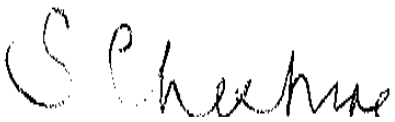
Directions given under the Human Fertilisation and Embryology Act 1990 (as amended) [Specific to clinics in Great Britain]

Traceability (Great Britain)

Ref: 0013(GB)
Version: 3

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Section 24(11A) of the Human Fertilisation and Embryology Act 1990 (as amended)
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 (Great Britain)
Reference number:	0013(GB)
Date version 1 issued:	16 April 2018
Chair's Letter reference:	CH(18)02
Date version 2 issued:	27 June 2018
Chair's Letter reference:	N/A
Date version 3 issued:	15 December 2020
Chair's Letter reference:	CH(20)02

1. Licensed centres in Great Britain 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 Great Britain must ensure that all containers (dishes, vials, ampoules, tubes etc.) used in the course of procurement, processing, use and storage of gametes and embryos are labelled with the patient's/donor's full name and a further identifier. If at some stages (e.g. labelling patient/donor sperm) it is not possible to label the dishes or tubes with the patient/donor name then it must be ensured that the patient/donor code used is uniquely identifying.