Directions given under the Human Fertilisation and Embryology Act 1990 (as amended) [Specific to clinics in Northern Ireland]

Traceability (Northern Ireland)

Ref: 0013(NI)
Version: 1

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 24(12)(a),(b),(c) and (d) and 24(12A) of the Human Fertilisation and Embryology Act 1990 (as amended) and Regulation 6 of the Human Fertilisation and Embryology (Amendment) Regulations 2018
These Directions come into force on:	31 December 2020 at 11pm
These Directions remain in force:	Until revoked
This version was issued on:	15 December 2020

Sally Cheshire CBE 15 December 2020

Chair of the Human Fertilisation and Embryology Authority

Version control	
Name of Directions:	Traceability (Northern Ireland)
Reference number:	0013(NI)
Date version 1 issued:	15 December 2020
Chair's Letter reference:	CH(20)02

1. Licensed centres in Northern Ireland must establish, implement and comply with documented procedures to ensure that:

   (a) all gametes and embryos, and
   (b) all relevant data relating to anything coming into contact with those gametes or embryos are traceable from procurement of gametes to patient treatment or disposal and vice versa.

2. The documented procedures referred to in paragraph 1 above should include the following information:

   (a) the unique and accurate identification of each patient/donor;
   (b) the unique and accurate identification of each set of gametes and embryos;
   (c) date of procurement;
   (d) place of procurement;
   (e) type of treatment;
   (f) description and origin of any and all products associated with the procurement, processing, use and storage of gametes and embryos, and
   (g) description of all processing applied to the procurement, use and storage or gametes and embryos.

3. Licensed centres in Northern Ireland must apply the Single European Code (SEC) to all gametes and embryos before distribution for human application to another licensed centre in Northern Ireland or within the EEA, except where:

   (a) the gametes or embryos are for 'partner donation'; defined as the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship; or
   (b) the embryos or gametes concerned were first placed in storage on or before 29 October 2016 and the gametes or embryos will be transported or delivered before 30 October 2021.

4. 'Distribution', in relation to gametes or embryos intended for human application, means transportation or delivery.[1]

Single European Code

5. The structure of the SEC shall be as follows:

[1] Section 2(1) of the Human Fertilisation and Embryology Act 1990, as amended. Where gametes or embryos are provided at a licensed centre, the subsequent use in treatment at the same centre does not amount to distribution.

Donation identification sequence			Product identification sequence		
ISO Country code[1]	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 letters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters yyyy/mm/dd
XI	**000123** HFEA Licensed Centre number	**00000000XX456** the Clinic's donor registration 'number' and a donation event-specific identifier, which together function as a unique donation number or code	**E0000059** 1 of 5 for reproductive cells (EUTC system) -Embryos (56) -Sperm (59) -Oocytes (57) -Ovarian tissue (58) -Testicular tissue (60)	**001** If sperm, for example, is distributed to more than one TE	**20181231** Date of expiry of consent, for example, 31 December 2018
SEC XI00012300000000XX456 E000005900120181231					

[1]The country code applied to licensed centres in Northern Ireland changed from GB to XI at 11pm on 31 December 2020.

6. Licensed clinics must use one of the following coding platforms to formulate the SEC
(a) The EU coding platform, which is available at https://webgate.ec.europa.eu/eucoding/reports/te/index.xhtml and incorporates the EU Tissue Establishment Compendium;

(b) ICCBBA 1SBT128 https://www.iccbba.org;

(c) Eurocode IBLS http://www.eurocode.org/

7. In all cases the 'unique donation number' must be the unique HFEA donor registration number and a donation event-specific identifier, which is applied by the licensed centre and submitted to the HFEA further to the donor registration process, preceded by zero(s) – as necessary such that it is formed of 13 alpha-numeric characters.

8. The 'expiry date' shall be the date on which the patient's consent to storage and use expires. This date will be sourced from the patient consent form.

9. Once the SEC is allocated the donation identification sequence must not be altered unless there is an encoding error. If this happens, a new code should be correctly issued and a record should be kept of the error and amended code.

10. The SEC must be attached to the container of the gametes/ embryos (straws, dishes, vials, ampoules, tubes etc) or where that is not possible it must be attached to the accompanying documentation and linked to it.

11. The SEC must be eye-readable. If a bar code is used, it must be accompanied by the SEC. When printed the 'donation identification sequence' and 'product identification sequence' must be separated by a space or displayed as two successive lines. The SEC must be preceded by the acronym "SEC".

SEC XI00012300000000XX456 E000005900120181231

12. The SEC shall not be submitted to the HFEA as part of the licensed centre's treatment data submission obligations set out in General Direction 0005.

13. A licensed centre must notify the HFEA when:
    (a) information about the centre, which is contained in the EU Tissue Establishment Compendium, requires update or correction;

    (b) the EU Tissue and Cell Product Compendium requires an update; or

    (c) the licensed centre identifies a situation of significant non-compliance with requirements relating to the SEC concerning embryos and gametes received from other EU tissue establishments.

Requirements as to labelling where the SEC does not apply

14. Where the circumstances in paragraph 1 (b) of these Directions apply or the use of the SEC is not required, the licensed centre must ensure that a uniquely identifying patient/donor code is attached to the container of the gametes/ embryos (dishes, vials, ampoules, tubes etc) or where that is not possible, attached to the accompanying documentation and linked to it.