states that the legislative provisions seek to protect and promote the health and safety of intending parents, others involved in the process (such as donors and surrogates) and, most importantly, the children who will be born as a result of AHR by ensuring safe, ethical and effective care.

Head 6 - Provision of AHR treatment

This Head provides that:

(1) AHR treatment may be provided to a person and his or her partner, if he or she has one, subject to a consideration of the welfare of any child who would be born as a result of the proposed treatment.

(2) A woman may be provided with AHR treatment, if the AHR treatment provider is satisfied, on reasonable grounds, that –

(a) in the woman's circumstances, she is unlikely to become pregnant or carry a pregnancy or give birth in the absence of such treatment; or

(b) pregnancy or child birth would not pose a disproportionate risk to the health of the woman or the child, in line with national medical and obstetric standards; and

(c) the provisions set out in Head 7 regarding the welfare of the child are met.

(3) AHR treatment shall not be provided to persons who are under the age of 21 years.

(4) AHR treatment shall only be provided to a woman who is 47 years of age or under, irrespective of whether the woman is using her own gametes, an embryo created using her gametes, or gametes or embryos donated by a third party.

(5) A man may be provided with AHR treatment, if the AHR treatment provider is satisfied, on reasonable grounds, that the man presents a reasonable expectation to be able to parent the child until that child reaches adulthood.

Explanatory Note

Subhead (1) states that AHR services can be provided to a person singly or together with his/her partner, if s/he has one, subject to a consideration of the best interests of any child who might be born as a result of the proposed AHR treatment and the broader provisions of this Act. This subhead recognises the principles of equality and non-discrimination and is in line with the provisions of the Children and Family Relationships Act 2015 and the Marriage Act 2015.

Subhead (2) sets out certain criteria for the provision of AHR treatment. For instance, that the woman would be unable to become pregnant, carry a pregnancy or give birth without

AHR treatment being provided and that neither pregnancy nor child birth would pose a disproportionate risk in line with accepted medical and obstetric standards. Subhead 2(c) states that the AHR treatment provider will have to consider the welfare of the child, as set out in Head 7, in making the final decision whether or not to provide AHR treatment.

Subhead (3) sets a lower age limit of 21 years. The reason for this age limit is to ensure that intending parents have reached an appropriate age to meet the criteria for a clinical diagnosis of infertility before being offered AHR treatments. The World Health Organization (WHO) and the International Committee for Monitoring Assisted Human Reproductive Technology define infertility as a failure to achieve a clinical pregnancy after 12 months or more of regular unprotected sexual intercourse. The UK's National Institute for Health and Care Excellence (NICE) has advised that couples wishing to undergo fertility treatment should be in a relationship for at least two years in order to allow for appropriate time to determine whether they actually require fertility treatment. This Head is not gender specific. The provisions of Part 9 of this Act clarify that it would be an offence for a person to provide AHR treatment in contravention of this age limit. While people under the age of 21 years would not be able to avail of AHR treatment, the provisions of Head 22(7) enable gametes of a person under 21 to be stored, for example, as part of a fertility preservation programme if s/he will need to receive medical treatment which could impact on his/her fertility.

Subhead (4) sets an upper age limit of 47 years for women for the provision of AHR treatment. Those providing AHR treatment need to make a clinical assessment of any prospective patient and ensure that AHR treatment does not represent a disproportionate risk to the health of the patient or to the health of any potential child. Female age is one of the main factors affecting the outcome of AHR and a woman's ability to conceive a child inevitably reduces with age. The provisions of Part 9 of this Act clarify that it would be an offence for a person to provide AHR treatment in contravention of this age limit.

Subhead (5) does not set a specific paternal age limit, rather it requires that a man seeking to access AHR treatments and services should be, in the view of the AHR treatment provider, reasonably expected, in light of his health and related factors (e.g. age), to parent any child born as a result of the AHR treatment into adulthood.

Head 7 - Welfare of the child

This Head provides that:

- (1) A person shall not be provided with AHR treatment unless account has been taken of the welfare of any child who may be born as a result of such treatment.
- (2) If treatment is refused, the AHR treatment provider shall clearly explain, in writing, the reason for the treatment refusal.
- (3) The process referred to in subhead (1) should be repeated by the AHR treatment provider if:
 - (a) there has been no contact between the provider and the intending parent or parents for two years or more; or
 - (b) it has reason to believe that the medical or social circumstances of the intending parent or parents have changed significantly.
- (5) The Regulatory Authority shall publish guidance to assist AHR treatment providers in complying with these provisions.

Explanatory Note

Subhead (1) - At the heart of deliberations regarding access to AHR treatments and services is a concern for the welfare of the child born as a result of such treatment. Subhead (1) requires that, in advance of providing treatment, an AHR treatment provider must consider the welfare of any child who would be born as a result of such treatment. This is in order to safeguard the health and wellbeing of such a child. The provisions of Part 9 of this Act clarify that it would be an offence for a person to provide AHR treatment in contravention of this subhead.

Subhead (2) requires that, in the case of a treatment refusal, the AHR treatment provider must explain clearly and in writing, the reason for such refusal. In its *Practice Consensus*, the Irish Fertility Society (IFS) states that: “where there is objective evidence of significant risk of harm to any child that may be conceived through fertility treatment there should be a presumption against treatment”. This statement is in line with the 2005 report of the Commission on Assisted Human Reproduction (CAHR), which recommended that legislation should be enacted which would confer on AHR service providers a discretion to deny AHR

treatments to individuals where there are serious concerns, supported by objective evidence, that the welfare of any resultant child could be at risk.

Subhead (3) states that in the interest of due process, an AHR treatment provider should repeat the process of considering the welfare of the child in the context of subhead (1) if a significant amount of time has passed since s/he last had contact with the intending parent or parents (e.g. it has been two years since they last underwent treatment) or there is reason to believe that the medical or social circumstances of the intending parent or parents have altered e.g. development of a serious medical condition.

Subhead (4) states that the Regulatory Authority will provide guidelines on how to comply with the requirements of this Head regarding welfare of the child considerations.

Head 8 - Counselling

This Head provides that:

(1) All intending parents wishing to undergo AHR treatment shall be provided with counselling from a counsellor who delivers services on behalf of the AHR treatment provider.

(2) When AHR treatment is to be provided to a couple, pre-treatment counselling shall be offered to the intending parents either individually, together or both.

(3) The counselling referred to in subhead (1) may:

(a) be available at the place where the AHR treatment is to be provided; and

(b) shall be provided by a counsellor in line with current best practice.

(4) Counselling should occur after the initial medical consultation and the provision of information regarding the proposed AHR treatment and shall be clearly distinguished from:

(a) the process of considering the welfare of the child outlined in Head 7; and

(b) the consent to treatment process.

Explanatory Note

Subhead (1) provides that all intending parents must receive counselling from a counsellor who is operating on behalf of the AHR treatment provider. Since AHR deviates from the expected norms of natural conception, it poses a number of complex ethical, social and legal questions which many people might not have considered prior to their engagement with it. In order to explore the various issues raised by AHR and to ensure that consent to treatment is informed and genuine, it is important that intending parents undergo pre-treatment counselling. Such counselling would provide an opportunity to discuss the possible medical and social implications of the proposed treatment for the intending parents, any child who might be born as a result of that treatment or for the intending parent's existing children, if any. Counselling could also provide advice in relation to additional supports or services available. The fact that individuals require support and advice to assist them at all stages of the process is well recognised internationally and is legislated for in most jurisdictions. The CAHR also recommended that counselling be available from appropriately qualified counsellors before, during and after treatment as an integral part of the service offered by AHR clinics.

Work is ongoing in the Department of Health in relation to implementing provisions for the designation and regulation of counsellors under the Health and Social Care Professionals Act 2005. Any subsequent regulatory developments in this area will be taken into consideration as the Assisted Human Reproduction Bill is developed.

Subhead (2) states that, where treatment involves a couple, intending parents should be provided with an opportunity to have counselling together, individually or both.

Subhead (3) states that the intending parents may be able to access the counselling from a counsellor, at the AHR treatment provider's premises. The counselling service must comply with current professional standards/guidelines on good practice in fertility counselling.

Subhead (4) states that counselling should be provided after the initial consultation and the provision of information regarding the proposed treatment between the AHR treatment provider and the intending parents. It also states that counselling must be distinct from the process of considering the welfare of the child under Head 7 and the consent process.

Head 9 - Consent

This Head provides that:

(1) Consent for AHR treatment shall be obtained, in the prescribed form, by the AHR treatment provider before treatment commences and shall cover all stages of treatment.

(2) A person's consent under subhead (1) shall—

(a) specify that each intending parent, has provided his or her consent to undergo each treatment procedure outlined in the consent form,

(b) not have been altered or revoked when the treatment procedure takes place,

(c) specify what to do with stored gametes, embryos, or both, as the case may be, if one or both intending parents dies or subsequently lacks capacity to make a decision,

(d) specify what to do in the event of post factum differences of opinion or changes of circumstances, and

(e) be sought again if the nature of treatment changes after initial consent has been given or if more than two years have elapsed since consent was provided.

(3)(a) A person's consent under subhead (1) shall not be considered valid unless—

(i) it was obtained in writing,

(ii) it was given voluntarily,

(iii) the person providing his or her consent had the capacity to give consent at the time in question,

(iv) the consent form was signed by the person giving consent.

(b) Prior to giving his or her consent under paragraph (a) the person in question shall have been provided with relevant information about the proposed AHR treatment or treatments, as the case may be.

(c) Separately from and subsequent to the provision of information referred to in paragraph (b), the person giving his or her consent shall have received the counselling referred to in Head 8.

(4)(a) A person may, while he or she has capacity to do so, revoke or alter his or her consent to AHR treatment before a given procedure has been performed.

(b) A revocation or alteration of consent under paragraph (a) shall be made in writing and signed by the person revoking or altering his or her consent..

(c) A person revoking or altering consent shall give notice of the revocation or alteration to the AHR treatment provider or as soon as practicable.

(5) Where a person is giving, altering or revoking consent in the context of subheads (3)(a) or (4)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

(6) The AHR treatment provider shall—

(a) retain the original of each consent or revocation or alteration of consent given to the provider under this Act, and

(b) ensure that a copy of each consent or alteration or revocation of consent is given to the person who gave the consent or revocation or alteration of consent.

Explanatory Note

Subhead (1) - According to the HSE's *National Consent Policy*, consent must be obtained before starting treatment and states that this requirement is consistent with fundamental ethical principles, with good practice in communication and decision-making and with national health and social care policy. The need for consent is also recognised in Irish and international law. Therefore, subhead (1) states that prior consent of persons receiving AHR treatment must be obtained prior to commencing such treatment and this consent must cover all of the various stages of treatment that apply, for example, gamete retrieval, embryo creation, and embryo transfer. The

provisions of Part 9 of this Act clarify that it would be an offence for a person to provide AHR treatment in contravention of this subhead.

Subhead (2) - In advance of treatment, prospective parents need to consider their views in relation a number of complex issues relating to their treatment. It is, therefore, imperative that intending parents are fully informed of the nature and consequences of the various treatments on offer and that they have been given the appropriate time to consider these issues prior to the commencement of treatment. Subhead (2) states that the consent form must clearly specify what treatment procedures the intending parent or parents, as the case may be, have provided his/her or their consent for and that the consent therein has not been altered or revoked at the time when the AHR treatment procedure is taking place. Subhead (2) also states that consent forms should anticipate challenges that might arise in the future (e.g. severe illness, death or relationship breakdown) and should require that each intending parent gives some consideration and makes informed decisions in light of those potential challenges. In addition, it may be necessary to obtain the consent of each intending parent again in situations where a significant amount of time has passed since the original consent was given (i.e. two years) or if the nature of the proposed treatment has changed, e.g. if it is proposed that donor gametes are used instead of the patient's own.

Subhead (3) sets out the criteria for a valid consent, for example, i.e. the consent must be in writing, voluntarily given and have been obtained following the provision of information relating to the proposed treatment as well as counselling.

Subhead (4) states a person may revoke or alter his/her consent at any time, provided s/he has capacity to do so, and before a given treatment procedure has been conducted. For example, in the case of IVF-based procedures consent could be revoked or altered up until the point that the embryo has been transferred to the woman's uterus. Subhead (4) also states that notice of the revocation or alteration must be given in writing and submitted to the AHR treatment provider as soon as practicable. This subhead takes account of the fact that people's circumstances and viewpoints may change over time.

Subhead (5) - In some situations, while the person providing, altering or revoking his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (5) states that in such instances

the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Subhead (6) states that an AHR provider must retain the original copy of the consent form (including any alteration or revocation of consent) and that the AHR provider must supply a copy of the consent, alteration or revocation to the intending parents.

Head 10 - Embryo transfer

This Head provides that:

(1)(a) A woman undergoing AHR treatment, who has a favourable prognosis, shall be offered single embryo transfer in each cycle.

(b) The transfer of two embryos should only be considered if no high quality embryos are available.

(2) An AHR treatment provider shall not transfer more than two embryos in any one treatment cycle.

(3) Where two embryos are to be transferred, the AHR treatment provider shall provide each intending parent with information regarding the risks associated with multiple pregnancies and multiple births.

Explanatory Note

Subhead (1) sets out that AHR providers must offer single embryo transfer in the first treatment cycle to women who have a favourable prognosis of treatment success. The purpose of this provision is to protect the health and wellbeing of the intending mother and the potential child through the reduction in the number of multiple births. Multiple births (i.e. twins or triplets) represent a significant health risk associated with AHR facing both mothers and babies. There is a general consensus that elective single embryo transfer should be indicated in young, good-prognosis patients with good quality embryos, thus, promoting a reduced twin rate without decreasing the chances of pregnancy. Patients' characteristics should be carefully evaluated when deciding on the embryo transfer policy, since poor prognosis factors such as advanced female age, poor embryo quality and some infertility factors may dictate the need for double embryo transfer. Subhead (1) also states that in all cases the transfer of two embryos should only be considered where no high quality embryos are available.

Subhead (2) states that irrespective of a woman's prognosis or her age no more than two embryos should ever be transferred in a single treatment cycle. The provisions of Part 9 clarify that contravening subhead (2) would be an offence under this Act.

Subhead (3) specifies that if two embryos are to be transferred in a single treatment cycle, then there is an obligation on the AHR treatment provider to explain the risks associated with multiple pregnancies and births.

PART 3 GAMETE AND EMBRYO DONATION

Head 11 - Interpretation (Part 3)

This Head provides that:

In this Part—

"supernumerary gamete" means a gamete that was collected and stored for use as part of a person's own AHR treatment (whether as an individual or as part of a couple), but which remains unused following the completion of that treatment.

Head 12 - Gamete donation for use in AHR or research

This Head provides that:

(1) A person, may donate his or her gametes to be used in providing AHR treatment to one or more other people if—

- (a) he or she has provided his or her consent,
- (b) he or she has attained the age of 18 years,
- (c) in the case of an egg donor, she is not more than 35 years of age, or
- (d) in the case of a sperm donor, he is not more than 40 years of age.

(2)(a) Subject to subhead (1), a person may donate his or her supernumerary gametes to be used in providing AHR treatment to one or more other people if—

- (i) the gametes were originally collected for use by the person, and his or her partner (if any), as part of his or her own AHR treatment,
- (ii) his or her own AHR treatment has been completed, and
- (iii) the consent to donate the supernumerary gametes is obtained separately from and subsequent to the conclusion of this person's own AHR treatment.

(b) In the case of supernumerary gametes to be used in providing AHR treatment, the limits on the maximum allowable age of the donor under subhead (1), refer to the age of the donor when the gametes were originally collected.

(c) In all other provisions under this Act, unless otherwise stated, reference to the donation of gametes to be used in providing AHR treatment, shall include supernumerary gametes.

(3)(a) A person, may donate his or her gametes to be used in research if—

- (i) he or she has provided his or her consent, and
- (ii) he or she has attained the age of 18 years.

(b) Subject to paragraph (a), a person may donate his or her supernumerary gametes to be used in research if—

- (i) the gametes were originally collected for use by the person, and his or her partner (if any), as part of his or her own AHR treatment,
- (ii) his or her own AHR treatment has been completed, and

(iii) the consent to donate the supernumerary gametes is obtained separately from and subsequent to the conclusion of this person's own AHR treatment.

(c) In all other provisions of this Act, unless otherwise stated, reference to the donation of gametes to be used in research, shall include supernumerary gametes.

(4) The use of a person's gametes in providing AHR treatment to one or more other people, or in research, in a way that does not comply with the provisions of subheads (1), (2) or (3) is prohibited.

(5)(a) A person's consent under subheads (1), (2) or (3) shall not be considered valid unless

-

- (i) it was obtained in writing,
- (ii) the consent was given voluntarily,
- (iii) the person providing his or her consent had the capacity to give consent at the time in question, and
- (iv) the consent form was signed by the person giving consent.

(b) Prior to giving his or her consent under paragraph (a), the donor -

- (i) shall have been provided with information about gamete donation, including the potential risks and implications involved and,
- (ii) separately from and subsequent to the provision of information, shall have received counselling about gamete donation, including the potential risks and implications involved, from a counsellor.

(6) Where a person is giving consent in the context of subhead (5)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

(7) In providing his or her consent to the donation of his or her gametes, under subheads (1), (2) or (3) a person—

- (a) shall, in the context of subheads (1) and (2), specify the AHR treatment procedures that his or her gametes may be used in,

(b) may, in the context of subhead (3), specify the types of research that his or her gametes may be used in,

(c) shall specify what should happen to donated, but unused, gametes if he or she should lack the capacity at some point in the future to make a decision about their disposition, and

(d) shall specify what should happen to donated, but unused, gametes if he or she dies.

(8) Notwithstanding the maximum limit of four families set out in Head 16, in providing his or her consent, the donor may specify a lower number of families that may have children following AHR treatment using his or her gametes, or embryos created using his or her gametes.

(9)(a) In providing his or her consent to the donation of his or her gametes the donor shall clarify if he or she consents for—

- (i) his or her gametes, or an embryo created using his or her gametes, to be used in providing AHR treatment to one or more other people by another AHR treatment provider in the State or in another jurisdiction,
- (ii) his or her gametes, or an embryo created using his or her gametes, to be used in research in another research facility in the State or in another jurisdiction.

(b) Prior to giving his or her consent to the export of his or her gametes, or an embryo created using his or her gametes, to another jurisdiction under paragraph (a), the donor shall have been notified in writing that the law pertaining to—

- (i) the use of donated gametes and embryos for AHR treatment, or
 - (ii) the use of donated gametes and embryos in research
- in other jurisdictions may not be the same as it is in the State.

(10) A person's will and preferences regarding the use of embryos created using his or her donated gametes outlined in accordance with subheads (8) or (9) will only be relevant if the person or persons for whom the embryos in question were created subsequently decide to donate those embryos.

Explanatory Note

Head 12 sets out the specific conditions that need to be met in relation to a person providing his/her consent to donate his/her gametes to one or more other people for use in their AHR treatment or for use in research.

Subhead (1) - states that a person may donate his/her gametes to one or more other people for use in their AHR treatment if certain additional conditions are met, which relate to the person providing his/her consent and meeting the specified age criteria. Part 9 of this Act, clarifies that contravening this provision would be an offence.

Subhead (2) - clarifies that supernumerary gametes may be donated to one or more other people to be used as part of their AHR treatment provided certain conditions are satisfied, including the provisions of subhead (1), namely: that the gametes in question were collected with the intention of being used by the person who is now seeking to donate the supernumerary gametes and his or her partner (if s/he has one) as part of his or her own AHR treatment; (ii) that the treatment of the person (and his or her partner [if s/he has one]) for which the gametes were originally collected has been completed; and (iii) that following the completion of his/her own AHR treatment and as part of a separate consent process, the person in question has provided his/her consent specifically for the donation of the supernumerary gametes. For the purposes of this provision a person's (or a couple's [where relevant]) AHR treatment would be considered completed when s/he decides that s/he no longer wishes the use the gametes as part of his/her own treatment, for whatever reason, whether the previous treatment was successful or otherwise. Part 9 of this Act, clarifies that contravening subhead 2(a) would be an offence.

Subhead 2(b) clarifies that, in the case of supernumerary gametes, the maximum age limit relates to the age of the person donating the gametes when the gametes were originally collected, rather than that person's current age.

Subhead 2(c) clarifies that, unless a provision in this Act specifies otherwise, a reference to the donation of gametes for use in providing AHR treatment will include supernumerary gametes.

Subhead (3) - This Act provides for people to donate their gametes, including supernumerary gametes, to be used in research under certain circumstances. Subhead (3)(a) states that a person may donate his/her gametes to be used in research if certain conditions are met, namely: (i) that person has consented to the donation; and (ii) that

person is an adult (i.e. 18 years of age or older). Subhead (3)(b) outlines the conditions that need to be satisfied in order for a person to donate his/her supernumerary gametes for use in research. Subhead (3)(c) clarifies that, unless a provision in this Act specifies otherwise, a reference to the donation of gametes for use in research will include supernumerary gametes. Part 9 of this Act, clarifies that contravening subhead 3(a) or 3(b) would be an offence.

Subhead (4) clarifies that it is prohibited for anyone to use a person's gametes, including his or her supernumerary gametes, to provide AHR treatment to others or for the purposes of research in a way that contravenes the provisions of subheads (1), (2) or (3).

Subhead (5) - The purpose of this provision is to clarify the criteria for a valid consent, under subheads (1), (2) or (3), to the donation of gametes. Subhead (5)(a) states that the person who consented to the donation of his/her gametes must have had the capacity to do so, must have provided his/her consent in writing and voluntarily, and the person must have signed the consent form.

Subhead (5)(b)(i) states that, prior to giving his/her consent, the prospective gamete donor must have been given information about the potential risks and implications associated with being a gamete donor. Subhead (5)(b)(ii) states that separately and subsequent to the provision of information, each prospective donor must also have received counselling from a counsellor about the potential risks and implications of being a gamete donor.

Subhead (6) - In some situations, while the person providing his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (6) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Subhead (7) - Subhead (7)(a) requires that when providing consent to gamete donation for AHR treatment, a donor specifies the types of AHR treatment procedures that s/he is willing for his/her gametes to be used in. Similarly subhead (7)(b) enables a donor, as part of the consent process, to specify, if s/he so wishes, what types of research his/her gametes may be used in. Subheads (7)(c) and (7)(d) require each donor to outline his/her will and preferences regarding the subsequent disposition of his/her donated, but unused gametes in case s/he might lack the capacity to make such a decision when required in the future or in the event of his/her death.

Subhead (8) - The purpose of subhead (8) is to enable a donor to stipulate how many other families can have children following AHR treatment using his/her gametes (or embryos created using those gametes), subject to the maximum limit of four families allowed under Head 16 of this Part.

Subhead (9) - Subhead (9)(a) clarifies that when providing consent to donate gametes for use in providing AHR treatment to others or for use in research, the donor in question must clarify if his/her consent includes permitting his/her gametes, or an embryo created using his/her gametes, to be transferred to another AHR or research facility in the State or in another jurisdiction to be used in providing AHR treatment to others or in research. Subhead (9)(b) states that prior to giving his/her consent to the export of his/her gametes, or an embryo created using those gametes, the donor must be notified of the potential difference in the law in other countries to which the gametes or embryos could be exported to.

Note: The wording of subhead (9)(b) is modified from the HFEA's Directions entitled Import and Export of Gametes and Embryos (Version 4 issued on 29 October 2015), Schedule 2(1).

Subhead (10) clarifies that it would only be in the context of a situation involving the subsequent donation of the embryos created with a particular donor's gametes that the will and preferences of that original gamete donor would become relevant.

Head 13 - Embryo donation for use in AHR or research

This Head provides that:

(1) It is prohibited for embryos, other than supernumerary embryos, to be donated for use in—

(a) providing AHR treatment to one or more other people, or

(b) research.

(2) Supernumerary embryos may be donated to be used in providing AHR treatment to one or more other people provided that—

(a) the embryos were originally created as part of providing AHR treatment for a person, and his or her partner (if any),

(b) the AHR treatment of the person, and his or her partner (if any), has been completed,

(c) the consent to donate the supernumerary embryos is obtained separately from and subsequent to the completion the AHR treatment of the person, and his or her partner (if any),

(d) where the embryos were originally created as part of providing AHR treatment to a person and his or her partner together, each of them has provided his or her consent for the donation of the supernumerary embryos, and

(e) the age of each person who provided the gametes that the embryos in question were created from, was below the maximum allowable ages for sperm and egg donors, as outlined under Head 12, when the gametes were originally collected.

(3) A person, may donate his or her supernumerary embryos to be used in research provided that—

(a) the embryos were originally created as part of providing AHR treatment for a person, and his or her partner (if any),

(b) the AHR treatment of the person, and his or her partner (if any), has been completed,

(c) the consent to donate the supernumerary embryos is obtained separately from and subsequent to the completion the AHR treatment of the person, and his or her partner (if any), and

(d) where the embryos were originally created as part of providing AHR treatment to a person and his or her partner together, each of them has provided his or her consent for the donation of the supernumerary embryos.

(4) The use of a person's embryos in providing AHR treatment to one or more other people, or in research, in a way that does not comply with the provisions of subheads (2) or (3) is prohibited.

(5)(a) A person's consent under subheads (2) or (3) shall not be considered valid unless -

- (i) it was obtained in writing,
- (ii) it was given voluntarily,
- (iii) the person providing his or her consent had the capacity to give consent at the time in question, and
- (iv) the consent form was signed by the person giving consent.

(b) Prior to giving his or her consent under paragraph (a), each donor -

- (i) must have been provided with information about embryo donation, including the potential risks and implications involved and,
- (ii) separately from and subsequent to the provision of information, must have received counselling about embryo donation, including the potential risks and implications involved, from a counsellor.

(6) Where a person is giving consent in the context of subhead (5)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

(7)(a) In providing his or her consent to the donation of his or her embryos, under Subheads (2) or (3), a donor—

- (i) shall, in the context of subhead (2), specify the AHR treatment procedures that his or her embryos may be used in,
- (ii) may, in the context of subhead (3), specify the types of research that his or her gametes may be used in,

(iii) shall specify what should happen to his or her donated, but unused, embryos if he or she should lack the capacity at some point in the future to make a decision about their disposition, and

(iv) shall specify what should happen to his or her donated, but unused, embryos if he or she dies.

(b) In situations where the donation of embryos requires the consent of two people and—

(i) in accordance with paragraph (a)(i) both people do not agree that the embryos, that are to be donated, can be used for a particular AHR treatment procedure, then those embryos cannot be used to provide that procedure to one or more other people,

(ii) in accordance with paragraph (a)(ii) both people do not agree that the embryos, that are to be donated, can be used for a particular type of research, then those embryos cannot be used for such research,

(iii) both people do not agree on a given course of action regarding the disposition of supernumerary embryos in storage in the situations outlined in paragraphs (a)(iii) or (a)(iv), then that course of action cannot be undertaken.

(8)(a) Notwithstanding the maximum limit of four families set out in Head 16 of this Part, in providing his or her consent, a donor of embryos may specify a lower number of families that may have children following AHR treatment using his or her embryos.

(b) Where the donation of embryos requires the consent of two people and one of those people specifies a lower number of families that may have children following AHR treatment using the embryos in question, than the other person, then this lower limit on the number of families shall apply.

(c) Notwithstanding paragraphs (a) and (b), where the embryos being donated were -

(i) created using gametes from a donor, and

(ii) that donor specified under Head 12 of this Part the number of families, below the maximum of four, that may have children following AHR treatment using his or her gametes, or embryos created using his or her gametes

then that lower limit on the number of families shall apply.

(9)(a) In providing his or her consent to the donation of his or her embryos a donor shall clarify if he or she is willing for—

- (i) his or her embryos to be used in providing AHR treatment to one or more other people by another AHR treatment provider in the State or in another jurisdiction,
- (ii) his or her embryos to be used in research in another research facility in the State or in another jurisdiction.

(b) Where the donation of the embryos requires the consent of two people and one of them does not provide consent, under paragraphs (a)(i) or (a)(ii), for the subsequent use of those embryos, then that person's will and preferences shall be upheld.

(c) Prior to giving his or her consent to the export of his or her embryos under paragraph (a) the donor must have been notified in writing that the law pertaining to—

- (i) the use of donated embryos for AHR treatment, or
- (ii) the use of donated embryos in research

in other jurisdictions may not be the same as it is in the State.

Explanatory Note

Head 13 sets out the specific conditions that need to be met in relation to a person or a couple providing consent to donate his/her or their supernumerary embryos for use in providing AHR treatment to others or for use in research.

Subhead (1) clarifies that, apart from supernumerary embryos, it is prohibited to donate any other embryos for use in providing AHR treatment to others, or for use in research.

Subhead (2) clarifies that supernumerary embryos may be donated to one or more other people for use in their AHR treatment if certain conditions are met, namely: (a) that the embryos were originally created with the intention of being used in providing AHR treatment to a person, and his or her partner (if s/he has one); (b) that the treatment in question has been completed; (c) that following the completion of the AHR treatment and as part of a separate consent process, the person and his/her partner (if s/he has one) specifically provided consent for the donation of the supernumerary embryos; (d) in cases where the embryos were originally created for a couple, each of them must have provided his/her

consent for the donation; and (e) that each of the people who provided the gametes from which the embryos in question were created, was below the maximum allowable ages for sperm and egg donors (i.e. 40 years of age and 35 years of age respectively) at the time when the gametes were originally collected.

Subhead (3) clarifies that supernumerary embryos may be donated to be used in research if certain conditions are met, namely: (a) that the embryos were originally created with the intention of being used in providing AHR treatment to a person, and his or her partner (if s/he has one); (b) that the treatment in question has been completed; (c) that following the completion of the AHR treatment and as part of a separate consent process, the person and his/her partner (if s/he has one) specifically provided consent for the donation of the supernumerary embryos; (d) in cases where the embryos were originally created for a couple, each of them must have provided his/her consent for the donation of the supernumerary embryos.

Subhead (4) clarifies that it is prohibited for anyone to use a person's embryos to provide AHR treatment to others or for the purposes of research in a way that contravenes the provisions of subheads (2) or (3). The provisions of Part 9 clarify that contravening subhead (4) would be an offence under this Act.

Subhead (5) - The purpose of this provision is to clarify the criteria for a valid consent, under subheads (2) and (3) to the donation of supernumerary embryos. Subhead (5)(a) states that the person who provided his/her consent to the donation must: have had the capacity to do so; must have provided his/her consent in writing and voluntarily; and s/he must have signed the consent form.

Subhead (5)(b)(i) states that, prior to giving his/her consent under paragraph (a), the prospective embryo donor must have been given information about the potential risks and implications associated with being an embryo donor. Subhead (5)(b)(ii) states that separately and subsequent to the provision of information, each prospective donor must also have received counselling from a counsellor about the potential risks and implications of being an embryo donor.

Subhead (6) - Where a person is giving consent in the context of subhead (5)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

Subhead (7) - Subhead (7)(a)(i) requires that when providing consent to embryo donation for AHR treatment, a donor specifies the types of AHR treatment procedures that s/he is willing for his/her embryos to be used in. Similarly subhead (7)(a)(ii) enables a donor, as part of the consent process, to specify, if s/he so wishes, what types of research his/her embryos may be used in. Subhead (7)(a)(iii) requires each donor to outline his/her will and preferences regarding the subsequent disposition of embryos which s/he has agreed to donate, but which remain unused in storage, in case s/he might lack the capacity to make such a decision when required in the future. Subhead (7)(a)(iv) requires that, when providing consent to the donation of embryos the donor also outlines what s/he wants to happen to his/her remaining donated but unused embryos in the event of his/her death.

In many cases, an embryo will have been created as part of providing AHR treatment to a couple, therefore, the consent of both parties would be required for any decisions in relation to the donation of such embryos. Subhead (7)(b)(i) clarifies that in such situations if one donor consents to the donated embryos being used in a given procedure, but the other donor does not, then the embryos cannot be used in that AHR procedure. Similarly, in relation to embryos donated by a couple for use in research, subhead (7)(b)(ii) clarifies that if one donor consents to the donated embryos being used in a particular type of research, but the other donor does not, then the embryos cannot be used for that type of research.

When providing consent to donate his/her embryos for use in providing AHR treatment to others or for use in research each donor must outline his/her will and preferences regarding the subsequent disposition of embryos, which s/he has agreed to donate, but which remain unused in storage, in certain scenarios (i.e. where s/he might lack capacity to make a decision or where s/he has died). Subhead (7)(b)(iii) clarifies that the will and preferences of both donors regarding the disposition of the donated but unused embryos remaining in storage would need to be compatible in order for a given course of action to be undertaken.

Subhead (8) - Under subhead (8)(a) a donor can stipulate how many other families can have children following AHR treatment using his/her embryos subject to the maximum limit of four families allowed under Head 16 of this Part. Subhead (8)(b) clarifies that, in the case of embryos donated by a couple, if one of the members of a couple sets a lower limit, than his/her partner, on the number of families that may have children following AHR using those donated embryos, then it would be this lower limit on the number of families that would apply. Subhead (8)(c) clarifies that, notwithstanding the consent of a person or couple to the donation of his/her or their supernumerary embryos and any limits s/he or they may set

under paragraphs (a) or (b), if the embryos in question were created using gametes from a donor and that donor had placed a specific limit on the number of families that may have children following AHR treatment using his/her gametes or embryos created using those gametes then this lower limit set by the original gamete donor shall apply.

Subhead (9) - Subhead (9)(a) clarifies that when providing consent to donate embryos for use in providing AHR treatment to others or for use in research, the donor in question must clarify if his/her consent includes permitting his/her embryos to be transferred to another AHR or research facility in the State or in another jurisdiction. Subhead (9)(b) clarifies that where a couple is involved if one of the embryo donors does not consent to the embryos being donated for use in another AHR or research facility in the State or in another jurisdiction then that donor's will and preferences must be upheld and the embryos cannot be used in another facility in Ireland or elsewhere. Subhead (9)(c) states that prior to giving his/her consent to the export of his/her embryos the donor must be notified of the potential difference in the law in other countries to which the embryos could be exported to.

Head 14 - Parentage and non-anonymity in the context of gamete and embryo donation

This Head provides that:

(1) Notwithstanding the other provisions in this Part, where donated gametes or embryos are used to provide AHR treatment in the context of a DAHR procedure or further DAHR procedure under the Act of 2015, then the provisions of that Act will also apply.

(2) Notwithstanding the other provisions in this Part, where donated gametes are used to provide AHR treatment in the context of a surrogacy agreement under this Act, the provisions of Part 6 will also apply.

Explanatory Note

Subhead (1) - Parts 2 and 3 of the Children and Family Relationships Act 2015 set out specific provisions, which apply to all AHR treatment procedures (i.e. DAHR procedures and further DAHR procedures) involving donor gametes and embryos, including the requirements regarding non-anonymous donation and clarifying parentage in the case of such DAHR procedures. Subhead 4(1) clarifies that, notwithstanding the other provisions of this Part that set out conditions relating to gamete and embryo donation, where gametes and embryos are donated to be used in providing AHR treatment to others in the context of a DAHR procedure or a further DAHR procedure as provided for under the Children and Family Relationships Act 2015, then the specific provisions of that Act will also apply.

Subhead (2) - Part 6 of this Act sets out specific provisions relating to AHR treatment in the context of surrogacy, which in some instances may involve donor gametes. These surrogacy provisions outline the conditions that need to be met in order for surrogacy to be permitted, clarify the situation relating to parentage in the context of surrogacy, and set out the requirements regarding non-anonymous donation.

Head 15 - Revocation or alteration of consent to donation

This Head provides that:

(1)(a) A donor may, while he or she has capacity to do so, revoke or alter his or her consent to the donation of his or her gametes or embryos for use in—

- (i) providing AHR treatment to one or more other people, or
- (ii) research.

(b) A revocation or alteration of consent under paragraph (a) must be made in writing and signed by the person altering or revoking his or her consent.

(2) Where a person is altering or revoking consent in the context of subhead (1) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

(3) A revocation or alteration of consent under subhead (1) shall not apply where, prior to receiving notification of the revocation or alteration of consent -

(a) the gametes to which the consent relates to have been used by the AHR treatment provider in the formation of an embryo as part of providing AHR treatment to one or more other people,

(b) the embryos to which the consent relates to have been used by the AHR treatment provider as part of providing AHR treatment to one or more other people, or

(c) the gametes or embryos to which the consent relates to have been used for the purposes of research.

(4) Where the donation of the embryos in question requires the consent of two people and one of these donors subsequently revokes his or her consent under subhead (1), then those embryos cannot be used in—

- (a) providing AHR treatment to one or more other people, or
- (b) research.

(5)(a) Where a donor's consent for the donation of his or her gametes, for use in providing AHR treatment to one or more other people, has been revoked under subhead (1) the gametes shall be disposed of, unless the donor provides consent for his or her gametes to be donated for use in research.

(b) Where a donor's consent for the donation of his or her gametes, for use in research, has been revoked under subhead (1), the gametes shall be disposed of.

(c) Where a donor's consent for the donation of his or her embryos, for use in providing AHR treatment to one or more other people, has been revoked under subhead (1) the embryos shall be disposed of, unless—

- (i) where the embryos were donated by one person only, that donor provides his or her consent for the embryos to be donated for research, or
- (ii) where the embryos were donated by two people together, each donor provides his or her consent for the embryos to be donated for research.

(d) Where the embryos in question in paragraph (c) were originally created using gametes provided by a different donor, any subsequent decision to donate those embryos for use in research shall be consistent with any previous decision by that donor regarding the use of embryos created using his or her gametes in research, as documented on the relevant consent form.

(e) Where a donor's consent for the donation of his or her embryos, for use in research, has been revoked under subhead (1) the embryos shall be disposed of.

(6)(a) Where the donation of embryos requires the consent of two people and one of these donors subsequently alters his or her consent under subhead (1), then before implementing the alteration of consent, the licence holder shall have regard to the consent of the other person donating the embryos in question.

(b) Notwithstanding subhead (2), where the embryos being donated were originally created using gametes provided by a different donor, then before implementing any alteration of consent by a donor of the embryos, the licence holder shall have regard, where applicable, to the consent of the original donor regarding the use of embryos created using his or her gametes.

Explanatory Note

Subhead (1) - Subhead (1)(a) clarifies that, provided s/he has capacity, a donor may if s/he so wishes revoke or alter his/her consent to the donation of his/her gametes or embryos for use in providing AHR treatment to others or for use in research. Subhead (1)(b) stipulates that any such revocation or alteration must be made in writing and signed by the person (i.e. the donor) in question.

Subhead (2) - In some situations, while the person altering or revoking his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (2) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Subhead (3) clarifies that the revocation or alteration of a given donor's consent under subhead (1) would not be applicable in situations where, before written notification of the relevant revocation or alteration of the consent is received: (a) the gametes in question have been used in the formation of an embryo as part of providing AHR treatment to one or more other people; (b) the embryos in question have been used as part of providing AHR treatment to one or more other people; or (c) the gametes or embryos in question have been used for the purposes of research.

Subhead (4) - Subhead (3)(a and b) clarify that, where a couple have consented to donate their supernumerary embryos, if one of those individuals subsequently changed his/her mind and revoked his/her consent to the donation, then the embryos in question could no longer be used in the provision of AHR treatment to one or more other people or research respectively.

Subhead (5) - Subhead (5)(a) clarifies that if a donor revokes his/her consent to the donation of his/her gametes for use in providing AHR treatment to others, those gametes must be disposed of unless that donor provides his/her consent for the gametes in question to be donated for use in research. Subhead (5)(b) clarifies that in situations where the gametes in question have been donated for use in research and the donor subsequently revokes his/her consent to then those gametes must be disposed of. Similarly where a donor revokes his/her consent to the donation of his/her embryos for use in providing AHR treatment to others, those embryos must be disposed of unless the relevant donor has provided his/her consent for those embryos to be donated for use in research. In cases where only one person has

donated the embryos, then his/her consent alone would be required for the embryos to be donated for research [subhead (5)(c)(i)]. However, where the embryos were donated by two people jointly then both of those people would have to provide consent for the embryos in question to be donated for research [subhead (5)(c)(ii)].

In situations where embryos were created using another third party gamete donor (i.e. the original gamete donor), certain conditions attached to that donor's consent may affect the subsequent disposition of embryos created using that donor's gametes. Subhead (5)(d) clarifies that in situations where consent to donate embryos for use in AHR has been revoked [i.e. under subhead (1)] and the donor or donors, as the case may be, of the embryos in question consent for those embryos to be donated for use in research this donation would only proceed provided it was consistent with an earlier decision of the original gamete donor regarding the use of embryos created using his/her gametes in research as specified on the consent form that s/he completed.

Subhead (5)(e) clarifies that following the revocation of a person's consent to the donation of his/her embryos for use in research, the embryos in question must be disposed of.

Subhead (6) - Subhead (6)(a) clarifies that in situations where two people have provided consent to the donation of embryos for use in providing AHR treatment to others or research and one of those donors subsequently alters his/her consent, then the licence holder must have regard to the consent of the other donor involved before implementing the alteration of consent.

Subhead (6)(b) clarifies that, notwithstanding the provisions of subhead (3), in situations where embryos made available for donation were originally created using gametes from a different donor (i.e. a "third party" gamete donor), in order to implement any alteration of consent from a donor of those embryos, the licence holder must consider the compatibility of this alteration with the previous consent of the original gamete donor, where this consent is applicable.

Head 16 - Limits on the use of donated gametes and embryos

This Head provides that:

(1) It is prohibited to use gametes or embryos that are donated for use in research for any other purpose.

(2)(a) Gametes, including embryos created using those gametes, or embryos provided by a given donor shall not be used in providing AHR treatment in the State where it would result in children being born to more than four families through the use of that donated material.

(b) Notwithstanding paragraph (a), where an AHR treatment procedure involves the use of donor sperm and donor eggs together, then the gametes, including embryos created using those gametes, of each of those donors shall not be used in providing AHR treatment in the State where the cumulative use of that donated material would result in children being born to more than four other families.

(3) Gametes, including embryos created using those gametes, or embryos provided by a given donor may continue to be used in providing AHR treatment in the State to produce siblings for existing children within each of the families permitted under subheads (2)(a or b).

(4) It is prohibited for an AHR treatment provider to undertake AHR treatment which, as part of the same procedure, involves—

(a) sperm provided by more than one man or eggs provided by more than one woman, or

(b) more than one embryo, where the gametes from which each embryo was created were not provided by the same people.

(5)(a) It is prohibited for an AHR treatment provider to use, as part of an AHR treatment procedure, gametes, including embryos created using those gametes, or embryos provided by a given donor, following the death of that donor.

(b) The provisions of paragraph (a) shall not apply where the AHR treatment provider had not been notified in writing about the death of the donor in question prior to using that donor's gametes, including embryos created using those gametes, or embryos in an AHR treatment procedure.

Explanatory Note

Subhead (1) clarifies that it is prohibited to use any gamete or embryo that has been donated for use research for any other purpose, which includes prohibiting such gametes or embryos being used in providing AHR treatment. Part 9 of this Act, clarifies that contravening this provision would be an offence.

Subhead (2) - Given concerns about preventing accidental consanguinity (i.e. marriage and reproduction between individuals who are genetically related), subhead (2)(a) stipulates that gametes from a given donor (including embryos created from those gametes) or donated embryos must not be used in providing AHR treatment to other people in Ireland where it would result in children being born to more than four families following the use of material donated by the same donor. This family limit is adjusted in situations where donor sperm and donor eggs are used as part of the same AHR procedure. In such instances the gametes of each of the donors in question may still be used to provide AHR treatment to others so long as the cumulative total of other families who have children using that donated material is not more than four [subhead (2)(b)]. Contravening this subhead would be an offence.

Subhead (3) - Notwithstanding the limits applied under subhead (2), any family who has used the gametes, including embryos created using those gametes, or embryos provided by a given donor may still use that material in AHR treatment to produce siblings for their existing children.

Subhead (4) prohibits, as part of a single AHR treatment procedure, (a) the use of sperm from more than one man or eggs from more than one woman; or (b) the use of multiple embryos, where the embryos in question were not all created using gametes from the same people. The provisions of Part 9 clarify that contravening subhead (4) would be an offence under this Act.

Subhead (5) clarifies that it is prohibited for material provided by a given donor [i.e. gametes, (including embryos created using those gametes, or embryos)] to be used by an AHR treatment provider in providing AHR treatment after that donor has died. However, this prohibition will not apply in situations where the AHR treatment provider had not received written notification of the death of the donor in question before that donor's material had been used. The provisions of Part 9 of this Act clarify that it would be an offence for a person to provide AHR treatment in contravention of this subhead.

Head 17 - Access to gamete and embryo donation for AHR purposes

This Head provides that:

(1) Access to gamete donation for use in AHR treatment procedures shall be permitted for people irrespective of their gender, marital status or sexual orientation where the AHR treatment procedure is provided in accordance with the provisions of Part 2 of this Act.

(2)(a) Gamete donation which would involve, as part of the AHR treatment procedure, the formation of an embryo through the fertilisation of the donor's gametes with the gametes from a close family member of the donor is prohibited.

(b) In paragraph (a) "close family member" means a parent, son, daughter, sibling (including half-brother or half-sister), grandparent, grandchild, aunt, uncle, nephew or niece, being such a family member from birth.

(3)(a) Access to embryo donation for use in AHR treatment procedures shall be permitted for heterosexual couples, female same sex couples and single women where—

- (i) the intention is that the intending mother would carry the pregnancy, and
- (ii) the AHR treatment procedure is provided in accordance with the provisions of Part 2 of this Act.

(b) The couples referred to in paragraph (a) shall be married, civil partners or cohabitants.

Explanatory Note

Subhead (1) - On the basis of equality and non-discrimination AHR treatment involving gamete donation will be available to people irrespective of gender, marital status or sexual orientation, where the procedure accords with the provisions of Part 2 of this Act.

Subhead (2) prohibits the use of gamete donation in an AHR treatment procedure, that would involve an embryo created through the fertilisation of the donor's gametes with gametes from a close family member of that donor, as defined in paragraph (b). The provisions of Part 9 of this Act clarify that it would be an offence for a person to contravene this subhead.

Subhead (3) - Under subhead (3) heterosexual couples, female same sex couples and single women may be eligible to access AHR treatment involving embryo donation provided

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that the intending mother will gestate the pregnancy and that the procedure accords with the provisions of Part 2 of this Act.

Head 18 - Consent, provision of information and counselling to undergo AHR treatment procedures involving donated gametes or embryos

This Head Provides that:

(1) The consent of an intending parent to undergo AHR treatment procedures involving donated gametes or embryos shall—

(a) be obtained prior to such treatment commencing,

(b) specify the procedures arising as part of the AHR treatment that he or she consents to, and

(c) be in accordance with the relevant provisions of—

- (i) Parts 2 and 3 of the Act of 2015, or where applicable
- (ii) Part 6 of this Act.

(2) An intending parent's consent under subhead (1) shall—

(a) specify that he or she has provided his or her consent to the treatment procedures outlined in the consent form,

(b) confirm that he or she has received all of the information and counselling outlined in the provisions of subhead (3),

(c) not have been altered or revoked when the treatment procedure takes place,

(d) specify what to do with stored gametes or embryos if an intending parent, or both intending parents (where two are involved), dies or subsequently lacks capacity, and

(e) specify what to do in the event of post factum differences of opinion or changes of circumstances.

(3)(a) An intending parent's consent under subhead (1) shall not be considered valid unless:

- (i) it was obtained in writing,
- (ii) it was given voluntarily,
- (iii) the person providing his or her consent had the capacity to give consent at the time in question, and
- (iv) the consent form was signed by the person giving consent.

(b) Prior to giving his or her consent under paragraph (a) the intending parent in question shall have been provided with information about -

- (i) AHR treatment procedures involving gamete or embryo donation, as applicable, including the potential risks and implications involved, and
- (ii) any other procedures to be carried out as part of the AHR treatment process, including information about the potential risks and implications involved.

(c)(i) Separately from and subsequently to the provision of information under paragraph (b), the intending parent giving his or her consent shall have received counselling about the implications of AHR treatment procedures involving donated gametes or embryos from a counsellor.

- (ii) Where two intending parents are involved this counselling may be provided to the intending parents individually, jointly, or both, in accordance with their will and preferences.

(4)(a) An intending parent may, while he or she has capacity to do so, revoke or alter his or her consent to any procedure involving donated gametes or embryos being carried out as part of his or her AHR treatment.

(b) A revocation or alteration of consent under paragraph (a) must be made in writing and signed by the person altering or revoking his or her consent.

(5) Where a person is giving, altering or revoking consent in the context of subheads (3)(a), or (4)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

(6) Where an AHR treatment procedure involving donated gametes or embryos required the consent of both intending parents and prior to the procedure one of the intending parents subsequently revokes his or her consent under subhead (4), then that procedure cannot be provided.

(7) A revocation or alteration of consent under subhead (4) shall not apply where, prior to receiving notification of the revocation or alteration of consent an AHR treatment procedure

has been performed with the objective of it resulting in the implantation of an embryo in the womb of the intending mother.

Explanatory Note

Subhead (1) sets out the conditions that must be fulfilled in relation to an intending parent's consent to AHR treatment involving donated material, namely: the consent must have been provided in advance of the treatment; the consent must outline the specific AHR treatment procedures that consent has been provided for; and as the case may be, the consent must also be in accordance with the relevant provisions arising in the context of DAHR procedures and further DAHR procedures under the Act of 2015, or where applicable, with the provisions of this Act relating to surrogacy.

Subhead (2) - In providing his/her consent under subhead (1) an intending parent must also: clarify that s/he has provided his/her consent to the particular AHR treatment procedures specified on the consent form; confirm that s/he has been given the information and counselling stipulated in subhead (3); specify what should happen to any stored gametes or embryos in the event that s/he, or both intending parents (where a couple is involved) dies or lacks capacity to make a decision regarding that material in the future; and clarify what should happen in the case of relationship breakdown or some other change of circumstances. In addition, the relevant intending parent's consent must not have been revoked or altered at the time that the AHR treatment procedure is taking place.

Subhead (3) - The purpose of this provision is to clarify the criteria for a valid consent, from an intending parent under subhead (1) to undergo AHR treatment which involves the use of donated gametes or embryos. Subhead (3)(a) states that the intending parent must: have provided his/her consent in writing and voluntarily; have had the capacity to provide his/her consent; and s/he must have signed the consent form.

Subhead (3)(b) states that, prior to giving his/her consent under paragraph (a), the intending parent must have been given information about AHR involving donated material, as well as any other procedures to be conducted as part of the treatment. This would include information about the potential risks and implications involved. Subhead (3)(c) states that separately and subsequent to the provision of information, each intending parent must also have received counselling about the potential implications of utilising donated material.

Subhead (4) clarifies that, provided s/he has capacity, an intending may if s/he so wishes revoke or alter his/her consent to any AHR treatment procedure that involves donated

gametes or embryos. Any such revocation or alteration must be made in writing and signed by the person (i.e. the intending parent) in question.

Subhead (5) - In some situations, while the person providing, altering or revoking his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (5) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Subhead (6) - Where each member of a couple has provided his/her consent to undergo an AHR treatment procedure involving donated gametes or embryos and one of those individuals subsequently changed his/her mind and revokes his/her consent under subhead (4), then the procedure in question could not be provided.

Subhead (7) clarifies that the revocation or alteration of a given intending parent's consent under subhead (4) would not be applicable in situations where, before written notification of the relevant revocation or alteration of the consent has been received, the donated gametes (including an embryo created using those gametes) or donated embryo, as the case may be, have been used in an AHR treatment procedure with a view to impregnating the intending mother.

Head 19 - Non-commercial gamete and embryo donation for AHR procedures or research

This Head provides that:

(1) It is prohibited for a person to provide or offer to provide any payment or any other reward to another person for the donation of a gamete or embryo for use in—

(a) providing AHR treatment to one or more other people, or

(b) research.

(2) It is prohibited for a person to receive or offer to receive any payment or any other reward from another person for the donation of a gamete or embryo for use in—

(a) providing AHR treatment to one or more other people, or

(b) research.

(3) Notwithstanding subheads (1) and (2), nothing in this Head applies to a payment or other reward that is the reimbursement or payment of reasonable expenses incurred by the person as part of the donation process.

(4)(a) In this Head "reasonable expenses", in relation to the person donating the gamete or embryo, means that person's—

- (i) travel expenses,
- (ii) medical expenses,
- (iii) counselling expenses, and
- (iv) any legal expenses

arising in relation to the donation process.

(b) An expense under paragraph (a) is only considered reasonable if—

- (i) the expense is actually incurred, and
- (ii) the expense can be verified by a receipt or other documentation.

Explanatory Note

Subhead (1) - In line with the proposed policy for altruistic gamete and embryo donation, subhead (1) clarifies that it is prohibited for a person to give or offer to give another person any payment or other reward for the donation of his/her gametes or embryos in order for those gametes/embryos to be used in the provision of AHR treatment procedures to other

people or in research. A payment or reward would include any payment, inducement, discount or priority in the provision of a service or treatment to a person to encourage him/her to donate. The provisions of Part 9 of this Act state that it would be an offence for a person to contravene this subhead.

Subhead (2) clarifies that it is prohibited for a person to receive/accept or offer to receive/accept any payment or reward from another person for the donation of his/her gametes or embryos in order for those gametes/embryos to be used in the provision of AHR treatment procedures to other people or in research. The provisions of Part 9 of this Act state that it would be an offence for a person to contravene this subhead.

Subhead (3) clarifies that the reimbursement of reasonable expenses incurred by the person as part of the donation process is permitted.

Subhead (4) - Subhead (4)(a) clarifies that in terms of gamete or embryo donation, reasonable expenses relate to the travel expenses, medical expenses, counselling expenses, and any legal expenses that arise for the person (i.e. the donor) specifically related to the donation process. Subhead (4)(b) clarifies that in order for an expense under these provisions to be considered reasonable it would have to have been incurred and be verifiable by evidence, either in the form of a receipt or other documentation.

Note: the wording of subhead (4)(a) was modified from section 19(3) of the Children and Family Relationships Act 2015.

Head 20 - Screening and evaluation of gamete and embryo donors

This Head provides that:

(1) All prospective gamete and embryo donors shall undergo a detailed medical assessment and evaluation in accordance with the relevant selection, evaluation and testing requirements of S.I. No. 158 of 2006.

(2) Where an AHR treatment provider decides that a prospective donor is not suitable to donate, the AHR treatment provider shall record the reasons for this decision, and explain these reasons to the prospective donor.

Explanatory Note

Subhead (1) - Given the potential health implications for children who may be born following AHR treatment procedures using donated material, as well as the recipients it is essential that potential donors are properly screened. Subhead (1) stipulates that all prospective donors (whether gamete or embryo donors) must be screened in accordance with the relevant selection, evaluation and testing requirements outlined in S.I. No. 158 of 2006.

Subhead (2) clarifies that in situations where an AHR treatment provider considers that a prospective donor is not suitable, for example, following health screening and counselling as part of the consent process, that AHR treatment provider must document this decision and the rationale for it and provide this explanation to the prospective donor.

Head 21 - Disclosing medical information

This Head provides that:

(1) An AHR treatment provider may disclose non-identifying medical information about a donor or a person born following the use of donated gametes or embryos in an AHR treatment procedure to a registered medical practitioner upon receipt of a written application from that registered medical practitioner stating that the disclosure is necessary—

(a) to avoid an imminent and serious risk to the health of a person; or

(b) to enable the registered medical practitioner to provide medical advice to a person regarding the existence of a genetic or hereditary condition that may be harmful to that person or to his or her children, including any future children he or she might have.

(2) Non-identifying medical information may be disclosed under subhead (1) without the consent of the person to whom the information relates.

Explanatory Note

Subhead (1) sets out the specific, limited circumstances under which an AHR treatment provider may disclose non-identifying medical information relating to a donor or a person born following an AHR treatment procedure involving donated material. This information may only be disclosed to a registered medical practitioner, where s/he has made a written request, which explains that the medical information in question is necessary to avoid and imminent and serious risk to a person's health or to enable that registered medical practitioner to provide medical advice to a person relating to a specific genetic or hereditary condition that may affect that person or his/her children.

Note: The wording of subhead (1) is modified from section 16 of the Assisted Reproductive Treatment Further Amendment Act 2014 [Victoria, Australia].

Subhead (2) - Given that the information that may be disclosed under subhead (1) is specifically limited to non-identifying medical information this precludes the need to obtain the consent of the person from whom the information originates (e.g. the donor or a person born following an AHR treatment procedure involving donated gametes or embryos).

Head 22 - Storage of gametes and embryos

This Head provides that:

- (1) A person or body shall not store or handle a gamete or an embryo for the purposes of AHR or research except in accordance with a licence issued by the Regulatory Authority under Head 69(1) or 70(1).
- (2)(a) A licence holder shall not store a person's gametes or embryos unless that person has provided his or her consent to the storage.
 - (b) A person's consent under paragraph (a) shall not be considered valid unless—
 - (i) it was obtained in writing,
 - (ii) it was given voluntarily,
 - (iii) the person providing his or her consent had the capacity to give consent at the time in question, and
 - (iv) the consent form was signed by the person giving consent.
- (3) Where a person is giving consent in the context of subhead (2)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.
- (4) In providing his or her consent to the storage of gametes or embryos, under subhead (2), a person—
 - (a) may specify how long he or she consents to the gametes or embryos being stored for, subject to the maximum storage period allowed under subhead (8).
 - (b) shall specify what should happen to the stored gametes or embryos if he or she should lack the capacity at some point in the future to make a decision about their disposition.
 - (c) shall specify what should happen to the stored gametes or embryos if he or she dies.
 - (d) where the gametes or embryos are stored as part of a couple's own AHR treatment, shall specify what should happen to the stored gametes or embryos in the case of post factum differences of opinion or changes of circumstances.

(5) In providing his or her consent to the storage of gametes or embryos, under subhead (2), as part of his or her own AHR treatment, a person shall be informed that, when the permitted storage period expires, any gametes or embryos remaining at that time will be disposed of, unless prior to the expiration of the storage period—

(a) the person provides his or her consent for the gametes or embryos to be donated for use in providing AHR treatment to one or more other people,

(b) the person provides his or her consent for the gametes or embryos to be donated for use in research, or

(c) the Regulatory Authority grants an extension to the storage period in accordance with subhead (8).

(6) In providing his or her consent to the storage of gametes or embryos, under subhead (2), for use in research, a person shall be informed that, when the permitted storage period expires, any gametes or embryos remaining at that time will be disposed of, unless prior to the expiration of the storage period the Regulatory Authority grants an extension to the storage period in accordance with subhead (8).

(7) Notwithstanding subhead (2), a person's gametes may be stored without his or her consent where—

(a) he or she is under the age of 18 years and his or her parent(s) or legal guardian(s) has provided consent for the collection and storage of the gametes, and

(b) a registered medical practitioner has certified in writing that the person is to undergo medical treatment and that in the opinion of the registered medical practitioner -

(i) the treatment is likely to cause a significant impairment to the person's fertility, and

(ii) the storage of the gametes is in the person's best interests.

(8)(a) Except with the approval of the Regulatory Authority under paragraph (b)—

(i) no gametes may be stored for more than 10 years, and

(ii) no embryos may be stored for more than 5 years.

(b) The Regulatory Authority may grant an extension to the storage periods outlined in paragraph (a) if—

- (i) before the storage period has expired, an eligible person makes a written application to the Regulatory Authority requesting such an extension, and
- (ii) the Regulatory Authority considers that there are reasonable grounds for granting such an extension in that particular case.

(c) In paragraph (b) an eligible person means—

- (i) a person who provided the stored gametes or embryos or whose gametes were used to create the stored embryos, or
- (ii) a person who is to be a participant in the AHR treatment procedure in which the stored gametes or embryos are to be used, or
- (iii) a registered medical practitioner on behalf of a person whose gametes are being stored in accordance with subhead (7), where that person is under the age of 18 years.

(9) Not less than six months before the expiration of the permitted storage period, a licence holder shall—

(a) make reasonable efforts to notify a person that the end of the storage period for his or her gametes or embryos is approaching, and

(b) as part of the notification provided under paragraph (a), a licence holder shall—

- (i) provide the person with information about the options available to him or her regarding the disposition of his or her stored gametes or embryos, and
- (ii) clarify that if the licence holder does not receive a response from the person on or before the specified date for the expiration of the storage period then that person's then gametes or embryos will be disposed of.

(10) Before the permitted storage period expires, a person may, while he or she has capacity to do so, revoke or alter his or her consent to the storage of his or her gametes or embryos.

(11) Subject to the provisions of this Head, once the permitted storage period for the stored gametes or embryos in question has expired, the licence holder involved shall dispose of those gametes or embryos.

(12) The Regulatory Authority may make regulations in relation to the storage of gametes and embryos by licence holders.

Explanatory Note

Subhead (1) states that a person or a body is not permitted to store or handle a gamete or an embryo that is intended for use in AHR or research unless s/he or the body in question has been granted a licence for that activity by the Regulatory Authority.

Subhead (2) stipulates that a licence holder (i.e. an AHR treatment provider or a researcher) must not store a person's gametes or embryos without that person's consent. The consent of the person in question would only be deemed valid if: s/he had capacity at the time the consent was given; the consent was documented in writing and given voluntarily; and the consent form was signed by the person giving consent. The provisions of Part 9 of this Act clarify that it would be an offence for a person to store gametes or embryos in contravention of this subhead.

Subhead (3) - In some situations, while the person providing his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (3) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Subhead (4) - In providing his/her consent under subhead (2) a person: may indicate specific storage periods for his/her gametes or embryos, subject to the maximum periods allowable; must clarify what should happen to any stored gametes or embryos in the event that s/he died or lacks capacity to make a decision regarding that material in the future; and where the gametes or embryos are stored on behalf of a couple, the person must clarify what should happen in the case of relationship breakdown or some other change of circumstances.

Subhead (5) - When a person is providing his/her consent to the storage of gametes or embryos for use in his/her own AHR treatment that person must be informed that any gametes or embryos that remain in storage at the end of the permitted storage period will be disposed of unless that person provides his/her consent, in accordance with the relevant provisions of this Part of the Act, for the material to be donated to others for use in AHR

treatment or donated for use in research, or unless the Regulatory Authority grants an extension to the storage period under subhead (8).

Subhead (6) - When a person is providing his/her consent to the storage of gametes or embryos for use in research that person must be informed that any gametes or embryos that remain in storage at the end of the permitted storage period will be disposed of unless the Regulatory Authority grants an extension to the storage period under subhead (8).

Subhead (7) outlines the specific limited circumstances in which a person's gametes may be stored without his/her consent, namely: where that person is under 18 years of age and his/her parent(s) or legal guardian(s) have given consent; and where a registered medical practitioner has certified in writing that the person in question is to undergo a medical treatment that the medical practitioner considers is likely to have significant negative impact on that person's fertility and that the storage of the gametes is, in the opinion of the medical practitioner, in the person's best interests.

Subhead (8) stipulates that gametes may not be stored for longer than 10 years and that embryos may not be stored for longer than 5 years, except with the express permission of the Regulatory Authority. The Regulatory Authority may extend the respective storage periods for gametes and embryos if it receives a written request for such an extension, before the current storage period has elapsed, and if the Regulatory Authority deems that there are reasonable grounds to grant the extension. This subhead also sets out the specific categories of people who may apply to the Regulatory Authority for an extension of the storage period. Storing gametes or embryos in contravention of this subhead would be an offence.

Subhead (9) - Under this subhead a licenced holder is obliged to make reasonable efforts to notify a person whose gametes or embryos are in storage when the end of the permitted storage period is approaching. When notifying the person in question the licence holder must: outline the options available to the person regarding the disposition of any gametes or embryos that remain in storage: and must clarify that if the person in question does not respond to this notification from the licence holder then the gametes and embryos in storage will be disposed of once the permitted storage period has elapsed.

Subhead (10) clarifies that a person whose gametes or embryos are in storage may, while s/he has capacity, revoke or alter his/her consent to that storage.

Subhead (11) clarifies that, where the provisions of this Head have been satisfied, a licence holder is permitted to dispose of stored gametes and embryos at the end of the permitted storage period.

Subhead (12) sets out that the Regulatory Authority may make specific regulations in relation to the storage of gametes and embryos.

PART 4 POSTHUMOUS ASSISTED REPRODUCTION

Head 23 - Interpretation (for Part 4)

This Head provides that:

In this Part—

"posthumous assisted reproduction (PAR)" refers to the use of a person's gametes (sperm or eggs), or an embryo created using a person's gametes, in an AHR treatment procedure after his or her death.

Head 24 - Posthumous assisted reproduction (PAR) procedures involving gametes or embryos

This Head provides that:

(1) Subject to the provisions of Part 2 of this Act, an AHR treatment provider may only undertake posthumous assisted reproduction (PAR) in situations where:

(a) The deceased person provided his or her consent for his or her gametes, or an embryo created using his or her gametes, to be used for PAR after his or her death,

(b) The gametes or embryo specified in paragraph (a) shall only be made available for use by the deceased person's surviving partner, where she will carry the pregnancy.

(c)(i) The surviving partner has received counselling, and

(ii) The surviving partner has provided her consent before any PAR procedure can be carried out, and

(d) Prior to the provision of PAR to the surviving partner, a minimum period of one year has passed since the deceased person died.

(2)(a) In the context of subhead (1), the use of donor gametes as part of PAR shall only be permitted where the AHR treatment procedure in question involves -

(i) an embryo created using the gametes of a deceased man and gametes from an egg donor, or

(ii) an embryo created using the gametes of a deceased woman and gametes from a sperm donor, and

(iii) the embryo in question in paragraphs (i) and (ii) was created before the deceased person died.

(b) Notwithstanding the provisions of this Head, the provisions of Part 3 of this Act, shall also apply to any PAR procedures involving an embryo created using donor gametes.

Explanatory Note

Head 24 deals with posthumous assisted reproduction (PAR), which is the application of AHR technology to achieve a pregnancy using the gametes, or an embryo created using the gametes of a deceased person. In most cases, the purpose of PAR is to enable one partner

to continue a parental project after the death of the other partner and to have the deceased person recognised as a parent of any children born following PAR.

Subhead (1) outlines the circumstances under which an AHR treatment provider will be permitted to undertake PAR and states that PAR treatments will have to accord with the provisions of Part 2 of this Act. Under subhead (1) PAR can be provided only if: the deceased person gave his/her consent specifically for his/her gametes, or an embryo created using his/her gametes, to be used for PAR; PAR involving the deceased person's gametes, or an embryo created using his/her gametes, will only be made available to the deceased person's surviving partner who will carry the pregnancy; the surviving partner must have received appropriate counselling following the deceased person's death and must have provided her consent for the treatment; and at least one year must have passed since the deceased person's death before PAR treatment can be provided. The provisions of Part 9 of this Act clarify that it would be an offence for a person to provide PAR treatment in contravention of this subhead.

Subhead (2) clarifies the limited conditions under which PAR involving material provided by a donor is permitted, namely: where the embryo involved was created using the sperm of a deceased man and a donated egg, or where the embryo was created using the eggs of a deceased woman and donor sperm and in both scenarios the embryo in question must have been created during the lifetime of the deceased person. Paragraph (b) states that the provisions of Part 3 of this Act, which relate to gamete and embryo donation more broadly, will also apply to any PAR procedure that involves an embryo created using donor gametes. The provisions of Part 9 of this Act clarify that it would be an offence for a person to provide PAR treatment in contravention of this subhead.

Head 25 - Posthumous retrieval of gametes for use in PAR

This Head provides that:

(1) Gametes shall only be permitted to be retrieved following a person's death for use in PAR if:

(a) The deceased person has provided his or her consent to the posthumous retrieval of his or her gametes for use in PAR by his or her surviving partner.

(b) The person requesting the retrieval and subsequent use of the gametes referred to in paragraph (a) was the partner of the deceased person at the time of the deceased person's death.

(2) Gametes that are retrieved from a deceased person for use in PAR, or an embryo created using those gametes, shall be subject to the provisions of Head 24.

(3) Where a person provides his or her consent to the posthumous retrieval of his or her gametes for use in PAR, the person shall also have provided his or her consent to the storage of those gametes and any embryo subsequently created using those gametes.

Explanatory Note

Subhead (1) allows gametes to be retrieved from the body of a deceased person in order to be used in PAR only if the deceased person provided his/her consent for the retrieval of the gametes for PAR and only if the person requesting the retrieval of the gametes for use in PAR is the surviving partner of the deceased person at the time of the deceased person's death. The provisions of Part 9 of this Act clarify that it would be an offence for a person to contravene this subhead.

Subhead (2) - Head 24 outlines the criteria that need to be fulfilled before PAR may be provided and subhead (2) states that posthumously retrieved gametes, or an embryo created with those gametes, will be subject to those provisions.

Subhead (3) – Under Head 24 PAR cannot be provided within one year of the death of a person whose gametes will be used in that treatment, which will, therefore, require any posthumously retrieved gametes to be stored before they can be used for PAR. Subhead (3) states that where a person has consented to posthumous retrieval of his/her gametes for PAR s/he must also have provided his/her consent for those gametes, or any embryos that are subsequently created using those gametes, to be stored.

Head 26 - Unused gametes and embryos stored for PAR

This Head provides that:

(1) Where a deceased person has provided his or her consent for his or her gametes, or an embryo created using his or her gametes, to be used for PAR and the deceased person's surviving partner does not undertake PAR, for whatever reason, then -

(a) the subsequent disposition of the deceased person's gametes shall be in accordance with the previously expressed will and preferences of the deceased person on the consent form,

(b) the subsequent disposition of any embryo created using the deceased person's gametes shall be in accordance with -

(i) the previously expressed will and preferences of the deceased person on the consent form, and

(ii) the consent of the deceased person's surviving partner.

(2) Where, following the provision of PAR to the deceased person's surviving partner, a deceased person's gametes, or an embryo created using his or her gametes, remain in storage, then -

(a) the subsequent disposition of the deceased person's gametes shall be in accordance with the previously expressed will and preferences of the deceased person on the consent form,

(b) the subsequent disposition of any embryo created using the deceased person's gametes shall be in accordance with -

(i) the previously expressed will and preferences of the deceased person on the consent form, and

(ii) the consent of the deceased person's surviving partner.

Explanatory Note

Subhead (1) states that where a deceased person gave consent for his/her gametes, or an embryo created using his/her gametes, to be used for PAR and the deceased person's surviving partner does not undertake PAR then; any subsequent decision regarding the disposition [i.e. donation (for use in research) or disposal] of the deceased person's gametes will be made in accordance with his/her previously expressed will and preferences expressed by that person in his/her consent form. In relation to an embryo, any subsequent decision regarding its disposition (i.e. donation or disposal) will be made in accordance with the will

and preferences of the deceased person, the consent of the deceased person's surviving partner.

Subhead (2) deals with situations where the surviving partner has completed her PAR treatment, and the gametes of the deceased person, or an embryo created using his/her gametes, remains in storage and outlines how decisions relating to the subsequent donation (for use in research) or disposal of that stored material will be handled.

Head 27 - Recognition of the deceased person as a parent of the child

This Head provides that:

(1) A deceased man shall be treated as the father of a child who was born as a result of PAR using his gametes, or an embryo created using his gametes, if:

(a) The man provided his consent to:

(i) PAR, and

(ii) Being treated as the father of a child born as a result of the procedure referred to in paragraph (a)(i), and

(b) The deceased man's surviving partner, who underwent the AHR treatment procedure involving PAR, provides her consent allowing the deceased man to be treated as the father.

(2) A deceased woman shall be treated as the parent of a child who was born as a result of PAR using her gametes, or an embryo created using her gametes, if:

(a) The woman provided her consent to:

(i) PAR, and

(ii) Being treated as the of a child born as a result of the procedure referred to in paragraph (a)(i), and

(b) The deceased woman's surviving partner, who underwent the AHR treatment procedure involving PAR, provides her consent allowing the deceased woman to be treated as the parent.

(3) A deceased person referred to in subheads (1) or (2) shall not be treated as the father or the parent, as the case may be, of a child born as a result of a PAR procedure unless that child was born within 36 months of the person's death.

Explanatory Note

The purpose of permitting PAR, as provided for in this Act, is to enable a person to continue a parental project in the event of the death of his/her partner. It is also to allow the deceased person to be recognised as a parent of a child born as a result of a PAR procedure in which his/her gametes, or an embryo created using his/her gametes, were used.

Subhead (1) states that a deceased man will be treated as a father of a child who was born as a result of PAR that involved his gametes, or an embryo that was created using his

gametes, if certain criteria are met, namely: that the deceased man provided his consent to the use of his gametes, or an embryo created using his gametes, in PAR and to being treated as the father of a child born as a result of such a PAR procedure; and if the deceased man's surviving partner, who underwent the PAR procedure, also gives her consent for the deceased man to be treated as the father of a child born as a result of that procedure.

Subhead (2) states that a deceased woman will be treated as the parent of a child who was born as a result of PAR that involved her gametes, or an embryo that was created using her gametes, if certain criteria are met, namely: that the deceased woman provided her consent to the use of her gametes, or an embryo created using her gametes, in PAR and to being treated as the parent of a child born as a result of such a PAR procedure; and if the deceased woman's surviving partner, who underwent the PAR procedure, also gives her consent for the deceased woman to be treated as the parent of the child born as a result of that procedure.

Subhead (3) states that a deceased person will not be treated as the father or parent of a child born as a result of PAR (involving his/her gamete or an embryo created using his/her gamete) unless that child is born within 36 months of the person's death. Provided that is the case, and that the consents required under either subhead (1) or subhead (2), as the case may be, have been given by the deceased and the mother of the child, the child shall then be regarded as having been born in the lifetime of the deceased and as having survived him/her. In recognition of this parent-child relationship the child will have certain rights, for example in relation to inheritance, and this will also allow the deceased person to be named on the child's birth certificate. The 36 month timeline is to facilitate the orderly administration of the deceased's estate, while also protecting the best interests of the child born as a result PAR.

Head 28 - Consent, provision of information and counselling

This Head provides that:

(1) A consent from a deceased person to the use of his or her gametes, or an embryo created using his or her gametes, for the purposes of PAR shall—

(a)(i) specify that he or she is providing consent to the use of his or her gametes, or an embryo created using his or her gametes, for use in PAR by his or her surviving partner,

(ii) name the person who is his or her partner.

(b) Confirm that he or she has received the information and counselling outlined in subhead (4).

(c) Specify the treatments arising as part of PAR for which he or she consents to his or her gametes, or an embryo created with his or her gametes, being used after his or her death.

(2) A consent from a deceased person to the posthumous retrieval of his or her gametes for use in PAR shall—

(a)(i) specify that he or she is providing consent to posthumous gamete retrieval for use in PAR treatments by his or her surviving partner,

(ii) name the person who is his or her partner.

(b) Confirm that he or she has received the information and counselling outlined in subhead (4).

(c) Specify the treatments or uses arising as part of PAR for which he or she consents to his or her posthumously retrieved gametes, or an embryo created using his or her gametes, being used after his or her death.

(3) In providing his or her consent for PAR the deceased person's surviving partner shall—

(a) confirm that she has received the information and counselling outlined in subhead (4), and

(b) confirm that, subsequent to the deceased person's death, she has received specific counselling referred to in Head 24.

(4)(a) A person's consent under subheads (1), (2) or (3) shall not be considered valid unless:

- (i) it was obtained in writing,
- (ii) it was given voluntarily,
- (iii) the person providing his or her consent had the capacity to give consent at the time in question, and
- (iv) the consent form was signed by the person giving consent.

(b) Prior to giving his or her consent under paragraph (a) the person in question shall have been provided with relevant information about

- (i) PAR,
- (ii) Posthumous gamete retrieval, where applicable, and
- (iii) Posthumous use of gametes and embryos in research.

(c) Separately from and subsequent to the provision of information referred to in paragraph (b), the person giving his or her consent shall have received counselling about the implications of PAR, posthumous gamete retrieval, and the posthumous use of gametes and embryos in research from a counsellor.

(5)(a) A person may, while he or she has capacity to do so, revoke or alter his or her consent to:

- (i) the use of his or her gametes, or an embryo created with his or her gametes, for the purposes of PAR, and where applicable,
- (ii) the posthumous retrieval of his or her gametes for use in PAR.

(b) A revocation or alteration of consent under paragraph (a) must be made in writing and signed by the person altering or revoking his or her consent.

(6)(a) A deceased person's surviving partner may, while she has capacity to do so, revoke or alter her consent to the treatment involving PAR up to the point where a procedure has been performed with the objective of it resulting in the implantation of an embryo in the womb of the surviving partner.

(b) A revocation or alteration of consent under paragraph (a) must be made in writing and signed by the person altering or revoking her consent.

(7) Where a person is giving, altering or revoking consent in the context of subheads (4)(a), (5)(a) or (6)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

Explanatory Note

Head 28 specifies the consent requirements that must be adhered to in the context of procedures involving PAR, including requirements regarding the provision of information and counselling.

Subhead (1) – A consent from a deceased person to use his/her gametes, or an embryo created using his/her gametes, for PAR must specify exactly what it is that the deceased person has provide his/her consent for. Subhead (1) states that a consent from a deceased person in relation to a PAR procedure involving the use of his/her gametes, or an embryo created using his/her gametes must: specify that s/he provides consent for the gametes or embryos in question to the used in PAR treatments by his or her surviving partner, as named on the consent form. The deceased person must also confirm that, prior to giving consent, s/he has received the information and counselling in relation to the potential implications and risks of PAR, and outline the treatments or uses in relation to PAR/AHR for which s/he permits his/her gametes, or an embryo created with his/her gametes to be used in after his/her death.

Subhead (2) states that a consent from a deceased person to retrieve his/her gametes following his/her death in order to use those gametes in a PAR procedure must specifically state that s/he is providing consent for the retrieval of his/her gametes following his/her death and their subsequent use in PAR by his/her surviving partner, as named on the consent form. The deceased person must also confirm that, prior to giving consent, s/he has received the information and counselling in relation to the potential implications and risks of gamete retrieval and PAR and outline the other treatments or uses in relation to PAR/AHR for which s/he consents to his/her posthumously retrieved gametes, or an embryo created using such gametes, being used after his/her death.

Subhead (3) – The surviving partner must have received all of the information and counselling necessary to enable her to make an informed decision, which is unaffected by grief resulting from the bereavement. ESHRE recommend a 1 year waiting period in order to allow for the grieving process before PAR treatment will be provided. Subhead (3) states that

in providing her consent for PAR, the surviving partner of a deceased person must confirm that she has received the information and counselling outlined in subhead (4) and that she has received additional counselling following the death of her partner.

Subhead (4) – Subhead (4)(a) states that a person’s consent under subheads (1), (2), or (3) will only be valid if it was obtained in writing, was given voluntarily, the person giving consent had capacity at the time to give his/her consent and if the consent form was signed by that person.

Intending parents need to be informed of the possible implications of the proposed treatment for themselves, any future children, and other family members. Therefore, subhead (4)(b) states that valid consent can only be obtained after the provision of up-to-date, accurate information about PAR, and other treatments as applicable. Subhead (4)(c) states that separately and subsequent to the provision of information, each person who consents to PAR must also have received counselling from a counsellor. It is important that each intending parent has been given adequate time to consider all relevant issues prior to providing his/her consent.

Subhead (5) – Subhead (5)(a) enables a person, provided s/he has the capacity to do so, to alter or revoke consent s/he previously gave to the use of his/her gametes, or an embryo created with his/her gametes, for PAR, and where applicable to the posthumous retrieval of his/her gametes. In order for consent to be valid it must be provided in writing, therefore, subhead (5)(b) states that any revocation or alteration of consent must also be provided in writing.

Subhead (6) – Allowing the surviving partner to alter or revoke her consent to PAR takes account of the fact that a person’s views in relation to PAR and its implications may change over time. This is particularly relevant once the initial grieving period following the death of a partner has passed. Subhead (6)(a) states that a surviving partner may alter or revoke her consent to PAR treatment that she intends to undergo up until the point that the relevant AHR treatment procedure has been performed with the aim of causing the implantation of an embryo in that woman’s womb. Subhead (6)(b) states that any revocation or alteration of consent must be provided in writing.

Subhead (7) - In some situations, while the person providing, altering or revoking his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (7) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

**PART 5 PRE- IMPLANTATION GENETIC DIAGNOSIS AND SEX
SELECTION**

Head 29 - Interpretation (Part 5)

This Head provides that:

In this Part—

"genetic disease" means a hereditary disease caused by a monogenic (single gene) or chromosomal mutation that entails a high risk to the person with the disease of having a short life expectancy, serious physical or mental disability or illness and poor treatability.

"life-limiting disease" means a disease for which there is currently no cure available and the likelihood is that the condition will lead to any child suffering from such a disease dying prematurely.

Head 30 - Pre-implantation genetic diagnosis (PGD)

This Head provides that:

(1) PGD shall be permitted in cases where there is a significant risk of a child being born with a serious genetic disease that is included in the list to be established and maintained by the Regulatory Authority.

(2) PGD for purposes other than those set out in subhead (1) is prohibited.

(3) Each intending parent involved shall provide his or her consent before any procedure involving PGD is carried out, in accordance with the provisions of Head 34.

Explanatory Note

Head 30 sets out the conditions under which PGD will be allowed and prohibits the use of PGD under any other circumstances.

Subhead (1) states that PGD will be permitted in cases where there is a significant risk of a child being born with a serious genetic disease that causes: severe physical or mental disability or illness; a high risk of shortened life expectancy; and for which there is no cure or limited effective treatment available. The Regulatory Authority shall establish and maintain a list of diseases for which PGD will be allowed and shall issue licences to AHR treatment providers to conduct PGD. Criteria which must be met for screening to be allowed will be established and should relate to the severity of the specific disease in question and its impact on the health, well-being and quality of life of the person to be born (e.g. potentially fatal or severely disabling).

Subhead (2) states that PGD is prohibited for any reasons other than those encompassed by subhead (1). Any person who provides PGD in contravention of this subhead commits an offence.

Subhead (3) states that each intending parent will be required to provide his/her consent before any procedure involving PGD can be carried out. In such instances consent must be provided in accordance with the provisions of Head 34, which include specific requirements regarding the provision of information and counselling to each intending parent prior to obtaining his/her consent.

Head 31 - Human leukocyte antigen (HLA) matching

This Head provides that:

(1) Subject to the approval of the Regulatory Authority, HLA matching may be permitted in cases where there exists a child of the intending parents who suffers from a serious disease, who would be the sibling of any child to be born following a HLA matching procedure and:

- (a) the disease in question is a life-limiting disease,
- (b) no equivalent alternative treatment is available to manage the sick child's illness,
- (c) the subsequent tissue-transfer procedure would have a reasonable chance of improving the condition of the sick child, and
- (d) the tissue-transfer procedure would not be detrimental to the welfare of the child to be born following HLA matching.

(2) The provision of HLA matching in cases other than those set out in subhead (1) is prohibited.

(3) Each intending parent involved shall provide his or her consent before any procedure involving HLA matching is carried out, in accordance with the provisions of Head 34.

Explanatory Note

Head 31 sets out the conditions under which HLA matching may be carried out.

Subhead (1) – HLA matching can be used to try to avoid the child to be born following AHR suffering from the same genetic disease as an existing sibling while also being a good tissue match for that existing child. It is also envisaged that HLA matching may be permitted solely for the purpose of tissue matching, without any diagnostic purpose for detecting disease, in cases where the existing child's disease meets the criteria set out in this Subhead. For example, in cases where there is a low risk that the child to be born following HLA matching would have the same disease, e.g. the disease is not a heritable genetic disease, as in the case of some leukaemias. In both cases, the sick child's illness would subsequently be treated through a tissue transfer procedure from the child to be born following HLA matching.

Subhead (1) states that that the Regulatory Authority may authorise the use of HLA matching on a case-by-case basis, where there is a sick child who would be the sibling of the child to

be born following HLA matching, subject to certain criteria being fulfilled. These criteria include that:

- the sick child has a life-limiting illness and, as such, is at risk of dying prematurely,
- there is no alternative way to treat the child's illness which is comparable, in terms of the outcome it produces, to the transplantation of healthy stem cells, bone marrow, or other tissue from a HLA-matched donor, i.e. the child to be born following HLA matching,
- the subsequent tissue-transfer procedure would be expected, based on the views of the senior treating clinician, to improve the health of the sick child or to improve his/her chances of survival.
- the child to be born would not be subjected to tissue-transfer procedures or other treatment that would be detrimental to his/her welfare, including his/her physical or psychological wellbeing.

Note: The wording of subhead (1) was modified from Denmark's Order No. 286 of 23 April 2004 on the use of pre-implantation diagnosis in specific cases.

Subhead (2) states that it is prohibited to provide HLA matching other than in the situations encompassed by subhead (1). Under Part 9 of this Act, any person who provides HLA matching in contravention of this subhead commits an offence.

Subhead (3) states that each intending parent will be required to provide his/her consent before any HLA matching procedure can be carried out.

Head 32 - Sex selection

This Head provides that:

(1) Sex selection shall be permitted in cases where there is a significant risk of a child being born with a serious genetic disease that affects only one sex or affects one sex significantly more than the other and that is included on the list to be established and maintained by the Regulatory Authority.

(2) Sex selection for purposes other than those outlined in Subhead (1) shall be prohibited.

(3) Each intending parent involved shall provide his or her consent before any sex selection procedure can be carried out, in accordance with the provisions of Head 34.

Explanatory Note

Head 32 outlines the circumstances under which sex selection will be allowed.

Subhead (1) relates to procedures which can be used to increase the likelihood that a child of a particular sex will be born. This includes sex selection through sperm sorting, which separates the X- and Y-chromosome-bearing sperm due to the differences in weight before fertilising the egg with this sorted sperm, either through IVF or through IUI. Sex selection also encompasses the use of PGD to determine the sex of an embryo so that embryos of the preferred sex can be transferred to the womb.

Subhead (1) states that these procedures will be permitted in cases where there is a significant risk that a child will be born with a serious genetic medical condition that affects only one sex or affects one sex significantly more than the other. It is envisaged that such conditions will be included in the list to be established and maintained by the Regulatory Authority. There are over 500 such sex-related genetic diseases (e.g. haemophilia, Duchenne muscular dystrophy, and Tay Sachs disease).

Subhead (2) states that except where permitted under subhead (1) sex selection is forbidden. This will, therefore, prohibit sex selection for non-medical (i.e., social) reasons, such as family balancing or a parent's desire to have a child of a particular sex. Under Part 9 of this Act, any person who provides sex selection in contravention of this subhead commits an offence.

Subhead (3) states that each intending parent involved will be required to provide his/her consent before any procedure involving sex selection can be carried out.

Head 33 - Regulation and oversight

This Head provides that:

(1) The Regulatory Authority shall be responsible for issuing licences for PGD, HLA matching and sex selection and shall monitor the activities of AHR treatment providers conducting those procedures.

(2) The Regulatory Authority shall be responsible for creating and maintaining a list of diseases for which

(a) PGD and sex selection will be permitted and

(b) HLA matching may be permitted subject to specific approval.

(3) The list of diseases referred to in subhead (2) will be periodically reviewed and amended as deemed necessary by the Regulatory Authority.

(4) AHR treatment providers may apply to the Regulatory Authority to undertake PGD, HLA matching or sex selection for a disease that is not currently on the list referred to in subhead (2).

Explanatory Note

Head 33 outlines the functions and the responsibilities of the Regulatory Authority in relation to PGD, HLA matching and sex selection.

Subhead (1) states that the Regulatory Authority will be responsible for the provision of licences for PGD, HLA matching and sex selection to AHR treatment providers conducting such procedures. The Regulatory Authority will also have responsibility for oversight and monitoring of activities involving PGD, HLA matching and sex selection by AHR treatment providers.

Subhead (2) states that the Regulatory Authority will be responsible for creating and maintaining a list of diseases for which PGD and sex selection can be carried out, and for which HLA matching may be permitted, subject to the approval of the Regulatory Authority.

Subhead (3) states that the list to be maintained by the Regulatory Authority will be reviewed and may be updated as knowledge about the genetic basis of certain disorders increases

and/or where it becomes possible to reliably diagnose an increasing number of diseases in embryos that meet the qualifying criteria for PGD, HLA matching and sex selection.

Subhead (4) allows AHR treatment providers to apply to the Regulatory Authority to carry out PGD, HLA matching and sex selection for a disease which is not already on the list of diseases maintained by the Regulatory Authority but which appears to meet the qualifying criteria set out by the Regulatory Authority.

Head 34 - Consent, provision of information and counselling

This Head provides that:

(1) Consent for treatments involving PGD, HLA matching and sex selection must be obtained prior to treatment commencing and must cover all stages of the treatment, in accordance with the consent provisions in Part 2 of this Act.

(2) A consent under subhead (1) shall—

(a) specify that each intending parent has consented to the treatment procedure outlined in the consent form,

(b) confirm that each intending parent has received all of the information and counselling outlined in the provisions of subhead (3),

(c) not have been altered or revoked when the treatment procedure takes place,

(d) specify what to do with stored gametes or embryos if an intending parent, or both intending parents (where two are involved), dies suddenly or subsequently lacks capacity, and

(e) specify what to do in the event of post factum differences of opinion or changes of circumstances.

(3)(a) A person's consent under subhead (1) shall not be considered valid unless:

(i) it was obtained in writing,

(ii) it was given voluntarily,

(iii) the person consenting had the capacity to give consent at the time in question,

(iv) the consent form was signed by the person giving consent.

(b) Prior to giving his or her consent under paragraph (a) the person in question shall have been provided with information about the disease in question and the procedure to be carried out from a geneticist, including information about the potential risks and implications involved, and

(c)(i) Separately from and subsequent to the provision of information referred to in paragraph (b), the person giving his or her consent shall have received counselling from a genetic counsellor.

(ii) Where two intending parents are involved this counselling may be provided to the intending parents individually, jointly, or both, in accordance with their will and preferences.

(4)(a) A person may, while he or she has capacity to do so, revoke or alter his or her consent to any procedure involving PGD, HLA matching or sex selection being carried out as part of his or her AHR treatment.

(b) A revocation or alteration of consent under paragraph (a) must be made in writing and signed by the person altering or revoking his or her consent.

(5) Where a person is giving, altering or revoking consent in the context of subheads (3)(a) or (4)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

(6) Where a procedure involving PGD, HLA matching or sex selection required the consent of both intending parents and prior to the procedure one of the intending parents subsequently revokes his or her consent under subhead (4), then that procedure cannot be provided.

Explanatory Note

Subhead (1) states that each intending parent's consent needs to be obtained before any PGD, HLA matching or sex selection procedure can be carried out and that the consent must cover all stages of the treatment process. Where the treatment is being provided to a couple, both intending parents must consent to all stages of the treatment process.

Subhead (2) states that consent must clearly specify what the intending parent(s) are consenting to and that the consent therein has not been altered or revoked. It also states that consent forms should anticipate challenges that might arise in the future (e.g. severe illness, relationship breakdown or loss of capacity or death of an intending parent) and should require that the intending parent(s) give some consideration and make informed decisions in light of those potential challenges.

In advance of treatment, intending parent(s) should consider their opinions and emotions in relation a number of complex issues and it is imperative that intending parents are fully informed of the nature and consequences of the various treatments on offer and that each intending parent has received the appropriate genetic counselling prior to giving his/her consent, which is specified in subhead (2)(b).

Subhead (3) - Subhead (3)(a) states that a person's consent will only be valid if it was obtained in writing, was given voluntarily, the person giving consent had capacity at the time to give his/her consent and if the consent form was signed by that person.

PGD, HLA matching and sex selection all raise complex ethical, social and legal questions that many people may not have previously considered whether for the intending parents themselves, their potential future children, and other family members. The provision of information and counselling would provide an opportunity to discuss the genetic and clinical information about the disease in question, the accuracy and validity of the proposed procedures and any alternative treatment options. Subhead (3)(b) states that valid consent can only be obtained after the provision of up-to-date, accurate information about the disease in question and the procedure by a geneticist.

Subhead (3)(c) states that separately and subsequent to the provision of information, each intending parent must also have received counselling from a genetic counsellor. Where there are two intending parents involved, the counselling should be offered to them individually, jointly or both, depending on the couple's preferences. It is important that each intending parent has been given adequate time to consider all relevant issues prior to the commencement of treatment.

Subhead (4) - Both medicine and medical science are continually advancing and an individual's values, beliefs, and preferences may change over time, for example, as a result of changing personal circumstances, which might influence his/her decisions regarding PGD, HLA matching or sex selection. Subhead (4)(a) allows people to change their mind after they have consented to procedures involving PGD, HLA matching or sex selection provided they have the capacity to do so. In order for consent to be valid it must be provided in writing, therefore, subhead (4)(b) states that any revocation or alteration of consent must also be provided in writing.

Subhead (5) - In some situations, while the person providing, altering or revoking his/her consent may have capacity, there may be some other reason why s/he is not able to sign the

relevant consent form him/herself. Subhead (5) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Subhead (6) – Where two intending parents are involved, subheads (1) and (2) require that each one has given his/her consent to the PGD, HLA matching or sex selection procedure as the treatment is being provided to both of them, jointly, as a couple. If one of the intending parents alters or revokes his/her consent under subhead (4) and no longer wishes to undergo a procedure involving PGD, HLA matching or sex selection, subhead (6) states that the procedure will not be provided.

PART 6 SURROGACY

Head 35 - Interpretation (Part 6)

This Head provides that:

In this Part—

"domestic surrogacy" means a surrogacy agreement undertaken by a surrogate and an intending parent who are habitually resident and where the embryo transfer is carried out in this State;

"donor-conceived child" has the same meaning as defined in the Act of 2015;

"gestational surrogacy" means a surrogacy agreement under which a surrogate's egg is not used to create any embryo used in the context of that agreement;

"intending parent" means a person who intends to become the parent of a child following the transfer of parentage under a Parental Order as part of a surrogacy agreement;

"Parental Order" means an order made by the court under Head 48 for the transfer of the parentage of a child;

"surrogacy agreement" means an agreement under which a woman agrees to attempt to become pregnant and, if successful, to act as a surrogate and to transfer the parentage of any child born as a result of the pregnancy to an intending parent or intending parents;

Head 36 – Surrogacy permitted under this Act

This Head provides that:

- (1) Surrogacy may be permitted under the following circumstances—
- (a) it is domestic surrogacy,
 - (b) it is gestational surrogacy,
 - (c) it is non-commercial in accordance with Head 40,
 - (d) the surrogacy agreement has been approved in advance of treatment by the Regulatory Authority under Head 37,
 - (e) the surrogate meets the requirements set out in Head 38,
 - (f) each intending parent, or the intending parents together, where there are two intending parents, meet the requirements set out under Head 39,
 - (g) each intending parent and the surrogate provides his or her consent under Head 45 prior to seeking authorisation of the agreement under Head 37,
 - (h) the treatment is provided in accordance with Part 2 of this Act;
 - (i) any donor gametes used as part of a surrogacy agreement shall be subject to the provisions of Part 3;
 - (j) the personal details of each intending parent, the surrogate, a donor, where applicable and any child born under the surrogacy agreement shall be recorded in accordance with Head 44 and Head 50.
- (2) Subject to subhead (3), it is prohibited for any person to intentionally provide a technical, professional or medical service that is to facilitate or give effect to a surrogacy agreement not permitted under subhead (1).
- (3) Nothing in this Head prohibits a qualified medical professional from providing medical treatment to a surrogate after she is pregnant.

(4) Surrogacy which does not comply with the provisions of this Head shall be prohibited.

Explanatory Note

Head 36 deals with surrogacy, whereby one woman (i.e. the surrogate) agrees to become pregnant, carry and deliver a child on behalf of another individual or couple (i.e. the intending parent(s)). Head 36 sets out the circumstances under which surrogacy may be permitted in Ireland. The intention of this legislation is to permit altruistic surrogacy in certain circumstances while, first and foremost, protecting the welfare and interests of any child who would be born under the surrogacy agreement, while also protecting the welfare and interests of the surrogate and the intending parents.

Subhead (1) outlines the criteria that must be met in order for surrogacy to be permitted, namely: (a) that all stages of the AHR treatment required to facilitate the surrogacy must be carried out in Ireland, although this does not prevent a couple from using embryos which were previously created outside of the surrogacy agreement, provided those embryos meet the other requirements for their use in surrogacy to be otherwise permitted under this Head, (b) that the surrogacy is gestational only, meaning that the surrogate does not provide the egg involved and IVF and an embryo transfer will be required to achieve the pregnancy, (c) it is non-commercial (i.e. altruistic) as set out in Head 40, (d) the details of the surrogacy agreement and the individuals involved must be submitted by the AHR treatment provider to the Regulatory Authority for its approval, which must be received in advance of any treatment being provided as part of the surrogacy, (e) and (f) state that the surrogate and the intending parent(s) meet the criteria set out in Heads 38 and 39, respectively, (g) consent from each party is obtained prior to the clinic seeking authorisation of the surrogacy, (h) the treatment is provided in accordance with the provisions of Part 2 of this Act, (i) where gametes provided by a donor were or will be used to create the embryo involved, they will be subject to the provisions relating to the use of donor gametes in Part 3, (j) the details of the surrogate, each intending parent involved in the surrogacy, and any child born under the agreement will be recorded in the National Surrogacy Register in accordance with Head 44 and Head 50. This provides a mechanism through which a child born under a surrogacy agreement can ascertain his/her identity and is in keeping with Ireland's obligations under the UN Convention on the Rights of the Child.

Subhead (2) states that the provision of any technical, medical or professional service that would help to facilitate surrogacy which is not permitted under subhead (1) is prohibited, which would include providing legal or practical advice on a professional basis to people seeking to engage in surrogacy abroad or in commercial surrogacy.

Subhead (3) clarifies that medical professionals can treat a surrogate who is already pregnant regardless of the legality of the surrogacy agreement.

Subhead (4) states that surrogacy which does not meet the provisions of this Head is not permitted. Under the provisions of Part 9 it would be an offence for any person to engage in such surrogacy, whether through provision of treatment or acting as a surrogate or intending parent.

Head 37 – Pre-authorisation of surrogacy agreements by the Regulatory Authority

This Head provides that:

- (1) A person shall not manage or participate in a surrogacy agreement prior to receiving authorisation from the Regulatory Authority.
- (2) An AHR treatment provider must apply, in the prescribed form, to and receive written authorisation for a surrogacy agreement from the Regulatory Authority before any treatment is provided under that agreement.
- (3) The Regulatory Authority may authorise a surrogacy agreement only if it—
 - (a) is satisfied that the agreement meets the criteria of Head 36, and
 - (b) has received the surrogacy agreement in writing, which—
 - (i) includes a written declaration stating that, in the view of each party, the surrogacy agreement meets the criteria of Head 36, and
 - (ii) has been signed by—
 - (I) the surrogate, and
 - (II) each intending parent involved.
- (4) An authorisation under subhead (3) shall only be valid for a period which may be determined by the Regulatory Authority, on a case by case basis, up to a maximum period of two years.
- (5) Upon making a decision on an application for authorisation under subhead (3) the Regulatory Authority must notify the AHR treatment provider of its decision in the manner to be prescribed.
- (6) If the Regulatory Authority refuses to authorise a surrogacy agreement then the AHR treatment provider may appeal that decision to the Appeals Committee of the Regulatory Authority.

Explanatory Note

Head 37 sets out the framework for the Regulatory Authority to provide the pre-authorisation of a surrogacy agreement.

Subhead (1) states that no person may manage or participate in their role of intending parent or surrogate before the agreement has been authorised by the Regulatory Authority. Clearly the parties involved in the agreement will have to set out their roles and seek counselling and legal advice in accordance with Head 43 in advance of seeking approval. However, they may not act in their roles in advance of approval and AHR treatment beyond the necessary medical assessments may not be provided in advance of approval either.

Subhead (2) requires any AHR treatment provider which is to provide AHR treatment to a surrogate or the intending parent(s) to have received written authorisation from the AHR Regulatory Authority in advance of doing so and clarifies that it is the AHR treatment provider that makes the application to the Authority. The supporting documents which will be required by the Regulatory Authority will be specified in regulations.

Subhead (3) states that the Regulatory Authority can only authorise a surrogacy agreement if it is (a) satisfied that the agreement is permitted under Head 36 and (b) has received a written copy of the agreement signed by each party and declaring that to the best of his or her knowledge it meets the criteria of Head 36.

Subhead (4) allows the Regulatory Authority to set a maximum period of validity for authorisation of a surrogacy agreement for two years, but to set a shorter period on a case by case basis, depending on the circumstances of the individuals involved. The two-year period allows for the fact that the AHR treatment process may take time to achieve a pregnancy.

Subhead (5) states the Regulatory Authority will inform the AHR treatment provider who applied for the authorisation of its decision in a form that will be set out in regulations. The regulations will likely require that the grounds for the refusal be outlined.

Subhead (6) enables the AHR treatment provider to appeal a refusal to authorise a surrogacy agreement by the Regulatory Authority to the Appeals Committee of the Authority.

Head 38 – The surrogate

This Head provides that:

(1) A woman may act as a surrogate as part of a surrogacy agreement under Head 36 only if she—

(a) is habitually resident in Ireland,

(b) has previously given birth to a child,

(c) is at least 25 years of age at the time of the submission of the application for authorisation for the surrogacy agreement under Head 37,

(d) is 47 years of age or under at the time of the embryo transfer as part of the surrogacy agreement, and

(e) prior to the submission of the application for authorisation of the surrogacy agreement under Head 37, was assessed and approved as suitable to act as a surrogate by a registered medical practitioner and also by a counsellor.

(2) Notwithstanding subhead (1), it is prohibited for a woman to act as a surrogate in this State under more than two authorised surrogacy agreements.

Explanatory Note

Head 38 sets out the requirements a woman must meet in order for her to act as a surrogate in Ireland.

Subhead (1) allows for a woman to act as a surrogate in Ireland only if she (a) is habitually resident in Ireland, (b) has previously given birth to a child, (c) is at least 25 years old when she seeks approval for the agreement, (d) is 47 years of age or under when the embryo is transferred to her uterus and (e) has undergone a medical assessment by a registered medical practitioner and a psychological assessment by a counsellor and been judged to be suitable to be a surrogate, both physically and psychologically.

This subhead ensures that the surrogate has experience of pregnancy and childbirth and that she will have sufficient maturity and life experience when consenting to the agreement.

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The upper age limit and the requirement for medical and psychological assessment are in line with the provisions of Part 2 of this Act and aim to protect the health and welfare of the surrogate.

Subhead (2) prevents a woman from acting as a surrogate in Ireland under more than two authorised surrogacy agreements.

Head 39 – The intending parents

This Head provides that:

- (1) A surrogacy agreement under Head 36 may involve either—
 - (a) two intending parents jointly, provided they are married, civil partners or cohabitants, or
 - (b) a single intending parent.

- (2) Each intending parent shall be at least 21 years of age at the time of submission of the application for authorisation for the surrogacy agreement under Head 37.

- (3) Every surrogacy agreement shall involve—
 - (a) an intending parent who is habitually resident in Ireland,
 - (b) an embryo which was or will be created using a gamete from an intending parent,
 - (c) an intending parent who is 47 years of age or under at the time of the application seeking authorisation for a surrogacy agreement under Head 37, and
 - (d) either of the following:
 - (i) where there is only one intending parent, an intending parent who—
 - (I) is unable to gestate a pregnancy,
 - (II) is unable to conceive a child for medical reasons,
 - (III) is unlikely to survive a pregnancy or giving birth, or
 - (IV) is likely to have her health significantly affected by a pregnancy or by giving birth, or
 - (ii) where there are two intending parents, together as a couple they—
 - (I) are unable to gestate a pregnancy,
 - (II) are unable to conceive a child for medical reasons,
 - (III) include a woman who is unlikely to survive a pregnancy or giving birth, or
 - (IV) include a woman who is likely to have her health significantly affected by a pregnancy or by giving birth.

(4) As part of the application for the authorisation for surrogacy agreement each intending parent shall provide a written undertaking that he or she will apply for a Parental Order in respect of any child born under that surrogacy agreement.

(5) Each intending parent who provided a gamete used to create the embryo to be transferred as part of the surrogacy agreement must have undergone the testing required for donors of reproductive cells under Regulation 11 of S.I. No. 158 of 2006 prior to the embryo transfer commencing.

Explanatory Note

Head 39 states the criteria which must be met by intending parents involved in any surrogacy agreement for the agreement to be approved.

Subhead (1) allows for (a) two people who are in a committed relationship and (b) single people, to be intending parents in a surrogacy agreement.

Subhead (2) clarifies any intending parent involved in a particular surrogacy agreement must be at least 21 years old when authorisation of the agreement from the Regulatory Authority is sought.

Subhead (3) sets out the other requirements which must be met by the intending parent(s). Where there are two intending parents, although both may meet the criteria of paragraphs (a) to (c), only one of them is required to meet each criterion. If the surrogacy agreement involves a single intending parent then s/he must meet all of the criteria as an individual. Paragraph (d) deals with individual intending parents and couples separately under subparagraphs (i) and (ii), respectively. Under subhead (3) every surrogacy agreement has to involve (a) at least one intending parent who is ordinarily resident in Ireland, (b) only embryos created, or which will be created, using the gametes of at least one intending parent, (c) at least one intending parent who is 47 years of age, or under, in order to ensure that one of the intending parents should live well into the child's adulthood. Paragraph (d) gives a list of reasons for which an individual or a couple may be permitted to engage a surrogate, as long as one of the conditions of paragraph (d) apply.

Subhead (4) requires each intending parent to provide a written undertaking that he or she will apply for a Parental Order in respect of the child.

Subhead (5) requires any intending parent who provided gametes that are used to create the embryo involved to have undergone the testing required for donors of reproductive cells under Regulation 11 of S.I. No 158 of 2006 in advance of that embryo being transferred.

Head 40 – Prohibition of commercial surrogacy

This Head provides that:

- (1) Commercial surrogacy agreements are prohibited.
- (2) A surrogacy agreement will be considered to be commercial in nature if any person—
 - (a) receives or agrees to receive any payment or any other reward in consideration of entering into or making or implementing that surrogacy agreement,
 - (b) offers, makes or gives or agrees to offer, make or give any payment or other reward in consideration of entering into or making or implementing that surrogacy agreement, or
 - (c) receives, makes or gives or agrees to receive, make or give any payment or other reward in consideration of facilitating the making or implementing that surrogacy agreement.
- (3) Notwithstanding subheads (1) and (2), nothing in this Head applies to a payment or other reward that is the reimbursement or payment of reasonable expenses, as outlined in Head 41.

Explanatory Note

This Head prohibits commercial surrogacy, which relates to people making or receiving payments in relation to a surrogacy agreement. The intention of subhead (2) is to prevent an intending surrogate from receiving or agreeing to receive payment (other than the surrogate's reasonable expenses), to prevent intending parents from offering or making payments for someone to enter a surrogacy agreement with them, and to prevent any intermediaries from offering or making payments or receiving or agreeing to receive payments in relation to a surrogacy agreement.

It is not intended to preclude payments for services required for authorised surrogacy agreements, including payments to legal practitioners for giving legal advice, or to counsellors or medical practitioners for assessing and treating the intending parents and / or the surrogate in relation to assisted reproduction procedures, etc. in connection with facilitating an authorised surrogacy agreement. As such, subhead (3) allows for payment of the reasonable expenses outlined in Head 41 in relation to surrogacy.

Head 41 – Surrogacy agreements and reasonable expenses

This Head provides that:

(1) A surrogacy agreement is not enforceable by or against any person, except as prescribed in this Head.

(2) A surrogate has the same right to manage her pregnancy as any other pregnant woman, regardless of any agreement with the intending parents.

(3) An obligation under a surrogacy agreement to pay or reimburse the surrogate's reasonable expenses is enforceable but only if the surrogacy agreement was made prior to the transfer of the embryo to the surrogate.

(4) For the purpose of this Act, the "reasonable expenses" are the surrogate's reasonable expenses associated with any of the following matters that are part of the surrogacy agreement:

(a) becoming or trying to become pregnant;

(b) the pregnancy or a birth;

(c) entering into and giving effect to a surrogacy agreement.

(5) The "reasonable expenses" associated with the pregnancy or birth in subhead (4) include the following:

(a) any pre-natal or post-natal medical expenses associated with the pregnancy or birth,

(b) any travel or accommodation expenses associated with the pregnancy or birth,

(c) the expense of reimbursing the surrogate for a loss of earnings as a result of unpaid leave taken by her, but only for the following periods:

(i) a period of not more than two months during which the birth happened or was expected to happen;

(ii) any other period during the pregnancy when the surrogate was unable to work on medical grounds related to pregnancy or birth.

(6) The “reasonable expenses” associated with entering into and giving effect to a surrogacy agreement in subhead (4) include the following:

(a) the expenses associated with the surrogate receiving counselling in relation to the surrogacy agreement (whether before or after entry into the agreement);

(b) the expenses associated with the surrogate and the surrogate’s husband, where applicable, receiving independent legal advice in relation to the surrogacy agreement or a parentage order related to the surrogacy agreement;

(c) the expenses, including the reasonable travel and accommodation expenses, associated with the surrogate and her husband, where applicable, being a party to proceedings in relation to making a parentage order as a consequence of the surrogacy agreement.

(7) The reasonable expenses of the surrogate and her husband, where applicable under subheads (4), (5) and (6) will include any other matters that the Minister may prescribe.

(8) An expense is reasonable under Subheads (4), (5), (6) and (7) only if—

(a) the expense is actually incurred, and

(b) the amount of the expense can be verified by receipts or other documentation.

Explanatory Note

This Head provides that a surrogacy agreement is not an enforceable contract, except in relation to the payment of the surrogate’s reasonable expenses, and then only if the agreement was made before the surrogate became pregnant – this is to ensure that intending parents cannot resile from any financial agreement made to the surrogate after she becomes pregnant.

Subhead (1) clarifies that the existence of the agreement between the surrogate and the intending parent(s) is not an enforceable contract.

Subhead (2) protects the surrogate's right to bodily autonomy and ensures she has the right to manage her pregnancy and the birth as she sees fit.

Subhead (3) states that although the agreement is not an enforceable contract, the intending parents are obliged to reimburse the surrogate's reasonable expenses provided that the surrogacy agreement was made prior to the embryo transfer.

Subhead (4) outlines what will be considered to be reasonable expenses in relation to the different stages of the surrogacy.

Subhead (5) provides examples of expenses which may be associated with the pregnancy and childbirth which will be considered to be reasonable.

Subhead (6) gives examples of expenses which may arise when making the surrogacy agreement, or giving effect to it. It includes the cost of legal advice for the surrogate's husband, if she has one, since if the surrogate has a husband he will be presumed to be the father of any child under Irish law. As such there would be potential expenses for him, either in relation to the provision of legal advice or if an intending parent seeks a declaration of parentage in court.

Subhead (7) provides for the Minister to outline any other expenses which relate to each stage of the surrogacy in regulations.

Subhead (8) states that for an expense to be considered "reasonable", it has to actually have been incurred and this needs to be verifiable with receipts or other documentation.

Head 42 - Advertisements for surrogacy

This Head provides that:

(1) A person shall not publish or cause to be published any advertisement, statement, notice or other material that—

(a) states or implies that a person is or may be willing to enter into or arrange a surrogacy agreement,

(b) seeks a person willing to act as a surrogate,

(c) states or implies that a person is or may be willing to act as a surrogate, or

(d) is intending or is likely to induce a person to act as a surrogate.

(2) In this Head “publish” means to disseminate or provide access, by any means, to the public or a section of the public.

Explanatory Note

This Head prohibits publication of advertisements concerning entering into or facilitating a surrogacy agreement.

Subhead (1) prohibits publication of anything that (a) states or implies that a person may be willing to arrange or act as an intermediary to a surrogacy agreement, (b) states or implies that a person is seeking a surrogate, (c) states or implies that a person may be willing to act as a surrogate or (d) attempts to persuade a person to act as a surrogate. The provisions of Part 9 clarify that contravening this subhead would be an offence under this Act.

Subhead (2) clarifies that publication covers any method of disseminating the information to the public.

Head 43 – Requirement for counselling and independent legal advice

This Head provides that:

- (1) The surrogate and each intending parent involved shall—
 - (a) have received counselling from a counsellor regarding the potential social and psychological implications at each stage of the surrogacy agreement, and
 - (b) have received legal advice from a legal practitioner and information about the legal implications of the surrogacy agreement prior to consenting to the agreement under Head 45.
- (2) The legal advice received by the surrogate should include her husband, where applicable, and shall be independent from the legal advice received by a intending parent.

Explanatory Note

Head 43 outlines the requirement for counselling and legal advice which needs to have been received by each party to a surrogacy agreement at different stages of the agreement. These stages are defined as being 1) before the agreement, 2) after the birth of the child but before the child is living with the intending parents and 3) at the time of the application for the transfer of parentage of the child. It is vital that before providing consent to any stage of the agreement, each party is appropriately informed of the potential psychological impact of the agreement and of his/her legal rights and responsibilities in respect of any child who is born under the surrogacy agreement.

Subhead (1) states that (a) the surrogate and each intending parent involved have to receive counselling from a counsellor at each stage of the surrogacy agreement. This will provide an opportunity to discuss the potential social and psychological implications of the surrogacy agreement for each individual who is party to the agreement, and, most importantly, for the child who may be born under the agreement. Subhead (1)(b) states that each party must also have received legal advice and information on the legal implications of the surrogacy agreement prior to consenting to the surrogacy agreement.

Subhead (2) requires that the legal advice received by the surrogate should include her husband, if she has one, since there may be legal implications for him, and that it should be independent of the legal advice received by the intending parents.

Head 44 – Information to be provided to and recorded by the Regulatory Authority in relation to a surrogacy agreement

This Head provides that:

(1) Prior to giving his or her consent to the surrogacy agreement, the surrogate and each intending parent involved shall be informed—

(a) that the surrogate will be the legal mother of any child born as a result of the surrogacy agreement,

(b) that the surrogate's husband, if she has one, will be presumed to be the legal father of any child born as a result of the surrogacy agreement unless the contrary is proven on the balance of probabilities as set out in section 46 of the Act of 1987, and a declaration under section 35 of the Act of 1987 that he is not that child's father is granted,

(c) that an intending parent will not automatically be the legal parent of any child born under the surrogacy agreement,

(d) that any person who is a donor in respect of a gamete which was used to create the embryo to be transferred to the surrogate under the surrogacy agreement will not be a parent of the child,

(e) that the information specified in subhead (3) will be recorded in the National Surrogacy Register in respect of—

(i) the surrogate,

(ii) each intending parent,

(iii) any child born under the surrogacy agreement, and, where applicable,

(iv) the donor of a gamete used to create the embryo that was transferred under the surrogacy agreement,

(f) that any child born under the surrogacy agreement, subject to Head 57, may access the information pertaining to each party to the relevant surrogacy agreement retained in the National Surrogacy Register and may seek to contact any relevant person,

(g) that the surrogate or each intending parent involved may be entitled to access the information outlined in Head 53 as applicable,

(h) that the surrogate and each intending parent involved has an obligation under subhead (4) to provide the information specified to the AHR treatment provider,

(i) having regard to the child's right to his or her identity, that it is desirable that the surrogate and each intending parent involved keep updated, in accordance with Head 57, the information in relation to him or her that is recorded on the National Surrogacy Register, and

(j) of the right of the surrogate and each intending parent involved to revoke his or her consent to the surrogacy agreement as outlined in Head 45.

(2) Prior to giving his or her consent to the use of an embryo created using his or her gamete, a donor in relation to that gamete shall be informed that—

(a) he or she shall not be a parent of that child,

(b) the information specified in subhead (3) in relation to him or her shall be recorded on the National Surrogacy Register,

(c) the child, subject to Head 57, may access the information referred to in Head 55 and seek to contact the donor,

(d) the information that the donor is entitled to obtain from the National Surrogacy Register is restricted to the information referred to in Head 53,

(e) having regard to the child's right to his or her identity, it is desirable that the donor keep updated, in accordance with Head 57, the information in relation to him or her that is recorded on the National Surrogacy Register, and

(f) the donor has a right to revoke his or her consent under Head 45.

(3) For every embryo transfer procedure carried out as part of a surrogacy agreement the AHR treatment provider shall acquire and retain a record of the following—

(a) the name, date of birth, nationality, and contact details of the surrogate, each intending parent involved and, where applicable, the relevant donor,

(b) in respect of each intending parent, whether or not he or she provided a gamete used in the surrogacy agreement,

(c) the date on which, and the AHR treatment provider at which—

(i) the embryo transfer took place, and

(ii) where applicable, the donor provided his or her gamete,

(d) the information provided to the AHR treatment provider under subhead (4).

(4) Following an AHR treatment procedure that is performed as part of a surrogacy agreement either an intending parent or the surrogate shall, as soon as is practicable after becoming aware of the fact, inform the AHR treatment provider concerned of the following:

(a) whether the embryo transfer resulted in a pregnancy,

(b) where the embryo transfer has resulted in pregnancy, the date on which the surrogate is expected to give birth,

(c) where paragraph (b) applies, after the pregnancy of the surrogate has come to an end—

(i) whether the pregnancy resulted in the birth of a live child, and

(ii) where the pregnancy resulted in the birth of a live child, the name, date and place of birth, sex, and address of the child.

(5) For each embryo transfer procedure carried out by an AHR treatment provider as part of a surrogacy agreement, the AHR treatment provider shall inform the Regulatory Authority of the following:

(a) that an embryo transfer procedure as part of a surrogacy agreement has been performed at the AHR treatment facility; and

(b) the information it has recorded in accordance with subhead (3).

(6) Subject to subhead (7), the AHR treatment provider shall provide to the Regulatory Authority the information required under Subhead (5) in relation to each embryo transfer carried out as part of a surrogacy agreement at the AHR treatment provider on each of the following dates:

(a) on a date that is no later than six months after the performance of the procedure concerned, and

(b) on a date that is no earlier than 12 months and no later than 13 months after the performance of the procedure concerned.

(7) Where the AHR treatment provider becomes aware of an error in any information provided under this Head, the provider shall, without delay, inform the Regulatory Authority of the error and it shall provide the Regulatory Authority with the corrected information.

Explanatory Note

Head 44 specifies the information that must be provided by the AHR treatment provider to each party to the surrogacy agreement, and, to any donor whose gametes were or will be used to create the embryo to be transferred to the surrogate, prior to the provision of AHR treatment that is part of the surrogacy agreement. It also sets out the requirements for recording of information in relation to surrogacy by the AHR treatment providers and the requirements relating to provision of information in relation to surrogacy by the treatment providers to the AHR Regulatory Authority.

Subhead (1) states that before a person who will be a surrogate or an intending parent under a surrogacy agreement can consent to the agreement, s/he must have been informed (a) that the surrogate will be the legal mother of any child born under the surrogacy agreement, (b) that if the surrogate has a husband he will be presumed to be the legal father of any child born to his wife under a surrogacy agreement, although this may be rebutted, (c) that the intending parent(s) will not be the automatic legal parent(s) of any child born under a surrogacy agreement, (d) a donor who provided or will provide a gamete used as part of the surrogacy agreement will not be a parent of the child born under that agreement, (e) that the information specified in subhead (3) will be recorded in the National Surrogacy Register in relation to each party to the agreement and any child born under the agreement, (f) that any child born who reaches 18 will have a right to access identifying information in the National Surrogacy Register in relation to any party to the agreement and may try to contact that party, subject to the requirements of Head 57, (g) that s/he may be entitled to access the information in Head 53, (h) that the surrogate and any intending parent are obligated under subhead (4) to inform the clinic of the outcome of any embryo transferred to the surrogate and of any pregnancy established as a result of that procedure, (i) that each party to the agreement should keep his/ her contact details on the National Surrogacy Register up-to-date, and (j) that each party to the agreement can revoke his/her consent in accordance with Head 45.

Subhead (2) states that before a donor whose gametes were or will be used to create the embryo to be transferred to a surrogate under a surrogacy agreement, the donor must be informed of the following: (a) that the donor will not be a parent of any child born under the agreement, (b) that information about the donor specified in subhead (3) will be recorded in the National Surrogacy Register, (c) that the child will be able to access that information on reaching the age of 18, (d) that the information to which the donor is entitled in respect of any child born through the use of the donor's gametes in surrogacy is restricted to non-identifying information in Head 53, (e) that the donor should keep his/her contact details on the National Surrogacy Register up-to-date and (f) that the donor has a right to revoke his/ her consent under Head 45.

Subhead (3) requires the AHR treatment provider to retain a record of certain information in respect of every embryo transfer carried out as part of a surrogacy agreement, specifically (a) the name, date of birth, nationality and contact details of the surrogate, each intending parent involved and the donor, where donor gametes were used to create the embryo, (b) whether or not the intending parent provided a gamete, (c) the date and location of the AHR treatment provider at which the embryo transfer occurred or where it applies, the location at which any donor involved provided his/her gamete and (d) the information which is received by the treatment provider under subhead (4).

Subhead (4) states that either the surrogate or an intending parent involved must inform the AHR treatment provider who transferred the embryo as part of the surrogacy as soon as possible after he or she knows (a) whether or not a pregnancy resulted from the transfer, where applicable (b) the date on which the surrogate is expected to give birth, and once the pregnancy ends, (c) (i) whether a live child was born to the surrogate and if so (ii) the name, date and place of birth, sex and address of that child.

Subhead (5) requires the AHR treatment provider to inform the Regulatory Authority of each embryo transfer that it carries out as part of a surrogacy agreement and to provide all of the information it has obtained under subhead (3) in respect of that surrogacy agreement.

Subhead (6) requires the information in subhead (5) be provided to the Authority within six months of the embryo transfer and updated between 12 and 13 months after the embryo transfer.

Subhead (7) allows for the AHR treatment provider to correct any errors in information provided to the Regulatory Authority.

Head 45 – Consent to the surrogacy agreement and to the treatment

This Head provides that:

(1)(a) Consent to the surrogacy agreement shall be obtained from each intending parent and the surrogate prior to the AHR Regulatory Authority providing authorisation for the agreement under Head 37.

(b) Consent under paragraph (a) shall include consent to any treatment as part of the surrogacy agreement, and must be provided in advance of treatment.

(2) A person who provides his or her consent under subhead (1) to the surrogacy agreement shall also—

(a) confirm that he or she has received the relevant counselling and legal advice required under Head 43,

(b) confirm that he or she has received all of the information required under Head 44,

(c) have given his or her consent to the recording of the information required under Head 44, and

(d) confirm that he or she understands that any child born under the surrogacy agreement may, in accordance with this Part, access the information specified in Head (44)(1)(e) in respect of any party to the surrogacy agreement and seek to contact that person.

(3)(a) A donor of a gamete that is used to create the embryo transferred under a surrogacy agreement—

(i) is not the parent of a child born under that agreement,

(ii) has no parental rights or duties in respect of the child, and

(iii) on, and after the coming into operation of this section, a reference in any enactment to a mother, father or parent of a child who was born under a surrogacy agreement as a result of the transfer of an embryo created using the donor's gamete shall be construed as not including the donor.

(b) Where an embryo to be transferred as part of a surrogacy agreement was or will be created using donor gametes, the donor of the gametes shall have provided his or her consent to the use of his or her gametes as part of a surrogacy agreement.

(c) A donor who consents under paragraph (b) shall—

- (i) confirm that he or she has received all of the information required under Head 44,
- (ii) have given his or her consent to the recording of the information which will be required under required under Head 44, and
- (iii) confirm that he or she understands that any child born under the surrogacy agreement may, in accordance with this Part, access the information specified in Head (44)(1)(e) in respect of the donor and seek to contact him or her.

(4) A person's consent under this Head will only be considered valid if—

- (a) it was obtained in writing,
- (b) it was given voluntarily,
- (c) the person providing his or her consent had the capacity to give consent at the time in question, and
- (d) the consent form was signed by the person giving consent.

(5)(a) A person may, while he or she has capacity to do so, revoke or alter his or her consent given under this Head at any stage prior to the transfer of the embryo under the surrogacy agreement.

(b) A revocation or alteration of consent under paragraph (a) shall be made in writing and signed by the person altering or revoking his or her consent.

(6) Where a person is giving, altering or revoking consent in the context of subheads (4)(d) or (5)(a) and has capacity but is otherwise unable to sign the form in question, he or she may direct another person who is 18 years of age or older, to sign the relevant form on his or her behalf and in his or her presence.

Explanatory Note

Head 45 specifies the requirements in relation to the consents that need to be obtained in respect of a surrogacy agreement in order for the consent to be valid. Any consent required must be informed and explicit consent.

Subhead (1) - Subhead (1)(a) states that before the Regulatory Authority can authorise a surrogacy agreement, the surrogate and each intending parent involved must have provided his/her consent to the agreement, and that consent (b) must also include consent to treatment.

Subhead (2) requires that any person who consents under subhead 1 must also confirm (a) that s/he has received relevant counselling and legal advice required under Head 43, (b) that s/he has been given all of the relevant information specified in Head 44, (c) that s/he consents to the information outlined in Head 44 being recorded in respect of him/her and (d) that s/he understands that any child born under the surrogacy agreement will, once s/he reaches the age of 18, be able to access the information relating to any party to the agreement in the National Surrogacy Register and could try to contact any of the parties. The requirement for counselling and legal advice to be provided to each party to the surrogacy agreement is to ensure that any consent provided is fully informed.

Subhead (3) – In some circumstances a donor gamete may have been used to create the embryo transferred as part of a surrogacy agreement. Subhead 3(a) clarifies that in such situations (i) the donor of the gamete is not the parent of any child born under a surrogacy agreement and (ii) the donor has no parental rights or duties in respect of that child and that (iii) following the commencement of this section, a reference in any enactment to mother, father or parent of that child will not be construed as including that donor.

Subhead (3)(b) states that if donor gametes are to be used as part of a surrogacy agreement, that donor must have specifically consented to the use of his or her gametes in surrogacy. This consent can be consent for the use of his/her gametes as part of a particular agreement only, through a directed donation, or could be a consent from the donor for the use of his/her gametes as part of surrogacy in general. Subhead (3)(c) states that a donor who consents under (b) must also (i) confirm that s/he has received all of the relevant information outlined in Head 44, (ii) consent to the information outlined in Head 44 being recorded in respect of him/her and (iv) confirm that that s/he understands that any child born under the surrogacy agreement in which the donor's gametes were used will, once s/he

reaches 18 years of age, be able to access to the information relating to the donor in the National Surrogacy Register and could try to contact the donor.

Subhead (4) outlines the requirements for consent under this Head to be considered valid, namely that (a) it is written, (b) and (c) it was given voluntarily when the person giving the consent had capacity to consent and (d) the consent was signed by the person consenting.

Subhead (5) - Subhead (5)(a) allows a person who has given consent under this Head to revoke or alter that consent and (b) states that the revocation or alteration must be in writing and signed by the person revoking or altering the consent.

Subhead (6) - In some situations, while the person providing, altering or revoking his/her consent may have capacity, there may be some other reason why s/he is not able to sign the relevant consent form him/herself. Subhead (6) states that in such instances the person in question may direct another person, who is at least 18 years of age, to sign the form on his/her behalf and in his/her presence.

Head 46 - Consent to child born under a surrogacy agreement to live with an intending parent

This Head provides that:

(1) Following the birth of a child under a surrogacy agreement, in order for the home of that child to be with an intending parent, the surrogate shall provide her consent.

(2) Where applicable, the surrogate and an intending parent shall comply with Part IVB of the Childcare Act 1991.

Explanatory Note

The surrogate will be the legal mother of any child born to her. As such, Head 46 states that following the birth of a child under a surrogacy agreement the surrogate must consent in order for the child to live with the intending parent(s). That consent must be informed and must be in writing.

Subhead (2) clarifies that if allowing the child to live with the intending parent(s) would be classed as a private foster arrangement, the surrogate and the intending parents must comply with Part IVB of the Childcare Act, 1991.

Head 47 – Application for a Parental Order

This Head provides that:

- (1) An application may only be made to the court for a Parental Order in respect of a child who was born under a surrogacy agreement that was permitted under Head 36.
- (2) An application under subhead (1) may only be made by—
 - (a) the surrogate,
 - (b) an intending parent, or
 - (c) two intending parents.
- (3) An application under subhead (1) shall not involve more than two intending parents.
- (4) An application under this Head shall be accompanied by evidence that the embryo from which the child to whom the application relates was born—
 - (a) was not created using an egg from the surrogate, and
 - (b) was created using a gamete from at least one intending parent of that child.
- (5) At the time of an application being made under subhead (1), the home of the child named in the application shall be with an intending parent named on the application.
- (6) An application under subhead (1) shall be made no earlier than six weeks and no later than six months after the day on which the child was born.
- (7) The court may extend the time referred to in subhead (6) if it is satisfied that—
 - (a) there are exceptional circumstances justifying the extension, and
 - (b) it is in the best interests of the child to do so.
- (8) Notwithstanding subhead (1), an application for a Parental Order in respect of a child shall only be made if the application also includes any living sibling who was born as a result of the same pregnancy.

(9) Unless the court directs otherwise, the following persons shall, in accordance with any regulations made pursuant to this Act, be served with notice of an application made under subhead (1)—

- (a) if the surrogate makes the application:
 - (i) each intending parent named in the application;
 - (ii) the surrogate's husband, where applicable;
 - (iii) the Attorney General; and
 - (iv) any other person the court considers appropriate.

- (b) if an intending parent, or two intending parents jointly make the application:
 - (i) the surrogate,
 - (ii) the surrogate's husband, where applicable;
 - (iii) the Attorney General; and
 - (iv) any other person the court considers appropriate.

- (c) if there were two intending parents and only one makes an application:
 - (i) the surrogate,
 - (ii) the surrogate's husband, where applicable;
 - (iii) the other intending parent;
 - (iv) the Attorney General; and
 - (v) any other person the court considers appropriate.

(10) Where the court receives an application for a Parental Order under subhead (1) in respect of a child, the court shall notify the Regulatory Authority without delay to enable the Authority to comply with its obligations under Head 50(3)(b).

Explanatory Note

The surrogate will be the legal mother of any child born under a surrogacy arrangement. A Parental Order is the mechanism through which the parental rights and responsibilities are transferred from the surrogate to the intending parent(s). This head sets out the rules governing making applications to the court for a Parental Order in respect of a child born under a surrogacy agreement.

Subhead (1) states that an application for a Parental Order may be made to the court only in respect of a child born under a surrogacy agreement that was permitted under Head 36.

Subhead (2) states that an application for a Parental Order may be made by the surrogate, one intending parent, or two intending parents.

Subhead (3) states that there may not be more than two intending parents making an application for a Parental Order. Where there were originally two intending parents involved in a surrogacy agreement but only one makes the application under subhead (2), the other intending parent will be served with a notice of the application under subhead (9).

Subhead (4) states that an application for a Parental Order in respect of a child must be accompanied by evidence that at least one intending parent provided a gamete used for the child's conception and that the surrogate's egg was not involved. Traditional surrogacy, in which the surrogate provides a gamete used in the conception of the child, is not permitted under Head 36.

Subhead (5) requires the child named in the Parental Order to be living with at least one intending parent at the time the application is made to the court.

Subhead (6) states that an application for a Parental Order in respect of a child cannot be made before six weeks have passed since the child was born and must be made before six months have elapsed since the child's birth. This is to allow the surrogate sufficient time to recover from the rigours of pregnancy and childbirth before participating in proceedings.

Subhead (7) allows the court to grant extensions to this timeframe if there are exceptional circumstances to justify the extension and it is in the best interests of the child involved to do so.

Subhead (8) requires that where more than one child is born to the surrogate under the agreement, any application made in respect of one child must include the sibling(s).

Subhead (9) outlines the people who must be served with notice of an application for a Parental Order in respect of a child. It requires any person who was originally a party to the surrogacy agreement to be served with notice when an application for a Parental Order is made, and also requires that where the surrogate has a husband, if he is the legal father of the child at the time the application is made then he must also be served with notice of the application. The Attorney General must also be served with a notice of the application under this Head.

Subhead (10) requires the court to notify the Regulatory Authority of an application for a Parental Order in respect of a child as soon as possible so that the Authority can carry out its obligations in respect of the National Surrogacy Register.

Head 48 – Grant of a Parental Order

This Head provides that:

(1) Subject to subhead (3), the court may grant a Parental Order applied for under Head 47 in respect of a child if it is satisfied that—

(a) the surrogacy met all of the requirements outlined in Head 36,

(b) the surrogate consents to the granting of the Parental Order,

(c) if the surrogate has a husband, and where relevant, he also consents to the granting of the Parental Order,

(d) each intending parent included in the application consents to the granting of the Parental Order,

(e) at the time of the hearing the home of the child to whom the Parental Order relates is with an intending parent named on the application, and

(f) the granting of the Parental Order is in the best interest of the child involved.

(2) The court may waive a requirement under subhead (1) for consent from the surrogate, or her husband, where relevant, if he or she—

(a) is deceased,

(b) lacks the capacity to provide consent,

(c) cannot be located after reasonable efforts have been made to find him or her, or

(d) for any other reason the court considers to be relevant.

(3) A consent to the granting for a Parental Order may be withdrawn at any time before the granting of the Parental Order.

(4) Proceedings under this Head shall be heard otherwise than in public.

Explanatory Note

Head 48 outlines what the Court may consider when making a decision on an application for a Parental Order in respect of surrogacy.

Subhead (1) provides a mandate for the court to grant a Parental Order in respect of a child if: (a) the surrogacy agreement was permitted under Head 36; (b) the surrogate consents to the granting of the Parental Order; (c) if the surrogate has a husband who is the legal father at the time of the hearing, he consents to the granting of the Parental Order; (d) each intending parent to whom parentage will be transferred consents to the grant of the Parental Order; (e) at the time of the court hearing, the child is living with at least one intending parent who is named on the application for the Parental Order; and (f) the granting of the Parental Order is considered by the court to be in the child's best interests.

The consent from each person required under subhead (1) must be given freely when the application is made. This must occur after the counselling required under Head 43 has been received by the surrogate and each intending parent. The surrogacy agreement is not enforceable and may not be used to show evidence of consent of any of the people whose consent is required under subhead (1).

Subhead (2) provides for the court to waive the consent of a surrogate, or her husband if relevant, who is deceased, lacks capacity to consent, cannot be traced, or for any other reason that the court considers relevant.

Subhead (3) allows for any person, whose consent is required under subhead (1) in order for the court to be able to grant a Parental Order, to withdraw consent that was previously given at any time until the Parental Order has been granted.

Subhead (4) states that court cases involving the transfer of parental rights and responsibilities through the Parental Order shall not be heard in public.

Head 49 – Effect of a Parental Order

This Head provides that:

- (1) Where the court grants a Parental Order under Head 48 in relation to a child—
 - (a) the child becomes the child of each intending parent named on the Parental Order, and
 - (b) the child is no longer the child of any person declared not to be a parent in the Parental Order.
- (2) Upon a Parental Order being granted under Head 48—
 - (a) the child under subhead (1) will be considered, with regard to the rights and duties of parents and children in relation to each other, as the child of each intending parent named on the Parental Order,
 - (b) with respect to the child under subhead (1)—
 - (i) the mother of the child, and
 - (ii) where applicable, any other parent of the childwill lose all parental rights and are freed from all parental duties.
- (c) Paragraph (b)(ii) will not apply where that person is one of the intending parents named on the Parental Order.
- (3) Where the court makes a decision in respect of a child, the court shall, without delay, notify an tArd Chláraitheoir and the Regulatory Authority of the decision in order to allow—
 - (a) an tArd Chláraitheoir to make a note in the entry in the register of births in respect of the child in accordance with Head 51(1)(b), and
 - (b) the Regulatory Authority to make an entry into the National Surrogacy Register under Head 50(3)(c).

Explanatory Note

Head 49 outlines the effect of a Parental Order that is granted.

Subhead (1) states that where the court grants a Parental Order in respect of a child, (a) the child then becomes the child of each intending parent declared in the Parental Order to be the child's legal parent and (b) that child simultaneously ceases to be the legal child of any

person who is declared in the Parental Order not to be the child's parent. The surrogate is the legal mother of any child she gives birth to under a surrogacy agreement until a Parental Order is granted.

Subhead (2) states that where a Parental Order is granted under Head 48 the child named in the Parental Order is (a) considered to be the child of the intending parent(s) declared to be the child's parent(s) in the Parental Order in terms of the rights and responsibilities of children and parents in respect of each other and (b) the surrogate and any other person with parental or guardianship rights and responsibilities in respect of the child will lose those rights and be freed of those responsibilities. Paragraph (c) prevents an intending parent who is the legal father of the child at the time of the court hearing from losing his parental rights and responsibilities in respect of the child where a Parental Order declaring him to be a parent of the child is granted.

Subhead (3) obliges the court to notify, as soon as possible, an tArd Chláraitheoir and the Regulatory Authority of a decision regarding an application for a Parental Order to allow: (a) an tArd Chláraitheoir to make a note in the register of births in respect of the child concerned; and (b) the Regulatory Authority to update the entry in the National Surrogacy Register in respect of the child.

Head 50 – The National Surrogacy Register

This Head provides that:

(1) The Regulatory Authority shall assign and maintain a register to be known as the National Surrogacy Register.

(2) The Regulatory Authority shall make an entry in the National Surrogacy Register in respect of each child born in the State following a surrogacy agreement, as soon as is practicable upon the Authority receiving the relevant information.

(3) An entry under subhead (2) shall contain the following particulars, where known:

(a) the information in respect of any child born under a surrogacy agreement, the relevant surrogate, each relevant intending parent and, where applicable, the relevant donor, as provided to the Regulatory Authority under Head 44(5),

(b) whether an application was made to the court for a Parental Order,

(c) where an application was made to the court for a Parental Order, whether the application was granted or not and the date of the decision.

(4) The Minister may prescribe the manner in which the information specified in subhead (3) is to be recorded on the National Surrogacy Register.

(5) Where the Regulatory Authority has made an entry under subhead (3)(a) and no entry has been subsequently made under subhead 3(b), the Regulatory Authority shall, no sooner than six months but no later than one year after first making the entry under subhead (3)(a), contact each intending parent involved and the surrogate, where necessary, to determine if an application for a Parental Order has been made.

(6) Where the Regulatory Authority determines in accordance with subhead (5) that no application for a Parental Order has been made, the Authority shall, without delay, inform an tArd-Chlárathóir that it holds a record in the National Surrogacy Register.

(7) Where the Regulatory Authority becomes aware of updated information in relation to subhead (3), or of an error in any information entered under subhead (3), it shall update or correct the information, as the case may be, without delay, and contact tArd-Chlárathóir, where necessary.

Explanatory Note

This Head provides for the Regulatory Authority to establish a National Surrogacy Register, containing the details of each party to a surrogacy agreement and any child born under the agreement. Information in respect of a surrogacy agreement will not be recorded in the National Donor Conceived Person Register (NDCPR). Where a given donor's gametes are used to create the embryo used as part of a surrogacy agreement, details of that donor will be recorded in the National Surrogacy Register. It should be noted that in some instances a person who acted as a donor in the context of surrogacy may also have separately acted as a donor in the context of a DAHR procedure under the Act of 2015, in such cases his/her details would separately be recorded in the NDCPR in accordance with the provisions of that Act.

Subhead (1) provides for the Regulatory Authority to establish and maintain a National Surrogacy Register, in which, under **subhead (2)**, the Authority will make an entry in relation to every child born under a surrogacy agreement. That entry will contain the particulars outlined in **subhead (3)** such as (a) the name, date of birth, sex, place of birth, and address of the child, the name, date of birth, nationality and contact details of the surrogate, each intending parent involved, and the donor, where applicable, the date and place of the embryo transfer, the date and place at which a donor provided a gamete used in the surrogacy, where applicable, as provided by the AHR treatment provider under Head 44, (b) whether or not an application for a Parental Order in respect of the child was made to the court and (c) where an application was made, the decision on the application and the date of the decision.

Subhead (4) allows the Minister to prescribe the form of an entry into the National Surrogacy Register.

Subhead (5) requires the Regulatory Authority to make the necessary enquiries to each intending parent involved and the surrogate, where necessary, between six months and one year after it first makes an entry into the National Surrogacy Register in respect of a child to determine if a Parental Order was applied for.

Subhead (6) obliges the Regulatory Authority to notify an tArd-Chláraitheoir, as soon as is practicable, that it holds a record in relation to that child upon determining that no application for a Parental Order was made, so that an tArd-Chláraitheoir can still make a note in the register of births in respect of the child. The intention is to protect the child's right to ascertain his/her identity by ensuring that s/he will be informed that s/he was born under a surrogacy agreement.

Subhead (7) provides for the Regulatory Authority to update and correct the information recorded in the National Surrogacy Register where it becomes aware of updated information or of an error in the information, and for the Authority to contact tArd-Chláraitheoir if necessary, to enable tArd-Chláraitheoir to correct an error.

Head 51 – Interaction of the National Surrogacy Register and the register of births

This Head provides that:

(1) An tArd-Chláraitheoir shall note in the entry in the register of births in respect of a child that that child was born under a surrogacy agreement and that additional information is available from the National Surrogacy Register in relation to the child where he or she receives a notification from—

(a) the Regulatory Authority under Head 50(6), or

(b) the court under Head 49(3).

(2) A note referred to in subhead (1) shall be released only to the child concerned, when he or she has attained the age of 18 years.

(3) Where a person who has attained the age of 18 years applies for a copy of his or her birth certificate, an tArd-Chláraitheoir shall, when issuing a copy of the birth certificate requested, also inform the person that further information relating to him or her is available from the National Surrogacy Register.

Explanatory Note

Head 51 outlines how the National Surrogacy Register, or the court, as the case may be, will interact with the register of births.

Subhead (1) - Under this subhead an tArd-Chláraitheoir is required to make a note in the entry in the register of births in respect of a child that the child was born under a surrogacy agreement and that a record in relation to the child is held on the National Surrogacy Register where an tArd-Chláraitheoir receives a notice from (a) the Regulatory Authority or (b) the court.

Subhead (2) states that the note made in the register of births under subhead (1) will only be released to that child when s/he is at least 18 years of age.

Under subheads (2) and (3) where a note was made in the register of births that the child was born under a surrogacy agreement and that there is extra information available in respect of him/her from the National Surrogacy Register, once that child is at least 18 years of age and applies for his/her birth certificate, an tArd-Chláraitheoir, shall, when issuing the

birth certificate, inform the child that further information relating to the child is available from the National Surrogacy Register.

The intention of this Head is that where a Parental Order is granted in respect of a child, the birth certificate will no longer be issuable by an tArd-Chláraitheoir, as is the case now in respect of adopted children. An tArd-Chláraitheoir would still inform the child who is 18 years of age or older of the availability of additional information from the National Surrogacy Register where a Parental Order is granted.

Head 52 – Issuing of surrogacy certificates where applicable

This Head provides that:

(1) An tArd-Chláraitheoir shall establish and maintain a Register of Parental Orders for Surrogacy.

(2) Where an intending parent presenting a Parental Order to an tArd-Chláraitheoir, an tArd-Chláraitheoir shall retain a copy of that order in the Register of Parental Orders for Surrogacy.

(3)(a) An tArd-Chláraitheoir shall establish and maintain an index to the register of births linking each Parental Order documented under subhead (2) with the relevant entry in the register of births.

(b) The index referred to in paragraph (a) shall not be open to public inspection, and no information from it shall be given to any person except by order of a court.

(4) A surrogacy certificate for the relevant child with the details of the parents declared on the Parental Order shall be issued by an tArd-Chláraitheoir, to—

(a) a person declared to be a parent on a Parental Order of which a copy has been provided to an tArd-Chláraitheoir , and

(b) a child who requests his or her surrogacy certificate.

(5) Any requirement of law for the production of a certificate of birth shall be satisfied by the production of a copy of a surrogacy certificate.

(6) Where a person who has attained the age of 18 years applies for a copy of his or her surrogacy certificate an tArd-Chláraitheoir shall, when issuing a copy of the relevant certificate requested also inform the person that further information relating to him or her is available from the National Surrogacy Register.

Explanatory Note

Head 52 provides for an tArd-Chláraitheoir to issue “surrogacy certificates” instead of birth certificates in relation to a child born under a surrogacy agreement in respect of whom a Parental Order was subsequently granted by the court. The details entered in the register of births, naming the surrogate as the mother of any child born to her under a surrogacy

agreement will not be subsequently amended solely because the court grants a Parental Order declaring the intending parent(s) to be the legal parent(s) of the child. The intention instead is that the mechanism dealing with civil registration of those children will be similar to the mechanism provided for adopted children. The “surrogacy certificate” issued by an tArd-Chláraitheoir will be identical to a standard birth certificate, with nothing to indicate that the child to whom the certificate relates was born under a surrogacy agreement. It is intended that the “surrogacy certificate” would replace the birth certificate and would be a legal document on equal footing with a birth certificate.

Subhead (1) states that an tArd-Chláraitheoir will be required to establish and maintain a Register of Parental Orders for Surrogacy.

Subhead (2) requires an tArd-Chláraitheoir to retain in that Register a copy of each Parental Order which is presented by an intending parent, or the intending parents, as the case may be.

Subhead (3) requires (a) an tArd-Chláraitheoir to create an index linking each Parental Order it has documented to the relevant entry in the register of births and (b) that the index between the Parental Orders documented and the birth register, and information it contains, will not be available to the public unless a court orders otherwise.

Subhead (4) states that a “surrogacy certificate” with the details of the intending parents declared to be the legal parents of the child on the Parental Order will be issued by an tArd-Chláraitheoir in respect of the child to (a) an intending parent, or (b) the child, upon request, in the same way that a birth certificate, or an adoption certificate is currently issued by an tArd-Chláraitheoir upon request.

Subhead (5) states that a surrogacy certificate will have the same legal status as a birth certificate and that the surrogacy certificate, or a copy of it, shall satisfy any requirements that would typically be satisfied by a birth certificate or copy of a birth certificate.

Subhead (6) states that where a child who is at least 18 years of age and in respect of whom an tArd-Chláraitheoir has a copy of a Parental Order requests his or her surrogacy certificate, an tArd-Chláraitheoir shall, when issuing the surrogacy certificate, inform the child that further information relating to him or her is available from the National Surrogacy Register.

Head 53 - Access to certain information from the National Surrogacy Register and the National Donor-Conceived Person Register

This Head provides that:

(1) A child born as a result of a surrogacy agreement who has attained the age of 18 years, or the parent of a child born as a result of a surrogacy agreement who has not attained the age of 18 years, may request the Regulatory Authority to provide him or her with the following information, where applicable—

(a) information in respect of a relevant donor that is recorded on the National Surrogacy Register, other than the relevant donor's name, date of birth and contact details; and

(b) the number of persons who have been born as a result of the use of a gamete donated by a relevant donor as part of a surrogacy agreement or, where applicable, a DAHR procedure under the Act of 2015, and the sex and year of birth of each of them.

(2) A donor may request the Regulatory Authority to provide him or her with information from the National Surrogacy Register on the number of persons who have been born as a result of the use of his or her gamete as part of a surrogacy agreement, and the sex and year of birth of each child.

(3) A donor-conceived child who has attained the age of 18 years, or the parent of a donor-conceived child who has not attained the age of 18 years may request the Regulatory Authority to provide him or her with information on the number of persons who have been born as a result of the use of a gamete donated by the same donor, and the sex year of birth of each of them.

(4) The Regulatory Authority shall comply with a request made in accordance with any subheads in this Head.

Explanatory Note

Head 53 outlines the information that a child (or his/her parents where s/he is under 18) who was born under a surrogacy agreement can access in respect of a donor who provided a gametes used in his or her conception and also in respect of other children who had a common donor. It also provides for the donor involved, or donor-conceived children who had a common donor, accessing certain information in respect of the child. In practice, it is

envisaged that the Regulatory Authority, once established, will house both the National Surrogacy Register and the National Donor Conceived Person Register and provision of information under this Head will be facilitated through the Authority checking both Registers in respect of a child's donor, regardless of whether the child was born as a result of a DAHR procedure or under a surrogacy agreement.

Subhead (1) permits a child born under a surrogacy agreement who is at least 18 years of age, or his/her parent if s/he is under 18, and who was conceived using a donor gamete to request from the Regulatory Authority (a) non-identifying information in respect of the donor, and (b) information on the number of children who had the same donor as the requesting child, and their sex and year of birth.

Subhead (2) - Under this subhead the donor is entitled to request from the National Surrogacy Register information on the number of persons born as a result of the use of his or her gametes, and the sex and year of birth of each of them. In practice it is likely that the donor will simply request the information from the Regulatory Authority, and the Authority will check both the National Surrogacy Register and the National Donor Conceived Person Register, where the donor had consented to the use of his/her gametes for DAHR and for surrogacy.

Subhead (3) permits a donor-conceived child who is at least 18 years of age, or his/her parent if s/he is under 18 to request from the Regulatory Authority information on the number of children who had the same donor as the requesting child, and their sex and year of birth. Under the Act of 2015, a donor-conceived child can access the information on the National Donor Conceived Person Register, but they will also need to be able to access the information on the National Surrogacy Register, where applicable.

Subhead (4) states that the Regulatory Authority will comply with a request received in accordance with this Head.

Head 54 – Information in respect of the surrogate or intending parents to be provided to a child

This Head provides that:

(1)(a) A child born under a surrogacy agreement who has attained the age of 18 years may request from the Regulatory Authority the name, date of birth and contact details of his or her surrogate or intending parent, as the case may be, that are recorded in the National Surrogacy Register.

(b) Hereafter in this Head, a person in respect of whom information is sought is referred to as the “relevant person”.

(2) Where the Regulatory Authority receives a request under subhead (1), it shall send to the relevant person a notice informing him or her that—

(a) a request under subhead (1) has been made by the child, and

(b) the Regulatory Authority shall, 12 weeks from the date on which the notice is sent, release to the child the information requested, unless the relevant person makes representations to the Regulatory Authority setting out why the safety of the relevant person or the child, or both, requires that the information not be released.

(3) Where a relevant person to whom subhead (2) applies makes representations to the Regulatory Authority in accordance with that subsection, the Regulatory Authority shall consider those representations, having regard to the right of the child to his or her identity, and—

(a) if satisfied that sufficient reasons exist to withhold the information concerned from the child, shall refuse the request under subhead (1) and notify the child of the refusal and, in doing so, may inform him or her of the content of the representations of the relevant person under subhead (2), or

(b) if not so satisfied, shall release the information to the child concerned.

(4) Where a relevant person to whom subhead (2) applies does not make representations in accordance with that subsection, the Regulatory Authority shall release the information to the child concerned.

(5) A child may, within 21 days of receipt of the notification under subhead (3)(a), appeal to the Court against the Regulatory Authority's refusal of his or her request under subhead (1).

(6) An appeal under subhead (5) shall—

(a) be on notice to the Regulatory Authority, and

(b) be heard otherwise than in public.

Explanatory Note

Head 54 outlines the information that can be provided to a child born under a surrogacy agreement in respect of the child's surrogate or his or her intending parent(s), where applicable.

Subhead (1) - Under this subhead a child born under a surrogacy agreement who is at least 18 years of age, may request from the Regulatory Authority the name, date of birth and contact details of his or her surrogate or intending parent(s) as the case may be.

Subhead (2) requires the Authority to inform the person in respect of whom the information is sought that the request has been made by the child and that the Authority will release the information sought within 12 weeks unless that person outlines why his/her, or the child's safety or wellbeing requires that the information not be released.

Subhead (3) states that, where a person has been informed of a request made seeking his/her information has made representations outlining the reasons why the information should not be released, the Regulatory Authority can decide whether or not those reasons are sufficient. The Authority then may either (a) refuse to release the information and notify the child who made the request of the refusal and, may inform the child of the content of the representations received in doing so.

Subhead (4) states that where a person has been informed of a request made seeking his/her information and s/he does not reply to the Regulatory Authority within 12 weeks, the Authority will release the information to the requesting child.

Subhead (5) provides for a child to appeal, a refusal by the Authority to release information sought under this Head, to the court within 21 days of receiving the notification of the refusal.

Subhead (6) requires (a) the Regulatory Authority to be served with notice of an appeal made under subhead (5) and (b) appeals to the Court under this Head not to be heard in public.

Head 55 - Information in respect of the donor to be provided to a child who was born under a surrogacy agreement as a result of the transfer of an embryo created using that donor's gamete

This Head provides that:

(1) This Head applies only to a child who was born under a surrogacy agreement as a result of the transfer of an embryo created using a donor gamete.

(2) A child referred to in subhead (1) who has attained the age of 18 years may request from the Regulatory Authority the name, date of birth and contact details of a relevant donor, as recorded in the National Surrogacy Register.

(3) Where the Regulatory Authority receives a request under subhead (2), he or she shall send to the relevant donor a notice informing him or her that—

(a) a request under subhead (2) has been made by the child referred to in subhead (1), and

(b) the Regulatory Authority shall, 12 weeks from the date on which the notice is sent, release to the child the information requested, unless the relevant donor makes representations to the Regulatory Authority setting out why the safety of the relevant donor or the child, or both, requires that the information not be released.

(4) Where a relevant donor to whom subhead (3) applies makes representations to the Regulatory Authority in accordance with that subhead, the Regulatory Authority shall consider those representations, having regard to the right of the child who was conceived using a donor gamete to his or her identity, and—

(a) if satisfied that sufficient reasons exist to withhold the information concerned from the child, shall refuse the request under subhead (2) and notify the child of the refusal and, in doing so, may inform him or her of the content of the representations of the relevant donor under subhead (3), or

(b) if not so satisfied, shall release the information to the child concerned.

(5) Where a relevant donor to whom subhead (2) applies does not make representations in accordance with that subhead, the Regulatory Authority shall release the information to the child referred to in subhead (1).

(6) A child referred to in subhead (1) may, within 21 days of receipt of the notification under subhead (4)(a), appeal to the court against the Regulatory Authority's refusal of his or her request under subhead (2).

(7) An appeal under subhead (6) shall—

(a) be on notice to the Regulatory Authority, and

(b) be heard otherwise than in public.

Explanatory Note

Head 55 outlines the information that can be provided to a child born under a surrogacy agreement as a result of the transfer of an embryo created using a donor gamete in respect of the donor.

Subhead (1) states that this Head is only applicable to a child born under a surrogacy agreement as a result of the transfer of an embryo created using a donor gamete.

Subhead (2) - Under this subhead a child described in subhead (1) who is at least 18 years of age, may request from the Regulatory Authority the name, date of birth and contact details of a donor who provided a gamete used as part of the child's surrogacy agreement.

Subhead (3) requires the Authority to inform the donor that the request has been made by the child and that the Authority will release the information sought within 12 weeks unless the donor outlines why his/her, or the child's safety or wellbeing requires that the information not be released.

Subhead (4) states that, where a donor has been informed of a request made seeking his/her information and the donor has made representations outlining the reasons why the information should not be released, the Regulatory Authority can decide whether or not those reasons are sufficient. The Authority then may either (a) refuse to release the information and notify the child who made the request of the refusal and, may inform the child of the content of the representations received in doing so.

Subhead (5) states that where a donor has been informed of a request made seeking his/her information and s/he does not reply to the Authority within 12 weeks, the Authority will release the information to the requesting child.

Subhead (6) provides for a child to appeal a refusal by the Authority to release information sought under this Head to the court within 21 days of receiving the notification of the refusal.

Subhead (7) requires that the Regulatory Authority to be served with notice of an appeal made under subhead (5) and clarifies that appeals to the court under this Head will not to be heard in public.

Head 56 – Information in respect of other persons on that can be requested from the Regulatory Authority

This Head provides that:

(1) This Head applies to—

(a) a child born under a surrogacy agreement as a result of the transfer of an embryo created using a donor gamete, and

(b) a donor-conceived child.

(2)(a) A child referred to in subhead (1) who has attained the age of 18 years may request from the Regulatory Authority the name, date of birth and contact details of any child with whom the requesting child shares a common donor.

(b) Where the Regulatory Authority receives a request for information under paragraph (a), it shall search the National Surrogacy Register and the National Donor Conceived Person register for the information.

(3) Where the Regulatory Authority receives a request under subhead (2) and where the child whose information is sought has previously recorded a statement under subhead (5), then the Regulatory Authority shall send that child a notice informing him or her that—

(a) a request under subhead (2) has been made by a child who shares his or her donor, and

(b) unless the child who receives the notice informs the Regulatory Authority, within 12 weeks of the date of the sending of the notice, that he or she objects to the release of the information requested in subhead (2), the Regulatory Authority shall grant the request.

(4) Where a child to whom a notice under subhead (3) has been sent does not, in accordance with that subhead, object to the release of the information concerned, the Regulatory Authority shall release that information to the requesting person.

(5) A child referred to in subhead (1) who has attained the age of 18 years may request the Regulatory Authority to record on the National Surrogacy Register or the National Donor Conceived Person Register, as the case may be, a statement of his or her name, date of

birth, and contact details, and confirming that he or she consents to the release of that information, where the Regulatory Authority has received a request under subhead (2).

Explanatory Note

Subhead (1) states that this Head applies to (a) children born under a surrogacy agreement in which the embryo transferred was created using a donor gamete and (b) a donor-conceived child under the Act of 2015.

Subhead (2) - Subhead (2)(a) allows for any child born as a result of an AHR treatment procedure that involved donor material who is at least 18 years of age to seek specific information from the Regulatory Authority in relation to other children born as a result of an AHR treatment procedure that involved donor material provided by the same donor.

Subhead (3) states that where the Regulatory Authority receives a request from a child in accordance with subhead (2), under paragraph (a) if the child about whom the information is sought has previously recorded a consent to the release of the information under subhead (5) then the Authority will send a notice to that person to inform him/her of the request and that unless s/he objects then the information will be released to the requesting child. Where no such statement has been recorded under subhead (5) by a child, then the Regulatory Authority will not contact that child and will not release his/her information upon request.

Subhead (4) states that where the Regulatory has sent a notice under subhead (3)(a), the information will not be released if the child objects within 12 weeks of the sending of the notice. This allows for the fact that a person may have previously recorded consent to the release of the information but may have subsequently changed his/her view on the matter.

Subhead (5) states that any child who was conceived through an AHR treatment procedure that involved donor material and who is at least 18 years old can ask the Regulatory Authority record, on the Register that applies to that child, a statement detailing his/her name, date of birth and contact details and that confirms that s/he consents to the release of the details in the statement in response to a request under subhead (2).

Head 57 – Additional provision in relation to Heads 53 to 56

This Head provides that:

(1) Where information relating to a person is, in accordance with this Part, recorded on the National Surrogacy Register, that person (or, in the case of a person who has not attained the age of 18 years, his or her parent or guardian) may request the Regulatory Authority to update the information concerned.

(2) The Regulatory Authority shall not—

(a) record on the National Surrogacy Register or on the National Donor Conceived Person Register a statement made by a person under this Part, or

(b) release information to a person in response to a request under this Part, unless the Regulatory Authority is satisfied that the relevant person has received counselling on the implications of his or her recording such a statement or, as the case may be, receiving such information.

Explanatory Note

Head 57 outlines the additional provisions that will apply to information held or released by the Regulatory Authority.

Subhead (1) permits a person whose details are recorded on the National Surrogacy Register to request that the Regulatory Authority update that information.

Subhead (2) states that the Regulatory Authority will neither (a) record a statement on either Register made by a person under this Part, nor (b) release information upon request unless the Authority is satisfied that the person who wishes to record a statement or access information has received counselling on the matter.

PART 7 EMBRYO AND STEM CELL RESEARCH

Head 58 - Interpretation (Part 7)

This Head provides that:

In this Part—

"animal" means an animal other than a human.

"embryonic stem cell" means a cell derived from the inner cell mass of five to seven day-old embryo, which is self-renewing and pluripotent.

"enucleated egg or embryo" means an egg or embryo from which the nuclear DNA has been removed.

"genome" means an organism's complete set of DNA, including all of its genes.

"human-animal hybrid embryo" shall be construed in accordance with Head 62.

"human embryo clone" means a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by a human sperm.

"induced pluripotent stem cell" means a somatic cell with a specialised function, such as a skin cell, that has been reprogrammed to be a pluripotent stem cell.

"mitochondrial replacement" shall be construed in accordance with Head 61.

"pluripotent stem cell" means a stem cell that can become all the cell types that are found in an implanted embryo, foetus or developed organism, but not embryonic components of the trophoblast and placenta, which are required to support development and birth.

"stem cell line" means stem cells that can be maintained and grown in vitro and that display an immortal or indefinite life span.

Head 59 - Prohibition of the creation of embryos for research

This Head provides that:

(1) The creation of an embryo specifically for use in research is prohibited, whether the embryo is created—

(a) by the fertilisation of a human egg by a human sperm, or

(b) through some other process.

Explanatory Note

In its current format, AHR can lead to the production of embryos that for many reasons (e.g. completion of a family or relationship breakdown) may not all be used by the intending parents and, therefore, will remain in storage following the completion of a person's or a couple's AHR treatment. One potential use of such supernumerary embryos is that they may be donated for use in research, subject to the consent of the person or couple for whom they were created. Given the existence of such supernumerary embryos and their potential to be used in research, it is not currently considered justified, or proportionate to permit the creation of embryos specifically for use in research.

Subhead (1) states that it is prohibited to create a human embryo specifically to be used in research and this prohibition applies whether the embryo was created through fertilisation or through some other mechanism. For example, this includes prohibiting the creation of embryos through somatic cell nuclear transfer (SCNT), which is a method of cloning that involves the insertion of the nucleus from a somatic cell (e.g. a skin cell) into an enucleated egg to create an embryo. Part 9 states that contravening this subhead by creating embryos specifically for research would be an offence under this Act.

Head 60 - Prohibition of cloning

This Head provides that it is prohibited to:

- (a) create a human embryo clone by any means,
- (b) place a human embryo clone into the body of a person,
- (c) place a human embryo clone into the body of an animal, or
- (d) use a human embryo clone for the purposes of research.

Explanatory Note

A human embryo clone is defined in this Part of the Act as a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by a human sperm. For example, this would encompass an embryo created through somatic cell nuclear transfer (SCNT). Such human embryo clones could potentially be used to generate embryonic stem cells that would be a genetically similar to the person who provided the original somatic cell nucleus used to create the SCNT embryo (i.e. the human embryo clone) and would be less likely to be rejected by his/her immune system. This process is known as therapeutic or research cloning. Reproductive cloning is the process of transferring an embryo created through SCNT into the uterus of a woman in the hope of establishing a pregnancy. In such instances any offspring born as a result of this process would be a near identical genetic match to the person whose somatic cell nucleus was used to create the human embryo clone. Given the lack of medical or scientific justification for conducting it, as well as the potential health risks involved, reproductive cloning is prohibited.

Head 60 clarifies that the creation of a human embryo clone by any means is prohibited [paragraph (a)], as are the potential uses of such a clone in reproductive cloning [paragraph (b)], including the transfer of such clones into an animal [paragraph (c)], or in research [paragraph (d)]. The prohibition on human reproductive cloning is in accordance with the consensus internationally, including such instruments as: the UN Declaration on Human Cloning (2005); the UNESCO Universal Declaration on the Human Genome and Human Rights (1997); and the Council of Europe's Additional Protocol to the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, on the Prohibition of Cloning Human Beings (1998). The provisions of Part 9 clarify that contravening this Head would be an offence under this Act.

Head 61 - Prohibition of modification of the human genome

This Head provides that:

(1) Where the genome of a human gamete or embryo has been modified such that the modification could be inherited by children born from that gamete or embryo or their descendants it is prohibited to place that gamete or embryo into the body of a woman in an attempt to achieve a pregnancy.

(2)(a) Mitochondrial donation and mitochondrial replacement involving human gametes or embryos is prohibited.

(b) In this section mitochondrial donation and mitochondrial replacement refers to the removal of any nuclear DNA from an egg or embryo, which has abnormal mitochondria and the insertion of this nuclear DNA into another enucleated egg or embryo, which has healthy mitochondria.

(3) It is prohibited to place a human gamete or embryo, referred to in Subhead (2), which has undergone mitochondrial donation or mitochondrial replacement into the body of a woman in an attempt to achieve a pregnancy.

Explanatory Note

The use of gene editing techniques to modify the genes of gametes or embryos constitutes a form of germline modification, as those genetic changes would be passed on to future generations and may become a permanent part of the human genome. Serious ethical and safety concerns have been raised about the potential risks and harms of using such techniques both at an individual level and in the long term, given the uncertainty around the impact such genetic engineering might have on future generations. In the specific case of mitochondrial replacement techniques, these technologies are currently being utilised in a very small number of countries (such as the UK), for the treatment of certain diseases caused by mitochondrial disorders. However, in light of the uncertainty regarding the long term impact and the potential safety concerns of such interventions and the fact that in certain cases other alternative options, such as PGD, gamete donation or adoption, may be available to enable people who are affected by mitochondrial disorders to have children, many countries and jurisdictions have prohibited mitochondrial replacement techniques and treatments.

Subhead (1) clarifies that where the genome of a human gamete or embryo has been modified such that the modification could be passed on to children and future generations, then it is prohibited to insert or transfer such a gamete or embryo into the body of a woman in an effort to achieve a pregnancy. This provision does not prevent basic and clinical research involving genome editing/modification from taking place, provided the cells, gametes or embryos involved are not subsequently used to establish a pregnancy. In addition, it is not intended that this prohibition would apply to the potential use of gene modification in somatic cells in research or medical applications in the future, where such modification would not be passed on to descendants. The provisions of Part 9 of this Act state that contravening this subhead is an offence.

Subhead (2) clarifies that research or treatment involving mitochondrial donation and mitochondrial replacement in human gametes or embryos is prohibited. Mitochondrial donation and mitochondrial replacement are defined as the removal of the DNA from the nucleus of an egg or embryo, which has abnormal mitochondria and the insertion of this nuclear DNA into another egg or embryo, whose nuclear DNA has been removed (i.e. an enucleated egg or embryo), which has normal, healthy mitochondria. Contravening this subhead is an offence under the provisions of Part 9 of this Act.

Subhead (3) clarifies that where mitochondrial donation and replacement has been performed on a human gamete or embryo, then it is also prohibited to insert or transfer such a gamete or embryo into the body of a woman in an effort to achieve a pregnancy. The provisions of Part 9 of this Act state that contravening this subhead is an offence.

Head 62 - Creation and use of human-animal hybrids

This Head provides that:

(1)(a) It is prohibited to create a human-animal hybrid embryo.

(b) For the purposes of this Part a human-animal hybrid embryo means an embryo created or altered by—

- (i) the fertilisation of a human gamete with an animal gamete,
- (ii) the fertilisation of an animal gamete with a human gamete,
- (iii) the insertion of an animal cell into a human embryo,
- (iv) the insertion of a nucleus from a human cell into an animal egg,
- (v) the insertion of a nucleus from an animal cell into a human egg, or
- (vi) any other combination of human and animal material as prescribed in Regulations.

(2) It is prohibited to use a human-animal hybrid embryo for any purpose, including but not limited to—

- (a) the provision of AHR treatment procedures and services,
- (b) the generation of embryonic stem cells, or
- (c) any other form of research.

(3) It is prohibited to place human-animal hybrid embryo into—

- (a) the body of a person, or
- (b) the body of an animal.

(4) It is prohibited to place—

(a) a human gamete or embryo into an animal, or

(b) an animal gamete or embryo into a person.

Explanatory Note

The creation of human-animal hybrid embryos for research purposes is permitted in certain jurisdictions. One commonly described method for creating such embryos is somatic cell nuclear transfer (SCNT) involving the transfer of a nucleus from a human somatic cell (e.g. a skin cell) into an enucleated animal egg. The creation of human-animal hybrid embryos is proffered as a potential source of embryonic stem cells, which does not involve the use of human embryos or human eggs. However, a number of ethical, legal, scientific and social concerns have been raised in relation to research involving human-animal hybrid embryos and its implications. For example, for many people there is an inherent negative response associated with mixing elements of humans and animals together. In addition, there are concerns that the mixing cells and/or embryos from human and animal species could potentially increase the risk of transferring animal diseases to humans.

Subhead (1) outlines the processes that, for the purposes of this legislation, would be deemed to result in the creation of a human-animal hybrid embryo and states that the creation of such human-animal hybrid embryos is prohibited. The provisions of Part 9 of this Act state that contravening this subhead is an offence.

Subheads (2 and 3) clarify that it is prohibited to use human-animal hybrid embryos for any purpose or to place such embryos in the body of a person or an animal. This prohibition would apply whether or not the human-animal hybrid embryos were created in Ireland. The provisions of Part 9 of this Act state that contravening this subhead is an offence.

Subhead (4) clarifies that it is not permitted to place a human gamete or embryo into the body of an animal nor to place the gamete or embryo of an animal into the body of a human. The provisions of Part 9 of this Act state that contravening this subhead is an offence.

Head 63 - Authorised research

This Head provides that:

- (1) Research applications shall be made to the Regulatory Authority for authorisation on:
 - (a) research involving embryos, or
 - (b) research involving the derivation, collection, storage or use of—
 - (i) embryonic stem cells or stem cell lines, or
 - (ii) induced pluripotent stem cells or stem cell lines.
- (2) The Regulatory Authority may only authorise the types of research referred to in Subhead (1) where the Authority is satisfied that—
 - (a) if the research involves embryos-
 - (i) it will only involve supernumerary embryos that were donated for use in research in accordance with the relevant provisions in Part 3, and
 - (ii) the proposed use of the supernumerary embryos is in accordance with the consent of the donors of those embryos.
 - (b) the research is likely to lead to advances in—
 - (i) knowledge, treatments or other procedures relating to assisted human reproduction, or
 - (ii) the knowledge or treatment of serious diseases or other serious medical conditions.
 - (c) the aims of the research referred to in paragraph (b) could not reasonably be achieved through alternative forms of research that do not require the use of, as the case may be—
 - (i) embryos,
 - (ii) embryonic stem cells or stem cell lines, or
 - (iii) induced pluripotent stem cells or stem cell lines.
 - (d) the research has been assessed and approved by a research ethics committee, and
 - (e) the research will be conducted in accordance with any other requirements as may be prescribed by the Regulatory Authority.

(3) The Regulatory Authority may permit the importation of embryonic stem cell lines or induced pluripotent stem cell lines for use in research that is authorised in accordance with Subhead (2).

(4)(a) It is prohibited to develop or maintain an embryo in vitro beyond the fourteenth day of its development following fertilisation.

(b) The fourteen-day limit referred to in paragraph (a), shall not include any time during which the development of the embryo in question has been suspended.

(5) Gametes and embryos that have been used for the purposes of research shall not be used for any other purpose, including as part of an AHR treatment procedure.

Explanatory Note

Head 63 sets out the specific, limited circumstances (i.e. for what purposes and under what conditions) in which research involving human embryos, including embryonic stem cell research is permitted. This Head places the same conditions and restrictions on induced pluripotent stem cell research because while their source (i.e. adult somatic cells) is not controversial, the potential uses to which they can be put are similar to embryonic stem cells.

Subhead (1) stipulates that any research involving human embryos or the derivation or use of embryonic stem cells/lines or induced pluripotent stem cells/lines can only be conducted where the Regulatory Authority has provided authorisation, i.e. through a specific licence.

Subhead (2) outlines the specific conditions that need to be met in order for the Regulatory Authority to be satisfied to authorise such research. In authorising such research the Regulatory Authority may attached additional requirements to be fulfilled by the researchers [Subhead 2(e)], for example, stipulating that adequate measures are put in place by the researchers to minimise the amount of embryos to be used in the research.

Subhead (3) - The Regulatory Authority may, in authorising embryonic or induced pluripotent stem cell research, allow the importation of such stem cell lines to be used in Ireland.

Subhead (4) stipulates that as part of conducting research no embryo may be developed or maintained beyond the 14th day of its development since fertilisation. This is a widely established cut-off point because it is the stage at which the primitive streak develops. It is important to note that any time during which the embryo was cryopreserved as part of its

storage, and its development was, therefore, suspended, does not count in calculating this 14-day limit. The provisions of Part 9 of this Act state that a person who contravenes this subhead commits an offence.

Subhead (5) clarifies that it is prohibited to use any gamete or embryo that has been used for research for any other purpose, which includes prohibiting such gametes or embryos being used in providing AHR treatment. The provisions of Part 9 of this Act state that a person who contravenes this subhead commits an offence.

PART 8 ASSISTED HUMAN REPRODUCTION REGULATORY AUTHORITY

Head 64 - Interpretation (Part 8)

This Head provides that:

In this Part—

"Board" means the Board of the Assisted Human Reproduction Regulatory Authority (AHRRA) created under Head 74;

"confidential information" means—

- (a) information that is expressed by the AHRRA to be confidential either as regards particular information or as regards information of a particular class or description,
- (b) proposals of a commercial nature or tenders submitted to the AHRRA by any person,
- (c) information contained on the National Donor Conceived Person Register,
- (d) information contained in the National Surrogacy Register, and
- (e) any information that would allow identification of persons availing of AHR treatments or related services.

Head 65 - Establishment of the Assisted Human Reproduction Regulatory Authority

This Head provides that:

(1) A body called An tÚdarás Rialála um Atáirgeadh Daonna Cuidithe or, in the English language, the Assisted Human Reproduction Regulatory Authority (to be cited as the AHRRA) is established to perform the functions assigned to it under this Act.

(2) The Minister shall by order appoint a day to be the establishment day of the AHRRA.

(3) The AHRRA is a body corporate with perpetual succession and may

(a) sue and be sued in its own name,

(b) with the consent of the Minister and the Minister for Finance, acquire, hold and dispose of land or an interest in land, and

(c) acquire, hold and dispose of any other property.

(4) The AHRRA shall provide itself with a seal as soon as may be after the establishment day.

(5) The seal of the AHRRA will be authenticated by the signature of

(a) the Chairperson of the Board; and

(b) the Chief Executive Officer of the AHRRA.

(6) Judicial notice shall be taken of the seal of the AHRRA, and every document purporting to be an instrument made by the AHRRA and sealed with the seal of the AHRRA authenticated in accordance with this Head shall, unless the contrary is shown, be received in evidence and be deemed to be that instrument without further proof.

Explanatory Note

This Head establishes and names the Regulatory Authority.

Head 66 - Objective of the AHRRA

This Head provides that:

The objective of the AHRRA is to protect, promote and, as far as practicable, ensure the health and wellbeing of children born as a result of assisted human reproduction, the intending parents, and other persons involved in the process.

Head 67 - Functions of the AHRRA

This Head provides that:

The AHRRA shall:

- (1) ensure compliance of AHR treatment providers with this Act by the granting, amending or revoking of licences to carry out AHR procedures and associated services,
- (2) ensure compliance with this Act by the granting, amending or revoking of licences to carry out embryo research, and embryonic and induced pluripotent stem cell research,
- (3) seek to resolve disputes arising from the granting, amending or revoking of licences under subheads (1) and (2),
- (4) collect and publish statistical information on AHR procedures including, but not limited to,
 -
 - (a) number of embryo and gamete donations in Ireland,
 - (b) types of AHR procedures performed by AHR treatment providers,
 - (c) number of AHR cycles and their outcomes,
 - (d) report on activities of AHR treatment providers, and
 - (e) any other AHR activities the AHRRA licences,
- (5) maintain and publish an up to date list of licenced AHR treatment providers,
- (6) provide, to the extent it considers appropriate, advice and information on activities governed by this Act,
- (7) publish and maintain codes of practice giving guidance for the proper conduct of activities carried on in pursuance of a licence under this Act,
- (8) undertake the functions assigned to the Minister under Parts 2 & 3 of the Act of 2015 including maintaining the National Donor Conceived Person Register (NDCPR),
- (9) authorise surrogacy agreements,
- (10) establish and maintain the National Surrogacy Register,
- (11) consider applications for extension to storage periods of gametes or embryos,

(12) establish and maintain a list of diseases for which—

- (a) PGD and sex selection will be permitted, and
- (b) HLA matching may be permitted, subject to specific approval;

(13) consider applications for HLA matching, and

(14) the Minister may regulate such additional functions connected with the functions of the AHRRA as the Minister determines, subject to such conditions (if any) as may be specified in the regulation.

Explanatory Note

Subheads (1) and (2) - The AHRRA will grant licences for fertility clinics, hospitals and medical practitioners to perform AHR procedures under strict conditions laid out in Head 69. Similarly research in the field of AHR and related topics will be subject to licencing from the AHRRA (see Head 70).

Subhead (3) - When requested a review of a decision to grant, amend or refuse a licence to an AHR treatment provider or a research facility will be conducted by the Appeals Committee which is provided for under Head 79(8)(a).

Subhead (4) allows for the AHRRA to collect and publish statistical information (non-identifying) on the use and success rates of these AHR procedures (e.g. pregnancy and birth rates), as recorded by treatment providers.

Subhead (5) provides for a list of licenced AHR treatments to be available to the general public.

Subhead (6) - Much of the information on AHR procedures is provided to patients directly through clinics' websites. This information would best be provided by an independent organisation, be it the AHRRA or a suitable service provider, to ensure patients receive information appropriate to their circumstances. It would also allow primary care practitioners, who are likely to be the first point of contact for many seeking AHR treatment, to direct patients to a suitable source of information and to inform themselves. Part of this role would include providing information to parents and child advocacy groups on best practice for informing donor conceived children of their status.

Subhead (7) - It is envisaged that the AHRRA will publish codes of conduct and guidance documents for counselling services, provision of services and any other areas that it deems necessary or where AHR facilities request clarification. These will likely be either technical documents (e.g. those specifying the standards for medical facilities and techniques) or more general documents (e.g. ethical advice for providing treatment).

Subhead (8) - Part 3 of the Children and Family Relationships Act 2015 allows for the establishment and maintenance of a National Donor Conceived Person Register (NDCPR) which will allow children born as a result of donor assisted human reproduction procedures to access specified information on reaching the age of 18.

Subhead (9) - Surrogacy agreements will be subject to the conditions laid out in Part 6 and all surrogacy agreements will require approval from the AHRRA.

Subhead (10) - Similar to the NDCPR, a National Surrogacy Register is established under this Act to allow children born as a result of surrogacy to access information on all relevant parties to the surrogacy agreement on reaching the age of 18.

Subhead (11) As provided for in Head 22 applications for extension to the storage periods for gametes and embryos will be considered by the AHRRA.

Subhead (12) - Makes provision for the AHRRA to create and maintain lists of diseases for which PGD and sex selection can be carried out, and for which HLA matching may be permitted, subject to the approval of the AHRRA.

Subhead (13) - Makes provision for AHRRA to allow HLA matching on a case by case basis subject to the provisions of Head 31.

Subhead (14) - Makes provision for other connected functions to be conferred on the AHRRA.

Head 68 - Delegation of functions of the AHRRA to other bodies

This Head provides that:

(1) The AHRRA may delegate functions, whether generally or in a particular case, to another body and where that body is able and willing to perform the function, the AHRRA may enter into an agreement with that body to perform the function on the AHRRA's behalf.

(2) If an agreement is entered into for a specified body to perform a function of the AHRRA, that body may—

(a) perform the function on the AHRRA's behalf in accordance with the agreement, and

(b) do any act or thing relating to the performance of that function that the AHRRA would be authorised by law to do if it performed the function.

(3) An agreement under this Head may contain terms and conditions relating to—

(a) the extent to which and the period for which a party to the agreement is authorised to perform the function of that other party to the agreement;

(b) the making of payments or the transfer of financial responsibility; and

(c) such other matters as are considered necessary to give effect to the agreement.

(4) An agreement under this Head may provide for charges payable by the party on whose behalf the function is to be performed to the other party to the agreement.

Explanatory Note

This Head allows the AHRRA to delegate functions prescribed under this act to both public and non-public bodies.

Head 69 - Licencing of AHR treatment providers

This Head provides that:

In this Head “AHR services” means AHR treatments and related services regulated by this Act.

(1) A person shall not provide AHR services at a facility unless a licence has been granted under this Act.

(2) In, or in respect of, an application for registration or renewal of a licence under this Head a person shall not knowingly make a statement which is false or misleading.

(3) A person seeking to register or renew a licence under this Head shall make an application to the AHRRA and include—

(a) the prescribed information,

(b) any other information the AHRRA reasonably requires the applicant to include,

(c) confirmation of a licence as a tissue establishment under the Tissues and Cells Regulations, where applicable; and

(d) the prescribed application fee.

(4) Applications for licence renewal must be made at least 6 months before the expiry of the current licence.

(5) A person who wishes to carry out AHR services at more than one location shall make a separate application for each location.

(6) The executive of the AHRRA shall make recommendations to the Board on whether to grant, amend or revoke a licence for the provision of AHR services under this Act.

(7) The decision to grant, amend, attach conditions to or revoke a licence is the responsibility of the Board.

(8) Appeals against decisions to grant, revoke or amend a licence under this Head are to be referred to the Appeals Committee.

(9) A register of licences granted under this Head will be maintained by the AHRRA, and published online, including:

- (a) the name of the facility,
- (b) address of the facility, and
- (c) the type of AHR services carried out by the facility.

(10) The AHRRA may attach conditions to a licence granted under this Head as it sees fit.

(11) On granting a licence under this Head the AHRRA shall issue a certificate containing the details of the licence which must be displayed at the location at which AHR services are provided.

(12) Standards required for the granting of a licence under this Head shall be laid out in regulations.

Explanatory Note

Subhead (1) makes provisions for the granting, amending or revoking of licences for AHR treatments and related services by the AHRRA.

Subhead (2) - Providing false information for the purposes of applying for a licence from the AHRRA is not allowed. The provisions of Part 9 of this Act state that a person who contravenes this subhead commits an offence.

Subhead (3) provides that the AHRRA shall designate the criteria against which licence applications may be made: this is likely to be a dynamic process as technology and medical standards change.

Subhead (4) - Renewal period for a licence is likely to be two years so a six month window would allow seamless transition to a new licence.

Subhead (5) - Each facility will need to be licenced independently even if operating under the umbrella of the same company. This is in order to ensure each facility is inspected and standards are maintained across all facilities. As there are currently only 13 clinics operating in Ireland this does not represent an undue burden for the inspection team.

Subheads (6) and (7) - Responsibility for the granting of licences will ultimately lie with the Board, with the executive of the AHRRA providing a recommendation based on the application and previous inspections.

Subhead (8) - If requested, a review of a decision to grant, amend or refuse a licence to an AHR treatment provider will be conducted by the Appeals Committee, which will be a Standing Committee of the Board, as per Head 79(8)(a). This is to ensure that licencing decisions are made on a sound clinical basis without parties immediately resorting to the courts.

Subhead (9) makes provision for a central register for facilities providing infertility treatment in Ireland.

Subhead (10) allows the AHRRA to attach additional provisions to a licence of an AHR treatment provider if it deems them necessary.

Subhead (11) provides that all registered clinics will be identified as such by the production of a certificate detailing their licence.

Subhead (12) makes provision for Regulations detailing the conditions required for the granting of a licence to be drafted and to include requirements for a robust organisational structure, a documented quality management system, appropriately qualified and trained personnel, suitable equipment in both design and number, an appropriate facility and good documentation practices.

Head 70 - Licencing of research

This Head provides that:

In this Head “research” means authorised research as specified by Part 7 of this Act.

(1) A person shall not conduct research at a facility unless a licence has been granted under this Act.

(2) In, or in respect of, an application for registration of a licence under this Head a person shall not knowingly make a statement which is false or misleading.

(3) A person seeking to register a licence under this Head shall make an application to the AHRRA and include—

(a) the prescribed information,

(b) any other information the AHRRA reasonably requires the applicant to include,

(c) the prescribed application fee, and

(d) documented confirmation that the research has been assessed and approved by a research ethics committee.

(4) The Scientific Advisory Committee and the Ethics Committee of the AHRRA shall make recommendations to the Board on whether to grant, amend or revoke a licence for research.

(5) Appeals against decisions to grant, amend or revoke a licence under this Head are to be referred to the Appeals Committee.

(6) A list of those granted licences under this Head will be maintained by the AHRRA, including—

(a) name of the facility,

(b) address of the facility, and

(c) the type of research carried out at the facility.

(7) The AHRRA may attach conditions to a licence granted under this Head as it sees fit.

(8) On granting a licence under this Act the AHRRA shall issue a certificate containing the details of the licence.

(9) Standards required for the granting of a licence under this Head shall be laid out in regulations.

Explanatory Note

Subhead (1) makes provisions for the granting of licences for research facilities working on embryo research, and embryonic and induced pluripotent stem cell research. The provisions of Part 9 of this Act clarify that a person who contravenes this subhead commits an offence.

Subhead (2) - Providing false information for the purposes of applying for a licence from the AHRRA is not allowed. The provisions of Part 9 of this Act clarify that a person who contravenes this subhead commits an offence.

Subhead (3) makes provision for the AHRRA to designate the criteria against which licence applications may be made, as this is likely to be a dynamic process as technology and medical standards change.

Subhead (4) makes provision for the recognition of the sensitive nature of research in this area and stipulates that recommendations from the Scientific and Ethical Committees will be considered before the Board may grant a licence. Granting of licences for medical research will be subject to ethical approval by the Ethics Committee while the Scientific Advisory Committee will examine the scientific credentials of both the work and those undertaking the research. This double lock will allow public confidence that research in this area conforms to high ethical and scientific standards while also allowing a framework for scientific and clinical innovation.

Subhead (5) makes provision that, where requested, a review of a decision to grant, amend or refuse a licence to an AHR treatment provider or a research facility will be conducted by the Appeals Committee.

Subhead (6) makes provision for maintaining a list of research facilities to aid the AHRRA in inspections and licencing.

Subhead (7) allows the AHRRA to attach additional provisions to a research licence if it deems them necessary.

Subhead (8) makes provision for the production of a licence for a research facility, which may be necessary for internal use of licence holders.

Subhead (9) makes provision for Regulations detailing the conditions required for the granting of a licence to be drafted and to include requirements for a robust organisational structure, a documented quality management system, appropriately qualified and trained personnel, suitable equipment in both design and number, an appropriate facility and good documentation practices.

General note: There is no provision for renewing of licences under this Head as it is envisaged that licences will be granted for individual projects and expire on completion of that project.

Head 71 - Duty of the AHRRA to provide information

This Head provides that:

(1) The AHRRA shall—

(a) monitor and keep under review occurrences and developments concerning matters relating to its functions, and

(b) without delay, furnish the Minister with information regarding—

(i) any occurrence or development that, in the opinion of the AHRRA, the Minister is likely to consider significant for the performance of his or her functions (whether under this Act or otherwise), or

(ii) any other occurrence or development that falls within a class of occurrences or developments of public interest or concern that has been specified in writing by the Minister.

(2) The Minister may issue guidelines in relation to the furnishing of information under subhead (1) and, if he or she does so, the AHRRA shall comply with those guidelines.

(3) The AHRRA shall submit, when required by the Minister to do so, a report on any matters connected with the functions of the AHRRA and specified by the Minister.

(4) A report under subhead (3) shall—

(a) address matters of general or specific concern; and

(b) be made in such form and within such period, as specified in the requirement.

Explanatory Note

This Head provides for the AHRRA to provide information to the Minister for Health as appropriate, in addition to the Annual Report.

Head 72 - Disclosure of confidential information

This Head provides that:

(1) Except in the circumstances specified in subhead (2), a person shall not disclose confidential information obtained while performing functions as—

- (a) a member of the Board or a committee of the AHRRA,
- (b) the Chief Executive Officer or an employee of the AHRRA,
- (c) a person engaged under Head 81(4) by the AHRRA as an adviser or consultant, or
- (d) an employee of a person referred to in paragraph (c).

(2) A person shall not contravene subhead (1) by disclosing confidential information if the disclosure—

- (a) is made to or authorised by the AHRRA,
- (b) is made to the Minister by or on behalf of the AHRRA or in compliance with this Act, and
- (c) is required by law.

Explanatory Note

This Head provides for the non-disclosure of confidential information, which is defined in Head 64, except in very limited circumstances.

Head 73 - Processing of personal data

This Head provides that:

(1) The AHRRA may process personal data for the purpose of the functions assigned to it by or under this Act.

(2) Such processing may go no further than is necessary for the carrying out of those functions.

Explanatory Note

With effect from 25 May 2018, the General Data Protection Regulation (GDPR) comes into force across the EU, replacing the existing Data Protection Directive 95/46/EC. The GDPR introduces substantial changes to EU data protection law. These include introducing a higher bar on relying on consent, and increases the amount of information that a body must provide to data subjects when collecting their personal data, to ensure that processing activities are fair and transparent. Our understanding is that public bodies are required to have a legislative basis for the processing (collecting etc.) of personal data, as it may be more difficult for them to rely on consent, particularly in cases where there is a clear imbalance between the data subject and the controller.

Subhead (1) provides that the AHRRA can collect, collate, analyse etc. personal data for the purposes of its functions.

Subhead (2) provides that the AHRRA may not use that data for purposes other than its functions.

Head 74 - Role of the Board

This Head provides that:

- (1) There shall be a Board of the AHRRA which shall be the governing body of the Authority, in the name of the Assisted Human Reproduction Regulatory Authority, to perform the functions of the Authority.
- (2) The functions of the Board shall be to—
 - (a) ensure that the objective of the AHRRA is fulfilled and that its functions are performed efficiently, effectively and to the highest standards;
 - (b) set the strategic objectives of the AHRRA consistent with the objective and functions set out in this Act, and
 - (c) ensure that the appropriate systems and procedures are in place to achieve the AHRRA strategic objectives, fulfil its objective and perform its functions.
- (3) In performing its functions, the Board shall act in utmost good faith with care, skill and diligence.
- (4) The Board may delegate to the Chief Executive Officer the day-to-day running of the AHRRA and any of its functions which it considers should be carried out by the Chief Executive Officer and the Board shall be responsible for monitoring, approving or reviewing the performance of such functions by the Chief Executive Officer.
- (5) If a function of the Board is delegated to the Chief Executive Officer, the delegation shall remain in force until the Board revokes it.
- (6) The Board will be required to adhere to the Code of Practice for the Governance of State Boards published by the Department of Public Expenditure and Reform.
- (7) The Board shall submit such information regarding the performance of its functions as may be requested by the Minister.

Explanatory Note

Subhead (1) sets out the role of the Board as the governing body of the Authority in the name of the AHRRA to lead, direct, and control the Authority in the performance of its functions and the fulfilment of its object. A similar provision can be found in the Child and Family Agency Act 2013 (s 21).

Subhead (2) provides detail on the functions of the Board which is collectively responsible for promoting the success of the AHRRA in achieving its object and functions, by leading and directing the Authority's activities. The Board will oversee the formulation and development of strategy, and provide strategic guidance.

Subhead (3) relates to the need for Board members to act in good faith, with due diligence and care, and in the best interest of the Authority. A similar provision is found in the National Asset Management Agency Act, 2009 (s18).

Subhead (4) provides for the delegation by the Board of the running of the Authority on a day-to-day basis to the CEO. In this context a key part of its role is holding the CEO to account. The Board will approve, monitor and review the AHRRA's performance, and the activities and effectiveness of management, holding the CEO to account.

Subhead (5) is a standard provision and is similar to provisions in the Health Act 2007, s14.

Subhead (6) provides that the Board must follow the Government Code of Practice for State Boards in every aspect of its performance, implementation and governance.

Subhead (7) makes provision for the Minister to request from the Board information in respect of the management of its functions.

Head 75 - Conditions of office of membership of the Board

This Head provides that:

(1) A person is not eligible for appointment as a member of the Board of the AHRRA if the person is—

- (a) a member of either House of the Oireachtas or of the European Parliament, or
- (b) regarded pursuant to section 19 of the European Parliament Elections Act 1997 as having been elected to the European Parliament to fill a vacancy, or
- (c) a member of a local authority.

(2) An appointed member who completes a term of office is eligible for reappointment to the Board, but may not serve as a member for more than two consecutive terms.

(3) A member may resign from office by letter sent to the Minister and the resignation shall take effect on the later of—

- (a) the date specified in the letter, or
- (b) the date of receipt of the letter by the Minister.

(4) Where a matter is to be decided by the Board at a meeting, any member of the Board present at the meeting who has an interest in the matter, otherwise than as such a member, shall—

- (a) at the meeting, in advance of any consideration of the matter, disclose to the Board the fact of the interest and the nature of the interest,
- (b) neither influence nor seek to influence a decision relating to the matter,
- (c) absent himself or herself from any meeting or that part of the meeting during which the matter is discussed,
- (d) take no part in any deliberation of the Board or committee of the Board relating to the matter, and
- (e) not vote on a decision relating to the matter.

(5) Where a member discloses an interest in a matter under subhead (4)—

(a) the disclosure shall be recorded in the minutes of the meeting, and

(b) for so long as the matter is being dealt with by the meeting, the member shall not be counted in the quorum for the meeting unless the Board or committee otherwise determines.

(6) Where, at a meeting of the Board or a committee of the Board, a question arises as to whether or not a course of conduct, if pursued by a member of the Board or Committee of the Board, as the case may be, would be a failure by the member to comply with the requirements of subhead (4)—

(a) the question may be determined by the Chairperson of the Board or of the Committee of the Board, as the case may be, whose decision shall be final, and

(b) if the question is so determined, particulars of the determination shall be recorded in the minutes of the meeting concerned.

(7) If satisfied that a member of the Board or a Committee of the Board has contravened subhead (4), the Minister may, if he or she thinks fit, remove that member from office or take any other action that the Minister considers appropriate.

(8) A person who is removed from office under subhead (7) is disqualified from membership of the Board or of a Committee of the Board.

(9) If an appointed member resigns, dies, ceases to hold office (other than by effluxion of time), ceases to be qualified to hold office or is removed from office, the Minister shall as soon as practicable appoint a person to fill the casual vacancy so arising.

(10) A person appointed under subhead (9) shall hold office for the unexpired period of his or her predecessor's term of office or such other period as the Minister may determine.

(11) A member of the Board and a member of the Committee of the Board shall be paid by the AHRRA, out of moneys at its disposal, such a fee and remuneration and allowances for expenses incurred by him or her as the Minister may from time to time, with the consent of the Minister for Finance, Public Expenditure and Reform, determine.

(12) A person is not eligible for membership of the Board or a Committee of the Board if the person is a member of the staff of the AHRRA.

(13) A person shall not be qualified for office and a member shall cease to be so qualified and shall cease to hold office if he or she—

(a) is adjudicated bankrupt,

(b) is convicted of an indictable offence,

(c) is convicted of an offence involving fraud or dishonesty,

(d) is disqualified or restricted from being a director of a company (or is deemed to be the subject of an order under Section 160 of the Companies Act 1990 or a disqualification order within the meaning of Chapter 4 of Part 14 of the Companies Act 2014),

(e) is sentenced to a term of imprisonment by a court of competent jurisdiction,

(f) is removed by a competent authority of any reason (other than failure to pay a fee) from any register established for the purpose of registering members of a profession.

Explanatory Note

This Head sets out the circumstances in which a person may not be appointed to the Board of the ARHHA and the conditions where a member of the Board will automatically cease to hold office. It recognises that effective working of the Board will mean that members, when appointed, must attend regularly meetings of the Board unless a long absence is approved by the Chairperson. It provides for a process by which a member may resign and how a member may be removed from office.

Head 76 - Membership of the Board

This Head provides that:

(1) The Board of the AHRRA shall consist of 11 members, one of whom will be the Chairperson.

(2) All 11 members shall be appointed by the Minister and shall be people who have experience or expertise in matters connected with the functions of the AHRRA, or in corporate governance and management generally.

(3) Members shall hold office for a period of up to four years from the date of appointment except where otherwise provided for under subhead (4).

(4) Notwithstanding subhead (3), the persons who are first appointed by the Minister to be members of the Board shall hold office as follows—

(a) five members for a term of office of three years, and

(b) five members for a term of office of four years,

(c) the Chairperson shall hold office for a period of four years,

and ordinary members who hold office for the periods specified in paragraphs (a) and (b) will be determined at the first meeting of the Board by lot to be drawn in the manner agreed at the meeting.

(5) The Minister may request relevant stakeholders to nominate appropriate candidates for consideration for appointment to the Board.

Explanatory Note

The Board of the AHRRA will be appointed by the Minister and consist of 11 members, ten ordinary members and one Chairperson. In relation to the nominations of members to the first Board, the Chair and five others will serve for four years, the remaining five members will service for three years. It is intended that every four years six members will be reappointed or replaced. This allows for continuity of expertise on the Board of the AHRRA.

The Minister may seek nominations from relevant stakeholders (e.g. Institute of Obstetricians and Gynaecologists, the Royal College of Physicians in Ireland and the Nursing and Midwifery Board of Ireland, the National Infertility Support Group, legal representation and Scientific, Research and Ethicist representation) for appointment to the Board.

Head 77 - Meetings of the Board

This Head provides that:

- (1) The Board shall hold as many meetings as are necessary for the performance of its functions, but in each year shall hold at least four meetings.
- (2) The Chairperson may at any reasonable time call a meeting of the Board.
- (3) Any five members of the Board may call a meeting of the Board if the Chairperson—
 - (a) refuses to call a meeting after being presented with a requisition for that purpose signed by not fewer than five Board members, or
 - (b) without refusing to call a meeting, does not call one within seven days of being presented with such a requisition.
- (4) At a meeting called under subhead (3), or where the Chairperson has called a meeting or cannot attend, or where the office of the Chairperson is vacant, the members present shall choose one those present to chair the meeting.
- (5) The quorum for a meeting of the Board shall be six members.
- (6) A meeting held while there is a vacancy on the Board will be valid irrespective of the vacancy, as long as there is a quorum.
- (7) With the exception of a meeting called in accordance with subhead (3) the Chairperson shall, if present, preside at all meetings of the Board.
- (8) Any question at a meeting shall be determined by a majority of the votes of the members present and voting on the question.
- (9) Where there is an equal division of votes, the Chairperson has a second and casting vote at all meetings at which he or she is present except where a meeting has been called in accordance with subhead (3), in which case the person chosen in accordance with subhead (4), has a second or casting vote.
- (10) The Board may regulate, by standing orders or otherwise, the procedures and business of the Board.

Explanatory Note

This Head contains the standard provisions for the meeting of a state board with the Board meeting, at a minimum, quarterly but with provisions in place to allow for extraordinary meetings to occur as necessary.

Head 78 - Removal of all members of the Board from office

This Head provides that:

- (1) The Minister may remove all the members of the Board from office if—
 - (a) the Board fails to achieve a quorum for three consecutive meetings,
 - (b) the Board does not comply with a judgment, order or decree of any court,
 - (c) the Board does not comply with a direction of the Minister or any other requirement imposed on it by or under any enactment including this Act, or
 - (d) the Minister is satisfied that the Board's functions are not being performed in an effective manner.

- (2) The Minister may, if of the opinion that the Board's functions are not being performed in an effective manner, appoint a person to—
 - (a) conduct an independent review of any matter giving rise to that opinion, and
 - (b) submit a report to the Minister on the results of the review.

- (3) The Board shall co-operate with any such review and give the person conducting it all reasonable assistance, including access to such premises, equipment and records as the person may require for the purposes of the review.

- (4) The removal of the members of the Board from office does not revoke or otherwise affect any delegation of the AHRRA's functions to the Chief Executive Officer under Head 74(4).

Explanatory Note

This Head allows the Minister to remove the Board if they fail to perform effectively or comply with existing legislation, as failure of the Board to perform effectively could have potentially serious and significant quality and safety consequences. This is modelled on the Child and Family Agency Act 2013.

Head 79 – Committees of the Board

This Head provides that:

(1) The Board may establish Committees to assist and advise it on matters relating to its functions and may determine the membership and terms of reference of each Committee.

(2) The Board may appoint to a Committee of the Board persons who are not members of the Board but have special knowledge and experience related to the purposes of the Committee.

(3) The appointment of a person to a Committee of the Board is subject to such terms and conditions as may be determined—

(a) under Head 75(11), to the extent that they relate to remuneration and allowances, and

(b) by the Board, in any other case.

(4) The Board shall specify in writing the purpose and terms of reference of each Committee of the Board.

(5) The acts of a Committee of the Board are subject to confirmation by the Board unless the Board dispenses with the necessity for confirmation.

(6) The Board may regulate the procedure of a Committee of the Board but, subject to any such regulation, a Committee may regulate its own procedure.

(7) The Board may at any time dissolve a Committee of the Board established under this Head.

(8) Notwithstanding subheads (4) and (7), the following Committees shall be maintained by the Board of the AHRRA—

(a) Appeals Committee

(b) Scientific Committee

(c) Ethics Committee

Explanatory Note

This Head allows for the AHRRA to establish any Committees they deem necessary for the smooth running of the organisation, e.g. Appointments, Audit and Governance, Compliance, Ethics and Standards, Ethics and Law Advisory, Horizon Scanning, Remuneration, Register Research, Statutory Approvals, Scientific and Clinical Advisory (the HFEA, which is the UK equivalent of the AHRRA, has a total of 12 committees). This will also allow the Board to form Committees to deal with individual issues that arise, if it so chooses, with subhead (7) enabling the disbanding of such Committees once their work is completed. Specific provisions are made for three Committees, the Appeals, Scientific and Ethics Committees, which are designated as essential for the operation of this Act.

Head 80 - Chief Executive Officer

This Head provides that:

(1) The Board shall appoint a person, recruited in accordance with the Public Service Management (Recruitment and Appointments) Act 2004, to be the Chief Executive Officer of the AHRRA.

(2) The Chief Executive Officer shall hold office, on such terms and conditions (including those relating to remuneration, allowances and superannuation) as may be determined by the Board with the prior approval of the Minister given with the consent of the Minister for Public Expenditure and Reform.

(3) The remunerations and allowances determined under subhead (2) are payable to the Chief Executive Officer by the AHRRA out of funds at its disposal.

(4) The Chief Executive Officer shall not hold any other office or position without the consent of the Board.

The Chief Executive Officer immediately ceases to hold office on—

(a) being nominated as a member of Seanad Éireann,

(b) being elected as a member of either House of the Oireachtas or of the European Parliament,

(c) being regarded, pursuant to section 19 of the European Parliament Elections Act 1997, as having been elected to the European Parliament to fill a vacancy, or

(d) becoming a member of a local authority.

(6) The Chief Executive Officer may be removed from office by the Board for stated reasons.

(7) The Chief Executive Officer may attend any meeting of the Board or of a Committee of the AHRRA.

(8) The Chief Executive Officer shall—

(a) carry on and manage and control generally the administration and business of the AHRRA in accordance with the strategic objectives set out by the Board,

(b) perform such other functions as may be assigned to him or her by or under this Act or any other enactment or as may be delegated to him or her by the Board, and

(b) provide the Board with such information (including financial information) relating to the performance of his or her functions and the implementation of the Board's policies as the Board may require.

(9) If the Chief Executive Officer is absent or the position of Chief Executive Officer is vacant, the function of the Chief Executive Officer under this section may be performed by an employee of the Board designated by the Board for an interim period.

Explanatory Note

Head 80 provides for the appointment and functions of the Chief Executive Officer (CEO).

Head 81 - Employees

This Head provides that:

(1) The Board of the AHRRA may, subject to subhead (2), appoint persons to be its employees, using an appropriate and transparent recruitment and selection process approved by the Board, and determine their duties.

(2) The Board of the AHRRA, with the approval of the Minister, given with the consent of the Minister for Public Expenditure and Reform, will determine the remuneration, allowances and superannuation of employees appointed under this Head.

(3) Remuneration and allowances of employees are payable by the Board of the AHRRA with funds at its disposal.

(4) The AHRRA may engage such consultants or advisers as it considers necessary for the performance of its functions.

(5) Fees due to a consultant or adviser engaged under this Head are payable by the Board of the AHRRA out of funds at its disposal.

Explanatory Note

Head 81 enables the AHRRA to appoint employees and to engage consultants and advisers to assist the Board and the CEO to carry out its objective and functions.

Head 82 - Appointment of authorised officers

This Head provides that:

(1) The AHRRA shall appoint one or more persons, including but not limited to employees of the AHRRA, to exercise any or all of the powers conferred on them by this Act and such a person shall be an authorised officer.

(2) Each authorised officer shall be given a certificate of his or her appointment and, when exercising any power conferred on them by this Act, shall produce, on request by any person affected, the certificate or a copy of the certificate, together with a form of personal identification.

(3) A body that has entered into an agreement with AHRRA under Head 68 shall appoint persons to be authorised officers for the purpose of that agreement and shall, as soon as may be, inform the AHRRA of any such appointment, and such persons shall have all the powers available to authorised officers under this Act while in performance of their duties.

Explanatory Note

Authorised officers will be appointed to carry out inspections of facilities licenced under Heads 69 and 70 and the duties assigned to the Minister under Part 3 of the Children and Family Relationships Act 2015 in relation to the maintenance of the NDCPR, and the authorised officer will carry identification to identify them as such.

Head 83 - Powers of authorised officers

This Head provides that:

(1) For the purposes of this Act an authorised officer may exercise any of the following powers—

(a) enter, at any reasonable time any premises or place—

(i) at which activities are being carried out under a licence granted under Head 69,

(ii) at which activities are carried out under a licence granted under Head 70,

(iii) at which he or she has reasonable grounds for believing is performing AHR treatments and related services,

(iv) at which he or she has reasonable grounds for believing is performing embryo, embryonic stem cell, or induced pluripotent stem cell research, or

(v) at which he or she has reasonable grounds for believing records or documents relating to activities governed by this Act,

(b) require any person on the premises or place referred to in paragraph (a) to produce any documents or records relating to activities governed by this Act, and

(c) secure for inspection—

(i) any documents or records related to activities governed by this Act, or

(ii) any such premises or place, or part thereof, in which documents or records related to activities governed by this Act are held.

(2) An authorised officer shall not enter a dwelling, other than—

(a) with the consent of the occupier, or

(b) pursuant to a warrant under subhead (3).

(3) Upon the sworn information of an authorised officer, a judge of the District Court may for the purposes of enabling an authorised persons to carry out an inspection under subhead (1) issue a warrant authorising a named authorised person, accompanied by such other authorised persons or members of the Garda Síochána as may be necessary, at any time or times, before the expiration of one month from the date of issue of the warrant, to enter the dwelling and perform the functions of an authorised officer under Head 83(1).

(4) A person commits an offence if he or she –

(a) obstructs or interferes with an authorised officer or a member of an Garda Síochána in the course of exercising a power conferred on him or her by this Act, section 31 of the Act of 2015, or a warrant under subhead (3), or

(b) fails or refuses to comply with a request or requirement of, or to answer a question asked by, an authorised officer, or in purported compliance with such request or requirement or in answer to such question gives information to an authorised officer that he or she knows to be false or misleading in any material respect.

(5) Where an authorised officer believes, upon reasonable grounds, that a person has committed an offence under this Act, the authorised officer may require that person to provide him or her with their name and the address at which they ordinarily reside.

(6) A person who commits an offence under this Head is liable–

(a) on summary conviction to a class A fine or imprisonment for a term not exceeding 12 months or both, or

(b) on conviction on indictment to a fine not exceeding €70,000 or imprisonment for a term not exceeding two years or both.

Explanatory Note

This Head makes provisions for the inspection of all facilities at which activities governed by this Act may take place, including the powers of an authorised officer to enter premises, to obtain a warrant to enter premises where permission is refused and the provision of an offence to obstruct an authorised officer in carrying out their duties under this Act.

Head 84 - Accounts of the AHRRA

This Head provides that:

- (1) The AHRRA shall cause to be kept all proper and usual books or other records of account of all money received or expended by it.
- (2) The Board shall, in respect of each financial year, cause to be prepared proper accounts of all income and expenditure and of the property, credits and liabilities of the AHRRA.
- (3) The financial year of the AHRRA shall be the period of 12 months ending on the 31st day of December in any year, commencing on the commencement of this Part.
- (4) The statement of accounts of the AHRRA for each financial year shall, as soon as may be after the end of the financial year, be prepared and the accounts of the AHRRA shall be submitted to the Comptroller and Auditor General for audit, as soon as practicable, and not later than three months after the end of the financial year to which the accounts relate.
- (5) Within one month of the Comptroller and Auditor General issuing an audit certificate for the accounts of the AHRRA, a copy of—
 - (a) the accounts, and
 - (b) the report of the Comptroller and Auditor General on the accounts, shall be presented to the Minister who, within two months after their receipt, shall cause copies thereof to be laid before each House of the Oireachtas.

Explanatory Note

This is a standard provision in respect of the financial accounts of State funded bodies. The AHRRA is required to keep proper account of all money received, prepare financial accounts and, after approval by the Board, submit these accounts to the C&AG for audit. They are then, along with the C&AG's certificate, submitted to the Minister.

Head 85 - Annual report of the AHRRA

This Head provides that:

(1) Not later than 30 April in each year, the AHRRA shall prepare and adopt an annual report in relation to the performance of the AHRRA's functions during the immediately preceding calendar year.

(2) As soon as may be but no later than 21 days after adopting the annual report, the AHRRA shall submit a copy of the annual report to the Minister.

(3) The Minister shall within 21 days of receiving the annual report cause copies of it to be laid before each House of the Oireachtas.

Explanatory Note

This is a standard provision setting out the need to prepare an annual report and make it available to the Minister.

PART 9 OFFENCES, PENALTIES AND PROCEEDINGS

Head 86 – Offences, Penalties, and Proceedings

This Head provides that:

(1) A person who contravenes Head 6(3), 6(4), 10(2), 12(1)(c), 12(1)(d), 22(2), 22(8), 69(2) or 70(2) commits an offence and shall be liable on summary conviction to a class A fine, or imprisonment for a term not exceeding 1 year, or both.

(2) A person who contravenes Head 7(1), 9(1), 12(1)(a), 12(1)(b), 12(2)(a), 12(3)(a), 12(3)(b), 16(1), 16(2), 16(5), 17(2), 24(1), 24(2) or 25(1) commits an offence and shall be liable –

(a) on summary conviction, to a class A fine, or imprisonment for a term not exceeding 1 year, or both, or

(b) on conviction on indictment, to a fine not exceeding €20,000, or imprisonment for a term not exceeding 2 years, or both.

(3) A person who contravenes Head 13(4), 16(4), 19(1), 19(2), 30(2), 31(2), 32(2), 36(4), 42(1), 59(1), 60, 61(1), 61(2), 61(3), 62(1), 62(2), 62(3), 62(4), 63(4), 63(5), 69(1), or 70(1) commits an offence and shall be liable –

(a) on summary conviction, to a class A fine, or imprisonment for a term not exceeding 1 year, or both, or,

(b) on conviction on indictment, to a fine not exceeding €100,000, or imprisonment for a term not exceeding 5 years, or both.

(4) In proceedings for an offence under this Act, it shall be a defence for a person against whom such proceedings are brought to show that he or she exercised due diligence and took all reasonable precautions to ensure compliance with such provisions of this Act as are alleged to have been contravened.

(5) Summary proceedings for an offence under this Act may be brought and prosecuted by the Regulatory Authority.

(6) Notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, summary proceedings for an offence under subhead (1), (2) or (3) may be instituted at any time within 12 months from the date on which the offence was committed or alleged to have been committed.

(7) Where an offence under this Act is committed by a body corporate and is proved to have been committed with the consent or approval of, or to have been attributable to any neglect on the part of any person who, when the offence was committed was a director, member of the committee of management, manager, secretary or other officer of the body concerned, or a person purporting to act in such a capacity, that person, as well as the body corporate, shall be deemed to have committed the offence and may be proceeded against and punished accordingly.

(8) Where the affairs of a body corporate are managed by its members, subhead (7) applies in relation to the acts and defaults of a member in connection with his or her functions of management as if he or she were a director or manager of the body corporate.

Explanatory Note

Head 86 sets out the offences under the legislation. Under this legislation some of the offences may be prosecuted summarily only. However, more serious offences will be indictable.

Subhead (1) provides that a person who contravenes Head 6(3), 6(4), 10(2), 12(1)(c), 12(1)(d), 22(2), 22(8), 69(2) or 70(2) commits an offence and is liable on summary conviction to a class A fine or imprisonment for a term of up to 1 year, or both. These offences may be prosecuted summarily only, and are not indictable.

Subhead (2) provides that a person who contravenes Head 7(1), 9(1), 12(1)(a), 12(1)(b), 12(2)(a), 12(3)(a), 12(3)(b), 16(1), 16(2), 16(5), 17(2), 24(1), 24(2) or 25(1) commits an offence is liable (a) on summary conviction to a class A fine or imprisonment for a term of up to 1 year or both, or (b) on conviction on indictment to a fine of up to €20,000 or imprisonment for a term of up to 2 years or both.

Subhead (3) provides that a person who contravenes Head 13(4), 16(4), 19(1), 19(2), 30(2), 31(2), 32(2), 36(4), 42(1), 59(1), 60, 61(1), 61(2), 61(3), 62(1), 62(2), 62(3), 62(4), 63(4), 63(5), 69(1) or 70(1) commits an offence is liable (a) on summary conviction to a class A fine or imprisonment for a term of up to 1 year or both, or (b) on conviction on indictment to a fine of up to €100,000 or imprisonment for a term of up to 5 years or both.

Subhead (4) clarifies that where proceedings are being brought, it shall be a defence for a person to show that s/he exercised due diligence made all reasonable efforts to comply with the provisions of the legislation.

Subhead (5) empowers the Regulatory Authority to prosecute summary offences under the Act.

Subhead (6) provides that notwithstanding section 10(4) of the Petty Sessions (Ireland) Act 1851, a prosecution for an offence under subhead (1) may be brought within 12 months from the date of the alleged commission of the offence.

Subhead (7) deals with offences under the Act committed by a body corporate and provides that where an offence is proved to have been committed with the consent or approval or to have been attributable to any neglect on the part of a person who was a director, member of the managing committee, manager, secretary or other officer of the body corporate, or a person purporting to act in that capacity, that person, as well of as the body corporate shall be guilty of the offence and prosecuted accordingly.

Subhead (8) states that where the affairs of a body corporate are managed by its members, subhead (7) applies to the acts and defaults of a member as if s/he were a director or manager of the body.