Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

Retention of records

Ref: 0012
Version: 4

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 13(4), 14(2), 15(3) and 24(2)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version was issued on:	1 July 2022

1. Subject to paragraph 2, licensed centres must retain a record of the following information for a period of at least 30 years from the date on which any gametes or embryos were used in treatment or, if not so used, the date on which any gametes or embryos were removed from storage:

    (a) patient or donor identifying information (first name; surname; date of birth; age and sex);
    (b) how, and by whom, the patient or donor has been reliably identified, where necessary;
    (c) the services provided to the patient or donor;
    (d) the medical history of the patient or donor;
    (e) the outcome of the welfare of the child assessment, where appropriate;
    (f) all consent forms, Statutory Notices listed in the Schedule to General Direction 0007, as well as any specific instructions relating to the use, storage, and/or disposal of gametes and embryos;
    (g) all clinical data (including administration of medicine and the results of any tests carried out) necessary for traceability;
    (h) all laboratory data necessary for traceability, including records relating to any taking of an embryo from a woman or other acquisition of an embryo; the use and storage of any gametes or embryos; any testing of an embryo; consumables, drug treatments, equipment and environment (including servicing, cleaning, testing and monitoring); what equipment was used (and by whom) and staff training;
    (i) any child born as a result of treatment provided to the patient; and
    (j) all other information necessary for traceability;
    (k) copies of the ‘Mitochondrial donation follow-up information sheet’.

2. The record of information specified in paragraph 1 must be kept for a period of at least 50 years from the date on which information about the treatment was first recorded if:

    (a) a patient has undergone treatment (other than basic partner treatment) at a licensed centre; and
    (b) the Person Responsible for that licensed centre is unable to confirm whether or not that patient has given birth to a child as a result of the treatment undertaken at that centre.

3. Licensed centres must retain a record of any information not specified in paragraph 1, which relates to the safety and quality of gametes and embryos, for a period of at least 10 years after the use of gametes or embryos in treatment or, if not so used, the date on which any gametes or embryos were removed from storage.

4. The Person Responsible for a research project must retain a record of the following information for a period of at least 3 years from the date the final report of any research project is submitted to the Authority:

    (a) the total number of embryos or human admixed embryos created, used or disposed of during the research project;
    (b) the results of the research project; and
    (c) the conclusions drawn from the research project.

5. Where a research project involves the derivation of stem cells for human application, a record of the information specified in paragraph 4 and relevant information specified in paragraph 1 must be retained for a period of at least 30 years from the date the final report of any research project is submitted to the Authority.

6. Centres licensed by the Authority to undertake preimplantation genetic diagnosis (PGD) must, in respect of each case of PGD, retain information in the patient records which fully details the reasons why the Person Responsible considered PGD to be appropriate in that particular case, in line with guidance in the Code of Practice (at 10.5, 10.6). This information shall include an explanation of why the Person Responsible considered there to be a particular risk that the embryo tested may have a gene, chromosome or mitochondrion abnormality.

Julia Chain 1 July 2022

Chair, Human Fertilisation and Embryology Authority

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