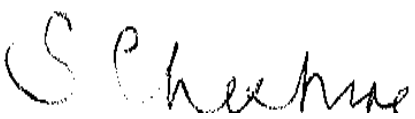
Directions given under the Human Fertilisation and Embryology Act 1990 (as amended)

Import and export of gametes and embryos

Ref: 0006
Version:7

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(d), 12(1)(g), 24(4),24(4A), 24(4AA), 24(4AB), 24(4AC), 24(4AD), 24(12) 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:	16 April 2018
These Directions remain in force:	Until revoked
This version was issued on:	22 June 2018

1. Licensed centres may receive gametes or embryos from another centre in Gibraltar or in a European Economic Area (EEA) state other than the United Kingdom, if the conditions in Schedule 1 to these Directions are satisfied.
2. Licensed centres may send gametes and embryos outside the United Kingdom to another centre in Gibraltar or in an EEA state other than the United Kingdom, if the conditions in Schedule 2 to these Directions are satisfied.
3. Licensed centres may receive gametes or embryos from a centre in a country which is not an EEA state or Gibraltar, if the conditions in Schedule 3 to these Directions are satisfied.
4. Licensed centres may send gametes or embryos outside the United Kingdom to a centre in a country which is not an EEA state or Gibraltar, if the conditions in Schedule 4 to these Directions are satisfied.



Sally Cheshire CBE **27 June 2018**

In accordance with the powers delegated by the Authority on 16 September 2015, under Section 6.6 of the Standing Orders.

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Schedule 1

Import of gametes and embryos from Gibraltar and the European Economic Area (EEA)

1. Licensed centres may only receive gametes or embryos from another centre in Gibraltar or in an EEA state other than the United Kingdom if the following conditions are satisfied[1]:

   (a) the centre from which the gametes or embryos are to be imported (the supplying centre) is accredited, designated, authorised or licensed under the laws or other measures of Gibraltar or the EEA state concerned, in accordance with the first, second, third and fourth Directives (2004/23/EC, 2006/17/EC, 2006/86/EC and 2015/566);
   (b) the person who provided the gametes is (and in the case of an embryo, both persons who provided the gametes from which the embryo was created are) identifiable;
   (c) the person who provided the gametes has (and in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom;
   (d) before giving consent, the person(s) referred to in paragraph (c) has been given written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and they have been given any further information which they may require;
   (e) no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;
   (f) the purpose of importing the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future; and
   (g) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice that is currently in force.

[1] Eggs or embryos which have been created abroad using either maternal spindle transfer or pronuclear transfer may not be imported. Such eggs or embryos are not 'permitted' within the meaning of the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) as they will not have been created within the circumstances prescribed by the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015. Licensed centres are prohibited by Section 3 of the HFE Act 1990 from using eggs or embryos in treatment unless they fall within the statutory definition of 'permitted'.

2. Before any gametes or embryos are imported, the receiving centre must obtain written confirmation from the supplying centre or appropriate Competent Authority that the centre meets the requirements set out in paragraph 1 (a) of this schedule. The receiving centre must also obtain written confirmation from the supplying centre that the requirements of paragraphs 1 (b), to (e) and (g) of this schedule have been met in relation to the gametes or embryos concerned. The written confirmation must be retained by the receiving centre for a period of three years and a copy provided to the Authority on request.
3. Whenever gametes or embryos are imported in accordance with these Directions, the Person Responsible of the receiving centre must ensure that the following information is submitted to the Authority using the Electronic Data Interchange (EDI) system, no later than 10 working days after the import has taken place:
    (a) the Donor Information form for each gamete donor (where donated gametes or embryos are imported);
    (b) the Patient and Partner Registration forms (where own gametes or embryos are imported); and
    (c) a notification of the import using the relevant Embryo and Gamete Movement – In (GI) form.
4. The receiving centre must apply the Single European Code (SEC), as specified in Annex A to these Directions, to all gametes and embryos imported in accordance with these Directions before any of those gametes or embryos are distributed for human application to another centre within the EEA (including the UK) and Gibraltar, except where:

    (a) the distribution is 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 at the receiving centre on or before 29 October 2016 and the gametes or embryos will be transported or delivered to the other centre on or before 30 October 2021.

Schedule 2

Export of gametes and embryos to Gibraltar and the European Economic Area (EEA)

1. Licensed centres may only send gametes and embryos outside the United Kingdom to another centre in Gibraltar or in an EEA state other than the United Kingdom ("the receiving centre") if the following conditions are satisfied:

   (a) the centre to which the gametes or embryos are to be exported is accredited, designated, authorised or licensed under the laws or other measure of Gibraltar or the EEA state concerned, in accordance with the first, second, third and fourth Directives (2004/23/EC, 2006/17/EC, 2006/86/EC and 2015/566);

   (b) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated;

   (c) before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country to which the gametes or embryos are to be exported as it is in the United Kingdom, and they have been given any further information which they may require;

   (d) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefit received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;

   (e) the purpose of exporting the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future;

   (f) the gametes or embryos are not to be exported if they cannot be lawfully used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre; and

   (g) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 14 (3) or (4) or by Regulations made under section 15 (5) of the Human Fertilisation and Embryology Act 1990 as amended, and the period for which the gametes and embryos may remain in storage in accordance with the consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.

2. Before any gametes or embryos are exported, the supplying centre must obtain from the receiving centre or appropriate Competent Authority written confirmation that the receiving centre meets the

requirements of paragraphs 1 (a). The written confirmation must be retained by the supplying centre for a period of 3 years and a copy provided to the Authority on request.

3. Whenever gametes or embryos are exported in accordance with these Directions, the Person Responsible of the supplying centre must ensure that the Embryo and Gamete Movement – Out (GO) form on the Electronic Data Interchange (EDI) system is completed and submitted to the HFEA no later than 10 working days after the export has taken place.

4. The supplying centre must keep all original records which it is required to maintain under its licence for the periods specified in Directions 0005 (Collecting and recording information for the HFEA), but copies of the following documentation must accompany the gametes or embryos to the recipient centre:

    (a) a copy of the consent form signed by each gamete provider;
    (b) a copy of the Donor Information form for each gamete donor (where donated gametes or embryos are exported);
    (c) a copy of the Patient and Partner registration forms (where own gametes or embryos are exported); and
    (d) a copy of the relevant Embryo and Gamete Movement – Out (GO) form.

5. The supplying centre must notify the receiving centre and the HFEA if there are any changes to the information supplied.

6. The supplying centre must apply the Single European Code (SEC), as specified in Annex A to these Directions, before the gametes or embryos are exported, 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 at the supplying centre on or before 29 October 2016 and the gametes or embryos will be transported or delivered before 30 October 2021.

7. Where the circumstances in paragraph 6 (a) and (b) of these Directions apply, the supplying 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.

Schedule 3

Import of gametes and embryos from outside of the European Economic Area (EEA) and Gibraltar

1. Licensed centres may receive gametes or embryos from a centre in a third country (i.e. a country which is not an EEA state or Gibraltar), if:[2]:

   (a) in relation to any import from a third country, the conditions in paragraph 3(a) to (j), 4 and 7(a) to (d) of this schedule are satisfied; and

   (b) in relation to any import other than a one-off import, the conditions in paragraph 5(a) to (f) of this schedule are satisfied; or

   (c) in relation to one-off imports, the conditions in paragraph 6(a) to (c) of this schedule are satisfied.

2. Reference to a one-off import is to gametes or embryos imported for the purposes of providing services to a particular (named) person or persons on one occasion only.

3. The conditions in paragraphs (a) to (j) below apply to all imports from a third country;

   (a) the centre from which the gametes or embryos are to be imported (the supplying centre) is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated;
   (b) the supplying centre has a quality management system in place which has been certified by an internationally recognised body;
   (c) the supplying centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa. The centre's traceability procedures should also include all materials or equipment that could have an impact on the quality or safety of the gametes or embryos;
   (d) the procurement and processing of the gametes or embryos has taken place in appropriate facilities and following procedures that minimise bacterial or other contamination;
   (e) the person who provided the gametes is (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, are) identifiable;

[2] Eggs or embryos which have been created abroad using either maternal spindle transfer or pronuclear transfer may not be imported. Such eggs or embryos are not 'permitted' within the meaning of the Human Fertilisation and Embryology (HFE) Act 1990 (as amended) as they will not have been created within the circumstances prescribed by the Human Fertilisation and Embryology (Mitochondrial Donation) Regulations 2015. Licensed centres are prohibited by Section 3 of the HFE Act 1990 from using eggs or embryos in treatment unless they fall within the statutory definition of 'permitted'.

(f) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being imported into the United Kingdom;
(g) before giving consent, the person(s) referred to in paragraph (f) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the United Kingdom as in the country from which the gametes or embryos are to be imported, and have been given further information which they may require;
(h) no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving importing money or other benefits;
(i) the purpose of importing the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future; and
(j) the gametes or embryos to be imported meet the UK requirements on screening in accordance with the Authority's standard licence conditions and the Code of Practice currently in force.

4. Before any gametes or embryos are imported, the receiving centre must obtain written confirmation from the supplying centre that the supplying centre meets the requirements of paragraphs 3 (a), (b), (c) and (d) of this schedule. The receiving centre must also obtain written confirmation from the supplying centre that the requirements of paragraphs 3 (e), (f), (g), and (j) of this schedule will be complied with in relation to the gametes or embryos concerned. The written confirmation must be retained by the receiving centre for a period of 3 years and a copy provided to the Authority upon request.

5. The conditions in paragraphs (a) to (e) below apply to all imports from a third country other than one-off imports. The receiving centre must:

(a) have a written agreement with the supplying centre which:
(i) specifies the quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the gametes or embryos to be imported with the standards laid down in the first Directive[3];
(ii) meets the requirements of Annex IV of the fourth Directive[4]; and
(iii) establishes the right of the Authority to inspect the activities, including the facilities of, any supplying centre for the duration of the written agreement and for a period of two years following its termination;
(b) provide to the Authority, if requested, any of the information referred to in Parts A to E of Annex I to the fourth Directive;
(c) provide to the Authority, if requested, any of the documents referred to in Part F of Annex I to the fourth Directive;
(d) the centre must:
(i) make available to the Authority for inspection any of the documents referred to in Part A and B of Annex III to the fourth Directive; and

[3] Section 1A of the Act states that "the first Directive" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells.

[4] Section 3(2)(c) of the Act, as amended, defined "the fourth" Directive as Commission Directive 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.

(ii) provide to the Authority, if requested, any document falling within paragraph (i);

(e) before any gametes or embryos are imported, the receiving centre must be in possession of a certificate issued by the Authority under section 24(4AD) of the Act, as amended, which includes the supplying centre as a third country supplier and which applies to the gametes or embryos to be imported;

(f) where the centre has been issued with a certificate under section 24(4AD) which does not refer to the supplying centre as a third country supplier or which does not apply to the gametes or embryos concerned, the receiving centre must apply to the Authority for its certificate to be amended and provide the Authority with any further information or documentation requested by the Authority. Before any gametes or embryos are imported, the receiving centre must be in possession of a certificate issued by the Authority which includes the supplying centre as a third country supplier and which applies to the gametes or embryos to be imported.

6. The conditions in paragraphs (a) to (c) below apply to one-off imports.

(a) the centre must provide to the Authority, if requested, any of the information referred to in Parts A to E of Annex I to the fourth Directive;

(b) before any gametes or embryos are imported as a one-off import, the centre must obtain written confirmation from the person or persons for whom the gametes or embryos are to be imported that gametes or embryos have not previously been imported for the purposes of providing that person or those persons with treatment services;

(c) the receiving centre must be in possession of a certificate issued under section 24(4AD) which includes one-off imports.

7. The conditions in paragraphs (a) to (d) below apply to all imports from a third country, the centre must:

(a) not make any substantial changes in connection with any imports from a third country unless the Authority has been notified of those changes and provided written confirmation of its approval of those changes[5];

(b) notify the Authority if the proposed import of gametes or embryos does not take place.

(c) without delay:

(i) notify the Authority of any serious adverse events or serious adverse reactions notified to the centre by the third country supplier (including events or reactions which the supplier knows or suspects are serious adverse events or reactions);

(ii) provide to the Authority the information laid out in Annexes III and IV to the first Directive (2006/86/EC) and any further information that the Authority may require);

(d) without delay, notify the Authority of any changes in circumstances[6] relating to the third country supplier, of which the centre is aware;

8. Whenever gametes or embryos are imported in accordance with these Directions, the Person Responsible of the receiving centre must ensure that the following information is submitted to the

[5] "Substantial changes" shall be construed in accordance with Article 3(3) of the fourth Directive. Substantial changes to a centre's import activities may include changes to the type of material to be imported (e.g. extending imports from gametes to embryos). Substantial changes may also include changes to the activities undertaken in third countries, which may have an influence on the quality and safety of the imported material.

[6] "changes of circumstances" means:

(a) any revocation or suspension of a third country supplier's authorisation to export gametes or embryos;

(b) any other decision taken for reasons of non-compliance by the competent authority or authorities of the country in which the third country supplier is based and which may be relevant to the quality and safety of imported gametes and/or embryos.

Authority using the Electronic Data Interchange (EDI) system, no later than 10 working days after the import has taken place:

(a) the Donor Information form for each gamete donor (where donated gametes or embryos are imported);
(b) the Patient and Partner Registration forms (where own gametes or embryos imported); and
(c) a notification of the import using the relevant Embryo and Gamete Movement – In (GI) form.

9. The receiving centre must apply the Single European Code (SEC), as specified in Annex A to these Directions, to all gametes and embryos imported in accordance with these Directions before any of those gametes or embryos are distributed for human application to another centre within the EEA (including the UK) and Gibraltar, except where:

(a) the distribution is 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 at the receiving centre on or before 29 October 2016 and the gametes or embryos will be transported or delivered to the other centre before 30 October 2021.

Schedule 4

Export of gametes and embryos outside of the European Economic Area (EEA) and Gibraltar

1. Licensed centres may send gametes or embryos outside the United Kingdom to another centre outside of the EEA and Gibraltar ("the receiving centre") if the following conditions are satisfied:

(a) the receiving centre is accredited, designated, authorised or licensed under the quality and safety laws or other measures of the country in which it is situated;
(b) the receiving centre has a quality management system in place which has been certified by an internationally recognised body;
(c) the receiving centre has a traceability system in place which ensures that all gametes and embryos are traceable from procurement of gametes to patient treatment and vice versa. The centre's traceability procedures should also encompass all materials or equipment that could have an impact on the quality or safety of the gametes and embryos;
(d) the person who provided the gametes has (and, in the case of an embryo, both persons who provided the gametes from which the embryo was created, have) given and not withdrawn consent in writing to the gametes or embryos being exported to the country in which the receiving centre is situated;
(e) before giving consent, the person(s) has been given a written notice stating that the law governing the use of gametes and/or embryos and the parentage of any resulting child may not be the same in the country in which the receiving centre is situated as it is in the United Kingdom, and they have been given any further information which they may require;
(f) no money or other benefit has been given or received in respect of the supply of the gametes or embryos unless the money or benefit paid or received is in accordance with Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving money or other benefits;
(g) the purpose of exporting the gametes or embryos concerned is to enable them to be used to provide treatment services, namely medical, surgical or obstetric services for the purpose of assisting a woman to carry a child or to be stored for such a purpose in the future;
(h) the gametes or embryos are not to be exported if they could not lawfully be used in licensed treatment services in the United Kingdom in the manner or circumstances in which it is proposed that the gametes or embryos be used by the receiving centre; and
(i) the remaining term of the relevant storage period for the gametes or embryos, as provided for in section 14 (3) or (4) or by Regulations made under section 15 (5) of the HFE Act 1990 amended, and the period for which the gametes and embryos may remain stored in accordance with the consent(s) of the relevant gamete provider(s), are not less than 6 months from the date on which they are to be exported.

2. Before any gametes or embryos are exported, the supplying centre must obtain from the receiving centre written confirmation that the receiving centre meets the requirements of paragraph 1 (a), 1 (b) and 1 (c) of this schedule. The written confirmation must be retained by the supplying centre for a period of three years and a copy provided to the Authority upon request.

3. Whenever gametes or embryos are exported in accordance with these Directions, the Person Responsible of the supplying centre must ensure that the Embryo and Gamete Movement – Out (GO) form on the Electronic Data Interchange (EDI) system is completed and submitted to the HFEA no later than 10 working days after the export has taken place.

4. The supplying centre should keep all original records which it is required to maintain under its licence for the periods specified in Directions 0005 (Collecting and recording information for the HFEA), but copies of the following documentation must accompany the gametes or embryos to the recipient centre:

(a) a copy of the consent form signed by each gamete provider;
(b) a copy of the Donor Information form for each gamete donor (where donated gametes or embryos are exported);
(c) a copy of the Patient and Partner Registration forms (where own gametes or embryos are exported); and
(d) a copy of the relevant Embryo and Gamete Movement – Out (GO) form.

5. The supplying centre must notify the receiving centres and the HFEA if there are any changes to the information supplied.

6. The licensed centre must ensure that a uniquely identifying patient/donor code is attached to the container of the gametes/ embryos (straws, dishes, vials, ampoules, tubes etc.) or where that is not possible, attached to the accompanying documentation and linked to it.

Annex A

The Single European Code

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

Donation identification sequence			Product identification sequence		
ISO Country code	Tissue Establishment code	Unique Donation Number	Product code	Split number	Expiry date
2 alpha characters	6 alpha-numeric characters	13 alpha-numeric characters	1+7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters Yyyy/mm/dd
GB	**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 GB00012300000000XX456 E000005900120181231					

2. Licensed clinics must use one of the following coding platforms to identify 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/

3. 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.

4. 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.

5. 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.

6. The SEC must be attached to the container (straws, dishes, vials, ampoules, tubes etc.) of the gametes/ embryos or where that is not possible it must be attached to the accompanying documentation and linked to it. It must be eye-readable. If a bar code is used, it must be accompanied by the SEC. When printed the 'donor 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 GB00012300000000XX456 E000005900120181231

7. 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.

8. 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.