EMBRYO PROTECTION AUTHORITY

# PROTOCOL

## Third Edition

JULY 2022

EMBRYO PROTECTION AUTHORITY

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**Third Edition - July 2022**

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# User Guide to the Protocol

## What is the purpose of the Protocol?

**The Embryo Protection Act (the Act) covers the use and storage of sperm, eggs and embryos for human application. One of the ways we help licensed tissue establishments (Tissue Establishments) comply with the Acts by publishing the Protocol. We have a duty under the Act to maintain a protocol that gives guidance about licensed activities and the people who carry them out.**

**This Protocol also serves as a useful reference for patients, researchers and those working in the fertility sector.**

## How is the Protocol structured?

**The Protocol consists of:**

- **Regulatory principles for licensed tissue establishments whether private or public, and**

- **Guidance notes**

**This Protocol has been prepared in line with EU Directives, National Legislations, HFEA Code of Practice as well as the BICA Practical Manual.**

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# Regulatory Principles for Licensed Tissue Establishments

**The Act requires the Embryo Protection Authority (EPA) to maintain a statement of the general principles that we consider should be followed in carrying out activities covered by the Act.**

## The principles:

- **A summary of the key behaviours and outcomes the EPA expects each licensed tissue establishment to demonstrate, and**

- **A means of communicating to the responsible person and staff at each licensed tissue establishment, patients, and the public the areas of compliance that the EPA regards as key.**

## Compliance and enforcement

**The EPA has a duty to promote compliance with:**

- **The Act, and**

- **The Protocol.**

**Regulatory principles will inform the inspection process. If the EPA becomes aware that a tissue establishment has not complied with the legislation or the Protocol, we may take action in line with provisions in the Act.**

## Regularity Principles

**The EPA expects the responsible person to ensure that their licensed tissue establishment demonstrates adherence to the following principles when carrying out activities licensed under the Embryo Protection Act.**

**Licensed tissue establishments must:**

**1. Treat prospective and current patients fairly, and ensure that all licensed activities are conducted in a non-discriminatory way**

**2. Have respect for the privacy, confidentiality, dignity, comfort and well-being of prospective and current patients**

**3. Have respect for the special status of the embryo when conducting licensed activities**

**4. Take account of the welfare of any child who may be born as a result of the licensed treatment provided by the tissue establishment, and of any other child who may be affected by that birth**

**5. Give prospective, current patients and donors sufficient, accessible and up-to-date information to enable them to make informed decisions**

**6. Ensure that the patient or patients and the donors have provided all relevant consents before carrying out any licensed activity**

**7. Conduct all licensed activities with skill and care and in an appropriate environment, in line with good clinical practice, to ensure optimum outcomes and minimum risk for patients, donors and offspring**

**8. Ensure that all premises, equipment, processes and procedures used in the conduct of licensed activities are safe, secure and suitable for the purpose**

**9. Ensure that all staff engaged in licensed activity are competent and recruited in sufficient numbers to guarantee safe clinical and laboratory practice**

**10. Maintain accurate records and information about all licensed activities**

**11. Report all adverse incidents (including serious adverse events and serious adverse reactions) and near misses to the EPA. As well as report all quality and safety issues relating to quality and safety of gametes and embryos during processes and storage. Investigate all complaints properly, and share lessons learned appropriately**

**12. Conduct all licensed activities with regard to the regulatory framework governing treatment involving gametes or embryos in accordance with the Embryo Protection Act 2012, the Embryo Protection (Amendment) Act 2018, and the Various Laws relating to Assisted Procreation (Amendment) Act 2022. including:**

- maintaining up-to-date awareness and understanding of legal obligations

- responding promptly to requests for information and documents from the EPA, and

- co-operating fully with inspections and investigations by the EPA or other agencies responsible for law enforcement or regulation of healthcare.

13. Reporting of activities supported by EPA forms and documentation including testing results, should include but are not limited to:

- Request for permission to cryopreserve gametes in oncology cases

- Request for permission to cryopreserve gametes in fertility preservation

- Request for permission to cryopreserve gametes by transgender persons prior to starting hormone therapy treatment

- Request for permission to discard gametes

- Request for permission to transfer gametes/embryos between licenced tissue establishments in Malta

- Request for permission to transfer gametes/embryos from a Malta Tissue establishment to abroad and from abroad to a Malta Tissue establishment

- **Request for ART Procedures (IUI, IVF, ICSI) as well as procedures making use of thaw and transfer of cryopreserved embryos and storage of gametes for patients undergoing an ART cycle**

- **Request for Additional Fertilisation of oocytes to be made in line with the EPA Protocol as approved by the Parliament Health Committee**

- **Request for Embryo Cryopreservation and potential Embryo Donation**

- **Request for Use of Third-Party Donation and duly inform immediately every donation made with full identity details of the donor.**

- **Prior Authorisation by the Authority for patients to undergo PGTM.**

- **Prior Authorisation by the Authority for the donation of cryopreserved Embryos**

- **Prior Authorisation by the Authority of the Agreement between the prospective parent or prospective parents and the licensee to regulate the cryopreservation of embryos.**

- **Prior authorisation by the Authority to be granted to a prospective parent or prospective parents who had cryopreserved embryos in tissue establishments abroad to bring two cryopreserved embryos to be transferred locally into the prospective parent or prospective parents for each cycle**

- **Outcomes of all procedures and storage carried out.**

- **To provide the Authority with all documentation and data in regard to reporting obligation of the Authority to the House of Representatives**

- **To pass on information to the Authority without delay of all confidential registers held by the licensee with full details of every medically assisted procreation procedure, germ line cell donation, cryopreservation of germ line cells and cryopreservation of embryos.**

- **To pass on information to the Authority re any Alterations to premises and equipment within the Tissue Establishment. Henceforth, all requests for permissions are to be submitted before the actual activities are embarked upon.**

- **To pass on information to the Authority when new personnel join or existing personnel leave the Tissue Establishment.**

- **Any other documentation that the Authority as Regulator may request in terms of the Embryo Protection Act**

**14. Ensure that all fees (as per schedule of fees) are paid to the Embryo Protection Authority within the timescale mentioned in the schedule of fees**

**15. Ensure that requests for information and/or documents from the Embryo Protection Authority are responded to promptly**

**16. Ensure that data provided to the Embryo Protection Authority about activities and data, which the Embryo Protection Authority is required to hold on its Register of Information, is accurate and provided by dates specified**

**17. Breaches in reporting duties with regards to the EPA may lead to prosecution by the Authority in accordance with the Embryo Protection Act.**

**18. Notify the Embryo Protection Authority immediately if s/he becomes aware of any decision or proposal to close their tissue establishment.**

**In the event of termination of activities, for whatever reason, the Responsible Person (RP) must ensure that all stored gametes and embryos are transferred to another licensed tissue establishment or licensed tissue establishments. The RP must ensure that all relevant information including traceability data and information concerning the quality and safety of gametes and embryos, is transferred with any stored gametes, embryos, or that records containing this information are made accessible as required.**

# Guidance Notes

## 1. The Licence Holder and the Responsible Person

**1.1 The licence holder and the Responsible person should be separate individuals. Clinics operating within a hospital or other healthcare organisation may find it advantageous for a senior hospital manager to hold the post of licence holder.**

**1.2 It is the responsibility of the licence holder to inform the EPA if the Responsible person is unable to perform their duties. Where the tissue establishment no longer has a Responsible person, the licence holder should seek the advice of the EPA as soon as possible on continuing to provide licensable activities.**

**Either the Responsible person or the licence holder may apply for a licence or for its variation or revocation.**

**However, only the licence holder may apply to a licence Authority to vary a licence in order to designate another individual to be the Responsible person.**

## Qualifications for the Role of the Responsible Person

**1.3 The Responsible person should have enough understanding of the scientific, medical, legal, social, ethical and other aspects of the tissue establishment's work to be able to supervise its activities properly. It is also important that the Responsible person possesses integrity, and managerial authority and leadership capability.**

**1.4 When applying to vary a licence in order to appoint a new responsible person, the licence holder must provide evidence that the proposed individual has the managerial authority and capability necessary to perform their duties.**

**1.5 The EPA expects the Responsible person to take any necessary specialist advice to allow them to run the tissue establishment professionally.**

**1.6 The role of the Responsible person should include:**

**(a) ensuring that human tissues and cells intended for human applications in the establishment for which that person is responsible are procured, tested, processed, stored and distributed in accordance with the Directives and the Acts.**

**(b) Maintaining an up-to-date awareness and understanding of legal obligations**

**(c) responding promptly to requests for information and documents from the EPA**

**(d) co-operating fully with inspections and investigations by the EPA or other agencies responsible for law enforcement, regulation or healthcare, and**

**(e) informing the EPA of any change to their professional registration.**

**1.7 The Responsible person is accountable for the overall performance of the Tissue Establishment and should ensure that there are clear responsibilities, roles and systems of accountability to support good governance. The RP is also to ensure that appropriate action is taken following feedback from the EPA, patients and staff including feedback outcomes from inspections, audits and any patient complaints.**

**1.8 The responsible person should ensure that all staff possess the competencies necessary for their role and have access to learning and professional development. All staff are encouraged, as appropriate, to contribute to discussions and decisions about improving patient care. The RP is also to ensure that all staff maintain an up-to-date awareness and understanding of legal obligations.**

# 2. Staff

## Tissue Establishment Staff

**2.1 The tissue establishment should establish documented procedures for staff management, ensuring all staff have:**

**(a) initial basic training and updated training as required**

**(b) an adequate knowledge and understanding of the scientific / technical process and principals relevant to their designated tasks**

**(c) adequate information of the broader legal, ethical and regulatory context of their work**

**(d) on-going competence assessment, with audits of this assessment**

**(e) an annual joint review (with their line manager)**

**(f) continuing education and professional development**

**(g) staff records**

**(h) appropriate access to meetings and communications, and**

**(i) A health care professional is under no obligation to participate in any procedure for the application of any technique of medically assisted procreation regulated by the Act when such professional considers such participation objectionable as a matter of conscience and declares his objection beforehand as per Article 20 of the Embryo Protection Act, 2012.**

**2.2 Staff records should include:**

**(a) job description that accurately reflects their task and responsibilities**

**(b) terms and conditions of employment**

**(c) a record of staff induction and orientation**

**(d) a record of health and safety training**

**(e) a record of education and training, including continuing professional development**

**(f) relevant educational and professional qualifications**

**(g) certificate of registration, if relevant**

**(h) absence record**

**(i) accident record**

**(j) a record of annual joint reviews**

**(k) occupational health record, and**

**(l) a record of any disciplinary action.**

**The tissue establishment should ensure that confidentiality of staff records is in line with best practice and relevant legislation.**

**2.3 All staff should maintain an up-to-date awareness and understanding of legal obligations and should support the responsible person in monitoring and improving the performance of the Tissue Establishment.**

**2.4 All staff should participate in an annual joint review that examines the needs of the tissue establishment and of the individual to improve the quality of the service to users and to encourage productive working relationships. Staff performing annual reviews must receive appropriate training.**

**2.5 The tissue establishment should have an effective way of communicating information to and receiving suggestions from staff. Tissue establishment management should also ensure that the accountabilities and reporting relationships shown in the tissue establishment's organisational chart are communicated within the tissue establishment.**

**2.6 Tissue establishment management should ensure that staff members who are in contact with patients, donors and their partners where applicable:**

**(a) follow the tissue establishment's patient support policy**

**(b) are prepared to offer appropriate emotional support to people suffering distress at any stage before, during and after treatment.**

**(c) understand and can explain the role of counselling, and**

**(d) know when and how to refer people to the tissue establishment's qualified and warranted counsellor.**

**2.7 Tissue establishment management is responsible for delivery of the patient support policy and for using intelligence to monitor and evaluate the effectiveness of the policy. Tissue establishment management should ensure that the policy addresses the emotional support needs of patients, donors, and their partners where applicable, in order to continuously improve their experience of treatment services.**

**2.8 Tissue establishments should require all prospective and existing staff to report promptly all criminal convictions they have had to the person responsible. In deciding whether or not an individual shall take part in a licensed activity at the tissue establishment, the responsible person should take into account relevant previous convictions and breaches of regulations.**

## Medical Staff

**2.9 The Responsible person should ensure that staff who must be registered with professional bodies are registered, their registration is up to date, and records of this are kept.**

**2.10 The individual with overall medical responsibility for treatment services involving in vitro fertilisation should:**

**(a) have completed training recognized by the Specialist Accreditation Committee.**

**(b) be on the General Medical Council's Specialist Register, and**

**(c) participate in a recognised programme of continuing medical education and professional development.**

**2.11 If the centre is licensed to provide insemination services only, the individual with overall clinical responsibility should:**

**(a) be a registered medical practitioner, and**

**(b) have sufficient experience in an established fertility centre to be qualified to take full charge of the centre's treatment services.**

**2.12 Other medical staff who takes part in providing treatment services should be registered medical practitioners with sufficient experience under supervision to qualify them to do so. Medical staff who do laparoscopies should be recognised by the Specialist Accreditation Committee. Medical staff in training should follow relevant training programmes under appropriate supervision.**

## Nursing Staff

**All nursing staff must be appropriately qualified and registered.**

**2.13 Nurses should be:**

**(a) working towards competencies set nationally, to ensure appropriate standards of clinical competence, and**

**(b) able to provide evidence of competence in the duties performed (for example, a certificate from a recognised body and qualification competent in that discipline or function).**

## Counselling Staff

**2.14 Treatment tissue establishments should ensure that Infertility counsellors are appointed to fulfil the role of counsellors. Every tissue establishment should see that enough counsellors are enrolled to offer a 24-hour service of counselling.**

**All counsellors should have specialist competence in infertility counselling and:**

**(a) hold a recognised counselling, clinical psychology, counselling psychology, psychotherapy or family therapy qualification to the level of diploma of higher education or above, and**

**(b) have received Infertility training of the British Infertility Counselling Association (or an equivalent body).**

**(c) have a Warrant in Counselling.**

**2.15 A member of staff appointed to the role of counsellor should be able to provide evidence of being an accredited member of or working towards accredited membership of, a recognized professional counselling body. The body should have a complaint/disciplinary procedure, and the individual should have agreed to abide by an appropriate code of conduct or ethics.**

**Prospective parent or parents shall not be provided with treatment services of any kind unless they have been given a suitable opportunity to receive proper counselling about the implications of being provided with treatment.**

**Before a person gives consent for treatment:**

**(a) s/he must be given a suitable opportunity to receive proper counselling about the implications of taking the proposed steps, and**

**(b) s/he must be provided with such relevant information as is proper.**

**2.16 Treatment establishments carrying out pre-implantation genetic diagnosis should ensure that patients have access to counsellors with appropriate knowledge and expertise in these specialisms, including a good understanding of the risks and implications for patients who have treatment and any children that may be born following such treatment.**

## Staff Engaged in Scientific Services

**2.17 Tissue establishment management should ensure that the Tissue Establishment has access to a nominated registered scientist to advise on and oversee scientific activities.**

**2.18 All healthcare scientists working in licensed tissue establishment should be registered or show evidence of working towards registration with a registered body where applicable.**

**All staff should be registered with a registered body within one-year of their becoming eligible, including those eligible as international applicants after training overseas.**

**2.19 Healthcare scientists from overseas who are registered in their own country but working in a licensed tissue establishment as a visiting scientist, should seek temporary registration with a registered body in Malta (such as Specialist Accreditation Committee or equivalent body).**

**2.20 Healthcare scientists employed in roles should follow an appropriate induction and training programme for the tasks performed. Each individual should maintain proper records of this training.**

**2.21 The individual responsible for the seminology laboratory should:**

**(a) possess a degree or higher national diploma in a relevant discipline**

**(b) have acquired sufficient experience in such a laboratory to supervise and be responsible for one, and**

**(c) be registered with a registered body as a clinical scientist or biomedical scientist, or be able to demonstrate equivalent training or expertise.**

**2.22 The individual responsible for the clinical embryology laboratory should:**

**(a) possess an appropriate scientific or medical degree**

**(b) have had sufficient experience in such a laboratory to be able to supervise and be responsible for one, and**

**(c) be registered with a registered body as a clinical scientist with specific expertise in clinical embryology.**

## Competence and Training of ICSI and embryo biopsy practitioners

**2.23 The responsible person should ensure that micromanipulation procedures such as ICSI and embryo biopsy are carried out only by practitioners who have the necessary competence.**

**2.24 Following training, the competence of each person performing micromanipulation procedures and embryo biopsy should be evaluated at intervals specified in the quality management system. Retraining should be given when required.**

**2.25 In the case of embryo biopsy, only the embryologist(s) practitioner(s) who have been designated and named on the clinic's licence may carry out the biopsy. If the clinic wishes to change the designated embryologist or add to the list of designated embryologists, the clinic will need to apply to the EPA Authority and the Licencing Authority.**

## Staff involved in genetic testing

**2.26 A senior clinical geneticist should be involved in the decision making process when deciding whether a patient should receive treatment involving embryo testing.**

**2.27 The tissue establishment should ensure that a multidisciplinary team is involved in providing the service. Where relevant the team should include reproductive specialists, embryologists, clinical geneticists, genetic counsellors, cytogeneticist and molecular geneticists. It should maintain close contact with the primary care physician or the referring clinician.**

**2.28 If the tissue establishment offers an embryo service, the individual responsible for this laboratory should**

**(a) hold an appropriate scientific or medical degree**

**(b) have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and be responsible for one, and**

**(c) be registered with the equivalent body as a clinical scientist with specific expertise in clinical genetics.**

**2.29 If genetic testing of those seeking treatment or considering donation is offered, the tissue establishment should ensure that an individual is available who understands the:**

**(a) nature of the tests conducted**

**(b) scope and limitations of the tests**

**(c) accuracy and implications of the tests, and**

**(d) meaning of the test results.**

**2.30 The tissue establishment should ensure that people seeking treatment have access to clinical geneticists and genetic counsellors where relevant.**

**2.31 The centre should work closely with the local genetics team of those seeking treatment.**

# 3. Treating People Fairly

## Relevant Legislation

**3.1 The Maltese Legislation protects people (including Tissue Establishment staff, current and prospective parents) from direct and indirect discrimination, harassment and victimisation on the basis of:**

**(a) race**

**(b) any disability**

**(c) gender**

**(d) religion or belief**

**(e) sexual orientation, and**

**(f) age.**

**3.2 The responsible person should have and be familiar with documented procedures to ensure their tissue establishment complies with equalities legislation.**

**3.3 The responsible person should ensure that the tissue establishment's systems, policies and procedures comply with current equality legislation and guidance.**

**3.4 Tissue establishments should ensure that staff, patients, donors and other visitors to the tissue establishment are treated fairly and with respect for their dignity and human rights. Tissue establishment staff should have received up-to-date training and be able to show they are competent in their obligations under equality law.**

**3.5 Attitudes towards assisted conception, gamete donation and the use of gametes and embryos may vary significantly between individuals, cultures and religions. All healthcare professionals should be sensitive to this. The responsible person should ensure employees have access to training and support to help them identify and meet the widest possible range of patients' and donors' needs and preferences.**

**3.6 Tissue establishments should be aware that for some patients, gender identity and sex orientation may be distinct and different. Tissue establishments treating trans patients should ensure that they take account of the particular needs of these patients and make appropriate changes to relevant processes and practices to accommodate their needs.**

**3.7 Tissue establishments should ensure that all activities and clinical structures and functions show respect for equality and diversity. Tissue establishments should review policies and procedures regularly to ensure they reflect equality and diversity adequately. Tissue establishments should also consider having equality policies.**

**3.8 The tissue establishment should ensure that all licensed activities are conducted in a non-discriminatory way and with proper respect for the privacy, confidentiality, dignity, comfort and well-being of all prospective and current patients.**

**3.9 A tissue establishment should provide or arrange investigations and treatments based on professional assessment and clinical judgment. They should take into account the needs and preferences of prospective or current patients, donors and others visiting the tissue establishment, including any reasonable adjustments, aids or help they may need.**

**3.10 Staff at a tissue establishment should not refuse or delay treatment because they believe that a patient's actions have contributed to their condition. All prospective and current patients must be treated with respect, whatever their life choices or beliefs.**

**3.11 The responsible person for a National Public Health Service tissue establishment should consider relevant policies of their primary care before refusing treatment.**

**3.12 Staff at the tissue establishment must not harass or victimise patients or donors by allowing their own personal views or judgments (For instance, their views about a patient's age, disability, gender reassignment, marriage and civil partnership, pregnancy and maternity, race, religion or belief, sex or sexual orientation) to adversely affect their professional relationship with the patients or donors, or the treatment they provide or arrange should challenge colleagues if they believe their behaviour does not comply with this guidance, or with the relevant legislative requirements.**

## Conscientious objection

**3.13 The tissue establishment should give prospective employees a full description of the tissue establishment's activities, and at the interview draw their attention to the provision that anyone who has a conscientious objection to participating in a particular activity done in the centre must not be obliged to do so.**

**3.14 If a staff member has a conscientious objection to providing a particular licensed activity governed by the Act, they should inform the responsible person. The responsible person should ensure that the patient, patient's partner or donor is given information on or referred to alternative sources of the treatment.**

**3.15 The responsible person should satisfy themselves that the staff member has a conscientious objection to providing a particular licensed activity and is not unlawfully discriminating against a patient on the basis of a protected characteristic.**

**3.16 If all staff at the tissue establishment conscientiously object to providing a particular licensed activity, the responsible person should:**

**(a) try to refer the person to another tissue establishment for treatment, and**

**(b) provide the patient with a written explanation of why the tissue establishment cannot treat them.**

**3.17 The responsible person should record:**

**(a) the reason(s) for the conscientious objection of any member of staff**

**(b) their efforts to provide the particular activity at the tissue establishment, and**

**(c) if that activity cannot be provided at the tissue establishment, efforts they have made to ensure the patient receives treatment elsewhere.**

## Addressing Communication Barriers

**3.18 The tissue establishment should consider the needs of people whose first language is not Maltese or English and those who face other communication barriers. Where consent is obtained, the tissue establishment should record any difficulties in communicating the implications of giving consent and in providing other information to the person (e.g. language barriers or hearing impairment) and an explanation of how these difficulties were overcome(e.g. the use of an independent interpreter).**

**3.19 The tissue establishment should ensure it establishes and accommodates any disabled patient's preferred means of communication. If appropriate, it should consider providing information in a variety of formats such as large print, 'easy read' or Braille.**

# 4. Infertility Counselling and Patient Support

**The psychological and social stress of infertility and assisted conception treatment has been well documented. There is general agreement in the literature that stress and distress in some form are significant sequel of infertility. This may involve depression, anxiety, sexual dysfunction, damaged self-esteem and a range of difficulties in interpersonal relationships. A review of the evidence into the efficacy of counselling suggests that psychological therapies have benefit in a range of somatic complaints including gynaecological problems, bereavement/loss and depressive disorders.**

**The purpose of counselling for infertility and assisted conception is to:**

**(i) Enable people to reflect upon and understand the implications of a proposed course of action for that person, their family, children born as a result and anyone else affected by the treatment**

**(ii) To provide emotional support before, during and after treatment, particularly if the person is experiencing stress, ambivalence or distress**

**(iii) To assist people in developing successful coping strategies for dealing with both the short and longer-term consequences of infertility and treatment**

**(iv) To help people to try to adjust and to accommodate to their particular situation.**

**The law requires that prospective parent or parents respectively receive independent clinical counselling to be offered before, throughout and after the procedures. Thus, counselling is to be offered when:**

**(a) prospective parents seek treatment that will create embryos in vitro**

**(b) prospective parents seek to store their gametes**

**4.1 The tissue establishment should provide counselling after the individual or couple has received oral and written information about the services to be provided and before they consent to treatment, donation, or to the storage or use of gametes or embryos. Counselling should be accessible in terms of location. The timing and frequency of counselling sessions should be agreed between counsellor and the person or couple concerned, in order to meet their needs.**

**4.2 The tissue establishment should make patients, donors and their partners (if applicable) aware that the offer of counselling is obligatory as specified in the Act. The offer should include written information giving the name(s) of the qualified counsellor(s), explaining their role, when they are available and how to access the service. The tissue establishment should allow enough time before treatment starts for patients to have counselling sessions.**

**4.3 The tissue establishment should take all practicable steps to provide counselling throughout the treatment, donation or storage processes, and afterwards if requested. Counselling should routinely be offered following adverse events and/or unsuccessful outcomes. If a person who has previously received treatment, or previously donated gametes or embryos requests further counselling at any point, the tissue establishment should take all practicable steps to help them obtain it.**

**4.4 If the possibility of treatment with donated gametes or embryos arises, the tissue establishment should give counselling about the implications of treatment with donated gametes and embryos, separately from counselling about the implications of treatment in general, and before treatment with donor gametes or embryos starts.**

**4.5 If the possibility of donating gametes or embryos for the treatment of others arises, the tissue establishment should give counselling about the implications of donation separately from counselling about the implications of treatment before the treatment starts. If treatment has already begun, it should continue only if the potential donor and, if applicable, his or her partner have been given counselling about the implications of donation.**

**4.6 The tissue establishment should offer people the opportunity to have counselling either with their partner or alone, depending on what each person prefers. In the case of counselling on the implications of treatment or donation, if two people are being treated together, then we would recommend they both attend the counselling session. Group sessions may also be offered in addition to individual and couple sessions.**

## The Provision of Counselling

**4.7 The provision of counselling should be clearly distinguished from:**

**(a) the assessment of a person's suitability to receive treatment, or to store their gametes or embryos**

**(b) the provision of information before obtaining consent or providing treatment.**

**4.8 The counselling service should comply with current professional guidance on good practice in infertility counselling. Counselling should be provided only by qualified and warranted counsellors.**

**4.9 The tissue establishment should ensure that arrangements are in place to provide, or refer people for, specialist counselling if appropriate, taking account of their duty of confidentiality under the EPA Act. This might include genetic counselling, and counselling for oncology patients or others requiring the long-term storage of gametes.**

**4.10 The tissue establishment should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions. The tissue establishment should also consider the use of other media for counselling sessions, such as video or audio calls in order to make counselling as accessible as possible for patients and donors.**

## Counselling Records and Confidentiality

**4.11 Information obtained during counselling should be confidential (although it may be disclosed in certain circumstances, for example if it gives rise to concerns about the suitability of a person to receive treatment). The written records of the professional counsellor should be kept in a secure place. These written records are confidential and should not be shared with others, including clinic staff. The Tissue establishment should ensure that their policies on record keeping and data protection include information on when the counselling records form part of the patient's medical record and therefore could be disclosed to the patient.**

## Oncology Sperm Preservation

**4.12 Counselling for oncology sperm banking may take place prior to the start of medical or surgical treatment but not necessarily. Many patients do not have the time or opportunity for counselling at this stage. However, if oncology patients do present as clients, counsellors should be aware of the very considerable stress that they are likely to be experiencing as a result of dealing with both life and fertility threatening issues. Great sensitivity is needed and it may not be appropriate to explore many of the longer-term issues in a first session, but wherever possible, counsellors should encourage and support them in considering some or all of the following:**

**(i) the emotional and physical issues concerning the need to deposit sperm**

**(ii) where fertility issues fit into their priorities**

(iii) thinking and planning for a future family in a present crisis situation

(iv) the reactions of partner, family and close friends

(v) issues around fertility to be considered for informed decision making

(vi) the assisted reproduction options open to them in the future

(vii) the possibility that fertility treatments may fail or that other pregnancy related difficulties may arise

(viii) the possibility of cancer recurrence after a child is born and the implications for the child and family

(ix) the eventual disposal of the preserved sperm

(x) current legal position

## Oncology Egg Preservation

4.13 Women who are considering egg preservation/vitrification prior to the start of oncology medical and/or surgical treatment should be encouraged to consider counselling about the implications of this treatment before making any final decision. If oncology patients do present as clients, counsellors should be aware of the very considerable stress that they are likely to be experiencing as a result of dealing with both life and fertility threatening issues. Great sensitivity is needed and it may not be appropriate to explore many of the longer-term issues in a first session but, wherever possible,

**counsellors should encourage and support them in considering the same issues as those listed for oncology sperm preservation as well as:**

**(i) the emotional issues related to the need to go through egg collection at a time of crisis**

**(ii) the possible risks involved for their health by undergoing fertility treatment**

**(iii) the possible risks associated with carrying a pregnancy after cancer therapy**

**(iv) the possibility of cancer recurrence after a child is born and the implications for the child and family**

**(v) the eventual disposal of stored eggs should they not be used in treatment**

**(vi) the current legal position**

**4.14 It is important to note that in cases where the oncology patient is under 18, counsellors should have particular expertise in counselling young people.**

## Oncology Embryo Storage

**4.15 Couples who are considering IVF procedures prior to the start of the women's oncology medical and/or surgical treatment should be encouraged to consider counselling about the implications of embryo creation and storage before making any final decision. Tissue establishments should have sufficient counselling resources to ensure that they can respond quickly and appropriately to patient's requests for counselling in these circumstances.**

**If oncology patients and their partners do present as clients, counsellors should be aware of the very considerable stress that they are likely to be experiencing as a result of dealing with both life and fertility threatening issues. Great sensitivity is needed and it may not be appropriate to explore many of the longer-term issues in a first session but, wherever possible, counsellors should encourage and support them in considering the same issues as those listed for oncology egg preservation.**

## Fertility Preservation (Social Reasons) Egg Preservation

**4.16 Counselling for women who have requested egg storage for social reasons should be encouraged and counsellors should support these clients in considering the following issues:**

**(i) The emotional issues arising from the need to consider egg preservation.**

**(ii) Where fertility issues fit into her priorities at this time in her life.**

**(iii) If the client is in a relationship:**

- **Whether both partners feel ready to commit having a family**
- **Whether embryo freezing has been considered**

**(iv) Whether the client feels any undue pressure to preserve eggs**

**(v) The attitudes of family and close friends**

**(vi) The realistic assisted reproduction options open to her / them in the future.**

**(vii) The possibility that treatment will fail when she / they decide to use the stored eggs**

**(viii) The possibility of eventual disposal of unused stored eggs.**

## Gamete Preservation for Transgender Persons

**4.17 The Gender Identity, Gender Expression and Sex Characteristics Act of 2015 (Cap 540) of the Laws of Malta was enacted in 2015. The vision of the Maltese Government as detailed in the Consultation Document on Transgender Healthcare is to develop a trans inclusive health care system and to organise gender affirmative health care for transgender persons using a person-tissue establishment approach that tends to the physical, mental and social aspects of care of the individual whilst respecting the person's gender identity.**

**Some transgender persons will want to have children. Since feminising / masculinising hormone therapy limits fertility it is important for patients to make decisions concerning fertility such as cryopreserving of gametes, before starting hormone therapy or undergo surgery to remove / alter their reproductive organs.**

**Trans patients, particularly those of a younger age, shall be able to store their gametes depending on their individual circumstances and if they comply with the requirements of the Embryo Protection Act.**

## Embryo Storage and potential embryo donation

**4.18 Couples who are considering IVF procedures with embryo cryopreservation should receive counselling about the implications of embryo creation, storage and potential embryo donation in circumstances as specified in the Embryo Protection (Amendment) Act, 2018, before making any final decision. Tissue establishments should have sufficient counselling resources to ensure that they can respond quickly and appropriately to patient's requests for counselling in these circumstances.**

**Counsellors should be aware of the very considerable stress that the prospective parent/s are likely to be experiencing as a result of dealing with both life and fertility issues. Great sensitivity is needed and Counsellors should be conversant with the Adoption Administration Act.**

## Implications counselling for pre-implantation genetic testing

**4.19 The tissue establishment should ensure that any person intending to begin treatment with PGTM has implications counselling. The implications counselling should be provided by a qualified counsellor. This should address potential risks and implications of PGTM and should allow full opportunity for the prospective parents to ask questions and discuss any concerns.**

## Patient support

**4.20 The tissue establishment should develop a patient support policy, to outline how the centre ensures that patients, donors and their partners (where applicable) receive appropriate psychosocial support from all staff they encounter before, during and after treatment. Psychosocial support is delivered by all members of staff and includes, but is not limited to, access to counselling. All patients, donors and their partners (where applicable) should be treated with sensitivity and respect, and supported through all aspects of their treatment and, in particular, if they are suffering distress at any stage.**

**4.21 The policy should include:**

**a) a definition of patient-centred care and how this will be delivered at the tissue establishment**

**b) a statement regarding each individual staff member's responsibility for supporting patients and managing their expectations**

**c) a list of written and online information to be provided and how patients will be able to access this**

**d) what the tissue establishment will provide in terms of**

**i) support groups**

**ii) forums for patients to engage with each other**

**iii) signposting to external groups and forums**

**iv) other events/groups/open evenings etc**

**e) the expectations about how all staff will communicate with patients, donors and their partners**

**f) an outline of customised support interventions at different stages of treatment and for different types of patients**

**g) the annual programme of training that will be provided to staff on different aspects of patient support, including skills training, adapted as appropriate to reflect staff members' role within the clinic**

**h) feedback mechanisms for collecting data on the patient/donor experience and**

**i) quality indicators for systematically monitoring and evaluating the tissue establishment's provision of patient support and patient care as contained in this policy.**

# 5. Information to be provided prior to consent

## Distinguishing the provision of information from the offer of counselling

**5.1 The provision of information should be clearly distinguished from the offer of counselling.**

## Information specific to the tissue establishment

**5.2 Before treatment is offered, the tissue establishment should give the woman seeking treatment and her partner, if applicable, information about:**

**(a) the tissue establishment's policy on selecting patients**

**(b) the tissue establishment's statutory duty to take account of the welfare of any resulting or affected child**

**(c) the expected waiting time for treatment**

**(d) fertility treatments available, including any treatment add ons which may be offered and the evidence supporting their use**

**(e) the availability of facilities for freezing and storing eggs, sperm and embryos**

**(f) where patients freeze and store eggs, sperm or embryos the tissue establishment should provide information about future use including information about consent to posthumous use**

**(g) the importance of informing the treatment tissue establishment about the eventual outcome of the treatment (including if no live birth results)**

**(h) the tissue establishment's complaints procedure.**

## Information about the treatment

**5.3 Before treatment is offered, the tissue establishment should give the woman seeking treatment and her partner, if applicable, information about:**

**(a) the likely outcomes of the proposed treatment (data provided should include the national live birth rate and clinical pregnancy rate, and the tissue establishment's most recent live birth rate and clinical pregnancy rate. Tissue establishments are encouraged to provide data per embryo transferred where relevant)**

**(b) the nature of the proposed treatment and any treatment add ons, including evidence of effectiveness. The tissue establishment should provide information in a lay format**

**(c) the implications of treatment, including for example, the possibility of a negative outcome which could cause distress or multiple pregnancy**

## Information about the risks of treatment

**5.4 Before treatment is offered, the tissue establishment should give the woman seeking treatment and her partner, if applicable, information about:**

**(a) the potential immediate and longer-term risks of the treatment and any treatment add ons used, including the risk to the patient and of any children conceived having developmental and birth defects**

**(b) the nature and potential risks of any alternative treatment options available so the patient can make an informed decision about their treatment**

**(c) the possible side effects and risks to the woman being treated and any resulting child**

**(d) the possibility of developing ovarian hyperstimulation syndrome (OHSS). Any information provided should include the possible symptoms of OHSS, what the woman being treated should do and who to contact if experiencing symptoms of OHSS**

**(e) the nature and potential risks (immediate and longer-term) of using emerging or unproven treatments, including reference to the clinic's experience and wider evidence base**

**(f) the potential risk of emotional distress associated with negative outcomes both during and after treatment.**

## Information about success rates

**5.5 The tissue establishment should ensure that the information provided on its website complies with the following guidance. This also applies to other relevant marketing communications of the tissue establishment and associated satellite and transport tissue establishments.**

**(a) The information should include the most recent data available from the past three years.**

**(b) Tissue establishments are encouraged to display live birth rate data per embryo transferred where relevant and this may be displayed alongside other success rate measures. The information should not highlight a high success rate that is not statistically significant where it applies only to a small, selected group of patients.**

**(c) The data should show split by maternal age and, if appropriate, by treatment type.**

**(d) The information should provide raw numbers rather than just percentages.**

**(e) The website should provide the national rate and like-for-like comparisons (the same year, maternal age, treatment type, etc.).**

**(f) The tissue establishment's published success-rate data should refer to the EPA as the source of national information.**

**(g) The information must state clearly that information on success rates is of limited value in comparing tissue establishments and choosing where to seek treatment.**

**(h) If the information refers to comparative costs, it should indicate the likely total cost for a typical cycle, based on the actual costs for recent patients, not individual items in tariffs.**

## Information about the cost of treatment

**5.6 Before treatment, storage or both are offered, the tissue establishment should also give the person seeking treatment or storage, and their partner (if applicable) a personalised costed treatment plan. The plan should detail the main elements of the treatment proposed (including investigations and tests), the cost of that treatment and any possible changes to the plan, including their cost implications. The tissue establishment should give patients the opportunity to discuss the plan before.**

## Further information to provide

**5.7 There are different kinds of information tissue establishments should give, where appropriate, to patients, patients' partners and donors prior to obtaining consent to treatment, storage or donation. Tissue establishment staff should familiarise themselves with all the appropriate information to provide. This information is contained in the following list of guidance notes:**

**(a) Consent to treatments, storage, and disclosure of information**

(b) Legal parenthood

(c) Multiple births

(d) Welfare of the child

(e) Donor recruitment, assessment and screening

(f) Procuring, processing and transporting gametes and embryos

(g) Storage of gametes and embryos

(h) Donor assisted conception

(i) Embryo donation

(j) Intra-cytoplasmic sperm injection (ICSI)

(k) Confidentiality and privacy

## Additional information for treating trans patients

**5.8 The tissue establishment should be aware that there are multiple terms used to refer to trans people and that terminology in this area is evolving. For inclusivity, this Protocol uses the term 'trans' to refer to all trans identities, including persons who consider themselves 'non-binary' (ie, identify as somewhere, either fixed or moveable, on the male-female continuum) and 'non-gendered' (ie, neither male, female, nor on the male-female continuum).**

**5.9 Before treatment or storage is offered to a trans person, the tissue establishment should (as with all patients) consider the treatment and storage options that are available to the patient, depending on their individual circumstances. For example, if a trans person is visiting the clinic prior to gender reassignment they may be seeking options for fertility preservation (ie, storage of either testicular or ovarian tissue, or eggs or sperm depending on whether they have undergone puberty); or if a trans person is visiting the clinic after gender reassignment they may be seeking ways to use their preserved tissue, eggs or sperm in treatment with a partner, or extend their storage periods due to premature infertility.**

**5.10 Before treatment, storage or both are offered, the tissue establishment should inform a trans person (as with all patients) that they may need to be screened as a donor at the time of egg or sperm collection depending on the treatment options they may wish to pursue in the future and explain the reasons why.**

**5.11 Before treatment, storage or both are offered to a person who is yet to undergo gender reassignment or who is not yet living in their acquired gender, the tissue establishment should inform them that should they change their identity before returning for further treatment, it will be necessary for them to provide evidence of their acquired identity and to verify that they are the person previously treated.**

**5.12 The tissue establishment should recognise the sensitivities of treating trans patients, and have practical ways of accommodating their needs with dignity and respect. For example, rather than making assumptions about how a trans patient would like to be addressed, tissue establishments should ask how they would prefer to be addressed. Tissue establishments may also need**

**to explain why gender at birth may be noted in medical records, should avoid making assumptions when referring to gender (eg, if a telephone enquiry is received regarding sperm storage, avoid assuming the caller is male), and should take privacy and sensitivity into consideration.**

# 6. Consent to Treatment, Storage, Donation and Disclosure of Information

**6.1 The tissue establishment should obtain written, effective consent from a person before using their gametes for their own treatment or their partner's treatment.**

**6.2 When a woman is to undergo additional fertilisation and an embryo transfer, the tissue establishment should:**

**(a) obtain her consent to the proposed number of eggs to be fertilised (especially in cases where the medical practitioner has requested permission from the EPA to fertilise more than two eggs up to the maximum allowed by the Protocol), or embryos to be transferred (maximum two) and**

**(b) record her consent in her medical records.**

**6.3 The tissue establishment should establish and use documented procedures to ensure that no activity involving the handling or processing of gametes or embryos is carried out without the appropriate consent having been given. This should include a documented assurance process to ensure that all relevant consent forms have been properly and correctly completed before treatment.**

**6.4 If, following treatment, the tissue establishment discovers errors in the consent provided by a patient or their partner, the tissue establishment should:**

(a) take all reasonable steps to notify the affected patient at the earliest opportunity

(b) assess the error(s) and potential impact, and consider the remedial actions that should be taken

(c) take all reasonable steps to support any affected patients (and their partner, if applicable), and

(d) report any error(s) as an adverse incident.

6.5 The tissue establishment should ensure that the person giving consent is able to give their consent freely. The tissue establishment should not pre-complete consent forms on behalf of the person giving consent. For example, a person giving consent to the storage of their gametes and/or embryos should be free to choose how long to consent to store for, within what is permitted by regulations.

6.6 The tissue establishment should give anyone seeking treatment or considering donation or storage enough time to reflect on their decisions before obtaining their consent. The tissue establishment should give them an opportunity to ask questions and receive further information, advice and guidance.

6.7 If the possibility of donating gametes or embryos for the treatment of others, arises during the course of treatment, the tissue establishment should allow potential donors enough time to consider the implications and to receive counselling before giving consent.

**6.8 The tissue establishment should ensure that consent is:**

**(a) given voluntarily (without pressure to accept treatment or agree to donation)**

**(b) given by a person who has capacity to do so**

**(c) taken by a person authorised by the establishment to do so, and**

**(d) given at the clinic (with both parties if a couple is being treated) where possible, clinics should record why a patient is not able to sign at the clinic and should have a documented process for ensuring consent forms being signed outside the clinic are signed by the correct person**

**6.9 The tissue establishment should ensure that anyone giving consent has been:**

**(a) given enough information to enable them to understand the nature, purpose and implications of the treatment or donation**

**(b) given a suitable opportunity to receive proper counselling about the implications of the proposed procedures**

**(c) given information about the procedure for varying or withdrawing consent, and**

**(d) given information in writing that is correct and complete.**

**6.10 If gametes or embryos are to be transferred/exported to a tissue establishment outside the Maltese Islands, the tissue establishment must obtain the consent of the gamete provider(s) to their transfer/export, to the country in which the receiving tissue establishment is situated. Such consent must then be provided to the tissue establishment receiving the gametes or embryos.**

**6.11 If gametes or embryos are to be transferred/imported into the Maltese Islands from a tissue establishment outside the Maltese Islands, the responsible person for the Malta tissue establishment must be satisfied that the provider has given written consent to the transfer/import of the gametes or embryos to the Maltese Islands and has not withdrawn that consent.**

**6.12 The tissue establishment should inform prospective parent/s that, according to the Embryo Protection (Amendment) Act 2018 the cryopreservation of embryos shall be regulated by an agreement between the prospective parent or prospective parents and the licensee subject to the prior authorisation of the Embryo Protection Authority and shall have a maximum term of validity of five years renewable up to a maximum permissible age for the transfer thereof into the prospective parent. Provided further that when the maximum permissible age for the transfer of the embryo into the prospective parent is reached, the Embryo Protection Authority shall authorise the donation of the cryopreserved embryos.**

**6.13 Tissue establishments should take all reasonable steps to verify the identity of anyone accepted for treatment, including partners who may not visit the centre during treatment. The centre should establish the relationship between a patient and their partner and a record of this should be retained in the patients' notes. If a patient's identity is in doubt or if a tissue establishment has reason to question whether the person is who they claim to be, the tissue establishment should verify their identity, including examining photographic evidence such as a passport or a photocard driving licence. The tissue establishment should record this evidence in the patient's medical records. Tissue establishments should have a process in place to verify the identity of a patient (and their partner, if applicable) if they return to the centre for subsequent treatment, to ensure the patient and their partner are the same people they treated initially. The clinic should establish whether the patient and their partner's personal circumstances have changed in the period since their last treatment, for example, whether the couple has divorced or separated since their previous treatment and give consideration to whether any changes in their personal circumstances impact on consent.**

**6.14 Where a patient has changed their name (eg, where someone has changed their name by deed, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, centres should take all reasonable steps to verify the patient's identity. This is to ascertain that a patient presenting for treatment or donation is the same person the centre previously**

**engaged with or treated. Tissue establishments should verify a patient's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the person's medical records. This can be a sensitive issue, and tissue establishments should take care to address identity issues with consideration. As evidence of their new name, centres should ask the person to provide one of the following:**

**(a) a marriage certificate, or**

**(b) evidence of a change in name (such as via deed)**

**For trans patients:**

**(c) a birth or adoption certificate in an acquired gender**

**(d) a Gender Recognition Certificate, or**

**(e) a letter from a doctor or medical consultation confirming that the change of gender is likely to be permanent, and evidence of a change in name (such as via deed).**

**Tissue establishments must ensure that a patient's records are updated to accurately reflect their new identity.**

**6.15 To avoid the possibility of misrepresentation or mistake, the tissue establishment should check the identities of patients and their partners, against identifying information in the medical records. This should be done at each consultation, examination and treatment or donation. If the partner**

**of a patient who is having treatment has not visited the clinic throughout the treatment, or does not return with the patient for subsequent treatment, tissue establishments should take reasonable steps to find out whether the patient's partner still consents to the treatment. This may include contacting the partner to confirm that their circumstances have not changed and that their consent is still valid. The tissue establishment should not commence treatment until it is satisfied that the partner in fact consents to the treatment.**

**6.16 The tissue establishment should consider the needs of people whose first language is not Maltese or English and those who face other communication barriers. Where consent is obtained, the tissue establishment should record:**

**(a) any difficulties in communicating the implications of giving consent and providing other information to the person (e.g. language barriers or hearing impairment), and**

**(b) an explanation of how these difficulties were overcome (e.g. the use of an independent interpreter).**

## Recording Consent and Related Information

**The law requires consent, or any subsequent variation or withdrawal of consent, to be in writing and signed by the person giving consent.**

**6.17 The tissue establishment should keep a copy of a person's signed consent form(s) electronically or as a hard copy and make a copy available to those giving consent and to EPA and made available to them upon request.**

**6.18 The tissue establishment should ensure that it documents in the medical records, that relevant information has been provided to the person giving consent and that the person has been offered counselling before giving consent.**

## Additional Consent Requirements for Storing Gametes and Embryos

**6.19 Written consent to the storage of gametes must:**

**(a) specify the maximum period of storage, and**

**(b) state what should be done with the gametes, if the person giving the consent dies or cannot, because of mental incapacity, with draw or vary the terms of the consent.**

**6.20 The tissue establishment should normally ask patients to give consent to storage at the same time as consent to the use of gametes and embryos. However, the tissue establishment should accommodate anyone seeking long-term storage of gametes who may wish to consent to storage separately from consent to use. Any patient who has given consent to storage but who has not given consent to use, should be informed that their gametes cannot lawfully be used in treatment unless they have given consent to use.**

**6.21 Provided that the cryopreservation of embryos shall be regulated by an agreement between the prospective parent or prospective parents and the licencee subject to the prior authorisation of the Embryo Protection Authority and shall have a maximum term of validity of five years renewable up to a**

**maximum permissible age for the transfer thereof into the prospective parent in terms of Article 7 of the Embryo Protection (Amendment) Act, 2018.**

**6.22 When an individual gives consent to the use of gametes for the treatment of others, the tissue establishment need not get consent from the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the tissue establishment should encourage them to seek their partner's support for the donation of their gametes.**

## Consent to Examination and Treatment

**6.23 Everyone has the right to withhold or give consent to examination and treatment. Unless there are exceptional circumstances, the tissue establishment may not examine, treat or receive gametes from people without first obtaining their consent. The only exceptional circumstance likely to arise during fertility treatment is:**

**(a) where the procedure is necessary to save the patient's life, and**

**(b) the treatment cannot be postponed, and the patient is unconscious or mentally incapacitated so cannot indicate their wishes.**

**6.24 The tissue establishment should comply with current professional guidelines on consent.**

## Consent to the Presence of Observers

**6.25 If a member of the tissue establishment's team wishes an observer to be present when a patient is being examined, treated or counselled, they should explain why beforehand and state who the observer is. The tissue establishment should give the patient appropriate information about the proposed observation and ask them whether they consent to the observer's presence.**

**Patients have the right to decide what identifying information should be disclosed and to whom.**

**Tissue establishments should obtain a patient's written consent before disclosing information relating to their treatment (or providing gametes for a partner's treatment), or the storage of gametes.**

**In addition, consent is needed from any person who could be identified through disclosure of information about a person's treatment or the storage of gametes. For example, consent would be needed from a patient's partner if they could be identified through disclosure of information about the patient's treatment.**

## Consent to Disclose Identifying Information

**6.26 Before obtaining consent to disclose information, the tissue establishment should give the person enough information for them to make a properly informed decision, including:**

**(a) precisely what information is to be disclosed**

**(b) the terms on which it is to be disclosed**

**(c) the reasons for disclosure (e.g. to keep the person's general practitioner (GP) informed about the fertility treatment)**

**(d) the implications of disclosure**

**(e) the categories of people to whom the information is to be disclosed.**

**6.27 The tissue establishment should seek consent to disclosure to the following categories of people:**

**(a) the patient's GP or the patient's partner's GP**

**(b) other healthcare professionals outside the tissue establishment (so they can provide the patient or the patient's partner with the best possible medical care)**

**(c) auditors or administrative staff outside of the tissue establishment (so they can perform their functions in connection with the tissue establishment's licensable activities), and**

**(d) medical or other researchers (so they can contact the patient about specific research projects or carry out non-contact research).**

**6.28 The tissue establishment should consider circumstances where they may need to disclose a person's gender history (eg, to those within the tissue establishment who need to know of a trans patient's previous identity to deliver safe and appropriate care) to determine whether they need to obtain the person's consent to disclosure of this information. This should be discussed in detail with the person and any consent obtained should be filed with their medical records.**

**6.29 The tissue establishment should renew consent to disclosure if the nature of treatment changes after initial consent has been given (eg, if during treatment, it is proposed that donor gametes are used instead of the patient's own.**

**6.30 The tissue establishment should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:**

**(a) the precise terms upon which it was disclosed and for which consent has been given, and**

**(b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.**

## Cases where Consent is not required for Storage

**6.31 Before storing someone's gametes without their consent, the tissue establishment should judge that the person is not competent to consent to the storage of gametes. When assessing the competence of children and adults to consent, the tissue establishment should follow current guidance produced by the Department of Health, the Medical Council and other professional bodies.**

**6.32 The tissue establishment should presume that it is in the child's best interests to store gametes unless circumstances suggest otherwise, (in cases of oncology treatment). When assessing whether it is in a child's best interests to procure and store their gametes, the tissue establishment should consider the child's short and long-term best interests. Consent should be sought from the child when they reach competence.**

**6.33 The tissue establishment should provide written information that children and young people can read and understand easily. This information should be given by a member of staff experienced in communicating with children.**

## Competence

**6.34 If the tissue establishment's staff doubts someone's competence to consent to a proposed procedure, or to the storage or use of gametes, they should:**

**(a) follow the current guidelines of professional bodies**

**(b) if they remain in any doubt, the tissue establishment should seek legal advice.**

## Variation and Withdrawal of Consent

**6.35 If someone wishes to withdraw consent to the storage or use of gametes they must do so in writing, except if they are unable to do so because of illness, injury or incapacity. In these cases, they can direct someone to sign on their behalf, provided that the person withdrawing consent is present at the time, and that the signature is also witnessed and attested to by at least one other person.**

**6.36 The tissue establishment should check the identity of anyone withdrawing or varying consent against identifying information held in the medical records. The tissue establishment should also ensure that the person withdrawing or varying consent has been given sufficient information to enable them to make an informed decision about doing so.**

**6.37 The tissue establishment should have procedures for dealing with disputes that may arise when one gamete provider withdraws their consent to the use or storage of gametes (e.g. in cases of separation / divorce). In this situation the tissue establishment should stop treatment and notify all relevant parties. Tissue establishments should provide information about counselling or mediation services as appropriate.**

## The End of Storage

**6.38 The tissue establishment should make efforts to stay in contact with patients who have gametes in storage for their own treatment. The tissue establishment should also explain to gamete providers and current patients the importance of informing the tissue establishment of any change in their contact details.**

**6.39 Tissue establishments should inform patients who have gametes in storage for their own treatment when the end of the permitted storage period is approaching. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options, and to access appropriate advice.**

**6.40 The Tissue Establishment should establish and use documented procedures to contact prospective parent/s who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching but long enough in advance to allow the Tissue Establishment and prospective parent/s to take any steps necessary to comply where extension of storage is an option for the prospective parent/s.**

**6.41 The Tissue Establishment should use all contact details available to them, including at least one written form of contact.**

**6.42 Prospective parent/s should be provided with information about the options available to them as the end of their permitted storage period approaches.**

**6.43 They should be given enough notice to enable them to consider those options and to access appropriate advice.**

**6.44 Options could include the donation of the gametes or embryos for the treatment of others.**

**6.45 If contact with the prospective parent/s is not possible, the Tissue Establishment should without delay inform the Embryo Protection Authority:**

**(a) in the case of embryos these will be given for adoption**

**(b) in the case of gametes, the Tissue Establishment is to record the steps it has taken in the patient's medical records.**

# 7. Legal Parenthood and Parental Responsibility

**7.1 As defined in the 'Embryo Protection (Amendment) Act 2018', 'prospective parent' means 'any person regardless of gender or sexual orientation, who has attained the age of majority and is a receiver or user of the medically assisted procreation techniques regulated under this Act.**

**7.2 For the purposes of this Protocol, the Embryo Protection Authority establishes that the woman who is entitled to treatment should be between the age of 18 and 48 years if using the woman's own oocytes which have been retrieved prior to the women attaining 46 years.**

**7.3 It further establishes that the woman referred in Guidance Note 7.2 above, if after undergoing retrieval up to the maximum age of 45 years will still have cryopreserved embryos, then the maximum age of that woman will be extended to 48 years.**

**7.4 It further establishes that the woman who is entitled to treatment should be between the age of 18 and 48 years if using donated oocytes.**

**7.5 Prospective parent / parents referred in Guidance Notes 7.2 to 7.4 above are referred to treatment if they have one of the following:**

**(a) Identified causes of infertility amenable to treatment by IVF**

**(b) Unexplained infertility for at least 2 years. In all cases where investigations show that there is no chance of pregnancy with expectant management and**

**where IVF is the only effective treatment, the couple is to be referred directly for IVF without having to wait for the two-year period.**

**(c) Same sex lesbian couples making use of donated sperm**

**(d) Single/partnered biological woman, irrespective of legal identity**

**(e) Has a family history of a monogenic disease which is listed as one of the diseases in the Guidance Notes 11 for Pre-Implantation Genetic Diagnosis for Monogenic diseases**

**7.6 The maximum permissible age of the prospective parent for implantation of embryos shall be 48 years in all cases.**

**7.7 Article 19 of the Embryo Protection Act states that "Any child born as a result of any medically assisted procreation procedure, including cases where the child was born from donated germline cells or a donated embryo, shall be considered to be the child of the prospective parent or parents who have expressed their consent in writing as provided in article 18 of the same Act, and shall for all intents and purposes of law be deemed to have been naturally born of the same prospective parent or parents without the intervention of any procedure as aforesaid; and notwithstanding the provision of any other law, any such child shall be registered in any act of civil status as the direct descendant of such prospective parents who shall enjoy such rights and bear such duties according to law in respect of such child.**

# 8. Multiple Births

**8.1 The Embryo Protection Authority requires tissue establishments to have a documented strategy to minimise multiple births and should have documented standard operating procedures for egg and embryo transfer.**

**Its purpose is to reduce the annual rate of multiple births resulting from treatments at the tissue establishment.**

**The strategy must set out:**

**(a) how the tissue establishment aims to reduce the annual multiple birth rate following treatment at that tissue establishment**

**(b) the circumstances in which the clinician together with the responsible person would consider it appropriate to recommend single embryo transfer (SET) to a patient (in setting out such circumstances, the tissue establishment should give proper consideration to relevant professional guidance) and**

**(c) the criteria for transferring eggs during gamete intra-fallopian transfer (GIFT).**

**8.2 The responsible person should ensure that the tissue establishment's annual multiple birth rate are well recorded.**

**8.3 When implementing the tissue establishment's strategy to minimise multiple births, the responsible person together with the clinician should consider the higher rate of multiple births from blastocyst transfers.**

**The tissue establishment must document regular audits that:**

**(a) assess progress in reducing its multiple birth rate, and**

**(b) help evaluate the effectiveness of its strategy.**

## Limits on Egg Fertilisation and Embryo Transfer

**8.4 The tissue establishment should not transfer more than two embryos in any treatment cycle.**

**8.5 If the treatment involves the use of super ovulatory drugs or the transfer of multiple eggs or embryos (maximum of two embryos) in any one cycle (whether fresh or previously cryopreserved), the tissue establishment should give people seeking treatment information about the risks of multiple pregnancy for the woman, the embryo and any resulting child(ren), including:**

**(a) the higher risk of miscarriage and complications during pregnancy**

**(b) the higher rate of premature birth and the problems arising from low birth weight, the higher rate of still birth, and the higher rate of perinatal mortality**

**(c) the higher rate of disability and other health problems, plus the potential need for extended stays in hospital before and after birth, and**

**(d) the possible practical, financial and emotional impact on the family and any children.**

**8.6 The tissue establishment should give the woman the opportunity to discuss the number of eggs or embryos to be transferred before egg collection and just before embryo transfer.**

**8.7 If a woman is to undergo an egg or embryo transfer, the tissue establishment should:**

**(a) obtain her consent to the proposed number of eggs or embryos to be transferred and the reasons for this (including her acceptance of the risk of multiple births), and**

**(b) record her consent in her medical records.**

**8.8 The tissue establishment should not fertilize more than two egg cells from one woman within one treatment cycle using her own eggs or donated eggs, where the prospective parent or prospective parents undergoing medically assisted procreation procedures do not expressly give their consent to the cryopreservation of embryos and to the donation of embryos if necessary in terms of Article 18 of the Act.**

# 9. Additional Fertilisation Permissions

**9.1 The medical practitioner in charge of the medically assisted procreation may, in consultation with the multidisciplinary team and with the permission of the Embryo Protection Authority, decide to fertilise more than two egg cells from one woman within one treatment cycle, provided that this is done in accordance with the established Protocol as discussed and approved in the Parliamentary Health Committee as per hereunder:**

## Methodology of Applications and Process

**9.2 The Clinical ART Multidisciplinary Team composed of the ART Consultant, Embryologists, Geneticist and Urologist assess on a case-by-case basis each patient that will be receiving ART treatment and the possibility of having additional fertilisation requests. The decision taken by the multidisciplinary team will be later communicated and discussed with the patient receiving treatment.**

**9.3 The ART Consultant together with and after discussions held with the prospective parent/s receiving infertility treatment, will take an informed decision on the number of oocytes that will be practical to fertilise, the two allowed by law and any additional oocytes to allow the possibility of having viable embryos that could result in a pregnancy and the possibility of a live birth.**

**9.4 The Consultant is then to apply to the Authority by filling the necessary required information on the already existing Additional Fertilisation Request Form (AFR Form), on the EEART online system. This is to be sent to the**

**Authority together with a detailed report of why an additional request is being made. This is to be also accompanied by any supporting documentation.**

**9.5 The application is vetted by the Authority CEO. This application will then be presented in detail by the CEO in the next Authority Board meeting.**

**9.6 During these Additional Fertilisation Request (AFR) sittings the Board is assisted by two representatives appointed by the Obstetrics and Gynaecology Association and representatives appointed by the Paediatric Association of Malta and a Urologist when necessary.**

## Criteria for Permissions to allow Additional Fertilisation

**9.7 The requests will be presented and discussed on a case-by-case basis and decisions for granting permission for additional fertilization will be based on the prospective parent/s receiving treatment infertility indicators, which include but not exclusive of: female factors (low ovarian reserve, PCOS, blocked tubes, etc.), male factor (azoospermia, oligospermia, evidence of testicular failure, morphology and motility issues), age of women receiving treatment, previous failed Assisted Reproduction Cycles, Oncology cases in male and female patients, fertility preservation, and any other medical conditions.**

**9.8 The decision taken by Board and Representatives is to clearly state either if no permission is granted and thus only two oocytes will be allowed to be fertilized; or if permission is granted, the number of oocytes that will be allowed to be fertilized: up to a maximum of twelve (12) as per hereunder.**

(a) Women who have not attained age 39 can be granted up to a maximum of 5 oocytes.

(b) Women aged 39 and who have not attained 46 years can be granted up to a maximum of 8 oocytes.

(c) Prospective parents undergoing PGTM will be allowed up to a maximum of 12 oocytes as per hereunder:

(i) Prospective parents where the woman has not attained 36 years of age will be allowed up to a maximum of 8 oocytes/embryos to undergo PGTM.

(ii) Prospective parents where the woman has attained 36 years of age and has not attained 46 years of age, will be allowed up to a maximum of 12 oocytes/embryos to undergo PGTM.

9.9 The decision of the Authority is Final and will be communicated in writing on the EEART system by the CEO of the Authority to the Consultant who had made the original request.

9.10 The Consultant is to inform the prospective parent/s with the Authority's decision before the IVF/ICSI cycle is performed.

## Cases of Patients who already have Cryopreserved Embryos

**The Authority will not allow any fertilisation of oocytes, (Not even the two oocytes allowed by the EPA Act) if the person/s seeking treatment already have cryopreserved embryos, unless the embryos were cryo-preserved for medical reasons known to the Authority.**

# 10. Welfare of the Child

**A woman must not be provided with treatment services unless account has been taken of the welfare of any child who may be born as a result of the treatment (including the need of that child for supportive parenting), and of any other child who may be affected by the birth.**

**10.1 This guidance note applies to all fertility treatments regulated by the Embryo Protection Authority, including intrauterine insemination (IUI).**

**10.2 The tissue establishment should have documented procedures to ensure that proper account is taken of the welfare of any child who may be born as a result of treatment services, and any other child who may be affected by the birth.**

**10.3 The tissue establishment should assess each patient and their partner (where applicable) before providing any treatment, and should use this assessment to decide whether there is a risk of significant harm or neglect to any child referred to in 10.2.**

**10.4 Counsellors should make their own independent decision in line with their professional codes of ethical practice as to whether they undertake welfare of the child assessments.**

**10.5 If such assessments are undertaken by the counsellor, it should be explained to the patient(s) that they are acting on behalf of the clinic and that this role differs from the typical therapeutic counsellor/client relationship. The tissue establishment should have an arrangement that enables patients**

**to access support from another counsellor who may be a member of the team or who works independently.**

**10.6 Limitations to confidentiality should be discussed with the patient, including the extent to which information will be shared with other members of the multidisciplinary team.**

**10.7 If it is necessary to contact external agencies (such as Appogg, Sedqa, or any other designate Child Protection Agencies), prior approval for same is to be sought from EPA, for additional information. The patient or patients should be asked to give written consent by completing the necessary form. The patient or patients should receive a copy of any correspondence sent out to external agencies.**

**10.8 If the assessment involves a couple, they would usually be seen together. A comprehensive history will be taken as part of the assessment process and this should include:**

**(a) Length of existing relationship**

**(b) Any existing children and their ages**

**(c) Number of children living with the prospective parent or parents (if any)**

**(d) Details of physical and mental health**

**(e) Details of substance or alcohol misuse (if any)**

**(f) Any safeguarding issues (including children and vulnerable adults)**

**(g)Any contact with police, probation, social services, and the reason for this contact**

**(h)The couple or individual's perception of the welfare of the child issue**

**(i) Any other information that the couple or individual choose to provide**

**10.9 The information gathered at the assessment is recorded in accordance with the confidentiality conditions explained to the patient or patients. It is kept in a secure place, which may be separate from the medical notes and may be shared with other members of the licensed tissue establishment multidisciplinary team to help determine the next course of action.**

**10.10 External agencies may be contacted, after the tissue establishment has sought approval from the Embryo Protection Authority, and the case may be referred to an Ethics Committee as part of the decision-making process to offer or decline treatment. Information to be shared with an Ethics Committee should be agreed with the patient(s) and presented in an anonymous way so that the patient(s) cannot be identified.**

**10.11 The tissue establishment should inform the patient(s) at each stage of this process and ensure that they are aware of their right to appeal and the opportunities for obtaining appropriate counselling if the decision made is not in their favour.**

**10.12 The tissue establishment should repeat the assessment if:**

**(a) the tissue establishment has been out of contact with the patient for two years or more**

**(b) the patient has a new partner**

**(c) a child has been born to the patient since the previous assessment, or**

**(d) the tissue establishment has reason to believe that the patient's medical or social circumstances have changed significantly.**

**10.13 Those seeking treatment are entitled to a fair assessment. The tissue establishment is expected to consider the wishes of all those involved, and the assessment must be done in a non-discriminatory way. In particular, patients should not be discriminated against on grounds of gender, race, disability, sexual orientation, religious belief or age.**

**10.14 The tissue establishment should take a medical and social history from each patient and their partner (when applicable). Where appropriate, the patient and their partner may be interviewed separately. The information gathered should relate to the factors in paragraphs 10.15–10.16 below.**

## Factors to take into Account during the Assessment Process

**10.15 The tissue establishment should consider factors that are likely to cause a risk of significant harm or neglect to any child who may be born or to any**

**existing child of the family. These factors include any aspects of the patient's or their partner's:**

**(a) past or current circumstances that may lead to any child mentioned above experiencing serious physical or psychological harm or neglect, for example:**

**(i) previous convictions relating to harming children**

**(ii) child protection measures taken regarding existing children, or**

**(iii) violence or serious discord in the family environment**

**(b) past or current circumstances that are likely to lead to an inability to care throughout childhood for any child who may be born, or that are already seriously impairing the care of any existing child of the family, for example:**

**(i) mental or physical conditions**

**(ii) drug or alcohol abuse**

**(iii) medical history, where the medical history indicates that any child who may be born is likely to suffer from a serious medical condition, or**

**(iv) circumstances that the tissue establishment considers likely to cause serious harm to any child mentioned above.**

**10.16 When considering a child's need for supportive parenting, tissue establishments should consider the following.**

**Supportive parenting is a commitment to the health, wellbeing and development of the child. It is presumed that all prospective parents will be supportive parents, in the absence of any reasonable cause for concern that any child who may be born, or any other child, may be at risk of significant harm or neglect. Where tissue establishments have concern as to whether this commitment exists, they may wish to take account of wider family and social networks within which the child will be raised.**

## Obtaining further Information during the Assessment Process

**10.17 The tissue establishment should obtain consent from the prospective parent and their partner (where applicable) to approach any individuals, agencies or authorities for any factual information required for further investigation if:**

**(a) information provided by the prospective parent or parents suggests a risk of significant harm or neglect to any child**

**(b) the prospective parents have failed to provide any of the information requested**

**(c) the information the prospective parents have provided is inconsistent, or**

**(d) there is evidence of deception.**

**A refusal to provide consent to disclosure of information should not, in itself, be grounds for denying treatment but the tissue establishment should take this into account in deciding whether to provide treatment.**

**The tissue establishment should discuss with the prospective parent or parents the reason for refusing to provide consent. Furthermore, the tissue establishment should inform the EPA about the refusal from the prospective parent or parents.**

**10.18 If information has been provided in confidence to a member of staff, the staff member should seek consent from the information provider to discuss it with other staff. If such consent is refused and the member of staff considers the matter to be crucial to a decision, they should use their discretion, based on good professional practice, in deciding whether to break that confidence. In line with professional guidance, patients should normally be informed of the decision to break confidence and the reasons for it, before the information is shared with other members of staff.**

## Refusing Treatment

**10.19 The tissue establishment should refuse treatment if it:**

**(a) concludes that any child who may be born or any existing child of the family is likely to be at risk of significant harm or neglect, or**

**(b) cannot obtain enough information to conclude that there is no significant risk.**

**10.20 In deciding whether to refuse treatment, the tissue establishment should:**

**(a) take into account the views of all staff who have been involved with caring for the patient and their partner, and**

**(b) give the patient and their partner the opportunity to respond to the reason or reasons for refusal before the tissue establishment makes a final decision.**

**10.21 If treatment is refused, the tissue establishment should explain, in writing, to the patient and their partner:**

**(a) why treatment has been refused**

**(b) any circumstances that may enable the tissue establishment to reconsider its decision**

**(c) any remaining options, and**

**(d) opportunities for obtaining appropriate counselling.**

**10.22 Decision of refusal by the Tissue Establishment should be communicated immediately to the Embryo Protection Authority.**

**Record Keeping**

**10.23 In all cases, the tissue establishment should record in the patient's medical records the information it has considered during the assessment. If further information has been sought or discussion has taken place, the record should reflect the views of those consulted in reaching the decision and the views of the prospective parents.**

# 11. Pre-implantation Genetic Testing for Monogenic diseases (PGTM)

**11.1 In Malta, PGTM is regulated by the Embryo Protection Authority (EPA). The Authority maintains a list of conditions for which PGTM has been approved, as per table reproduced hereunder:**

**List of Conditions approved by EPA for PGTM**

**Finnish Nephrotic Syndrome**

**Gangliosidosis**

**Huntington Disease**

**Joubert Syndrome**

**Maple Syrup Urine Syndrome**

**Nemaline Myopathy**

**Spinal Muscular Atrophy**

**Tay-Sachs Disease**

**Walker-Warburg Syndrome**

**11.2** For conditions not already on the list, the EPA considers a number of factors, including how serious the condition is, the likelihood of it being inherited and the testimony of people affected by the condition before deciding whether to approve it for PGTM testing.

**11.3** In order for a new condition to be considered for PGTM testing approval, a couple must have a licensed PGTM clinic apply to the EPA on their behalf.

**11.4** When pre-implantation genetic diagnosis (PGTM) is used to combine IVF and genetic testing as a means of avoiding the transmission of a genetic disease, the medical practitioners shall follow the principles of the Ethical Guidelines as per hereunder:

**11.4.1** Pre-implantation genetic diagnosis (PGTM) is a technique that may be used to combine IVF and genetic testing as a means of avoiding the transmission of a genetic disease as listed in the protocol. PGTM shall not be allowed for the selection of embryos for eugenic purposes.

**11.4.2** PGTM should only be used for the detection of serious genetic conditions as approved by the Authority, and which conditions significantly affect the health of an individual who might be born.

**11.5** The use of PGTM should be a matter of discussion between those seeking PGTM (i.e., the prospective parents) and the clinical team on the seriousness of the genetic condition.

**11.6** A senior clinical geneticist should be involved in the decision-making process when deciding whether a particular patient should receive treatment involving PGTM.

**11.7** The Tissue Establishment offering treatment should ensure that a multidisciplinary team is involved in providing the PGTM service. The team should include reproductive specialists, embryologists, clinical and molecular geneticists, genetic counsellors. It should also maintain close contact with the primary care medical doctor or the referring clinician.

**11.8** If the Tissue Establishment offers the PGTM service, the individual responsible for this laboratory should:

(a) hold an appropriate scientific or medical degree

(b) have acquired sufficient experience in an appropriately accredited medical genetics diagnostic laboratory to supervise and be responsible for one, and

(c) be registered with a recognised body by the EPA as a clinical scientist with specific expertise in clinical genetics and is conversant on the nature of tests conducted, the scope and limitations of the tests, accuracy and implications of the tests and the meaning of the test results.

**11.9** The Tissue Establishment should ensure that the prospective parents seeking treatment should have access to the clinical geneticists and the genetic counsellors.

**11.10** Genetic counselling requires specialist training and knowledge. Tissue Establishments are to ensure, that genetic counselling should only be undertaken by an infertility counsellor if s/he has additional

qualification in genetic counselling. In the absence of this, patients should be referred to specialist genetic counselling services. Genetic counselling addresses the risk of patients using their own gametes, but it does not address the emotional issues associated with infertility. Therefore, the Tissue Establishment's counselling service should continue to be available before, throughout and after the investigations, decision-making and treatment.

11.11 The Tissue Establishment should consider the following factors when deciding if PGTM is appropriate in particular cases:

(a) the views of the people seeking treatment in relation to the condition to be avoided, including their previous reproductive experience

(b) the likely degree of suffering associated with the condition

(c) the availability of effective therapy, now and in the future

(d) the speed of degeneration in progressive disorders

(e) the social support available, and

(f) the family circumstances of the people seeking treatment.

11.12 The Tissue Establishment may offer PGTM but withhold the patient's test results (PGTM with non-disclosure). However, this should only be offered under the following conditions:

**(a) that patients are given the opportunity to receive genetic counselling on the implications prior to giving consent,**

**(b) that protocols are established to limit, as far as possible, the risk of unwanted disclosure to the patients. Tissue Establishments should consider using a different embryology laboratory from their own, in order to minimise the number of Tissue Establishment staff who know the patient's genetic status.**

**11.13 The Tissue Establishment should document its reasons for offering PGTM with non-disclosure to a patient. This record should include:**

**(a) written informed consent from the patient to perform PGTM with non-disclosure,**

**(b) a statement from the people seeking treatment confirming that they have been given the opportunity to receive genetic counselling and that they have, prior to giving consent, received information:**

**(i) on the risks of inadvertent disclosure,**

**(ii) that where all embryos are suitable for transfer this is not evidence of the patient's genetic status,**

**(iii) that where no embryos are suitable for transfer this is not evidence of the patient's genetic status.**

**11.14 The clinical team of the Tissue Establishment, having discussed with the prospective parents seeking PGTM, and determined the condition to be sufficiently serious to warrant PGTM, need to apply to the Regulatory Authority EPA and provide the EPA with a report prior to starting any PGTM procedure, detailing:**

**(a) the nature of the genetic condition,**

**(b) if testing is to be for Polar Body PGTM, Day 3 Blastomere PGTM or on a Day 5 Blastocyst PGTM,**

**(c) proof that the prospective parents have received genetic counselling and have given a joint informed consent to undergo the procedure,**

**(d) original or copy of results of genetic testing, karyotypes or other specific testing of the index patient, spouse or partner, children, or other family members (when appropriate),**

**(e) female reproductive history, gynaecological and fertility status,**

**(f) male reproductive history, andrological history, fertility status, results of sperm analysis (especially in cases where the genetic disorder(s) for which PGTM is desired has effects on sperm parameters,**

**(g) reports on health problems of female and male partners that may affect genetic diagnosis, or the outcome of IVF and pregnancy (when appropriate). Health status may need to be re-evaluated over time,**

**(h) a genetic counselling report**

**11.15 The Authority, if the condition is listed in the approved conditions, will issue a permission for the prospective parents to undergo PGTM. It is only after an approval is granted that a PGTM procedure can go ahead as per hereunder:**

**(a) Prospective parents where the woman has not attained thirty-six (36) years of age will be allowed up to a maximum of eight oocytes/embryos to undergo PGTM.**

**(b) Prospective parents where the woman has attained thirty-six (36) years and have not attained forty-six (46) years of age will be allowed up to a maximum of twelve oocytes/embryos to undergo PGTM.**

**11.16 The Tissue Establishment should ensure that people seeking PGTM are given the appropriate information about the treatment. This should include:**

**(a) the process, procedures and possible risks involved in IVF and biopsy procedures when providing a sophisticated genetic test,**

**(b) the experience of the Tissue Establishment in carrying out the procedure,**

**(c) that sophisticated genetic tests can reveal additional genetic information about an embryo(s) and that the clinical effect of these findings on a child born may not be known,**

**(d) All information, oral and written, should be in language that can be understood by a layperson as technical terminology may lead to patient misunderstanding,**

**(e) Written information about treatment should be available prior to a consultation,**

**(f) When PGTM involves the treatment of a couple, both partners should, when possible, attend consultations,**

**(g) An independent interpreter should be present, when necessary, although a family member could act as translator in the absence of an alternative,**

**(h) Counselling should be offered both before, during and after each IVF/PGTM cycle. The counselling provided should be non-directive and include all reproductive options available to the couple, enabling them to reach their own conclusion about the suitability of treatment,**

**(i) Costs and timelines should also be discussed to ensure that patients are fully informed of all aspects of IVF and PGTM before treatment starts. The social and psychological impact needs to be considered, especially in couples already responsible for the care of affected children,**

**(j) Additional counselling may be needed after completion of the laboratory work-up,**

**(k) Individualised post-consultation letters should contain a summary of the information discussed,**

**(l)The patients should sign a written informed consent for all procedures they will undergo, and which are PGTM-related.**

**11.17 The Tissue Establishment should also provide information to those seeking treatment to help them make decisions about their treatment, including:**

**(a) genetic and clinical information about the condition being tested for,**

**(b) the likely impact of the condition on those affected and their families,**

**(c) information about treatment and social support available, and**

**(d) information from a relevant patient support group or the testimony of people living with the condition, if those seeking treatment have no direct experience of it themselves.**

**11.18 If the person seeking treatment has already been given information about the particular genetic disorder, for example from another genetics Tissue Establishment, the Tissue Establishment need not provide this information again. However, the Tissue Establishment should ensure that the information has been provided to a satisfactory standard of breadth and clarity.**

**11.19** **Before providing PGTM, the Tissue Establishment should ensure that those seeking treatment have had sufficient opportunity to fully consider the possible outcomes of genetic testing and their implications.**

**11.20** **Embryos from which biopsies have been taken or resulting from gametes from which biopsies have been taken, should not be transferred with any other (non-biopsied) embryos in the same treatment cycle.**

**11.21** **Embryos that after biopsies have been carried out result that they have a gene that will develop a serious disease, cannot be discarded as per the Embryo Protection Act, thus, such embryos are to be cryopreserved in a dedicated storage facility, separate from embryos not diagnosed with the disease.**

**11.22** **Any embryos, that after undergoing PGTM biopsies have inconclusive diagnosis, are to be clearly labelled and cryopreserved in the same dedicated storage facility as the embryos diagnosed with the disease.**

**11.23** **Any embryos that after undergoing PGTM result that they are not diagnosed with the disease being tested for but might be carriers of that disease can be transferred into the prospective parents requiring treatment and are to be cryopreserved with the embryos not diagnosed with the disease.**

**11.24** **The use of an embryo known to have a gene of a serious disease as described above, should be subject to consideration of the welfare of any resulting child and should have approval from the Authority. Prior**

to use, the prospective parents must give their consent, after receiving adequate information for same use.

11.25 Embryos known to have a gene of serious disease as described above, will only be placed for adoption once an effective treatment for same disease has been found.

11.26 If a Tissue Establishment decides that it is appropriate to provide treatment services to a woman using an embryo known to have a gene of a serious disease as described above, it should document the reason for the use of that embryo and inform the Authority without due delay.

11.27 The Tissue Establishment should have an adequate labelling system, written or barcoded (electronic), with two unique patient identifiers plus the embryo/cell(s) number is used to match the sample's diagnostic result with the embryo from which that sample was taken. This should ensure traceability throughout the IVF and PGTM process until reporting of the final results.

11.28 The labelling system should be comprehensible and practical for both the IVF and PGTM centres. Printed sticker labelling may be superior to pens, as labelling should be legible and uneditable.

11.29 Labelling and sample identification should be confirmed for critical and high-risk steps by an independent observer and signed.

11.30 After biopsy, the sample may be analysed in house or sent for genetic testing in another centre.

**11.31 The PGTM work-up report should contain at least the following information:**

**(a) administrative information including**

**(i) title or name of the report;**

**(ii) number of the report (as used for document control, when available);**

**(iii) pagination including the actual and total number of pages (the patient identifier and report name/number must be present on each additional page);**

**(iv) full date of the report;**

**(v) name and address of the physician referring the patient;**

**(vi) identification of the person(s) performing the diagnosis/authorising the release of the report and their signature;**

**(vii) identity of the IVF/PGTM centre with full contact details;**

**(b) patient (male and female)/sample identification:**

**(i) full given name(s) and surname, or unique patient identification code;**

**(ii) unequivocal date of birth;**

**(iii) gender;**

**(c) specific for the preclinical work-up report:**

**(i) date of DNA sample collection;**

**(ii) date of DNA sample arrival in the laboratory;**

**(iii) samples and genetic status of relevant family members can be mentioned only with their informed consent and should be in accordance with general data protection regulations (GDPR) and/or local privacy regulations;**

**(d) restatement of the clinical question, i.e., the indication(s) being requested for analysis, the type of required testing, the referral reason, parental karyotypes/genomes;**

**(e) specification of genetic tests used:**

**(i) brief information on the methods used in the analysis;**

**(ii) full details of the extent of the tests, including software, where appropriate;**

**(iii) where a commercially available kit is used, this should be clearly identified in the report, including the reference and version of the kit.**

**(f) a clear description and interpretation of results;**

**(g) a clear summary of the results;**

**(h) error rates/limitations of the test/misdiagnosis (a general figure should be stated for the overall cycle/treatment).**

**11.32 Before starting a clinical PGTM cycle, relevant documents should be available, labelling of samples should be checked, and genetic counselling provided to the prospective parent/s.**

**11.33 The PGTM laboratory should ensure that it has clearly documented procedures for all steps of the examination process (explicit instructions and a summary of validation results) and release of results (diagnosis, reporting, embryo transfer policy). These procedures should be covered in a service-level agreement between the PGTM and IVF centres.**

**11.34 The IVF Centre should ensure that the method used for PGTM should have been previously implemented, tested, and validated in the PGTM centre.**

**11.35 Clinical results are to be reviewed and signed or electronically validated by a suitably qualified person (name, qualification, date).**

**11.36 The PGTM clinical cycle report contains an interpretation of the clinical results and guidance on which embryos are genetically transferable. The same recommendations apply as specified for the preclinical work-up report, together with the following items:**

**(a) unique cycle/treatment code;**

**(b) date of oocyte retrieval;**

**(c) date of biopsy;**

**(d) date of biopsy sample arrival in the laboratory;**

**(e) information on the sample type (including number of samples and controls);**

**(f) unique ID number for each cycle and/or biopsy sample tested;**

**(g) indication for PGTM.**

**11.37 When scoring results from polar body (PB) testing, it is recommended to report what was detected in each PB and then infer the oocyte diagnosis. It is recommended to test both PBs.**

**11.38 When scoring results from blastomere/trophectoderm (TE) testing, it is recommended to report what was detected in the sample and then infer the embryo diagnosis.**

**11.39 A written or electronic report should be securely transmitted to the IVF centre to ensure transfer and/or cryopreservation of the correct embryos. Results should not be communicated orally.**

**11.40 Reporting time should be kept as short as possible and when fresh transfer is intended, reporting time should be adapted to allow the IVF centre to organise the embryo transfer.**

**11.41** **The report should be clear, concise, accurate and easily understandable by non-geneticists and that the overall result and interpretation (including transfer recommendation) are presented per embryo.**

**11.42** **In case of no diagnosis and re-biopsy to try and obtain a result, this should be included in the report.**

**11.43** **The final clinical cycle report must be signed by appropriately qualified (authorised) personnel (name, qualification, date), and the clinical cycle results are discussed with the couple before embryo transfer.**

**11.44** **The report is stored in the patient file in both the PGTM and the IVF centre, according to local regulations and a copy of which is sent to the Regulatory Authority EPA together with cryopreservation details of the embryos that can be transferred as well as the cryopreservation details of the embryos diagnosed with the disease.**

**11.45** **Tissue establishments should compare PGTM live birth rates and matched non-PGTM [routine IVF or intracytoplasmic sperm injection (ICSI)] live birth rates within that IVF centre.**

**11.46** **When in-house genetic analysis is not feasible, transport PGTM is an option. In transport PGTM, patients have the IVF treatment (oocyte retrieval, embryo culture, biopsy and transfer, pregnancy follow-up) at their local IVF centre, but genetic testing is performed at a collaborating PGTM centre with significant experience in PGTM.**

**11.47** **The IVF centre and PGTM centre should have in place an official agreement (Service-Level Agreement) dealing with legal, insurance and accountability issues about the transport PGTM procedures.**

**11.48** **Transportation companies entitled to transport biopsied material should certify their suitability to transport the biopsied material, provide the likelihood of a sample loss or sample delivery delay and provide actions taken against these risks.**

**11.49** **The IVF centre and outsourced PGTM centre should make arrangements to ensure that patients have had adequate PGTM counselling.**

**11.50** **The IVF centre and PGTM centre should have in place a set of clinical/laboratory validated protocols, including tubing/spreading protocols, and shipment protocols specifying approximate transportation time and ensuring cell and/or DNA integrity.**

**11.51** **In addition, practical and logistic arrangements on who will be responsible for the various stages of the PGTM treatment should be clearly established.**

**11.52** **The IVF centre and PGTM centre should delineate clear and sufficient lines of communication as documented in written procedures and compliant with the GDPR during all stages of a transport PGTM treatment.**

**11.53** **The IVF/PGTM centres should agree on the feasibility, the number, and the timing of transport PGTM cycles and define a schedule.**

**11.54 All diagnostic results and reports are sent in written form (complying with the GDPR).**

**11.55 PGTM centres should be accredited and certified, as PGTM is of a multidisciplinary nature, the various units involved should each be accredited/certified for their defined tasks and according to the most appropriate quality standards. For each unit, responsibilities should be clearly outlined/described and transition of responsibility from one unit to the other during the PGTM process should be well defined and guaranteed.**

# 12. Donor Recruitment, Assessment and Screening

**12.1 As per the Embryo Protection (Amendment) Act, 2018 Article 9(1) 'The donation of germ line cells for the purpose of medically assisted procreation shall be a confidential agreement between donor and the licensee'.**

**12.2 The donation of germ line cells for the purpose of medically assisted procreation shall be limited to one donation only and such donation shall be used in one prospective parent only.**

**12.3 The Embryo Protection Authority shall keep the records of the identity of the donor for a period of sixty-five years.**

## Age of Prospective Donors

**12.4 All prospective donors both male and female must be over eighteen years but has not attained the age of thirty-six years on date of donation.**

## General Enquiries to be made

**12.5 The recruiting tissue establishment should take reasonable steps to verify the identity of the prospective donors by asking for appropriate identification (identification card or passport). Failure to obtain satisfactory evidence the tissue establishment shall reject the gametes for treatment.**

**12.6 Where a donor has changed their name (eg, where someone has changed their name by deed, has married and taken their partner's surname, or has obtained a gender recognition certificate) or has changed their physical appearance (eg, where someone has undergone gender reassignment or is living in the gender they most closely identify with but which is different from their gender at birth) since their previous consultation, examination or donation, tissue establishments should take all reasonable steps to verify the donor's identity. This is to ascertain that a donor presenting for donation is the same person the tissue establishment previously engaged with or treated.**

**Tissue establishments should verify a donor's identity by asking for evidence of their previous name (eg, a passport or photocard driving licence) and verifying details against the donor's medical records. This can be a sensitive issue for donors and tissue establishments should take care to address identity issues with consideration. As evidence of their new name, tissue establishments should ask donors to provide one of the following:**

**(a) a marriage certificate, or**

**(b) evidence of a change in name (such as via deed)**

**Tissue establishments must ensure that a donor's records are updated to accurately reflect their new identity.**

**12.7 When obtaining gametes or embryos for treatment of others (whether directly from donor, from another licensed tissue establishment or from a foreign supplier), the tissue establishment should take appropriate steps to discover whether gametes from that donor have been obtained for use in licenced treatment before and, if so:**

**(a) establish which tissue establishment is the primary tissue establishment for that donor**

**(b) notify that tissue establishment that is proposes to use that donor's gametes**

**(c) seek authorisation to do so, if appropriate, and**

**(d) ensure that the limit in Malta of one family per donor is not exceeded**

## Family and other Relevant History

**12.8 Before a prospective donor provides gametes, the recruiting tissue establishment should take their medical family histories (when available). The tissue establishment should encourage prospective donors to provide as much other non-identifying biographical information as possible, so that is may be available to prospective recipients, parents and resulting children. If a prospective donor cannot give a full and accurate family history, the tissue establishment should record this fact and take it into account in deciding whether or not to accept their gametes or embryos for treatment.**

**12.9 The tissue establishment should seek the prospective donor's consent to approach their GP for further factual information if it suspects the donor might be unsuitable. The tissue establishment should always seek further information if:**

**(a) information provided by the patients suggests there are risk factors that might affect anyone treated using their gametes or a child born as a result.**

**(b) the prospective donor has failed to provide any information requested**

**(c) the information provided by the prospective donor is inconsistent, or**

**(d) there is evidence of deception.**

**12.10 If the prospective donor refuses to give such consent, the tissue establishment should take this into consideration when deciding whether to accept that donor. Such refusal should not in itself be grounds for not accepting the donor. The tissue establishment should discuss with the prospective donor their reason for refusing.**

## Suitability of Donor and Selection Criteria

**12.11 Donors must be selected on the basis of their age, health and medical history, provided on a questionnaire and through a personal interview performed by a qualified and trained healthcare professional. This assessment must include relevant factors that may assist in identifying and screening out persons whose donation could present:**

**(a) A health risk to others, such as the possibility of transmitting diseases (such as sexually transmitted infections), or**

**(b) Health risks to themselves (e.g. superovulation, sedation or the risks associated with the egg collection procedure or**

**(c) The psychological consequences of being a donor**

**12.12 The donors must be negative for:**

**(a) HIV 1 and 2: Anti-HIV-1,2**

**(b) Hepatitis B: HBsAg & Anti-HB**

**(c) Hepatitis C: Anti-HCV-Ab and**

**(d) syphilis**

**on a serum or plasma sample, tested in accordance with Annex III, of the EUTCD 2006/17/EC**

**12.13 Sperm donors must additionally be negative for chlamydia on a urine sample tested by the nucleic acid amplification technique (NAT)**

**12.14 HTLV-I antibody testing must be performed for donors living in or originating from high-incidence areas or with sexual partners originating from those areas or where the donor's parents originate from those areas**

**12.15 In certain circumstances, additional testing may be required depending on the donor's history and the characteristics of the cells donated (e.g. RhD, malaria, CMV, *T. cruzi*).**

**12.16 The tests must be carried out by a qualified laboratory, authorised as a testing tissue establishment by the competent authority, using EC-marked testing kits where appropriate. The type of test used must be validated for the purpose in accordance with current scientific knowledge.**

**12.17 The biological tests will be carried out on the donor's serum or plasma; they must not be performed on other fluids or secretions such as the aqueous or vitreous humour unless specifically justified clinically using a validated test for such a fluid.**

**12.18 Tissue establishments should take a blood sample and screen potential donors both before accepting them as donors, and before using the donated gametes and embryos in treatment.**

**12.19 Sperm donations other than by partners will be quarantined for a minimum of 180 days, after which repeat testing is required. If the blood donation sample is additionally tested by the nucleic acid amplification technique (NAT) for HIV, HBV and HCV, testing of a repeat blood sample is not required. Retesting is also not required if the processing includes an inactivation step that has been validated for the viruses concerned.**

**12.20 Genetic screening for autosomal recessive genes known to be prevalent, according to international scientific evidence, in the donor's ethnic background and an assessment of the risk of transmission of inherited conditions known to be present in the family must be carried out, after consent is obtained. Complete information on the associated risk and on the measures undertaken for its mitigation must be communicated and clearly explained to the recipient.**

**12.21 Before accepting gametes for the treatment of others, the recruiting tissue establishment should consider the suitability of the prospective donor. In particular, the tissue establishment should consider:**

**(a) personal or family history of inheritable disorders**

**(b) personal history of transmissible infection (as outlined by the superintendence of public health (SPH).**

**(c) the level of potential fertility indicated by semen analysis (when appropriate)**

**(d) the implications of the donation for the prospective donor and their family, especially for any children they may have at the time of donation or in the future, and**

**(e) the implications for any children born as a result of the donation, in the short and long term.**

**12.22 Where a prospective recipient is happy to accept a donor from a different ethnic background, the tissue establishment can offer ART treatment, subject to the normal welfare of the child assessment.**

**12.23 Tissue establishments should not perform treatment that involves donations by an ascendant to a descendant; descendant to an ascendant; and siblings whether of the full or half blood.**

**12.24 The tissue establishment should ensure that its procedures for recruiting donors are fair and non-discriminatory.**

**12.25 A prospective donor should not be accepted if the tissue establishment concludes that a recipient or any child born as a result of treatment using the donor's gametes is likely to experience serious physical, psychological or medical harm, or where the tissue establishment cannot get enough further information to conclude there is no significant risk.**

**12.26 When the tissue establishment decides that a prospective donor is unsuitable to donate, it should record the reasons and explain them to the prospective donor. The tissue establishment should present the reasons for the decision sensitively and answer any questions in a straightforward and comprehensive way.**

**12.27 The tissue establishment should offer counselling to all prospective donors who are considered unsuitable for any reason. When the tissue establishment refuses to accept a prospective gamete donor because of physical or psychological problems that require separate treatment or specialist counselling, the tissue establishment should provide reasonable assistance to the individual to obtain relevant treatment or counselling.**

**12.28 If information affecting the suitability of a prospective donor becomes known after the selection process, the tissue establishment should review the prospective donor's suitability and take appropriate action.**

**12.29 The tissue establishment should tell gamete donors that they should inform the tissue establishment if, after the donation:**

**(a) they discover they are affected by an unsuspected genetic disease, or**

**(b) they find they are a carrier of a harmful recessively inherited condition (eg, through the birth of an affected child).**

**12.30 If a tissue establishment learns that a donor has a previously unsuspected genetic disease or is a carrier of a harmful inherited condition, the tissue establishment should:**

**(a) notify the Embryo Protection Authority immediately**

**(b) Notify other tissue establishments who have received gametes obtained from that donor (applicable where there is transfer of gametes between tissue establishments)**

**(c) The Embryo Protection Authority is to inform patients who have had a live birth as a result of treatment with gametes from that donor, and offer these patients appropriate counselling if the child has still not reached age of majority. Inform the donor conceived child if he has reached aged of majority**

**(d) Carefully consider when and how a woman who is pregnant, as a result of treatment with gametes from that donor, is given this information.**

## Information for Prospective Donors

**12.31 Before any consents or samples are obtained from a prospective donor, the recruiting tissue establishment should provide information about:**

**(a) What information (both non-identifying and identifying) about the donor must be collected by the tissue establishment and held on the Embryo Protection Authority Register**

**(b) The Tissue establishment will disclose non-identifying information about the donor, for example to prospective recipients (prior to choosing a donor).**

**(c) The Embryo Protection Authority's obligation to disclose non-identifying, medical and identifying information to a donor-conceived child, who applies for such information on attaining age of majority**

**(d) The screening that will be done, and why it is necessary**

**(e) The possibility that the screening may reveal unsuspected conditions (eg, low sperm count, genetic anomalies or HIV infection) and the practical implications**

**(f) The scope and limitations of the genetic testing that will be done and the implications for the donor and their family**

**(g) The importance of informing the recruiting tissue establishment of any medical information that may come to light after donation that may have health implications for any woman who receives treatment with those gametes or for any child born as a result of such treatment**

**(h) The procedure used to collect gametes, including any discomfort, pain and risk to the donor (eg, from the use of super ovulatory drugs)**

**(i) The legal parenthood of any child born as a result of their donation (There shall be no link of filiation in accordance with the provisions of the Civil Code between the embryo fertilised using donated germ line cells and the donor)**

**(j) The restriction on using gametes from an individual donor when the prospective parent gives birth as a result of treatment using such gametes (one donation one parent).**

**(k) The importance of supplying up-to-date contact information to the tissue establishment.**

**(l) The importance of the identifying information being provided to people born as a result of their donation.**

**(m) the procedure for donors to withdraw consent for the use of their gametes prior to those gametes being fertilised.**

**12.32 Except in cases of a direct donation, the prospective parents or prospective parent shall only be entitled to obtain such generic information as specified in the Protocol about the donor whose identity shall in all cases remain confidential.**

**12.33 The tissue establishment should inform donors that anyone born as a result of their donation will have access to the following non-identifying information provided by them on the Donor Identification Form or reaching age of majority:**

**(a) Physical description**

i. **Height**

ii. **Weight**

iii. **Skin Colour**

iv. **Eye Colour**

v. **Hair Colour**

**(b) Year and Country of birth**

**(c) Ethnic group**

**(d) If the donor had any genetic children on date of registration**

i. **Number of children**

ii. **Sex of those children**

iii. **In Malta or Abroad**

**(e) Other details the donor may have chosen to provide**

i. **Religion / Belief**

ii. **Current Occupation**

iii. **Hobbies / Interests**

iv. **Other Skills**

**(f) Marital status (at the time of donation)**

**(g) Ethnic group(s) of the donor's parents**

**(h) If the donor was adopted or donor conceived (if they are aware of this)**

**(i) Reason for donating altruistically**

**(j) Details of virology and genetic screening tests**

**(k) A personal message**

**12.34 The medical records that may affect the health of the child and the Identity of the donor or of the person from whom an adopted embryo originated shall be accessible to the child conceived from the germ line cells of such donor either upon the child reaching eighteen years of age or, subject to the consent of the Embryo Protection Authority, at any earlier stage in exceptional circumstances in which the life or health of the child born from such germ line cells is at risk.**

**12.35 The tissue establishment should inform donors that anyone born as a result of their donation will have access to the following identifying information provided by them on the Donor Identification Form or reaching age of majority:**

**(a) Full names (and any previous names at registration)**

**(b) Date of birth**

**(c) Place and Town of birth**

**(d) Last known postal address**

**(e) If postal address has not been updated since registration, address at time of registration will be given**

**12.36 The Embryo Protection Authority shall keep the records of the identity of the donor for a period of sixty five years.**

**12.37 If the Embryo Protection Authority becomes aware of serious illness it shall be obliged to disclose the information to the parent or parents and, in the case that the child has attained majority, to the child.**

**12.38 The Responsible Person must obtain and retain (for three years) written evidence that the sending (exporting) Tissue Establishment is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD). A copy of the information retained must be provided to the Embryo Protection Authority.**

## Provision of Counselling to those Considering Donation

**12.39 If the possibility of donating gametes or embryos for the treatment of others, arises during the course of treatment, the tissue establishment should allow potential donors enough time to consider the implications and to receive counselling before giving consent.**

**12.40 Where someone intends to donate gametes or embryos for the treatment of others, the tissue establishment should ensure it obtains written consent to do so from that person.**

**12.41 The tissue establishment is not required to obtain the consent of the donor's partner or spouse. However, if the donor is married, in a civil partnership or in a long-term relationship, the tissue establishment should encourage them to seek their partner's support for the donation of their gametes.**

## Requirements for the Procurement of Gametes

**12.42 Procurement of gametes shall be carried out by persons who have successfully completed a training programme specified by a clinical team specialising in the tissues and cells to be procured or a tissue establishment authorised for procurement.**

**12.43 The tissue establishment shall have written agreements with the staff or clinical teams responsible for donor selection, unless they are employed by the establishment, specifying the procedures to be followed to assure compliance with the selection criteria for donors.**

**12.44 The tissue establishment shall have written agreements with the staff or clinical teams responsible for gamete procurement, unless they are employed by the same establishment, specifying the type(s) of gametes to be procured and the protocols to be followed**

**12.45 There shall be standard operating procedures (SOPs) for the verification of:**

**(a) donor identity;**

**(b) the details of donor or donor family consent or authorisation;**

**(c) the assessment of the selection criteria for donors**

**(d) the assessment of the laboratory tests required for donors**

**12.46 There shall also be SOPs describing the procedures for procurement, packaging, labelling and transportation of the gametes to the point of arrival at the tissue establishment.**

**12.47 Procurement shall take place in appropriate facilities, following procedures that minimise bacterial or other contamination of procured tissues and cells, in accordance with EUTCD.**

**12.48 Procurement of materials and equipment shall be managed in accordance with the standards and specifications laid down in relevant national and international regulation, standards and guidelines covering the sterilisation of medicines and medical devices. Qualified, sterile instruments and procurement devices shall be used for gamete procurement.**

**12.49 Procurement of gametes from donors shall take place in an environment that ensures their health, safety and privacy.**

**12.50 The procedures for the procurement of tissues and cells shall be carried out in accordance with the requirements of the EUTCD.**

**12.51 A unique identifying code shall be allocated to the donor and the donated tissues and cells, during procurement or at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material. The coded data shall be entered in a register maintained for the purpose.**

**12.52 The Embryo Protection Authority shall ensure that all tissue establishments, including importing tissue establishments (as defined in Directive 2015/565/EU, as amended) –**

**(a) allocate a Single European Code (SEC) as required by the EU Commission Directive 2004/23/EC on standards of quality and safety for donation, procurement, testing, processing, preservation and distribution of all human tissue and cells intended for human application. The directive also sets out that to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells (including reproductive cells)**

**distributed in the EU (by way of a SEC) providing information on the main characteristics and properties of those tissues and cells.**

**(b)The SEC is applied to the movement of gametes and embryos between licensed clinics (or tissue establishments) within and outside of Malta. Movement of 'partner' embryos and gametes are exempt from the requirements if distributed between tissue establishments in Malta. This code is to be applied at the latest before distribution / export for human application**

**(c)allocate a donation identification sequence after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells from a third country supplier. The donation identification sequence shall include:**

> **(i) their EU tissue establishment code as assigned in the EU Tissue Establishment Compendium;**
>
> **(ii) a unique donation number allocated by the tissue establishment, unless such number is allocated centrally at national level or is a globally unique number as used by the ISBT128 coding system. Where allowed, in case of pooling of tissues and cells, a new donation identification number shall be allocated to the final product;**

**(d)do not alter the donation identification sequence once it is allocated to tissues and cells released for circulation, unless it is necessary to correct an encoding error; any correction requires proper documentation;**

**(e)use one of the permitted product coding systems and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human application;**

**(f)use an appropriate split number and expiry date. For tissues and cells for which no expiry date is defined, the expiry date shall be 00000000 at the latest before their distribution for human application;**

**(g)apply the Single European Code on the label of the product concerned in an indelible and permanent manner and mention that code in the relevant accompanying documentation at the latest before its distribution for human application. The tissue establishment may entrust this task to a third party or third parties, provided the tissue establishment ensures compliance with Directive 2015/565/EU, as amended, in particular in terms of uniqueness of the code. Where the label size precludes the application of the Single European Code on the label, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation;**

**(h)notify the competent authority when:**

**(i) information contained in the EU Tissue Establishment Compendium requires an update or correction;**

**(ii)the EU Tissue and Cell Product Compendium requires an update;**

**(iii)the tissue establishment observes a situation of significant noncompliance with the requirements relating to the Single European Code concerning tissues and cells received from other EU tissue establishments;**

(i)take the necessary measures in case of incorrect application of the Single European Code on the label:

| DONATION IDENTIFICATION SEQUENCE (DIS) | | | PRODUCT IDENTIFICATION SEQUENCE | | | |
|---|---|---|---|---|---|---|
| TE code | | Unique Donation number | Product code | | Split number | Expiry date |
| ISO country identifier | TE number | | Product Coding System identifier | Product number | | |
| 2 alphabetic characters | 6 alpha-numeric characters | 13 alpha-numeric characters | 1 alphabetic character | 7 alpha-numeric characters | 3 alpha-numeric characters | 8 numeric characters |

12.53 The Embryo Protection Authority will check compliance at inspections, by sampling donor gamete and embryo movements into and out of the clinic to ensure the SEC has been applied appropriately.

12.54 Tissue establishments identifying an error or change in relation to its details held on the EU Tissue establishment compendium must notify the EPA inspector as soon as practicable.

12.55 Clinics receiving gametes or embryos from a licensed clinic or tissue establishment without a SEC must note this is a serious adverse incident and report it to the EPA using the current incident reporting channel.

## Payments or other Benefits for Donors

12.56 No person shall pay consideration to a donor or to any other person to arrange for the services of a donor or offer to pay such consideration.

**12.57 Oocytes donors may be compensated for the costs and expenses of the Stimulation treatments.**

**12.58 Oocytes donors will be entitled as prospective parents to avail themselves of the Leave for Medically Assisted Procreation as per National Legislation (SL 452.114).**

**12.59 The tissue establishment should ensure that donors understand that donating gametes and embryos is voluntary and unpaid and that oocytes donors may be compensated as per paragraph 12.57 above.**

**12.60 Tissue establishments should keep a central log of all expenses paid to oocytes donors. This log should be made available to EPA inspectors, and should contain the following information:**

**(a) date of payment**

**(b) amount of payment**

**(c) donor (name or unique identifier)**

**(d) reason for payment (nature of expense: visit to clinic for oocytes tracking and / or medications for stimulation)**

**(e) total amount paid to the oocytes donor to date for the cycle**

**(f) receipts that show all expenses incurred.**

# 13. Screening and Storage of Samples to Prevent Cross-Contamination

**13.1 The tissue establishment should ensure that no gametes or embryos are placed in storage unless the people who provided the gametes have been screened in accordance with current professional guidelines.**

**13.2 Prior to the processing of patient gametes or embryos, intended for use in treatment or storage, the tissue establishment must:**

**(a) carry out the following biological tests to assess the risk of cross contamination (for donors biological tests refer to Chapter 12)**

**(i) HIV 1 and 2: Anti-HIV – 1, 2**

**(ii) Hepatitis B: HBsAg/Anti-HBc**

**(iii) Hepatitis C: Anti-HCV-Ab**

**(b) devise a system of storage which clearly separates:**

**(i) quarantined/unscreened gametes and embryos,**

**(ii) gametes and embryos which have tested negative, and**

**(iii) gametes and embryos which have tested positive.**

**13.3 Tissue establishments should:**

**(a) assess the risks of cross-contamination during the quarantine period**

**(b) put procedures in place to minimise these risks, and**

**(c) document the rationale for the chosen quarantine procedures.**

# 14. Procuring, Processing and Transporting of Gametes and Embryos

**14.1 In respect of gametes and embryos preparation processes, these shall require compliance with the Commission Directive 2004/23/EC of the European Parliament and of the Council of 31st March, 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.**

**14.2 These shall also require compliance with the requirements laid down in the provisions of the third Directive. Directive 2006/86/EC (the third Directive) implements Directive 2004/23/EC as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.**

**Relevant Provisions of the Third Directive**

**(a) Reception of gametes and embryos at the tissue establishment Annex II, Part A**

**(b) Processing of gametes and embryos (validation, documentation and evaluation of critical procedures) Annex II, Part B**

**(c) Storage and release of gametes and embryos (criteria to be complied with, including standard operating procedures Annex II, Part C**

**(d) Distribution and recall of gametes and embryos (criteria to be complied with, including procedures to be adopted) Annex II, Part D**

**(e) Final labelling of gametes and embryo containers for distribution (information to be shown on container label or in accompanying documentation) Annex II, Part E**

**(f) External labelling of the shipping container (information to be shown on label on shipping container) Annex II, Part F**

**14.3 There must be a documented system in place that ensures the identification of all gametes and embryos from procurement to use.**

**14.4 There must be a documented system in place for ratifying that gametes and/or embryos meet appropriate specifications of safety and quality for use and for their transportation/distribution.**

**14.5 The tissue establishment should, where appropriate, have documented procedures that cover:**

**(a) superovulation regimes**

**(b) egg retrieval**

**(c) sedation**

**(d) resuscitation**

**(e) sperm aspiration**

**(f) gamete and embryo transfer**

**(g) insemination**

**(h) follow-up after treatment, including management of complications, and establishing if any patients have experienced OHSS, and**

**(i) prevention and management of ovarian hyper-stimulation syndrome including maintaining clinical relationships with local hospitals who may treat the licensed tissue establishments patients for OHSS and seeking to put in place agreements around related appropriate information and data sharing.**

**14.6 In addition to meeting the requirements in licence conditions, the tissue establishment should, at the time of procurement, label each package containing gametes and embryos in a way that is not susceptible to unauthorised or undetectable alteration. If the size of the packaging permits, the identity of the patient, patient's partner or donor should also be noted.**

**14.7 The tissue establishment should not obtain gametes for treatment from anyone under the age of 18 unless:**

**(a) those gametes are intended for the patient's own treatment in oncology cases and transgender persons**

**(b) the tissue establishment can satisfy itself that the patient is capable of giving effective consent to the use of the gametes for that purpose, and**

**(c) the patient has given effective consent to the use of their gametes for that purpose.**

**14.8 A tissue establishment should store or use only sperm that has been obtained directly from the provider, another licensed clinic or a centre with which the licensed centre has a transport arrangement, or that has been imported in line with EPA approvals.**

**14.9 The tissue establishment should ensure that if sperm is produced at another part of the hospital / treatment centre and not within the tissue establishment itself, it should follow protocols to ensure, that:**

**(a) the identity of the sperm provider is confirmed**

**(b) the sperm provider confirms he produced the sperm**

**(c) the date and time of the sperm production is confirmed, (and is no more than two hours before the tissue establishment received the sperm)**

**(d) the sperm has not been interfered with, and**

**(e) the sperm receptacle is clearly labelled with the sperm provider's full name and unique identifier.**

**The tissue establishment's documented procedures should ensure that this information is recorded in the patient's medical records.**

## Reception at the Tissue Establishment of Prospective Parents own Gametes / Embryos previously stored at another Tissue Establishment

**14.10 The tissue establishment must put in place, maintain and implement a procedure for the receipt of gametes and/or embryos from another tissue establishment or third-party premises to ensure that:**

**(a) the consignment of gametes and/or embryos is verified against Standard Operating Procedures (SOPs) and specifications. These must include information relating to the transport conditions, packaging, labelling, patient documentation, and any other associated documentation and samples. These must also include the technical requirements and other criteria considered by the establishment to be essential for the maintenance of acceptable quality, and**

**(b) the gametes and embryos received are quarantined until they, along with associated documentation, have been inspected or otherwise verified as conforming to requirements. The review of relevant patient/donor and procurement information and thus acceptance of the donation needs to be carried out by specified/authorised persons**

**14.11 The following data must be registered at the tissue establishment:**

**(a) consent including the purpose(s) for which the gametes and/or embryos have been imported (such as storage in Malta for use in IVF procedures already scheduled)**

**(b) patient identification and characteristics: age, sex and presence of risk**

**(c) all required records relating to the procurement and the taking of the patient history**

**(d) gametes and embryos obtained and relevant characteristics, and**

**(e) the results of laboratory tests and of other tests.**

**(f) a properly documented review of the complete patient/donor evaluation against the selection criteria by an authorised and trained person.**

**14.12 In addition to the requirements in licence conditions, the documented procedures against which each consignment of gametes and embryos is verified should include requirements for:**

**(a) patient, patient's partner, donor verification**

**(b) packaging and transport**

**(c) labelling of containers for procured gametes, and**

**(d) labelling of shipping containers and any associated documents.**

**14.13 The documented procedure for the receipt of gametes or embryos from another tissue establishment should also ensure that records are kept to demonstrate that before gametes or embryos are released, all appropriate specifications have been met.**

**14.14 The tissue establishment's documented procedures should ensure that the relevant legal requirements are met for registering patients, patients' partners and donors.**

**14.15 If a container used to ship packaged gametes or embryos has not been validated by the manufacturer or supplier for specified transport conditions, these conditions should be validated by the tissue establishment or third party responsible for transport.**

**14.16 The tissue establishment's documented procedures should ensure that the following are recorded:**

**(a) packaging and labelling procured gametes for distribution**

**(b) transporting gametes and embryos**

**(c) labelling shipping containers, and**

**(d) recalling gametes and embryos.**

**14.17 All gametes and embryos must be packaged and transported in a manner that minimises the risk of cross-contamination and preserves the required characteristics and biological functions of the gametes or embryos. The packaging must also prevent contamination of those responsible for packaging and transportation.**

**14.18 The packaged gametes/embryos must be shipped in a container that is designed for the transport of biological materials and that maintains the safety and quality of the gametes or embryos.**

**14.19 The transport conditions, including temperature and time limit, must be specified and the labelling of every shipping container must include as a minimum:**

**(a) a label marked "TISSUES AND CELLS" and "HANDLE WITH CARE"**

**(b) the identification of the establishment from which the package is being transported (address and telephone number) and a contact person in the event of problems**

**(c) the identification of the tissue establishment of destination (address and telephone number) and the person to be contacted to take delivery of the package**

**(d) the date and time of the start of transportation**

**(e) the type of gametes/embryos plus their identification code**

**(f) specifications concerning conditions of transport relevant to the quality and safety of the gametes or embryos**

**(g) specifications concerning storage conditions such as "DO NOT FREEZE"**

**(h) in the case of all gametes and embryos, the following indication: "DO NOT IRRADIATE"**

**(i) when a product is known to be positive for a relevant infectious disease marker, the following indication: "BIOLOGICAL HAZARD".**

**If any of the information under the points above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. The sheet must be packaged with the primary container in a manner that ensures that they remain together.**

**14.20 The container/package must be secure and ensure that the gametes or embryos are maintained in the specified conditions. All containers and packages need to be validated as fit for purpose.**

## Quality and Safety of Gametes and Embryos

**14.21 The tissue establishment should establish and use documented procedures to ensure that:**

**(a) procedures involving the manipulation of gametes or embryos (e.g. sperm**

**preparation, separation of eggs from cumulus cells, and fertilisation of eggs) are performed in a controlled environment with appropriate air quality**

**(b) the risk of bacterial or other contamination is minimised**

**(c) appropriate measures are in place for handling contaminated samples**

**(d) gametes or embryos are handled in a way that protects those properties that are required for their ultimate clinical use, and**

**(e) all blood products with which gametes or embryos may come into contact, except those of the woman receiving treatment, are pre-tested for HIV, hepatitis B and hepatitis C.**

**14.22 Where tissues or cells are exposed to the environment during processing, without a subsequent microbial inactivation process, an air quality with particle counts and microbial colony counts equivalent to those of Grade A as defined in the current European Guide to Good Manufacturing Practice (GMP), Annex 1 and Directive 2003/94/EC is required with a background environment appropriate for the processing of the tissue/cell concerned but at least equivalent to GMP Grade D in terms of particles and microbial counts.**

**If the environmental air quality drops below Grade D during a procedure involving the manipulation of gametes or embryos, those gametes or embryos should be used in treatment only if the tissue establishment can assure itself that this poses no extra risk to the woman to be treated or to any resulting child.**

**14.23 Air quality monitoring should be used as a routine measure of quality assurance (e.g. through particle counts or the use of settle plates, recording any cultures observed). The process of validating air quality should include:**

**(a) documenting culture conditions, and**

**(b) mapping temperature and using control charts to predict the effects of any change in procedures.**

**14.24 Where possible, cryopreserved gametes should be accompanied by documents that indicate their expected post-thaw quality.**

**14.25 The tissue establishment should not use for treatment gametes exposed to a material risk of contamination or damage that may harm recipients or resulting children. If in any doubt about these risks, the tissue establishment should seek expert advice.**

# 15. Transfers, Imports and Exports of Gametes and Embryos Previously Stored

**15.1 Where a tissue establishment wishes to import gametes or embryos into Malta, or export them from Malta, the responsible person must ensure that:**

**(i)where the gametes are exported or imported for the use of a patient and that the gametes are of the patient, any of the prospective parent or parents or donor, that the patient or donor is registered with the EPA, and the relevant registration forms are completed.**

**15.2 Any tissue establishment which is to import germline cells or embryos shall comply with the EU directive 2004/23/EC of the European parliament and of the council, Maltese Legislation subsidiary legislation 483.08 "Equivalent Standards of quality and safety of imported tissues and cells regulations" and Embryo Protection (Amendment) Act, 2018.**

## Information for Patients

**15.3 Before a patient considers obtaining his / her gametes or embryos from outside Malta, the tissue establishment should inform them that special criteria relating to Malta standards must be met and that they are to comply with the importing of embryos as per the Embryo Protection (Amendment) Act, 2018.**

## Imports and Exports Decisions

**15.4 The decision listed hereunder summarises what tissue establishments must consider when transferring gametes and embryos:**

**(a) within Europe**

**(b) outside Europe.**

**15.5 Where a tissue establishment wants to export or import gametes or embryos to or from another European state, the responsible person must obtain and retain (for three years) written evidence that the receiving or sending tissue establishment is accredited, designated, authorised or licensed in accordance with the requirements of the European Tissues and Cells Directive (EUTCD).**

**15.6 If all the above conditions are met then the Malta tissue establishment can complete the import or export and must then notify the Embryo Protection Authority by completing the Embryo or Gamete movement forms as applicable.**

**15.7 For transfers to or from tissue establishments within Europe, this evidence may include documented certification from the competent authority that the tissue establishment complies with the requirements of the EUTCD, is included in a national database of registered tissue establishments, or both.**

**15.8 A copy of the information retained must be provided to the Authority.**

**15.9 All other requirements on import and export of gametes and embryos relating to identification, consent, parenthood, use of the gametes and embryos, and screening must be met.**

**15.10 Where a tissue establishment wants to export or import gametes or embryos to or from a country outside Europe (third Country), the responsible person must obtain and retain (for three years) written evidence that:**

**(a) the receiving or sending tissue establishment is accredited, designated, authorised or licensed under the laws or other measures of the country in which it is situated in relation to quality and safety**

**(b) the tissue establishment has appropriate quality management and traceability systems, and**

**(c) the gametes or embryos have been procured and processed in appropriate facilities and following procedures that minimise bacterial or other contamination.**

**15.11 If all the above conditions are met, then the Malta tissue establishment can complete the import / export and must then notify the Embryo Protection Authority by completing the Embryo or Gamete movement form as applicable.**

**15.12 A copy of the information retained must be provided to the Authority.**

**15.13 All other requirements on import and export of gametes and embryos relating to identification, consent, parenthood, use of the gametes and embryos, and screening must be met.**

**15.14 As per Article 7(5) of the Embryo Protection (Amendment) Act, 2018. A prospective parent or prospective parents, who have cryopreserved embryos in Tissue Establishments abroad may apply to be granted an authorisation by the Embryo Protection Authority to bring two cryopreserved embryos to be transferred locally into the prospective parent/s for each cycle**

**15.15 The Embryo Protection Authority shall not authorise the transfer of more than two embryos for each cycle**

# 16. Storage of Gametes and Embryos

**16.1 Cryopreservation and storage of gametes will be allowed for:**

**(a) Supernumerary gametes resulting from IVF cycles**

**(b) Oncology Cases**

**(c) Fertility Preservation**

**(d) Transgender persons prior to starting hormone therapy.**

**16.2 Oocytes may be cryopreserved in authorized tissue establishments up to the maximum permissible age for the fertilization and transfer thereof into the prospective parent unless they are donated in terms of the Act.**

**16.3 It shall not be lawful to extract and commence cryopreservation of oocytes after the death of the person from whom they originate.**

**16.4 Sperm cells may be cryopreserved in authorized tissue establishments during the lifetime of the person from whom they originate.**

**16.5 Embryos which cannot be transferred into the prospective parent within a treatment cycle shall be cryopreserved in licensed tissue establishments for future use by that prospective parent/s.**

**16.6 Cryopreservation of embryos shall be regulated by an agreement between the prospective parent/s and the licensee subject to the prior authorisation of the Embryo Protection Authority and shall have a maximum term of validity**

**of five years renewable up to the maximum permissible age for the transfer thereof into the prospective parent.**

**16.7 The consent of the prospective parent or parents is to be expressed in writing specifying whether they consent to cryopreservation of any supernumerary embryos and whether they consent to the donation of embryos, to and in the presence of the medical practitioner in charge of the procedure.**

**16.8 Where the prospective parents are married or in a stable relationship, their consent shall be expressed jointly in writing in the prescribed Embryo Protection Authority form, for Embryo Storage and Embryo donation.**

**16.9 When the prospective parent/s give their consent to cryopreservation of any supernumerary embryos and for the donation of embryos if necessary, the medical practitioner in charge of the procedure shall implant up to a maximum of two embryos.**

**16.10 When the prospective parent/s do not give their consent to the cryopreservation of any supernumerary embryos and to the donation of embryos if necessary, the medical practitioner in charge of the procedure shall only fertilize up to a maximum of two eggs.**

**16.11 Consent to cryopreservation may only be withdrawn in writing by the prospective parent or prospective parents jointly before fertilisation.**

**16.12 The tissue establishment should establish documented procedures to ensure that all storage and handling of gametes and embryos comply with licence conditions, regulations, and relevant patient and donor consent.**

**16.13 The tissue establishment should ensure that the storage facilities for gametes and embryos:**

**(a) are dedicated for the purpose, and adequate for the volume and types of activities**

**(b) are designed to avoid proximity to ionising radiation (radioactive material), any known potential source of infection, or chemical or atmospheric contamination, and**

**(c) have a storage-location system that minimises the amount of handling required to retrieve gametes and embryos.**

**16.14 The tissue establishment should also have emergency procedures to deal with damage to storage vessels, failure of storage conditions or both. These should also include a third-party agreement to transfer to another tissue establishment if the need arises.**

**16.15 The tissue establishment's documented procedures should also ensure that:**

**(a) gametes and embryos are stored under controlled conditions that are validated and monitored**

**(b) gametes and embryos are packaged for storage in a way that:**

(i) prevents any adverse effects on the material

(ii) minimises the risk of contamination

(c) records are kept indicating every occasion when gametes and embryos are handled during storage and release, and by whom

(d) records are kept indicating that gametes and embryos meet requirements for safety and quality before release, and

(e) risk assessments (approved by the responsible person) are done to determine the fate of all stored material whenever any of the following is introduced:

(i) a new donor selection criterion

(ii) a new criterion for testing donors, patients' partners or patients

(iii) a new processing step to enhance safety, quality or both

(iv) a new procedure for appropriate disposal of gametes and embryos.

## Safety of Equipment Used to Store Cryopreserved Gametes and Embryos

16.16 Tissue establishments should store gametes and embryos in a designated area. Access to this area should be limited to staff authorised under the terms of the tissue establishment's licence. Cryopreservation dewars should be fitted with local alarms and be linked to an auto-dial or

**similar facility (e.g. a link to a fire alarm board) to alert staff to non-conformities outside normal working hours.**

**16.17 The tissue establishment should have adequate staff and funding for an 'on-call' system for responding to alarms out of hours, and adequate spare storage capacity to enable transfer of samples if a dewar fails.**

**16.18 A tissue establishment storing gametes and/or embryos for oncology patients and / or patients whose future fertility may be impaired by a medical condition or procedure should divide individual patients' samples into separate storage vessels, in case of dewar failure.**

## Information for those Seeking Storage of Gametes or Embryos

**16.19 If the treatment involves the creation of embryos in vitro, the tissue establishment should give people seeking treatment information about the availability of facilities for freezing embryos, and about the implications of storing and then using stored embryos.**

**16.20 When a tissue establishment enters into a contractual agreement with a patient regarding the practicalities of storage (eg, an agreement to pay storage fees or store whilst funding is available) the patient should be given enough information to understand the terms and conditions of the agreement and the steps the tissue establishment will take if these terms and conditions are broken.**

**16.21 This agreement should be separate from the consent provided by the patient. Depending on the terms of the agreement, the tissue establishment should provide information about the circumstances in which the patient's gametes or embryos could be removed from storage before their consent expires. For example, that the tissue establishment may only continue to store the patient's gametes or embryos for the period specified in their consent if the patient, or their funding provider, continues to pay the storage fees.**

**16.22 If there is an intention to store gametes or embryos, or where this possibility arises during treatment, in addition to relevant information about treatment and donation, the tissue establishment should give those providing the gametes or embryos relevant information about:**

**(a) the possible deterioration or loss of viability of gametes or embryos as a result of storage, and the potential risk of cross-contamination between samples**

**(b) statutory storage periods for gametes and embryos which permit patients to store. In the case of embryos, patients should also be given relevant information about the requirement for both gamete providers to consent to any extension of storage**

**(c) the likelihood of a live birth resulting from previously cryopreserved embryos or gametes, and**

**(d) screening tests to be done, the cost of these, the reason for them and the implications of the tests for the gamete providers.**

**16.23 Oncology patients and other patients requiring long-term storage should be given specific information tailored to their needs and circumstances. Where relevant, this should include information appropriate for children and young people.**

**16.24 The tissue establishment should ensure that, before someone consents to gametes or embryos being stored, they are told:**

**(a) the options available if a person providing gametes or resulting embryos dies or becomes mentally incapacitated**

**(b) that it is unlawful to store embryos and gametes beyond the period of consent, the tissue establishment having a legal obligation to dispose of gametes once consent has expired. In case of embryos the Embryo Protection Authority will authorise embryo adoption.**

## Treatment using Cryopreserved Eggs

**16.25 The tissue establishment should ensure that the following sets of eggs or embryos are only transferred during the same treatment cycle in exceptional circumstances, with an upper limit of 2% of all cases:**

**(a) fresh eggs and eggs that have been cryopreserved, or**

**The circumstances justifying such a transfer should be specified in the patient's notes.**

## Storage Review

**16.26 The tissue establishment should establish documented procedures to ensure that:**

**(a) reviews of stored gametes are done at least once every two years to:**

**(i) reconcile the tissue establishment's records with material in storage**

**(ii) review the purpose and duration of storage, and**

**(iii) identify any action needed.**

**16.27 The tissue establishment should operate a bring-forward system in order to ensure sufficient advance notice of the end of the statutory storage period (or such shorter period as specified by a person who provided the gametes) for gametes in storage.**

## End of Storage

**16.28 The tissue establishment should make efforts to stay in contact with patients who have gametes or embryos in storage for their own treatment, and with any woman to be treated with stored gametes or embryos (where she is not a gamete provider.) The tissue establishment should also explain to gamete providers and current patients the importance of informing the tissue establishment of any change in their contact details**

**16.29 The tissue establishment should establish and use documented procedures to contact patients who have gametes or embryos in storage for their own treatment when the end of the permitted storage period is approaching but long enough in advance to allow the centre and patient to take any steps necessary.**

**16.30 The tissue establishment should use all contact details available to them, including at least one written form of contact. Patients should be provided with information about the options available to them as the end of their permitted storage period approaches. They should be given enough notice to enable them to consider those options and to access appropriate advice.**

# 17. Embryo Adoption

**17.1 The Embryo Protection Authority may give for adoption the embryos to a third party who qualifies for medically assisted procreation procedures, in those cases where:**

**(a) After the fertilization of the egg cells but before the implantation of the embryos into the womb has taken place, death of the woman ensues;**

**(b) For any other reason the implantation of the embryos into the womb of the prospective parent cannot take place including those cases where the prospective parent refuses said implantation;**

**(c) Prospective parent has reached the maximum permissible age for the implantation;**

**(d) Prospective parent/s fail to renew the contract with the licensee where the cryopreserved embryos are being stored for future use.**

**17.2 The adoption of an embryo may only take place if the Embryo Protection Authority, on the application of a prospective parent or prospective parents, so decides.**

**17.3 The Embryo Protection Authority shall inform the Social Care Standards Authority of embryo availability.**

**17.4 The Embryo Protection Authority shall only issue its authorisation if the prospective parent or prospective parents have been declared as physically fit by a medical practitioner for the transfer of an embryo and following a favourable recommendation issued by the Adoption Board in accordance**

**with the Adoption Administration Act (Cap 495) determining the eligibility and suitability or otherwise of the prospective parent or prospective parents.**

**17.5 If the prospective parent or parents wish to give their embryos for adoption before they have reached the permissible age of transfer they shall do so in writing to the EPA. If the prospective parents are married or in a stable relationship their consent shall be done jointly.**

# 18. Witnessing and assuring Patient and Donor identification

## Witnessing Clinical and Laboratory Procedures

**18.1 Witnessing protocols should ensure that every sample of gametes or embryos can be identified at all stages of the laboratory and treatment process to prevent any mismatches of gametes or embryos.**

**18.2 Tissue establishments are responsible for ensuring that witnessing protocols are relevant to their local systems and condition.**

**18.3 Electronic systems such as barcoding and radio frequency identification (RFID) for assisted conception are appropriate, subject to a risk assessment as set out in paragraph 18.31 –18.43.**

**18.4 Witnessing protocols should be followed when any of the following clinical or laboratory procedures takes place:**

**(a) Collecting eggs**

**(i) Cross-check identifying information that the egg provider gives against records and laboratory data sheets, or cross-check information entered into the electronic system and the allocation of the barcode or RFID tag.**

**(ii) Cross-check information marked on egg collection dishes and lids against the patient's medical records. This step does not need to be**

manually witnessed if an electronic system (barcoding or RFID) is being used.

(b) Collecting sperm

(i) Cross-check identifying information that the sperm provider gives against records, the laboratory data sheet and sperm receptacle, or cross-check information entered into the system and the allocation of the barcode or RFID tag.

(c) Preparing sperm

(i) Cross-check information on tubes against the documents and information on the sperm receptacle (when the sperm sample is transferred onto a preparation column). This step does not need to be manually witnessed if an electronic system (barcoding or RFID) is being used.

(d) Mixing sperm and eggs or injecting sperm into eggs

(i) Verify identifying information on the dishes and tubes and confirm that the sperm and eggs should be mixed or the sperm injected into eggs.

(e) Transferring gametes or embryos between tubes or dishes

(i) Cross-check information marked on dishes and tubes against the patient's records, and the information marked on the dishes and tubes that the gametes or embryos are being transferred from.

**(f) Transferring embryos into a woman**

**(i) Cross-check identifying information that the patient provides against the patient's medical records or the electronic system (or both) and the laboratory data sheet, and confirm that these are the correct embryos to transfer.**

**(g) Inseminating a woman with sperm prepared in the laboratory**

**(i) Cross-check identifying information that the patient provides against the patient's medical records, or cross-check information entered into the electronic system and the allocation of a barcode or RFID tag.**

**(ii) Verify the sperm provider's identifying information in their records, the electronic system and on the sperm container, and confirm that this is the correct sperm provider.**

**(h) Placing gametes or embryos into cryopreservation**

**(i) Cross-check identifying information on the storage container against the patient's records and the information on the tube or dish that the gametes or embryos are being transferred from.**

**(ii) Cross-check where in the dewar the gametes or embryos are placed.**

**(i) Removing gametes or embryos from cryopreservation**

**(i) Cross-check information on the storage container against information in the patient records to confirm they are the correct gametes or embryos to remove.**

**(ii) Cross-check information from the storage container and the patient records or their information on the electronic system against the thaw dish or tube (and, if applicable, attach a barcode or RFID tag to the thaw dish or tube).**

**(j) Disposing of gametes**

**(i) Cross-check information on the storage container against information in the patient records to confirm they are the correct gametes or embryos to dispose of. In case of embryos these will be given for donation.**

**(k) Transporting gametes or embryos**

**(i) Cross-check information on the storage container against information in the patient's medical records to check that these are the correct gametes or embryos to transport.**

**(ii) Check that information on the storage container is correct.**

**18.5 Each stage of the witnessing trail should check the patient's or donor's and their unique identifying code. The dishes or tubes should be labelled with the female patient's name and unique identifying code as soon as possible.**

## Keeping a Record of Witnessing

**18.6 The checking of identifying samples, patients and donors, and the witnessing of these checks, should be recorded when the clinical and laboratory procedures take place. This means that embryologists performing procedures that need to be witnessed cannot work alone. This will ensure that the witnessing protocol has the maximum potential to identify errors in the treatment process at the time the procedures take place.**

**18.7 When the witnessing check of the procedure takes place, a record should be made in the patient or donor notes stating:**

**(a) the procedure and witnessing check**

**(b) the date and time of the procedure and of the witnessing check**

**(c) the signature of the person doing the procedure, and doing the witnessing check**

**(d) the signature of the witness.**

**A hard copy of electronic witnessing should be retained.**

**18.8 There should be a separate record of the name, job title and signature of everyone who carries out or witness's laboratory and clinical procedures.**

## Witnessing Training

**18.9 Tissue establishments should have an induction programme for new staff to ensure they understand the principles of witnessing and follow the tissue establishment's protocols. Staff should receive refresher training as the tissue establishment decides is appropriate.**

**18.10 Staff should receive appropriate training if a new system for witnessing is introduced.**

## Appropriate Person to Witness

**18.11 Tissue establishments should consider who is the most appropriate person to witness clinical and laboratory procedures. This will usually be someone who has completed the tissue establishment's training programme for new staff, and refresher training (as appropriate), to ensure they fully understand the principles of witnessing procedures and follow the tissue establishment's protocols. For exceptions to this, refer to paragraphs 18.13 and 18.14.**

**18.12 At egg collection and embryo transfer, the appropriate person to witness is another embryologist, clinician or nurse.**

**18.13 At sperm collection, tissue establishments may consider the patient or donor to be the appropriate person to witness the crosschecking of their identifying information against their records, the laboratory data sheet and the sperm receptacle.**

**18.14 Insemination clinics performing intrauterine insemination (IUI) with partner sperm may consider the patient to be the appropriate person to verify the sperm provider's details.**

## Interruptions and Distractions in the Clinic and Laboratory

**18.15 The tissue establishment should consider the implications of distractions in the clinic and laboratory, such as from phones and external noise, and ensure they are minimised.**

**18.16 When considering the protocol its uses for witnessing procedures, and the most appropriate person to witness checks, the tissue establishment may wish to take into account the implications of interruptions to the work of laboratory and clinical staff, particularly embryologists performing critical procedures. Interrupting and returning to a task is a common source of human error.**

## Patient and donor Identification

**18.17 Tissue establishments should establish procedures to ensure patients, donors, and their gametes and embryos are accurately identified.**

**At the assessment stage, tissue establishments should use appropriate evidence to verify the identity of donors and patients seeking treatment (e.g. Identity card, passport or photocard driving licence).**

**18.18 When collecting eggs or sperm, transferring embryos and carrying out insemination, staff should ask patients and donors to give their own identifying information (full name and date of birth), rather than asking the patient to confirm or reject information read out to them.**

**18.19 Tissue establishments should consider how patients and donors with disabilities or whose first language is not Maltese or English will be asked to identify themselves. If possible, tissue establishments should provide an independent interpreter for patients and donors whose first language is not Maltese or English.**

**18.20 Tissue establishments should ensure that each sample of gametes and embryos is uniquely identified. All samples of gametes and embryos should be labelled with at least the patient or donor's full name and a unique identifier. If, when using donor gametes, it is not possible to label the dishes or tubes with the donor name:**

**(a) the dishes or tubes should be labelled with the donor code to uniquely identify that donor, and**

**(b) the dishes or tubes should be labelled with the female patient's name and further identifier as soon as possible.**

**18.21 Tissue establishments should allocate a unique identifier to each sample of gametes or embryos to ensure it can be accurately identified at all stages of the laboratory and treatment process. This identifier should use the patient's or donor's full name and two or more of the following identifiers:**

**(a) the patient's or donor's date of birth**

**(b) Identity card number**

**(c) Hospital number**

**(d) a Donor code**

**18.22 Tissue establishments should consider the most appropriate way to label dishes or tubes when they are likely to be seen by the patient.**

**18.23 Tissue establishments should consider when to change the labelling from showing the male partner's identifying information to the female patient's identifying information. Tissue establishments may consider it appropriate to label all dishes and tubes with both partners' names and identifying codes throughout.**

**18.24 Tissue establishments should ensure that other patients or donors gametes or embryos are not introduced into the critical working area until the procedure is complete. In particular, during sperm preparation, no more than one sample should be processed in the critical working area at any one time. However, it is acceptable for tissue establishments to cryopreserve gametes**

from more than one patient at one time, provided that procedures are in place to keep the samples separate.

## Risk Assessment

18.25 Tissue establishments should do a risk assessment before introducing or changing witnessing protocols. Tissue establishments should consider integrating protocols into the whole laboratory and clinical process and risk-reduction procedures. Tissue establishments may wish to identify and specify key points when mismatching of gametes and embryos is most likely to occur.

18.26 Tissue establishments should be aware of the risks associated with staff doing repetitive activities. The risk of mismatching gametes and embryos is higher when repetitive activities are taking place. Tissue establishments should bear this in mind when selecting the most appropriate person to witness procedures. Similarly, when using witnesses, tissue establishments should consider staff workload and hours, and should ensure staff takes regular breaks.

18.27 Tissue establishments should have formal risk control measures to minimise the risk of writing incorrect or incomplete identifying data on patient's medical records. There is a risk of error when copying details from sample containers and patient's records to other records. The risk is particularly high when a record sheet becomes separated from the patient's records and is relied on during a witnessed step.

18.28 As part of a quality review, audits of the patient's medical records should include checking for transcription errors (or omissions) in patient identifiers,

**such as the misspelling of names and the absence of unique identifiers on a record sheet, particularly in laboratory records.**

**18.29 Tissue establishments should check their compliance with witnessing protocols regularly, including during the audit of their quality management system.**

**18.30 As part of their risk assessment for sperm preparation, tissue establishments may consider witnessing the cross-checking of information on tubes only at the start and end of the procedure, not at every stage in it.**

## Risk Assessment: Electronic Witnessing Systems

**18.31 Before introducing new electronic systems or protocols for witnessing, tissue establishments should do a risk assessment covering the following:**

**(a) Tissue establishments should ensure that any system will not harm gametes and embryos. In establishing that this is the case, tissue establishments should consider what the supplier or manufacturer has done to satisfy itself that the system will not harm gametes and embryos (e.g. commissioned independent reports or carried out irradiance readings)**

**(b) Tissue establishments should be aware that the reliability and safety of different electronic systems may vary**

**(c) Tissue establishments should evaluate the evidence that the supplier or manufacturer provides to support the safety and reliability of its system (e.g. false positive and negative matches and breakdown), plus any other relevant studies**

**(d) Any software should be fully tested, quality assured and risk assessed**

**(e) Tissue establishments should consider what the manufacturer has done to ensure that any labels and tags will continue to be effective when placed in long-term cryo-storage.**

**18.32 Tissue establishments should be aware that although they cannot completely eliminate the potential for human error in any electronic witnessing system, effective risk assessment should mitigate this.**

**18.33 If tissue establishments use an electronic system (barcode or RFID) with 'forcing functions' (which prevent the user omitting key matching tasks in the process by preventing them from proceeding with subsequent task steps), then as part of their risk assessment they may wish to consider that manually witnessing transfer steps are not necessary.**

**This exemption should not apply however to:**

**(i) mixing sperm and eggs,**

**(ii) injecting sperm into eggs, and**

**(iii) placing eggs and sperm into and removing them from cryo-preservation.**

**18.34 Tissue establishments should consider any potential loopholes in the system that could allow users to circumvent key steps, thus negating**

**safeguards against error. Tissue establishments should consider implementing a system that allocates a unique identifier to each system user.**

**18.35 Tissue establishments should not rely solely on electronic systems to check the identity of patients and samples.**

**18.36 Tissue establishments should have procedures to ensure that all witnessing steps can still be done if the electronic system fails, and that witnessing staff maintain their manual witnessing skills for all critical steps.**

**18.37 In addition to using the electronic system of identification (information stored on barcodes or RFID tags), tissue establishments should continue to manually label all culture dishes, tubes, lids and straws with the patient's full name and unique identifier. If the electronic identification fails (e.g. losing a barcode label or RFID tag from a sample), tissue establishments should revert to manual identification.**

**18.38 Tissue establishments should consider whether the barcode or RFID tags are suitable for use on storage containers (i.e. are able to withstand long periods of cryopreservation).**

## Risk Assessment: Barcoding

**18.39 Tissue establishments considering installing a barcode system should consider as part of their risk assessment:**

**(a) the type and power of light used in the barcode equipment**

**(b) the length of time the gametes and embryos are likely to be exposed to it, and**

**(c) whether exposure to this light is likely to harm the gametes and embryos.**

**18.40 Although there is substantial evidence about using barcodes with human tissue, as far as the EPA is aware no independent studies have yet been done on the effect of light on human gametes and embryos. So the EPA does not have enough evidence to consider barcoding to be risk free.**

**18.41 Barcoding equipment may use a range of light sources. The EPA is aware of two types of barcoding systems marketed for use in assisted conception: those using white-light-emitting diodes and those using laser light.**

**18.42 Considering the evidence of damage to human cells from some powers of laser light, tissue establishments must weigh up the degree of possible risk of using laser light barcoding systems. Tissue establishments should only consider using class 1 or 2 lasers.**

**18.43 Barcode equipment that uses ultraviolet or infrared light should not be used. These sources of radiation are known to heat, and so potentially damage human cells.**

## Risk Assessment: Radio Frequency Identification Systems

**18.44 Tissue establishments considering installing an RFID system should, as part of their risk assessment, consider the frequency of the radio waves used in the RFID system and whether exposure to them is likely to harm gametes and embryos.**

**Tissue establishments should be aware that detectable changes in temperature may result in DNA damage. Tissue establishments should do this risk assessment in the context of other risk factors in the tissue establishment and the environment (e.g. mobile phone signals).**

**18.45 Although there is evidence for the use of RFID in a medical setting, as far as the EPA is aware no independent studies have yet been done on the effect of electromagnetic radiation on human gametes and embryos. So, there is not yet a compelling evidence base to enable the EPA to consider RFID systems to be risk free.**

## Establishing, Maintaining and Documenting the Quality Management System

**18.46 Tissue establishments should identify and evaluate risks and the impact of work processes. Any potential failures that may affect patient or donor safety should be taken into account. A risk should be:**

**(a) adequately identified**

**(b) assessed**

**(c) entered into a risk register**

**(d) maintained and reviewed in accordance with the level of risk identified**

**(e) all decisions and actions in response to a risk should be adequately documented**

**(f) written documentation should be available to support and oversee the process.**

# 19. Traceability

**19.1 Traceability means the ability**

**(a) to identify and locate gametes and embryos during any step from procurement to use**

**(b) identify the donor and recipient of particular gametes or embryos**

**(c) to identify any person who has carried out any activity in relation to particular gametes or embryos, and**

**(d) to identify and locate all relevant data relating to products and materials coming into contact with particular gametes or embryos and which can affect their quality or safety.**

## Traceability Requirements

**19.2 Procedures for ensuring traceability of gametes and embryos should be documented. Tissue establishments should ensure that:**

**(a) they uniquely and accurately identify:**

**(i) the patient**

**(ii) the patient's partner, donor or both, as applicable**

**(iii) gametes and embryos, and**

**(iii) any containers used for the receipt and distribution of gametes and embryos.**

**(b) quarantined, non-quarantined and rejected material is clearly distinguishable at all processing stages**

**(c) they keep records of the equipment and materials used to receive, process, store gametes and embryos and discard gametes**

**(d) they keep registers of received, processed, stored, distributed gametes or embryos. Registers should enable a tissue establishment to investigate adequately if a problem is identified after the gametes have been used. Registers should also enable the tissue establishment to identify:**

**(i) a patient, patient's partner or donor**

**(ii) processing steps applied to gametes or embryos (or both) and, if applicable, third parties involved in processing**

**(iii) individual procurement of gametes and embryos**

**(iv) the institution from which gametes and embryos have come**

**(v) distributed gametes or embryos, and**

**(vi) the institutions to which gametes or embryos have been sent (for a patient's use).**

**19.3 For the system of identification, tissue establishments should use an identifying code that contains at least the following information:**

**(a) for donors:**

**(i) their identity, and**

**(ii) the tissue establishment's identity.**

**(b) for gametes and embryos:**

**(i) a unique code**

**(ii) split number (if applicable), and**

**(iii) end of statutory storage period.**

**19.4 The tissue establishment's traceability procedures should cover any materials or equipment that could affect the quality or safety of gametes and embryos, for example:**

**(a) culture media**

**(b) serial numbers or batch numbers of equipment and materials coming into contact with gametes and embryos, and**

**(c) records of the monitoring and maintenance of the required conditions in incubators and storage tanks.**

**19.5 For gametes that have been stored at the tissue establishment (e.g. for oncology or fertility preservation patients) and then supplied to another tissue establishment (e.g. to be stored or used in treatment), the tissue establishment will not be expected to hold traceability data for subsequent processes involving those gametes outside the tissue establishment. However, the storing tissue establishment 's record keeping procedures should show a link to the tissue establishment to which the gametes are supplied, so that the complete process from procurement to use or disposal can be traced if needed.**

# 20. Donor Assisted Conception

## Information for People Seeking Treatment with Donated Gametes and Embryos

**20.1 The tissue establishment should give people seeking treatment with donated gametes or embryos:**

**(a) non-identifying information about donors whose gametes are available to them, including the goodwill message**

**(b) information about genetic inheritance and, in particular, the likelihood of inheriting physical characteristics from the donor, and**

**(c) information about the age of the donor and the associated risk of miscarriage and chromosomal abnormalities.**

**20.2 The tissue establishment should provide information to people seeking treatment with donated gametes or embryos about legal parenthood, and the collection and provision of information, specifically:**

**(a) there shall be no link of filiation between the child born from donated germ line cells or adopted embryos and the persons from whom donated germ line cells or adopted embryos originated**

**(b) information that tissue establishments must collect and register with the Embryo Protection Authority about the donors**

**(c) what information may be disclosed to people born as a result of donation and in what circumstances, and**

**(d) a donor-conceived person's right to access non-identifying (generic) information and identifying information about the donor from the age of 18.**

**20.3 The tissue establishment should give people seeking treatment with donated gametes or embryos information about genetic and other screening of people providing gametes. This information should include details about:**

**(a) the sensitivity and suitability of the tests, and**

**(b) the possibility that a screened provider of gametes may be a carrier of a genetic disease or infection**

**(c) in the case of fresh egg donation, the screening requirement of the donor and the risk of infection for the recipient**

**20.4 The tissue establishment should provide information that explains the limitations of testing procedures and the risks of treatment to anyone seeking treatment with donated gametes or embryos. The tissue establishment should make available appropriate counselling.**

**20.5 If a woman is to receive donor insemination treatment, then, before treatment commences, the tissue establishment should discuss with her the number of treatment cycles to be attempted if she does not conceive initially. The tissue establishment and the woman should together review this situation regularly.**

**20.6 Women should be informed that the simultaneous implantation of embryos originating from different persons in a prospective parent during the same cycle is prohibited.**

## The importance of informing children of their donor origins

**20.7 The tissue establishment should tell people who seek treatment with donated gametes or embryos that it is best for any resulting child to be told about their origin early in childhood. There is evidence that finding out suddenly, later in life, about donor origins can be emotionally damaging to children and to family relations.**

**20.8 The tissue establishment should encourage and prepare patients to be open with their children from an early age about how they were conceived. The tissue establishment should give patients information about how counselling may allow them to explore the implications of treatment, in particular how information may be shared with any resultant children.**

## Implications of Donor Conception and the Provision of Counselling

**20.9 If it is possible that the question of treatment with donated gametes or embryos may arise, the tissue establishment should raise this with the person or couple seeking treatment before their treatment starts. The tissue establishment should allow people enough time to consider the implications of using donated gametes or embryos, and to receive counselling before giving consent.**

## Access to Information for Donor-Conceived People and Parents

**20.10 The tissue establishment should inform people seeking treatment with donated gametes or embryos that any resulting children will have access to the following non-identifying information about the donor from the age of 18:**

**(a) Physical description**

i. **Height**

ii. **Weight**

iii. **Skin Colour**

iv. **Eye Colour**

v. **Hair Colour**

**(b)Year and place of birth**

**(c) Ethnic group**

**(d) If the donor had any genetic children on date of registration**

i. **Number of children**

ii. **Sex of those children**

iii. In Malta or Abroad

(e) Other details the donor may have chosen to provide

i. Religion / Belief

ii. Current Occupation

iii. Hobbies / Interests

iv. Other Skills

(f) Marital status (at the time of donation)

(g) Ethnic group(s) of the donor's parents

(h) If the donor was adopted or donor conceived (if they are aware of this)

(i) Reason for donating altruistically

(j) Details of virology and genetic screening tests

(k) A personal message

20.11 The tissue establishment should inform people seeking treatment with donated gametes or embryos that the medical records that may affect the health of the child and the Identity of the donor or of the person from whom an adopted embryo originated shall be accessible to the child conceived from

**the germ line cells of such donor either upon the child reaching eighteen years of age or, subject to the consent of the Embryo Protection Authority, at any earlier stage in exceptional circumstances in which the life or health of the child born from such germ line cells is at risk.**

**20.12 The tissue establishment should inform people seeking treatment with donated gametes or embryos that any children born as a result of the donation will have access to the following identifying information about the donor, from the age of 18:**

**(a) Full names (and any previous names at registration)**

**(b) Date of birth**

**(c) Place and Town of birth**

**(d) Last known postal address**

**If postal address has not been updated since registration, address at time of registration will be given.**

# 21. Intra – Cytoplasmic Sperm Injection (ICSI)

## Information for People Seeking Treatment with ICSI

**21.1 Before treatment is offered, the tissue establishment should give the woman seeking treatment and her partner, if applicable, specific information about the risks of ICSI which might lead to:**

**(a) a reduced number of eggs being available for treatment (compared to IVF), due to eggs being immature or damaged by the process of ICSI**

**(b) children conceived having inherited genetic, epigenetic or chromosomal abnormalities (including cystic fibrosis gene mutations, imprinting disorders, sex chromosome defects and heritable sub-fertility).**

**21.2 Where appropriate, tissue establishments should also provide patients with information about the possibility of genetic testing of the male partner.**

## The use of ICSI

**21.3 The tissue establishment's clinical protocols should set out when ICSI can be used. The reasons for using ICSI in any particular case should be explained in the patient's medical records.**

**21.4 With respect to any ICSI programme, the tissue establishment should ensure that:**

**(a) ICSI and other embryos are transferred during the same treatment cycle only in exceptional circumstances, with an upper limit of 2% of all ICSI embryo transfers, (maximum transfer of two embryos in each cycle)**

**(b) the circumstances justifying such a transfer are specified in the patient's notes, and**

**(c) oocytes that have failed to fertilise by normal IVF or ICSI are not re-inseminated by any means.**

# 22. Research and Unlawful Procedures

## Unlawful Procedures

**In terms of the statutory provision under the Embryo Protection Act 2012, the Embryo Protection (Amendment) Act, 2018, and the Various Laws relating to Assisted Procreation (Amendment) Act 2022, it is prohibited to:**

**22.1 Artificially fertilizes any egg cell for any purpose other than that of bringing about the pregnancy to the prospective parent;**

**22.2 Intentionally fertilizes more egg cells than the maximum amount established by this Protocol from one woman within one treatment cycle:**

**Provided that the medical practitioner in charge of the medically assisted procreation may, in consultation with the multidisciplinary team and with the permission of the Embryo Protection Authority, decide to fertilise more than two egg cells within one treatment cycle, provided that this is done in accordance with this Protocol.**

**22.3 No more egg cells can be fertilized until all the cryopreserved embryos have been implanted in the prospective parents from whom they originate from any prior medically assisted procreation treatment, except in those instances which may be specified in this Protocol and with the prior authorisation of the Authority, in which case, the fertilisation of more egg cells may be permissible.**

**22.4 When the prospective parent or parents undergoing medically assisted procreation procedures do not give consent to cryopreservation of embryos and the donation of fertilized eggs if necessary, in terms of article 18, it shall not be lawful to fertilize more than two eggs within each treatment cycle.**

**22.5 In one treatment cycle no more than two embryos shall be transferred into the prospective parent or parents**

**22.6 removes an embryo from a woman before the completion of implantation in the womb in order to transfer the embryo to another woman;**

**22.7 selects or discards an embryo for eugenic purposes: Provided that the Protocol may specify that certain exceptional circumstances shall not constitute selection of embryos for eugenic purposes; provided, however, also that the medical experts as listed in the Protocol shall provide information and explanations relating to the testing of human egg cells (oocytes) and other testing which is available to the prospective parent or prospective parents and the said prospective parent or prospective parents shall decide which testing shall be carried out after consulting with the medical experts**

**22.8 carries out an artificial fertilization of, or transfers a human embryo into, a woman who is prepared to give up her child permanently after birth (surrogate mother).**

## Improper use of Human Embryos

**22.9 other than for the purpose of implantation in a prospective parent, as may be authorized by the provisions of the Act disposes of, hands over or acquires a human embryo produced outside the body, or removes such embryo from a prospective parent before the completion of implantation in the womb**

**22.10 causes a human fertilised egg to develop further outside the body for any purpose other than in order to bring about a pregnancy.**

## Prohibition of Selection of Sex

**22.11 artificially fertilizes a human egg cell with a sperm cell that is selected for the sex chromosome contained in it.**

**22.12 Nothing contained in Article 10 sub-article (1) of the Embryo Protection Act, 2012, shall be understood as preventing the selection of a sperm cell by a medical practitioner in order to prevent the child from falling ill with a sex-linked genetic illness.**

## Prohibition of Cloning

**22.13 Any intervention seeking to create a human being genetically identical to another embryo, *foetus*, or human being, whether living or dead, is prohibited and for the purpose of this article, the term "genetically identical" means a human being sharing with another the same nuclear gene set.**

## Unauthorised Fertilisation, Embryo Transfer, and Artificial Fertilisation after Death

**22.14 Artificially fertilizes an egg cell without the consent of the woman, whose egg cell is to be fertilized, or without the consent of the man, whose sperm cell will be used for fertilization.**

**22.15 Transfers an embryo into a woman without her consent.**

**22.16 Knowingly artificially fertilizes an egg cell with the sperm of a man before or after his death except in the case where the deceased person has donated his sperm, and**

**22.17 Knowingly artificially fertilizes an egg cell of a woman before or after her death except in the case where the deceased person has donated her egg cells.**

**22.18 Nothing in the Embryo Protection Act shall be construed or interpreted in a way as to impede, for medical reasons and according to accepted medical norms, the taking and freezing of sperm or egg of a person with the aim of making use of that same sperm or egg at a later stage for the generation of an embryo.**

## Prohibition of Artificial Alteration of Human Germ Line Cells

**22.19 Wilfully alter in an artificial way the genetic information of a human germ line cell.**

**22.20 Knowingly uses a human germ line cell with artificially altered genetic information for fertilization.**

**22.21 No offence shall arise, against the medical practitioner carrying out the medically assisted procedure, under article 13 sub-article (1)of the Embryo protection Act, 2012, where the alteration of the genetic information of a germ line cell is the unintended consequence of inoculation, radiation or chemotherapeutic or treatment.**

## Prohibition of Formation of Chimerae and Hybrids

**22.22 Unites embryos with different genetic material to a cell conglomerate using at least one human embryo; or**

**22.23 joins a human embryo with a cell that contains genetic information different from the embryo cells and induces them to develop further; or**

**22.24 fertilizes a human egg cell with the sperm of an animal or fertilizes an animal's egg cell with the sperm of a man, with the intention of generating an embryo capable of development,**

**22.25 transfers to a woman or an animal an embryo arising out of a procedure described in article 14 sub-article (1) of the Embryo Protection Act, 2012, or transfers to an animal a human embryo**

## Prohibition of Experimentation on Human Embryos

**22.26 Any experimentation on human embryos is prohibited.**

**22.27 The creation of human embryos for the purpose of research or experimentation or for any other purpose not permitted under the Embryo Protection Act, is prohibited**

**22.28 Clinical interventions on a human embryo are allowed on condition that said interventions pursue an exclusively diagnostic and, or therapeutic purpose related to the embryo and are in the interests of the health and development of the embryo itself. Provided that nothing shall in any way be construed as prohibiting clinical interventions deemed permissible in terms of the Protocol, nor prohibiting the prospective parent and, or prospective parents from opting for the cryopreservation of the human embryo after the carrying out of any such intervention wherever such an option is deemed permissible in terms of the Protocol**

## Wilful Cause of Death of Embryos

**22.29 wilfully causes the death of any embryo**

**22.30 This article shall also apply to any human clone created in breach of article 11 of the Embryo Protection Act, 2012.**

**22.31 All of the above Unlawful Procedures carry fines and/or imprisonment, or both.**

# 23. Quality Management System

## Definition of the Quality Management System

**23.1 The quality management system is defined as:**

**'The organisational structure, defined responsibilities, procedures, processes and resources for implementing quality management (i.e. the co-ordinated activities to direct and control an organisation with regard to quality), including all activities which contribute to quality, directly or indirectly'. (International Organization for Standardization)**

**NOTE: This definition indicates that every process and activity taking place in the tissue establishment is a part of the quality management system.**

**23.2 The tissue establishment shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended results of its quality management system.**

**23.3 The tissue establishment shall monitor and review information about these external and internal issues. Issues can include positive and negative factors or conditions for consideration. Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local. Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the tissue establishment.**

**23.4 Due to their effect or potential effect on the tissue establishment's ability to consistently provide products and services that meet patient and applicable statutory and regulatory requirements, the tissue establishment shall determine**

**(a) the interested parties that are relevant to the quality management system**

**(b) the requirements of these interested parties that are relevant to the quality management system.**

**23.5 The tissue establishment shall monitor and review information about the interested parties and their relevant requirements.**

**23.6 The tissue establishment shall determine the boundaries and applicability of the quality management system to establish its scope. When determining this scope, the tissue establishment shall consider**

**(a) the external and internal issues**

**(b) the requirements of relevant interested parties**

**(c) the products and services of the tissue establishment.**

**23.7 The tissue establishment shall apply all the requirements of the International Standard if they are applicable within the determined scope of its quality management system. The scope of the tissue establishment's quality management system shall be available and be maintained as documented information. The scope shall state the types of products and**

**services covered, and provide justification for any requirement of the International Standard that the tissue establishment determines is not applicable to the scope of its quality management system. Conformity to the International Standard may only be claimed if the requirements determined as not being applicable do not affect the tissue establishment's ability or responsibility to ensure the conformity of its products and services and the enhancement of patient satisfaction.**

**23.8 The tissue establishment shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.**

**23.9 The tissue establishment shall determine the processes needed for the quality management system and their application throughout the tissue establishment, and shall:**

**(a) determine the inputs required and the outputs expected from these processes**

**(b) determine the sequence and interaction of these processes**

**(c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes**

**(d) determine the resources needed for these processes and ensure their availability**

**(e) assign the responsibilities and authorities for these processes**

**(f) address the risks and opportunities as determined in accordance with the requirements**

**(g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results**

**(h) improve the processes and the quality management system.**

**23.10 To the extent necessary, the tissue establishment shall:**

**(a) maintain documented information to support the operation of its processes**

**(b) retain documented information to have confidence that the processes are being carried out as planned.**

**23.11 The tissue establishment should:**

**(a) identify the processes needed for quality management, for providing and managing resources and for assisted conception procedures, and**

**(b) ensure these processes, including the interaction between them, are effective and continually improved.**

## Establishing, Maintaining and Documenting the Quality Management System

**23.12 Tissue establishment management should ensure the quality management system is established and maintained by:**

**(a) appointing a quality manager**

**(b) establishing a quality policy**

**(c) establishing quality objectives and plans**

**(d) ensuring resources are available to implement and maintain the system**

**(e) making tissue establishment staff aware of the importance of the system and the need to keep to its requirements**

**(f) defining responsibilities, authorities and reporting relationships in the tissue establishment**

**(g) conducting management reviews of the system, and**

**(h) establishing and reviewing contracts with third parties.**

**23.13 Tissue establishment management should appoint a quality manager who, regardless of their other responsibilities, must be responsible for:**

**(a) ensuring that the quality management system is implemented and maintained**

**(b) reporting to tissue establishment management on how the quality management system works and how effective it is, and**

**(c) co-ordinating awareness of tissue establishment users' needs and requirements.**

**23.14 The tissue establishment's documents to support its quality management system should include:**

**(a) the quality policy, with quality objectives and plans**

**(b) a quality manual**

**(c) documents needed to ensure the tissue establishment's processes are planned and operate effectively, and**

**(d) records and procedures required by this Protocol.**

**The tissue establishment should ensure that all documents are available for inspection by the EPA.**

## Quality Policy and Quality Objectives

**23.15 The quality policy is defined as:**

**'The overall intentions and direction of an organisation related to quality as formally expressed by tissue establishment management. A quality policy statement defines or describes an organisation's intentions and commitment to quality and provides a framework for setting quality objectives and planning'. (International Organization for Standardization)**

**23.16 Tissue establishment management should ensure the quality policy includes a commitment to:**

**(a) providing a service that meets its users' needs and requirements. This should include ensuring that all staff who come into contact with patients, donors and their partners (where applicable) provide the good quality supportive care before, during and after treatment, as outlined in the tissue establishment's patient support policy**

**(b) meeting the provisions of this Protocol and standard licence conditions**

**(c) continually improving the effectiveness of the quality management system**

**(d) upholding good professional practice, and**

**(e) ensuring the health, safety and welfare of all staff and visitors to the tissue establishment.**

**23.17 The quality policy should be:**

**(a) signed and issued by the responsible person**

**(b) communicated, understood and available throughout the tissue establishment, and**

**(c) reviewed for continuing suitability.**

**23.18 Tissue establishment management should establish documented quality objectives. These should:**

**(a) include objectives needed to meet users' needs and requirements, including their need for supportive care and treatment, from clinic staff, before, during and after treatment or donation**

**(b) be measurable and consistent with the quality policy, and**

**(c) be reviewed regularly.**

**23.19 Tissue establishment management should establish a plan to achieve and maintain the quality objectives. The plans should be reviewed regularly.**

## Quality Manual

**23.20 The tissue establishment should establish and maintain a quality manual.**

**The quality manual should include:**

**(a) a brief description of the tissue establishment, including its legal identity, and the scope of its services**

**(b) the quality policy, or reference to it**

**(c) an organisation chart defining accountability and reporting relationships in the tissue establishment**

**(d) text to accompany the organisational chart and a definition of the tissue establishment's place in any parent organisation, and**

**(e) an outline of the processes and documentation established for the quality management system.**

## The Quality Management Review

**23.21 The review of the quality management system should include consideration of changes in:**

**(a) the volume and scope of work**

**(b) staff**

**(c) premises**

**(d) the performance of third parties that could affect the quality management system or the tissue establishment's services, and**

**(e) the results of the following activities:**

**(i) quality indicators for monitoring the tissue establishment's performance in the provision of emotional support and patient care**

**(ii) assessment of user satisfaction, and the monitoring and resolution of complaints**

**(iii) staff suggestions**

**(iv) an internal audit of all elements of the quality management system, including assisted conception processes**

**(v) participation in external reviews, and inter-tissue establishment and inter-laboratory comparisons**

**(vi) identification, investigation, control, recording and notification of serious adverse events and reactions, and**

**(vii) continual improvement, including the status of corrective and preventive actions.**

**23.22 The tissue establishment should normally review its quality management system at least every 12 months but more often when a quality management system is being established.**

**23.23 The management review should include the results of monitoring, evaluation and improvement activities.**

**23.24 The results of the review of the quality management system should be recorded and should include the decisions and actions for improving the quality management system. Tissue establishment staff should be informed of the results of the quality management review.**

## Quality Indicators

**23.25 The tissue establishment should establish quality indicators for systematically monitoring and evaluating the tissue establishment's contribution to the provision of emotional support and patient care.**

## Assessing User Satisfaction

**23.26 The tissue establishment should assess whether or not the service has met users' needs and requirements, including the extent to which they felt supported before, during and after their treatment or donation. It should keep records of the information it collects and the actions it takes. Methods should include user surveys for all aspects of the service.**

## Staff Suggestions

**23.27 Tissue establishment management should encourage staff to make suggestions for improving any aspect of the tissue establishment's service. Suggestions should be evaluated, implemented as appropriate, and feedback provided to the staff. Records of suggestions and management action should be maintained.**

## Internal & External Audits

**23.28 The tissue establishment should establish an internal audit process to determine whether the quality management system:**

**(a) conforms to the planned arrangements for assisted conception processes**

**(b) conforms to the requirements of this Protocol and to the standards established by the tissue establishment, and**

**(c) is effectively implemented and maintained.**

**23.29 The tissue establishment should establish a documented procedure to:**

**(a) define the responsibilities for planning and conducting audits**

**(b) define the audit criteria, scope, frequency and methods**

**(c) ensure audits are carried out by trained staff**

**(d) ensure action is taken promptly to start corrective action**

**(e) check the effectiveness of the action taken, in a subsequent audit, and**

**(f) keep records of audits, to include:**

**(i) the processes, areas or items audited**

**(ii) any areas that do not comply with the quality management system**

**(iii) recommendations and timescales for action, and**

**(iv) action taken and its effectiveness.**

**23.30 The quality manager should plan the audit programme. It must take into account the importance of the processes and areas to be audited, and the results of previous audits. Auditors should not audit their own areas of responsibility. The Quality Manager should ensure that second party audits are carried out wherever necessary on procured suppliers taking evidence obtained from Third Party Agreements.**

**23.31 The audit should focus in particular on quality indicators established for systematically monitoring and evaluating the tissue establishment's assisted conception processes.**

## Participating in External Reviews, and Inter-Tissue Establishment and Inter-Laboratory Comparisons

**23.32 The tissue establishment should, where possible, participate in inter-tissue establishment comparisons and inter-laboratory comparisons. The tissue establishment should evaluate the results of these comparisons and use relevant findings to improve its service.**

**23.33 For inter-laboratory comparisons, the laboratory should establish documented procedures to define the responsibilities and requirements for participation to ensure that:**

**(a) a record of participation is maintained, to include reasons for failure to participate**

**(b) supervisory staff and staff doing the examinations evaluate the returned results against agreed performance criteria, and, when nonconformities are identified, participate in implementing and recording corrective action, and**

**(c) the effectiveness of the corrective action is verified. When a formal inter-laboratory comparison programme is not available, the laboratory should develop a way of determining the acceptability of procedures not otherwise evaluated. Whenever possible, this should use external materials, such as exchange of samples with other laboratories.**

**23.34 The tissue establishment should assess any external reviews indicating nonconformities or potential nonconformities and take appropriate corrective or preventive action to ensure it continues to comply with the requirements and expectations of this Protocol. The tissue establishment must keep a record of corrective and preventive action it takes.**

## Monitoring, Evaluation and Improvement

**23.35 The tissue establishment's processes for monitoring, evaluation and improvement should:**

**(a) show that procedures and outcomes are satisfactory when judged against relevant professional standards**

**(b) show that the assisted conception processes are followed in a way that meets users' needs and requirements**

**(c) ensure conformity of the quality management system, and**

**(d) continually improve the effectiveness of the quality management system.**

**23.36 The tissue establishment shall ensure that third party provided processes, products and services conform to requirements.**

**23.37 The tissue establishment shall determine the controls to be applied to third party provided processes, products and services when:**

**a) products and services from third party providers are intended for incorporation into the tissue establishment's own products and services**

**b) products and services are provided directly to the patients by third party providers on behalf of the tissue establishment**

**c) a process, or part of a process, is provided by a third party provider as a result of a decision by the tissue establishment.**

**23.38 The tissue establishment shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of third party providers, based on their ability to provide processes or products and services in accordance with requirements. The tissue establishment shall retain documented information of these activities and any necessary actions arising from the evaluations.**

**23.39 The tissue establishment shall ensure that third party provided processes, products and services do not adversely affect the tissue establishment's ability to consistently deliver conforming products and services to its patients.**

**23.40 The tissue establishment shall:**

**a) ensure that third party provided processes remain within the control of its quality management system**

**b) define both the controls that it intends to apply to a third party provider and those it intends to apply to the resulting output**

**c) take into consideration the potential impact of the third party provided processes, products and services on the tissue establishment's ability to consistently meet patient and applicable statutory and regulatory requirements and the effectiveness of the controls applied by the third party provider**

**d) determine the verification, or other activities, necessary to ensure that the third party provided processes, products and services meet requirements.**

**23.41 The tissue establishment shall ensure the adequacy of requirements prior to their communication to the third-party provider.**

**23.42 The tissue establishment shall communicate to third party providers its requirements for:**

**a) the processes, products and services to be provided**

**b) the approval of products and services, the methods, processes and equipment and the release of products and services**

**c) competence, including any required qualification of persons**

**d) the third party providers' interactions with the tissue establishment**

**e) control and monitoring of the third party providers' performance to be applied by the tissue establishment**

**f) verification or validation activities that the tissue establishment intends to perform at the third party providers' premises.**

**23.43 The tissue establishment should establish a documented procedure to identify and manage nonconformities and incident findings. These findings should be appropriately investigated and documented to include the following actions taken:**

**(a) remedial or immediate actions**

**(b) root cause analysis to determine the causes of nonconformities**

**(c) evaluating the need for action to ensure nonconformities do not recur**

**(d) promptly determining and implementing action needed**

**(e) recording the results of corrective action taken, and**

**(f) reviewing the corrective action taken and its effectiveness, and**

**(g) risk based thinking and opportunities**

**23.44 When planning for the quality management system, the tissue establishment shall consider the issues and determine the risks and opportunities that need to be addressed to:**

**a) give assurance that the quality management system can achieve its intended results**

**b) enhance desirable effects**

**c) prevent, or reduce, undesired effects**

**d) achieve improvement.**

**23.45 The tissue establishment shall plan:**

**a) actions to address these risks and opportunities**

**b) how to integrate and implement the actions into its quality management system processes and evaluate the effectiveness of these actions.**

**23.46 Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.**

**23.47 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.**

**23.48 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new patients, building partnerships, using new technology and other desirable and viable possibilities to address the tissue establishment's or its patients' needs.**

# 24. Complaints

## Complaint Procedure

**24.1 The tissue establishment should ensure that staff understands the complaints procedure and the right of people to complain.**

**24.2 It may be appropriate to deal with a complaint as soon as it arises, without using a formal complaints procedure. In such cases, staff should deal promptly and thoroughly with issues as they are raised. Staff should treat all complaints seriously and show the complainant due respect, however minor the complaint may appear. Staff should not deter people from making formal complaints if they wish to do so.**

**24.3 The tissue establishment should ensure that staff is given appropriate training in complaints handling and that there are written procedures for:**

**(a) acknowledging and investigating complaints, and**

**(b) collecting suggestions and compliments.**

## The Complaints Officer and Complaints Register

**24.4 The tissue establishment should nominate a member of staff to act as complaints officer. The complaints officer should be:**

**(a) the first point of contact when a person makes a formal complaint, and**

**(b) responsible for investigating complaints and ensuring the complaints procedure operates effectively.**

**24.5 The tissue establishment should display notices prominently to explain the complaints procedure and give the complaints officer's name and contact details. This information should also be given to patients.**

**24.6 The tissue establishment should ensure there is someone else of at least equivalent seniority available to deal with complaints in case a person feels unable to complain to the complaints officer.**

**24.7 The tissue establishment's complaints officer should keep an accurate complaint register. For each complaint, the following should be recorded in the register:**

**(a) what has been done to resolve the complaint**

**(b) all communication with the complainant (including verbal), and**

**(c) the outcome, and any action taken as a result.**

**24.8 The tissue establishment's complaints register should be made available to EPA inspectors during inspections.**

## Investigating Complaints

**24.9 Complaints should be investigated by staff who were not involved in the circumstances that gave rise to the complaint.**

**24.10 If a complainant is unhappy with the outcome of the investigation of their complaint, they should be informed of further action they could take (e.g. going to the EPA or the Ombudsman).**

**24.11 In NHS tissue establishments, the complaints procedure should comply with standards required of NHS services. In private tissue establishments, the procedures should comply with this Protocol.**

# 25. Third Party Agreements

**25.1 A licensed tissue establishment should establish a third-party agreement where a third party is carrying out the following two categories of activity:**

**(a) procuring, testing or processing gametes and embryos, or both, for example:**

**(i) laboratories preparing sperm**

**(ii) Tissue establishments where patients are assessed, given fertility-stimulating drugs and monitored, and eggs are retrieved (transport tissue establishments / tissue establishments)**

**(iii) tissue establishments where sperm is procured**

**(b) supplying goods or services (including distribution services) that may affect the quality and safety of gametes and embryos, for example:**

**(i) companies supplying equipment and materials, eg, suppliers of culture media**

**(ii) companies monitoring air quality in laboratories**

**(iii) clinical or laboratory premises leased from a hospital or other institution, e.g. using theatres for collecting eggs under general anaesthetic**

**(iv) courier companies.**

**25.2 Third party premises may be inspected as part of the EPA process and when investigating adverse incidents. If third party premises are unsuitable, the Embryo Protection Authority will refer to the Licencing Authority so the licence holder's licence may be varied or revoked.**

**25.3 If facilities or services that a third party provides are used in a treatment process, the responsible person for that process should be satisfied that the provider's procedures can be integrated with the tissue establishment's quality system. In particular, the third party's procedures should:**

**(a) allow the entire service to be audited, and samples to be fully traced**

**(b) minimise cross-contamination (where relevant)**

**(c) follow relevant professional guidelines, and**

**(d) ensure that adverse incidents are reported and that any affected gametes and embryos can be effectively recalled.**

## Transport Tissue Establishments / Tissue establishments

**25.4 Transport tissue establishments / tissue establishments should give attention to requirements covering information, counselling, the welfare of the child and confidentiality. The responsible person should put in place effective procedures to ensure such tissue establishments are given relevant information about these requirements and any changes to them, in a clear and timely way. These requirements should form part of a third-party agreement.**

## Third Party Procurement of Gametes and Embryos

**25.5 If a tissue establishment has a third-party agreement with another tissue establishment for procuring gametes and embryos, that tissue establishment should keep extra third-party procurement documents that should include, but not be limited to:**

**(a) identification, name and address of the tissue establishment to receive the gametes**

**(b) patient, patient's partner or donor identification**

**(c) identification of the procured gametes and embryos**

**(d) identification of the staff member responsible for the procurement session**

**(e) date and time of procurement**

**(f) a record of any procedures performed on the gametes and embryos**

**(g) a record of any adverse incidents, and**

**(h) where appropriate, identification or batch numbers (or both) of any reagents and transport media used.**

## Agreements between Licensed Tissue Establishments

**25.6 Where a licensed tissue establishment arranges for any part of treatment to take place at another licensed tissue establishment, the responsible person at the original tissue establishment retains overall responsibility for that treatment. The responsible person at the original tissue establishment should therefore satisfy themselves that treatment arranged at other licensed tissue establishments complies with all relevant legal requirements, quality and safety considerations, and Protocol guidance. This will include giving attention to requirements covering information, counselling, the welfare of the child and confidentiality.**

**25.7 The responsible person at the original tissue establishment should check with EPA regarding any inspection reports about the second tissue establishment, and establish regular written confirmation from the second tissue establishment. Where the original tissue establishment sends a large volume of treatment to a particular tissue establishment, checks should be carried out regularly and no less than annually.**

# 26. Premises, Practices and Facilities

## Definition of Premises

**26.1 The Embryo Protection Authority defines premises as the specific area where a tissue establishment conducts its business, as identified on a floor plan submitted by the tissue establishment to the Embryo Protection Authority.**

**26.2 The tissue establishment should provide the EPA with a floor plan that defines the licensed premises, including the purpose of each room.**

**26.3 The tissue establishment should ensure it can provide ongoing assurance that its premises are fit for purpose, and evidence of:**

**(a) maintenance of lifts**

**(b) fire safety**

**(c) maintenance of ventilation and heating systems**

**(d) electrical safety**

**(e) medical gas safety**

## Moving to New Premises

**26.3 Before moving to new premises, the tissue establishment should contact and inform the Embryo Protection Authority. The tissue establishment should notify the EPA in writing of the intended move, by submitting an application with information about the new premises. The EPA will consider the application and information, and may need to inspect the premises.**

## Changing Existing Premises

**26.4 The tissue establishment should notify the EPA in writing of any planned changes to the premises by submitting, in advance, an application with information on the planned changes.**

**26.5 The EPA will consider the application and information, and may need to inspect the premises.**

## Acquiring Additional Premises

**26.6 If a tissue establishment wishes to conduct licensed activities not subject to a third-party agreement in premises other than those specified on the current licence (e.g. in a different building), it should notify the EPA in writing. The tissue establishment should also submit an application with information about the additional premises.**

## Tissue Establishment Facilities

**26.7 The tissue establishment should provide for the privacy, dignity and respect of all prospective and current patients and donors, as well as providing a safe working environment for all staff. Consultation and the exchange of personal information should be carried out in private (i.e. cannot be overlooked or overheard by others).**

**26.8 The tissue establishment should have facilities for reception, clinical and counselling activity, laboratory work, storage of confidential records, storing gametes and embryos, and staff.**

**26.9 The tissue establishment should display a copy of its Certificate of Licence where it can easily be read by current and potential patients and donors.**

**26.10 The tissue establishment should have appropriate procedures to ensure premises comply with relevant requirements for safety and air quality, and these procedures should be validated.**

**26.11 The responsible person together with clinicians should assess how many treatment cycles can safely be accommodated by the tissue establishment. The assessment should consider the tissue establishment's premises, equipment, staffing levels and the skill mix of staff members. Activity should be adjusted according to the findings of the assessment.**

## Clinical Facilities

**26.12 The tissue establishment should ensure that its clinical facilities:**

**(a) provide privacy and comfort for those:**

**(i) considering donation and seeking treatment**

**(ii) undergoing examination and treatment, and**

**(iii) producing semen specimens.**

**(b) are equipped with backup and emergency clinical facilities that:**

**(i) are equivalent to those provided as standard practice in other medical facilities**

**(ii) are appropriate to the degree of risk involved in any planned procedure, and**

**(iii) can cope with emergencies known to occur in this clinical field.**

## Counselling Facilities

**26.13 The tissue establishment should ensure that counselling facilities provide quiet and comfortable surroundings for private, confidential and uninterrupted sessions.**

## Laboratory Facilities

**26.14 The tissue establishment's laboratories should comply with current professional guidelines, legislation and regulations.**

**26.15 Procedures must be evaluated for hazards to laboratory staff, and precautions put in place to minimise potential hazards.**

## Staff Facilities

**26.16 The tissue establishment should have staff amenities that are easily accessible and include:**

**(a) toilet facilities**

**(b) a rest area with basic catering facilities and a supply of drinking water**

**(c) a changing area and secure storage for personal belongings, and**

**(d) storage for protective clothing.**

## Infection control

**26.17 Infection control policies should ensure that staff and patients are protected from acquiring infections in the course of providing treatment. In particular, these policies should ensure that:**

**(a) there are effective procedures in place for preventing and controlling infections, such as hand decontamination, policies on wearing sterile gloves, dress code, and the safe use and disposal of sharps**

**(b) staff are aware of their role in these procedures**

**(c) a person is identified as the infection control lead for the centre**

**(d) management systems are in place to ensure infection control issues are dealt with.**

## Management of medicines

**26.18 Where controlled drugs are used, tissue establishments should be aware of the legal requirements, and have a controlled drugs accountable officer.**

**26.19 Tissue establishments should have policies and procedures in place for:**

**(a) storing, disposing of, and managing the wastage of medicines, ensuring medicines can be accurately identified, are within date, and are kept safely (to prevent unauthorised access)**

**(b) managing medicine stock, ensuring staff can identify and respond when new stock is needed**

**(c) prescribing and dispensing medicines, ensuring only suitably qualified staff prescribe medicines, patients are given information on the risks and side**

**effects, and patients receive appropriate medicines (taking into account factors such as medical history and allergies)**

**(d) administering medicines, ensuring only suitably qualified staff do so, and patients who self-administer receive clear written and spoken instructions**

**(e) dealing effectively with any emergencies following the administration of medicines by developing appropriate contingency plans.**

**26.20 Centres should ensure they keep accurate records that clearly set out the medication a patient is receiving.**

## The surgical pathway

**26.21 Before doing an operation, tissue establishments should assess the suitability of a patient to have this, including a review of their medical history, allergies and known reactions to medicines.**

**26.22 The consultant anaesthetist or person administering the sedative should review the patient's notes before an operation. This review should take into account that patients having operations, under either general anaesthetic or sedation, are at risk of compromise to airway, breathing and circulation. There should be an anaesthetic chart in the patient's notes, containing information such as:**

**(a) known drug allergies**

**(b) previous problems with anaesthetics or sedatives**

**(c) airway assessment**

**(d) whether the patient is taking any regular medication**

**(e) any post-operative instructions (eg, whether the patient will need antibiotics).**

**26.23 When doing a surgical procedure, tissue establishments should ensure that they:**

**(a) use a theatre check list**

**(b) monitor the patient before inducing the anaesthetic or sedative, and throughout the procedure**

**(c) have contingency plans in case problems arise during an operation, such as a severe allergic reaction or major bleeding**

**(d) have a contingency plan is case that patient needs to be admitted to a hospital in emergency situations**

**(e) have a discharge policy, ensuring that patients are discharged appropriately and by suitably trained staff.**

**26.24 Tissue establishments should keep accurate documentation about the operation undertaken, including the anaesthetic or sedative given, and details of patient monitoring.**

**26.25 Tissue establishments should ensure patients receive safe and appropriate post-operative care in line with professional guidelines. Where a general anaesthetic or sedative is used, Tissue establishments should have a fully equipped recovery area, staffed by recovery staff trained to professional standards. Second recovery areas should provide close and continued supervision of all patients, who should be visible to the nursing staff.**

**26.26 Where recovery areas are not available or not required, Tissue establishments should consider how they can be sure that the relevant staff and equipment are in place for safe post-operative care.**

**26.27 Tissue establishments should ensure that their procedures are suitable for the type of anaesthetic or sedative provided.**

**26.28 Tissue establishments should ensure that only an appropriately qualified person provides an anaesthetic.**

**26.29 If an anaesthetic is used at remote sites, Tissue establishments should have a resuscitation team led by an Advanced Life Support provider. Where this is not the case, the anaesthetists should provide competency-based evidence of their ability to provide both advanced life support and the safe transport of a patient requiring multi-system support**

## Safeguarding

**26.30 Tissue establishments are expected to have a policy and procedures for safeguarding those who use their services. These should set out what staff should do if they suspect that a person has been abused, neglected or harmed in any way. The policy and procedure should include:**

**(a) a statement of roles and responsibilities, authority and accountability that is specific enough to ensure all staff understand their roles and limitations**

**(b) how to deal with allegations of abuse, including procedures for providing immediate protection in emergency situations, assessing abuse and deciding when intervention is appropriate, and reporting suspicions to the Embryo Protection Authority and police when necessary**

**(c) what to do if necessary action is not taken**

**(d) a comprehensive list of points of referral, explaining how to access support, advice and protection at all times (including outside normal working hours), with contact addresses and telephone numbers**

**(e) how to record allegations of abuse, any investigations and subsequent action**

**(f) a list of sources of expert advice**

**(g) a full description of channels of inter-agency communication, for example with local authorities, and procedures for decision making**

**(h) a list of all services that might offer victims access to support or redress.**

**26.31 Tissue establishments should review procedures annually, or more often to incorporate any lessons learned or changes to legislation.**

**26.32 Tissue establishments should provide training for staff on the safeguarding policy and their responsibilities, including:**

**(a) awareness that abuse can happen, and the duty to report this**

**(b) recognition of abuse, and responsibilities for reporting this.**

**26.33 If abuse, neglect or harm is suspected, it may be in the best interests of the individual to disclose confidential patient information. The safeguarding policy should set out the principles governing the sharing of information. These principles can be summarised as follows:**

**(a) Information should be shared only on a 'need to know' basis, when it is in the best interests of the patient or donor.**

**(b) Confidentiality and secrecy are two different things.**

**(c) The individual should give informed consent to disclosure, but if this is not possible, it may be necessary to disclose personal or sensitive personal information, despite a duty of confidentiality or legislation that would ordinarily prohibit disclosure.**

**(d) It is inappropriate to give assurances of absolute confidentiality in cases where there are concerns about abuse.**

**(e) Exchange or disclosure of personal information should be in line with the General Data Protection Regulation (GDPR) where this applies.**

# 27. Equipment and Materials

**27.1 For the purpose of this Protocol, 'equipment and materials' includes all equipment, disposables, reagents, and calibration and control materials used in the conduct of assisted procreation processes.**

## Protection and Hygiene of Staff

**27.2 The tissue establishment should provide proper clothing and equipment for the personal protection and hygiene of staff carrying out licensed activities, together with written instructions for their use.**

### Managing Equipment and Material

**27.3 The tissue establishment should establish documented procedures for managing equipment and materials, including:**

**(a) selecting and procuring equipment and materials**

**(b) ensuring the traceability of any products or materials that come into contact with gametes or embryos and that affect their quality and safety, and**

**(c) maintaining inventory information and records for stock control.**

**(d) ensuring software-driven equipment is effectively validated, and revalidated after any software update.**

## CE marking

**27.4 The tissue establishment should use only media and consumables that have been CE-marked at a classification suitable for their intended purpose. Modifying existing devices (for example, adding calcium ionophore to culture medium) or using them 'off label' for purposes not intended by the manufacturer (for example, using a medium for a different purpose from that specified) has safety implications.**

## Safety of Equipment used to Store Cryopreserved Gametes and Embryos

**27.5 All tissue establishments storing gametes and embryos should have effective alarms and monitoring systems to ensure the safety of cryopreserved gametes and embryos. These systems should have:**

**(a) local alarms (i.e. on individual dewars for either temperature or liquid nitrogen level)**

**(b) an auto-dial facility or similar (e.g. link to fire-alarm board) to contact staff outside normal working hours**

**(c) adequate staffing and funding to implement formal emergency procedures, including having on-call arrangements, and**

**(d) adequate spare storage space or vessels to enable transfer of samples if a vessel fails.**

# 28. Adverse Incidents

## Definitions

**28.1 An 'adverse incident' is any event, circumstance, activity or action which has caused, or has been identified as potentially causing harm, loss or damage to patients, their embryos and/or gametes, or to staff or a licensed tissue establishment. This includes serious adverse events, serious adverse reactions, breaches of confidentiality, and ovarian hyper stimulation syndrome (OHSS) which has a severity grading of severe or critical.**

**28.2 A serious adverse event is defined as:**

**(a) any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of gametes or embryos intended for human application and which, in relation to a person who receives treatment services or non-medical fertility services–**

**(i) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or**

**(ii) might result in, or prolong, hospitalisation or illness, or**

**(b) any type of gametes or embryo misidentification or mix-up'.**

**28.3 A serious adverse reaction is defined as:**

**An unintended response, including a communicable disease, of gametes intended for human application or a person who receives treatment services or non-medical fertility services, which may be associated with the procurement or human application of gametes or embryos and which is fatal, life threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or illness.**

**28.4 A 'near miss' is an occurrence that, but for luck, skill or judgment, would in all probability have become an adverse incident.**

## Reporting and Timescales

**EPA requires tissue establishments to report all adverse incidents and near misses to the EPA. This includes adverse incidents occurring at third party premises, where there is a third-party agreement in force between the tissue establishment and that third party.**

**Tissue establishments must report all adverse incidents or near misses to the EPA by telephone within 12 working hours of their identification. This verbal notification must include the:**

**(a) tissue establishment's name**

**(b) tissue establishment identification number**

**(c) contact details of the person responsible**

**(d) date of the initial notification or report**

**(e) name of any individual affected**

**(f) date and time of the adverse incidents and near misses**

**(g) details of gametes or embryos involved in the incident, and**

**(h) type of incident, including any transmission of infectious agents.**

**28.5 In addition, the tissue establishment must inform the EPA in writing of all adverse incidents or near misses occurring at that tissue establishment (or, if the event relates to treatment that involves a third party, at a tissue establishment with which it has a third-party agreement) by completing an adverse incident form.**

**28.6 The tissue establishment's documented procedures should ensure that any adverse incident or near miss that may result in harm to the patient, patient's partner or donor is recorded and reviewed.**

**28.7 If an adverse incident or near miss occurs, tissue establishments are expected to:**

**(a) review relevant procedures to minimise the risk and avoid re-occurence of the incident happening again, and**

**(b) inform the EPA of the revised procedures.**

**28.8 When investigating serious adverse events and reactions, the tissue establishment should evaluate all assisted procreation processes directly related to the adverse event, and all relevant processes involving the:**

**(a) management of resources**

**(b) training and competence of staff**

**(c) equipment**

**(d) materials**

**(e) information systems, and**

**(f) control of environment.**

**A copy of the investigation report should be submitted to the EPA.**

**28.9 When reporting cases of OHSS with a severity grading of severe or critical the tissue establishment must complete the OHSS incident report on the EEART platform within 5 working days from occurrence.**

**28.10 The Authority also expects tissue establishments to report adverse incidents that arise from the use of equipment and materials, to the EPA.**

**28.11 The Authority also expects tissue establishments to report adverse incidents that arise from the use of equipment and materials. Reports of this nature should be sent to the EPA. An 'adverse incident' in this context is an**

**incident that produces, or has the potential to produce, unwanted effects involving the safety of patients, users and others.**

**28.12 The tissue establishment should, in line with professional body guidance, inform patients and patient's partner where applicable, of any adverse incidents that may have resulted in harm to them, their gametes or their embryos.**

# 29. Confidentiality and Privacy

## Confidentiality

**29.1 Tissue establishments must treat all patients with dignity and respect and must take appropriate measures to maintain their confidentiality.**

**29.2 The tissue establishment should ensure that information provided in confidence, including all information relating to donors, patients and children born as a result of treatment, is kept confidential and disclosed only in the circumstances permitted by law. The tissue establishment should ensure that patients, their partners, and donors do not have access to any other person's records without first getting that person's consent.**

**29.3 If the tissue establishment is in doubt about whether a proposed disclosure is lawful, it should seek independent legal advice.**

## Breach of Confidentiality

**29.4 If confidentiality is breached (including disclosure of information in breach of either the Embryo Protection Act, the General Data Protection Regulation (GDPR), the tissue establishment should consider it an adverse incident and therefore investigate the cause(s) of the breach, take appropriate remedial action, and notify and submit a full explanation to the EPA. This is to include what mitigating actions have been put in place to prevent a similar breach taking place.**

**Consideration should also be given, depending on the level of risk to the data subject, to whether the breach should be reported to the Commissioner of Data Protection, and whether any patients affected by the breach should be informed, particularly if their sensitive personal data (including 'special category data') has been disclosed or if there is a risk of detriment to the patient.**

## Access to Medical Records

**29.5 For the purposes of this Protocol, a record is defined as information created, received and maintained as evidence by a tissue establishment or person, in meeting legal obligations or in transacting business. Records can be in any form or medium provided they are readily accessible, legible and indelible.**

**29.6 The tissue establishment must establish a documented procedure for controlling access to medical records. This should ensure that arrangements are in place for:**

**(a) properly identifying applicants**

**(b) promptly considering and responding to applications for access to confidential records**

**(c) a designated individual in the tissue establishment being responsible for receiving, checking and arranging authorised access to confidential records**

**(d) giving all individual patients and donors who provide information about themselves access to their own individual records of that information and an opportunity to correct any information that is incorrect**

**(e) ensuring proper procedures are in place to maintain confidentiality when records are stored off site, and**

**(f) ensuring that individuals are aware of their rights under the Data Protection Act to access their own medical records.**

**NOTE: When the tissue establishment is part of a larger organisation, the appropriate department of the parent organisation may do some of these procedures, where relevant.**

**29.7 The tissue establishment should have clear security procedures to prevent unauthorised access to records, and take particular care if records are kept outside the licensed premises (eg, when counselling takes place outside the tissue establishment). The security procedures should be appropriate to the record keeping system, whether paper-based, electronic or in any other format. Extra scrutiny is recommended if the tissue establishment has laboratory equipment that stores patient-identifying information electronically.**

**29.8 To mitigate the risks of unauthorised people inadvertently gaining access to patient-identifying information through electronic records, the tissue establishment should:**

**(a) ensure that such information cannot be transferred to portable media-storage devices**

**(b) ensure that when hardware is removed from the premises, identifying information has been removed**

**(c) consider making it a policy that no data is stored on any third-party device unless there is a process for anonymising or deleting the data**

**(d) record and audit potential access to identifying information**

**(e) have systems in place to reduce the risks of malicious access to data; these systems should include anti-virus software, firewalls, and network segmentation (including user-/network-level usernames and passwords)**

**(f) know what software is installed on tissue establishment systems and what it allows**

**(g) ensure agreements/contracts with the relevant providers set out expectations.**

**29.9 If the tissue establishment's service providers require access to identifying information to do their job, then the tissue establishment must take steps to ensure that any person accessing data is suitable.**

**29.10 A person whose medical records are held by the tissue establishment is normally entitled to receive a copy of their own medical records, so long as they ask in writing (including by electronic means). The source of the information and an explanation of any unusual or technical terms should be given.**

## Requests under the Data Protection Act

**29.11 The tissue establishment should comply promptly with 'access requests' made under the Data Protection Act. Usually, such requests will be for copies of medical records. The tissue establishment must check the identity of the person making the request and may also request written consent and proof of identity from the partners of applicants if the medical record contains information relating to them.**

## Disclosing Non-Identifying Information: General

**29.14 The tissue establishment may disclose information that does not identify or could not reasonably be expected to lead to the identification of a person owed a duty of confidentiality. If the tissue establishment is unsure whether information it proposes to disclose could identify the person, it should seek independent legal advice.**

## Authorised Disclosure

**29.15 If the tissue establishment refers a person seeking treatment to another licensed tissue establishment, it should provide relevant information in line with good clinical practice. The tissue establishment must always supply information relevant to the welfare of the child.**

**29.16 Before obtaining consent to disclose information, the tissue establishment should give the person enough information for them to make a properly informed decision, including:**

**(a) precisely what information is to be disclosed**

**(b) the terms on which it is to be disclosed**

**(c) the reasons for disclosure (e.g. to keep the person's GP informed about the fertility treatment)**

**(d) the implications of disclosure,**

**(e) the categories of people to whom the information is to be disclosed.**

**29.17 The tissue establishment should seek consent to disclosure to the following categories of people:**

**(a) the patient's GP or the patient's partner's GP**

**(b) other healthcare professionals outside the tissue establishment (provide the patient or the patient's partner with the best possible medical care)**

**(c) auditors or administrative staff outside of the tissue establishment (so they can perform functions designated to them in connection with the tissue establishment's licensable activities), and**

**29.18 The tissue establishment should renew consent to disclosure if the nature of the treatment changes after initial consent has been given.**

**29.19 The tissue establishment should ensure that people to whom they disclose identifying information know that the information remains protected by the existing common law on confidentiality. Those receiving information should also be told:**

**(a) the precise terms upon which it was disclosed and for which consent has been given, and**

**(b) that if they disclose the information they have received, a child might learn in an inappropriate way that they were born as a result of fertility treatment.**

# 30. Record Keeping and Document Control

## Records to Keep

**30.1 This guidance note does not summarise all the record keeping requirements of a licensed tissue establishment. The responsible person should familiarise themselves with the Chapters, which have been discussed in the guidance notes of this Protocol as well as refer to the Embryo Protection Act 2012, the Embryo Protection (Amendment) Act 2018, and the Various Laws relating to Assisted Procreation (Amendment) Act 2022, requirements.**

## Definitions

**30.2 A record is hereby defined as 'information created or received, and maintained as evidence by a tissue establishment or person, in meeting legal obligations or in transacting business. Records can be in any form or medium providing they are readily accessible, legible and indelible.'**

**30.3 A documented procedure is hereby defined as 'a set of written instructions describing the steps in a specific process, including the materials and methods to be used, and the expected end product. This term has the same meaning as standard operating procedures.'**

## Document Control

**30.4 The tissue establishment should have document control procedures in place to:**

**(a) ensure that all documents include:**

**(i) a unique identifier (for instance, the edition, or current revision date or revision number)**

**(ii) page numbers and total number of pages (e.g. 'page 5 of 10')**

**(iii) authority for their issue, and**

**(iv) author identification**

**(b) control all records required to:**

**(i) provide evidence of conforming to legal requirements**

**(ii) operate the quality management system effectively, and**

**(iii) conduct assisted conception processes.**

**The procedures must cover the identification, collection, indexing, access, storage, maintenance, confidentiality and safe disposal of records.**

**30.5 When a tissue establishment's document control system allows documents to be amended by hand pending their re-issue, the procedures and authority for such amendments should be defined; amendments should be clearly marked, initialled and dated; and a revised document should be re-issued as soon as practicable.**

**30.6 Documents should be reviewed, revised and reapproved at a frequency that ensures they remain fit for purpose. The maximum interval between reviews should be 12 months.**

**30.7 Access to registers and data must be restricted to people authorised by the responsible person and the EPA for inspection purposes.**

**Managing Information**

**30.8 The tissue establishment should establish documented procedures for managing data and information. These should include:**

**(a) accurate recording of information**

**(b) security of data and safeguards against unauthorised modification, addition, deletion, disclosure or transfer of information**

**(c) resolution of data discrepancies**

**(d) maintenance and disaster recovery**

**(e) storage, archiving and retrieval, and**

**(f) secure disposal.**

**30.9 If using off-site storage facilities for archived records, the tissue establishment should establish procedures to ensure patient confidentiality is maintained. These should include:**

**(a) removal of all patient identifying information that might be visible to staff outside the licensed tissue establishment, and**

**(b) ensuring files are properly sealed when they are being transported between the tissue establishment and storage facility**

# 31. Obligations and Reporting Requirements of Tissue Establishments

**31.1 One of the functions and powers of the EPA as stated in Article 4 of the Act is to carry out inspections in order to ensure that the standards of best practice are being respected and implemented and that all information and documentation required under article 18 of the Act is being kept appropriately and for this purpose to access clinics and any other places as necessary.**

## Legal Obligations toward the EPA

**31.2 Tissue establishments have various legal obligations toward the EPA. The responsible person should familiarise themselves with these, which include:**

**(a) allowing EPA inspectors to enter tissue establishment premises or relevant third-party premises at all hours**

**(b) allowing EPA inspectors to inspect tissue establishment or relevant third-party premises, including inspecting equipment and records, taking away copies of records and other required items, and observing any activity, and**

**(c) notifying the EPA of any new activities or treatment services, before those services or activities are carried out.**

**31.3 The law also requires tissue establishments to provide certain information to the EPA, either on request or at intervals or by deadlines specified by EPA. This includes information relating to:**

**(a) the quality or safety of gametes and embryos**

**(b) the traceability of gametes and embryos**

**(c) adverse incidents and near misses**

**31.4 It shall be the duty of every licensee to keep a confidential register with full details of every medically assisted procreation procedure including IUI's, germ line cell donation, cryopreservation of germ line cells and cryopreservation of embryos in terms of the Embryo Protection Act and to pass on this information to the Embryo Protection Authority without delay**

**(a) register information, including:**

**(i) registration information for donors, patients and patients' partners (where applicable)**

**(ii) information on the intention to treat**

**(iii) IVF treatment and embryo creation information**

**(iv) treatment outcome information.**

## Collecting and recording information for the EPA

**31.5 The responsible person should ensure that mechanisms used to monitor data collection, recording and submission are regularly reviewed to ensure that requirements are met.**

**31.6 The responsible person should ensure that checks on the quality of data submitted to the Embryo Protection Authority include reconciliation of Register data to source documentation (ie, patient and donor records) held by the tissue establishment. Some system and process errors may be identified only in this way.**

**31.7 The responsible person should inform the Embryo Protection Authority, immediately, if staff move out of the tissue establishment. Such a move may mean that staff will still have access to previous data, (ie, patient and donor registration, and linked gamete source/treatments and pregnancy outcomes) of patients, if such information does not reach EPA on time, to block the staff from being a user on the EEART platform.**

**31.8 The responsible person should tell the Embryo Protection Authority as early as possible, if they expect to close the tissue establishment, and should make adequate arrangements for:**

**(a) accessing and storing patient and donor records in the future**

**(b) submitting outstanding information to the Authority, and**

**(c) providing outcome data that will be pending when the tissue establishment closes.**

## 32. Fees to be paid to the Embryo Protection Authority (EPA) by all Service Providers of Tissue Establishments / Clinics both Public and Private

**32.1 The Embryo Protection Authority is funded from a combination of fees from the sector it regulates and from the Government Budget. In line with moving forward so that the Authority become totally autonomous, it is envisage that fees from the sector will cover the majority of the full cost of Regulation, with the vision that when the number of cycles increase these will fully fund the cost of regulation.**

**32.2 The EPA does not charge individual patient for fertility treatment. It is the Service Providers of Tissue establishments both public and private, that pay a fee to the EPA towards the costs of being regulated and inspected.**

**32.3 The Annual fees must be paid on 2nd January of each year, while the procedure and storage fees will be paid on the submission of forms and reports within a month from procedure / storage taking place.**

**32.4 Hereunder list of Fees coming into effect on date of publication of this Protocol.**

**32.5 Annual Fees:**

**IVF treatment and storage tissue establishments**

- **Annual Fee € 1500.00**

**Storage only tissue establishments**

- **Annual Fee € 500.00**

**IUI treatment centres**

- **Annual Fee € 500.00**

**32.6 Recurrent Fees:**

**IUI Treatment using partner gametes**

- **No fee will be charged**

**IUI Treatment using donor gametes**

- **€100.00 per procedure performed irrespective of outcome**

**IVF/ ICSI treatment using partner gametes**

- **€ 175.00 per procedure performed irrespective of outcome**

**IVF/ ICSI treatment using donor gametes**

- **€ 200.00 per procedure performed irrespective of outcome**

**Embryo Transfer procedures**

- **€ 150.00 per procedure performed irrespective of outcome**

**TESA/PESA procedures for surgical extraction of sperm**

- **€ 100.00 per procedure performed irrespective of outcome**

**Biopsy prior to PGTM procedures**

- **€ 50.00 per embryo biopsied irrespective of outcome**

**Storage of Gametes including storage after movement from other tissue establishments and storage of donor gametes after distribution/importation**

- **€ 80.00 per storage procedure performed irrespective number of oocytes/sperm stored**

**Embryo Cryopreservation including storage after movement from other tissue establishments**

- **€ 325.00 per embryo cryopreserved**

**32.7 Variation Fees:**

**All Tissue establishments – Variation to services or Change of Premises**

- **€ 1000.00 for each change**

**This Protocol has been compiled and approved by the members of Embryo Protection Authority during the Authority's Board meetings.**

**Embryo Protection Authority Board is composed of:**

| | |
|---|---|
| **Chairman** | **The Hon. Mr Justice Philip Sciberras LL.D, UOM** |
| **Vice Chairperson** | **Ms. Josephine Abdilla MBA Henley, DIP Mang. Henley** |
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| **Authority Secretary** | **Ms. Moira Gialanze'** |

**This Protocol has been submitted to the Deputy Prime Minister and Minister for Health to be published together with a Legal Notice and to the Chairperson of the Health Committee of the House of Representatives to be discussed at the Health Committee and placed on the Table of the House of Representatives of the Parliament of Malta.**

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