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

Import and export of gametes and embryos (Great Britain)

Ref: 0006(GB)
Version: 9

These Directions are:	General Directions
Sections of the Act providing for these Directions:	Sections 12(1)(d),12(1)(g), 24(4), 24(4ZA), 24(4A), 24(4AA), 24(4AB), 24(4AC), 24(4AD) and 24(13) of the Human Fertilisation and Embryology Act 1990 (as amended)
These Directions come into force on:	30 June 2021 at 11pm
These Directions remain in force:	Until revoked
This version was issued on:	09 June 2021

1. Licensed centres in Great Britain may receive gametes or embryos from a centre in a third country, if the conditions in Schedule 1 to these Directions are satisfied.
2. Licensed centres in Great Britain may send gametes or embryos to a centre in a third country, if the conditions in Schedule 2 to these Directions are satisfied.

Julia Chain **09 June 2021**

Chair of the Human Fertilisation and Embryology Authority

Version control	
Name of Directions:	Import and export of gametes and embryos (Great Britain)
Reference number:	0006(GB)
Date version 1 issued:	1 October 2009
Chair's Letter reference:	CH(09)05
Date version 2 issued:	6 April 2010
Chair's Letter reference:	CH(10)03
Date version 3 issued:	29 October 2015
Chair's Letter reference:	CH(15)02
Date version 4 issued:	3 April 2017
Chair's Letter reference:	CH(17)01
Date version 6 issued:	16 April 2018
Chair's letter reference:	CH(18)02
Date version 7 issued:	27 June 2018
Chair's Letter reference:	N/A
Date version 8 issued:	15 December 2020
Chair's Letter reference:	CH(20)02
Date version 9 issued:	09 June 2021
Chair's Letter reference:	CH(21)02

Schedule 1

Import of gametes and embryos from a third country

1. A licensed centre in Great Britain may receive gametes or embryos[1] from a centre in a third country (meaning any country other than the United Kingdom[2]), if:

   (a) in relation to any import, the conditions in paragraph 3(a) to (j), 4, 7(a) to (d) and 8 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 (e) 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 third country supplier) 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 third country supplier has a quality management system in place which has been certified by an internationally recognised body;

   (c) the third country supplier 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 third country supplier'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;

[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] This Schedule does not apply to the transfer of gametes or embryos by a licensed centre in Northern Ireland to one in Great Britain. Such a transfer does not require the authority of these Directions as the transfer is not outside of the UK.

(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 HFEA 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 HFEA'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 third country supplier that the third country supplier meets the requirements of paragraphs 3 (a), (b), (c) and (d) of this schedule. The receiving centre must also obtain written confirmation from the third country supplier that the requirements of paragraphs 3 (e), (f), (g), (h) 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 three years and a copy provided to the HFEA upon request.

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

(a) have a written agreement with the third country supplier 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 required by the Human Fertilisation and Embryology Act 1990, as amended ('the Act').

(ii) meets the requirements of Annex A to these Directions [3]; and

(iii) establishes the right of the HFEA to inspect the activities, including the facilities of the third country supplier for the duration of the written agreement and for a period of two years following its termination;

(b) provide to the HFEA, if requested, any of the information referred to in Parts A and B of Annex B to these Directions;

(c) make an application to the HFEA for a certificate under section 24(4AD) of the Act and, in support of that application, provide to the HFEA the information and documents referred to in Annex C to these Directions;

[3] Annex A sets out the minimum requirements concerning the contents of written agreements between third country suppliers and receiving centres.

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

(e) where the receiving centre has been issued with a certificate under section 24(4AD) which does not refer to the third country supplier concerned or which does not apply to the gametes or embryos concerned, the receiving centre must apply to the HFEA for its certificate to be amended and provide the HFEA with any further information or documentation requested by the HFEA. Before any gametes or embryos are imported, the receiving centre must be in possession of a certificate issued by the HFEA which includes the third country supplier concerned 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 receiving centre must provide to the HFEA, if requested, any of the information referred to in Annex C to these Directions ;

(b) before any gametes or embryos are imported as a one-off import, the receiving 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. The receiving centre must:

(a) not make any substantial changes in connection with any imports from a third country unless the HFEA has been notified of those changes and provided written confirmation of its approval of those changes[4];

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

(c) without delay:

(i) notify the HFEA of any suspected or actual serious adverse events or serious adverse reactions notified to the receiving centre by the supplying centre which may influence the quality and safety of the gametes or embryos they import;

(ii) provide to the HFEA the information specified in licence conditions T120 and T121 and any further information that the Authority may require;

(d) without delay, notify the HFEA of any changes in circumstances[5] relating to the third country supplier, of which the receiving 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 all required information regarding the import

[4] The following will be considered substantial changes:
- changes to the material to be imported (e.g. extending imports from gametes to embryos);
- changes to activities in third countries which may have an influence on the quality and safety of imported material;
- a change of third country supplier.

[5] "changes of circumstances" means:
(a) any revocation or suspension of a third country supplier's authorisation to export gametes or embryos; and
(b) any other decision taken for reasons of non-compliance by the authority or authorities in the country concerned responsible for regulating tissue establishments in the country in which the supplying centre is based and which may be relevant to the quality and safety of imported gametes and embryos.

is submitted to the HFEA in accordance with the data submission methods and timeframes set out within General Direction 0005 (Collecting and recording information for the HFEA):

(a) the Donor Information form for each gamete donor (where donated gametes or embryos are imported);
(b) the Patient and Partner registration records (where own gametes or embryos are imported); and
(c) a notification of the import using the relevant Movement-in record.

Schedule 2

Export of gametes and embryos

1. A licensed centre in Great Britain may send gametes or embryos to a centre in a third country (meaning any country other than the United Kingdom)[6] 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 HFEA 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 14 (5) of the Act and the period for which the gametes and embryos may remain stored in accordance with the consent(s) of

[6] This Schedule does not apply to a transfer of gametes or embryos by a licensed centre in Great Britain to a licensed centre in Northern Ireland as the transfer is not outside of the UK. However, section 2B(4)(b) of the Act defines 'third country' as a country other than Northern Ireland or an EEA state as regards imports to Northern Ireland. In order to receive gametes or embryos from a licensed centre in Great Britain, a transfer of gametes or embryos to a licensed centre in Northern Ireland will need to meet the requirements of schedule 1 of GD0006 (NI).

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 all required information regarding the export is submitted to the HFEA in accordance with the data submission methods and timeframes set out within General Direction 0005 (Collecting and recording information for the HFEA).
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, but copies of the following documentation must accompany the gametes or embryos to the receiving 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 records (where own gametes or embryos are exported); and
    (d) a copy of the relevant Movement-out record.
5. The supplying centre must notify the receiving centre and the HFEA if there are any changes to the information supplied.

Annex A

Minimum requirements concerning the contents of a written agreement between a receiving centres and any third country supplier

The written agreement between the receiving centre and the third country supplier shall contain at least the following provisions:

1. Detailed information on the specifications of the receiving centre aimed at ensuring that the quality and safety standards required by the 1990 Act are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported gametes and embryos are of equivalent standards of quality and safety.

2. A clause specifying that the third country supplier provides the information set out Part B of Annex B to these Directions to the receiving centre.

3. A clause ensuring that the third country supplier informs the receiving centre of any suspected or actual serious adverse events or reactions which may influence the quality and safety of gametes and embryos imported or to be imported by the receiving centre.

4. A clause ensuring that the third country supplier informs the receiving centre of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export gametes or embryos or other such decisions of non-compliance by the authority or authorities in the third country responsible for regulating tissue establishments in that country.

5. A clause guaranteeing the HFEA the right to inspect the activities of the third country supplier, including on-site inspections, should it wish to do so as part of its inspection of the receiving centre. The clause should also guarantee the receiving centre the right to regularly audit its third country supplier.

6. The agreed conditions to be met for the transport of gametes and embryos between the third country supplier and the receiving centre.

7. A clause ensuring that donor records relating to imported gametes and embryos are kept by the third country supplier or its sub-contractor, in line with data protection legislation within the meaning of section 3(a) of the Data Protection Act 2018.

8. Provisions for the regular review and, where necessary, revision of the written agreement including in order to reflect any changes in the standards required by the Human Fertilisation and Embryology Act 1990.

9. A list of all standard operating procedures of the third country supplier relating to the quality and safety of imported gametes and embryos.

Annex B

Minimum requirements concerning the documentation to be made available to the HFEA by a centre intending to import gametes or embryos from a third country supplier

The receiving centre shall make available and shall provide when requested by the HFEA the most up-to-date version of the following documents regarding the receiving centre and its third country suppliers.

A. Documentation relating to the receiving centre

1. A copy of the primary label, repackage label and transport container.

2. A list of relevant and up-to- date versions of standard operating procedures (SOPs) relating to the receiving centre's import activities including SOPs on reception and storage of imported gametes and embryos at the receiving centre, management of adverse events and reactions, management of recalls and traceability from donor to recipient.

B. Documentation relating to third country suppliers

1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not.

2. Detailed information on the testing centre(s) used by the third country supplier and the tests performed by such centres.

3. Detailed information on the methods used during the processing of the gametes or embryos including the details of the validation for the critical processing procedure.

4. A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier.

5. Detailed information on the conditions for release of gametes and embryos by the third country supplier.

6. Details of any sub-contractors used by the third country supplier including the name, location and activity undertaken.

7. A summary of the most recent inspection of the third country supplier by the authority in the third country responsible for regulating tissue establishments in that country, including the date of the inspection, type of inspection and main conclusions.

8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the receiving centre.

9. Any relevant national or international accreditation.

Annex C

Information and documents to be provided to the HFEA in support of an application for a certificate under section 24(4AD)

A. General information on the receiving centre

i. Name of centre

ii. Reference number previously allocated to the centre by the HFEA

iii. Centre address and postal address (if different)

iv. Status of the applicant: first authorisation or renewal

v. Name of applying unit if different from the above address

vi. Name of the site of reception of imports (if different from the above)

vii. Visiting address of the site of reception

viii. Postal address of the site of reception (if different)

B. Contact details for the application

i. Name of PR

ii. Address of PR

iii. Telephone number of PR

iv. Email address of PR

C. Details of tissues and cells to be imported

i. A list of the tissues and cells to be imported, including one-off imports, (i.e. gametes and/or embryos)

ii. One-off imports

iii. Product name of imported tissues and cells

iv. Trade names if different to product name

v. Name of the supplying centre for each type of tissue and cell to be imported

D. Location of activities

i. Which activities are carried out prior to import by the third country supplier per type of tissue or cell

-Donation

-Procurement

-Testing

-Processing

- Preservation
- Storage

ii. Which activities are carried out prior to import by subcontractors of the third country supplier per type of tissue or cell

-Donation
- Procurement
- Testing
- Processing
- Preservation
- Storage

iii. A list of all activities carried out by the receiving centre subsequent to import per type of tissue or cell

iv. Names of the third countries in which the activities prior to import take place per type of tissue or cell

E. Details of third country supplier

i. Name of supplier

ii Name of contact person

iii. Visiting address

iv. Postal address (if different)

v. Telephone number (including international dialling code)

vi. Emergency contact number (if different)

vii. E-mail address

F. Documentation to accompany the application

i. A copy of the written agreement with the third country supplier

ii. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the receiving centre

iii. A copy of the third supplying centre's export authorisation certificate. (This should include the contact details of the third country’s authority or authorities concerned with regulating the third country supplier in that country).