

Annex I: Summary of changes to the Code of Practice in October 2021

2nd update to the 9th edition

Legislative changes

Since the Code of Practice was last updated in 2019 there have been legislative changes that now need to be incorporated into the Code. We have already communicated these changes to licensed clinics through Chair's Letters, and the requirements are already in force.

EU Exit

Guidance note 15: Procuring, processing and transporting gametes and embryos

Guidance note 16: Import and exports

Guidance note 19: Traceability

Guidance note 26: Equipment and materials

Guidance note 30: Confidentiality and privacy

Following the United Kingdom's (UK) exit from the European Union (EU) and the introduction of [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2019](#) and [2020](#), certain provisions now apply in relation to Northern Ireland (NI) only and, in some instances, to Great Britain (GB) only. Additionally some Standard Licence Conditions (SLCs) have been amended to reflect changes in the legislation necessitated by EU Exit, these include T20, T30, T31, T51 T53, T100 and T101. The Code has been updated to reflect these changes including:

- That the Single European Code is now only a requirement for centres in NI (though centres in GB can continue to use it).
- That the requirements for import certification are now different depending on if the sending/receiving centre is located in GB or NI.
- Introduction of the UKCA mark for new medical devices placed on the market in GB after 30 June 2023, and the UK(NI) mark which should go along with the CE mark for new medical devices certified for the market in NI by a UK notified body.
- Introduction of UK GDPR which brings EU GDPR into UK law.

Clinics should already be compliant with the 2019 and 2020 Regulations. For more information, please see the Chair's letters sent to all clinics in [December 2020](#) and [June 2021](#). New clinic Licences were activated on 1 July 2021.

Storage: COVID-19 Regulations

Guidance note 17: Storage of gametes and embryos

To address difficulties arising due to the COVID-19 pandemic and fertility clinics being temporarily closed in April 2020, [The Human Fertilisation and Embryology \(Statutory Storage Period for Embryos and Gametes\) \(Coronavirus\) Regulations 2020](#), were introduced and came into force in July 2020. These Regulations make changes to section 14 of the 1990 Act as well as to the 2009 Regulations which enable patients who satisfy certain requirements to store their gametes or embryos for a further two-year period. Guidance has been added to guidance note 17 on the Coronavirus regulations, including some examples of scenarios where extension of storage would be permissible.

More detailed guidance has also been added on the correct application of the 2009 Regulations as they apply to gametes and embryos first placed in storage both prior to 1 October 2009 when the regulations came into effect.

Clinics should already be compliant with the 2020 COVID Regulations. For more information, please see the Chair's letter sent to all clinics in [June 2020](#).

Main changes

More substantive changes to guidance which will be added to the Code in order to build upon and clarify areas of existing HFEA guidance. These areas have been identified through enquiries with the sector and discussions with HFEA staff and stakeholders.

Definition of a family for the 10-family limit

Guidance note 11: Donor recruitment, assessment and screening

Guidance note 20: Donor assisted conception

The HFEA policy states that donor gametes should not be used to create more than 10 families (or any lower limit specified by the donor). We have received queries from a number of clinics about how we define a family under the limit, specifically in scenarios where a couple who conceives a child using donor sperm separate, and one or both parties return to a clinic seeking further treatment using the same donor, alone or with a new partner. It is not always clear to clinics whether in these circumstances each person having treatment would be creating a new family, or whether this should be considered an extension of the existing family.

Guidance has been updated in the following ways:

- To add a definition which states that a 'family' under the 10-family limit is defined as the patient to be treated and their partner (if they have one) and any existing legal child or children of either partner.
- To include examples of scenarios where the definition may be useful.
- To add that before any consents or samples are obtained from a prospective donor, the recruiting centre should provide information about how a family is defined under the 10 family limit.
- To add that as part of discussions about the implications of using donated gametes or embryos, centres should explain to prospective patients the 10-family limit and how a family is defined.

Guidance on the use of electronic consenting platforms

Guidance note 5: Consent to treatment, storage, donation, training and disclosure of information

New technology and the introduction of electronic consenting (e-consenting) platforms, as well as the effect of COVID-19 and the increase in virtual consultations has increased the use of and demand for e-consent in UK fertility clinics. We have introduced a section entitled 'Guidance for centres considering introducing electronic methods of taking consent' to guidance note 5 on Consent to explain what we expect from clinics using e-consenting including:

- The need to ensure platforms are reliable, validated, quality assured and risk-assessed.
- The importance of processes being in place to verify that consent is given by the correct person, and that patients have secure access to clinic staff who can answer questions.
- The need for platforms to have inbuilt security measures, individual accounts, replicate HFEA consent forms exactly, and use qualified electronic signatures.
- The need for centres to have procedures in place to ensure that there is a clear record of what patients has consented to if both paper and electronic consents have been used, particularly if consent is varied or withdrawn.

Legal parenthood when relationships break down and patients return for further treatment

Guidance note 6: Legal parenthood

Legal parenthood can be complex, particularly when relationships break down and patients return for further treatment, and generates many enquiries from clinics and patients. To help clinics in these situations we have updated our guidance to:

- Highlight the importance of centres recording whether a patient is married or in a civil partnership when she comes for treatment alone.
- Make clear that a woman can only withdraw consent to her partner being the child's legal parent if donor sperm or embryos are used in the treatment and the woman and her partner are not married or in a civil partnership and only before the sperm or embryo(s) are placed in the woman.
- Include additional guidance on difference in legal parenthood when a woman has a male or female civil partner or spouse, versus when she has a partner who is not a civil partner or spouse.

Witnessing

Guidance note 18: Witnessing and assuring patient and donor identification

Currently our witnessing guidance requires that centres use a patient's or donor's full name and one or more additional identifier. Not using a third identifier may result in a risk of misidentification of a sample, and we encourage centres to have systems in place to minimize this risk. Instead of allowing processes which may introduce risk, this update will now require centres to use a patient's or donor's full name and two additional identifiers.

Additionally, we have added to 18.4 to include a witnessing step when donor gametes or embryos are allocated to a patient.

Medicines management

Guidance note 25: Premises, practices and facilities

Medicines management is an area in which we have seen a high number of non-compliances on inspection. To help reduce non-compliances in this area we have provided additional guidance:

- To include that clinics should be aware of and comply with relevant regulations, best practice, and professional body guidance pertaining to medicines management and controlled drugs, and have awareness and understanding of the relevant legal requirements.
- To include that clinics should have a controlled drug register and that entries in the register satisfy the relevant legal requirements for record-keeping in respect of controlled drugs.
- That clinics should ensure that controlled drugs are only accessible to authorised persons, and should be aware of and comply with waste management regulations relating to the disposal of controlled drugs.
- We have additionally added many more reference links under the 'Other legislation, professional guidelines and information' section.

Smaller changes

Smaller additions to our Code of Practice, mostly incorporation of guidance or information previously communicated through our Clinic Focus newsletter.

Reference to CMA guidance on consumer law for the fertility sector

Guidance note 4: Information to be provided prior to consent

The Competition and Markets Authority (CMA) and the Advertising Standards Authority (ASA) have published [new guidance](#) for fertility clinics in the UK, which explains what clinics should do to make sure their terms and practices are fair under consumer law and how to ensure compliance with advertising codes. We have referred to this guidance in guidance note 4 to provide more guidance on obligations under Consumer Protection and contractual arrangements, which has been taken from the CMA guidance on consumer law for the fertility sector.

Additional information about add-ons

Guidance note 4: Information to be provided prior to consent

Due to our continued work on add-ons, we have included additional references to what information should be provided about treatment add-ons.

Storing gametes and embryos that have been imported into the UK

Guidance Note 17: Storage

Guidance from a July 2019 [clinic focus article](#) about storage periods for imported gametes and a February 2021 [clinic focus article](#) providing clarification on how to calculate storage periods for gametes and embryos that may have been exported then re-imported back into the UK.

Storage when legal proceedings are threatened or commenced

Guidance note 17: Storage

Guidance from a 2003 [Chair's Letter CH\(03\)03](#) about withdrawal of consent and ongoing storage when legal proceedings are threatened or commenced.

Exporting gametes or embryos for patients seeking commercial surrogacy abroad

Guidance note 14: Surrogacy

Guidance from a December 2020 [clinic focus article](#) providing clarification about whether, or in what circumstances, it is possible to export gametes or embryos for surrogacy, particularly when patients intend entering into commercial surrogacy arrangements abroad.

Disclosure of medical records of a deceased patient

Guidance note 30: Confidentiality and privacy

Guidance from an August 2020 [clinic focus article](#) providing clarification on key points to consider if centres receive a disclosure request for the medical records of a deceased patient at their clinic.

Corrections, clarifications and minor amendments

The following corrections and minor clarifications have been made:

- Preimplantation Genetic Screening (PGS) terminology change to Preimplantation genetic testing for aneuploidies (PGT-A) and Preimplantation Genetic Diagnosis (PGD) terminology change to Preimplantation genetic testing for monogenic/single gene disorders (PGT-M) and Preimplantation genetic testing for Structural Rearrangement (PGT-SR). This includes changing the name of Guidance Note 9.
- Inclusion of other Clinic Focus articles, Chair's Letters and other guidance under the 'Other legislation, professional guidelines and information' section of guidance notes.