

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

Import and export of gametes and embryos

Ref: 0006
Version: 1

These Directions are:	GENERAL DIRECTIONS
Sections of the Act providing for these Directions:	Sections 12 (1) (d) and (g); 24 (4) and (4A)
These Directions come into force on:	1 October 2009
These Directions remain in force:	Until revoked
This version issued on:	1 October 2009

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 a European Economic Area (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 another centre in a non-European Economic Area (EEA) state other than 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 another centre outside of the European Economic Area (EEA) and Gibraltar, if the conditions in Schedule 4 to these Directions are satisfied.

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1 July 2009

Chair of the Compliance Committee in accordance with delegated powers granted by the Human Fertilisation and Embryology Authority on 17 December 2008.

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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 a European Economic Area (EEA) state other than the United Kingdom if the following conditions are satisfied:
 - (a) the centre from which the gametes or embryos are to be transferred (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 and third Directives (2004/23/EC, 2006/17/EC and 2006/86/EC);
 - (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 transferred to 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 transferred, and they have been given any further information which they may require;
 - (e) 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;
 - (f) the purpose of transferring 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.
2. Before any gametes or embryos are transferred, the receiving centre must obtain written confirmation from the supplying centre or appropriate

Competent Authority that the centre meets the requirements set out in paragraphs 2 a) and that the requirements of paragraphs 2 (b), (c), (d), (e), (f) and (g) of these Directions 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 transferred in accordance with these Directions, the receiving centre must submit to the Authority, no later than 5 working days after the transfer has taken place:

- (a) a copy of the Donor Information form (where donated gametes are supplied) and forms (where donated embryos are supplied);

- (b) a copy of the Patient and Partner Registration forms (where the gametes or embryos are supplied for own use); and

- (c) a copy of the relevant Notification of Import form notifying the Authority that the transfer has taken place.

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 transferred 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 and third Directives (2004/23/EC, 2006/17/EC and 2006/86/EC);
 - (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 carry a child or to be stored for such a purpose in the future;
 - (f) the gametes or embryos are not 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 15 (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 supplying centre must complete the relevant Notification of Export form, notifying the HFEA that a transfer has taken place, and submit this form to the HFEA no later than 5 working days after the transfer has taken place. This form must be signed by the Person Responsible at the supplying centre.
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 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 the gamete provider (where gametes are supplied) and Consent forms signed by both gamete providers (where embryos are supplied);
 - (b) a copy of the Donor Information form (where donated gametes are supplied) forms (where donated embryos are supplied);
 - (c) a copy of the Patient and Partner registration form (where the gametes or embryos are supplied for own use); and
 - (d) a copy of the relevant Notification of Export form.

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

1. Licensed centres may receive gametes or embryos from another centre in a non-EEA state other than Gibraltar, if the following conditions are satisfied:
 - (a) the centre from which the gametes or embryos are to be transferred (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;
 - (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 transferred to 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 transferred, and have been given further information which they may require;
 - (h) no money or other benefits has been given or received in respect of the supply of the gametes or embryos unless the money or benefits 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;

(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 that is currently in force.

2. Before any gametes or embryos are imported, the receiving centre must obtain written confirmation from the supplying centre that the centre meets the requirements of paragraph 1 (a), (b), (c) and (d) of this schedule and that the requirements of paragraphs 1 (e), (f), (g), (h), (i) 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.

3. Whenever gametes or embryos are imported in accordance with these Directions, the receiving centre must submit to the Authority, no later than 5 working days after the transfer has taken place:

(a) a copy of the Donor Information form (where donated gametes are supplied) and forms (where donated embryos are supplied);

(b) a copy of the Patient and Partner Registration forms (where the gametes or embryos are supplied for own use); and

(c) a copy of the relevant Notification of Import form notifying the Authority that the transfer has taken place.

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

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 benefits 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 the Directions 0001 (Gamete and embryo donation) or any subsequent Directions given by the Authority relating to giving and receiving of 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 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 15 (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 transferred in accordance with these Directions, the supplying centre must complete the relevant Notification of Export form, notifying the HFEA that a transfer has taken place, and submit this form to the HFEA no later than 5 working days after the transfer has taken place. This form must be signed by the Person Responsible at the supplying centre.
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 the gamete provider (where gametes are supplied) and Consent forms signed by both gamete providers (where embryos are supplied);
 - b) a copy of the Donor Information form (where donated gametes are supplied) and forms (where donated embryos are supplied);
 - c) a copy of the Patient and Partner Registration forms (where the gametes or embryos are supplied for own use); and
 - d) a copy of the relevant Notification of Export form.
5. The supplying centre must notify the receiving centres if there are any changes to the information supplied.