

Committee Paper

Committee:	Authority
Meeting Date:	9 May 2007
Agenda Item:	9.
Paper Number:	HFEA (09/05/07) 373
Paper Title:	Imports and Transfers under EUTCD – New Procedures
Author:	Helen Coath, Policy Manager
For Information or Decision?	For information
Resource Implications:	The work is being managed within existing resources, under the planning for implementation of the EU Tissues and Cells Directive.
Implementation:	For implementation with the requirements of the new Regulations, transposing the EU Tissues and Cells Directive into UK law. The Regulations are scheduled to commence on 7 th July 2007.
Communication:	Changes to existing policy to be communicated to centres through a letter to centres, information posted on the website, the HFEA Update and guidance in the 7 th edition of the Code of Practice. Patients will be informed at the Patient Panel and Q and A's will be available on the HFEA website.
Organisational Risk:	High – the timeframe for the process of ensuring compliance with the Regulations is tight, as is the deadline for incorporating new guidance to be included in the Code of Practice.
Recommendation to the Committee:	Members are asked to note the new procedures.
Evaluation:	The Tissue Directive implementation work is ongoing and the Core Project Management Group continually monitors developments. Proposals will be developed to evaluate the effect of the new Regulations on the sector.

Introduction

1. The EU Tissues and Cells Directive (EUTCD) will be transposed into UK law through new Regulations, making it an integral part of the HF&E Act 1990. The Regulations will be laid before Parliament shortly. The amendments to the 1990 Act have required significant changes to our current policy on imports and exports within Gibraltar and the European Economic Area (EEA), specifically the movement of gametes and embryos between EEA countries which will be treated as transfers.
2. At the last meeting of the Authority, decision making for this issue was delegated to the Regulation Committee. On 4 April the Regulation Committee considered the proposals for the new procedures and made a decision on the approach to be taken.
3. This paper sets out the new procedures. Revised guidance, forms and Directions can be seen in the annexes to this paper. The new guidance has been incorporated into the new Code of Practice, which will be published at the beginning of May.

Implications of the new procedures on current HFEA policy

4. The table below identifies how current policy will be affected by the new requirements.

Current Policy	What the Directive says about this	Consequence of extending the requirement to transfers (imports and exports)	What the new procedures say
All donors must be identifiable.	The Directive does not require donors to be identifiable.	The Directive allows Member States to impose more stringent requirements in relation to quality and safety. It is possible to require the donors of all imported donations to be identifiable, as this is a more stringent safety requirement.	All gametes or embryos transferred into the UK from the EEA should come from identifiable donors.
Non-partner sperm must be quarantined for 180 days, after which it must be re-tested and all non-partner donors must be screened for CMV.	<p>The Directive states that if non-partner sperm is tested by the nucleic acid amplification technique (NAT), repeat testing, and by inference quarantine, is not required.</p> <p>The Directive does not require all non-partner donors to be CMV screened. It only requires CMV testing in certain circumstances.</p>	It is therefore appropriate to require a more stringent standard in terms of the screening requirements in relation to imports.	All gametes/embryos imported from the EEA should meet the UK requirements on screening, as set out in licence conditions and the 7 th edition of the Code of Practice.
Donors may be reimbursed for all demonstrable out-of-pocket expenses (including payment for loss of earnings) incurred within the UK in connection with gamete or	Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. In that case, Member States define the conditions under which	Limits on payments to donors are explicitly mentioned in the Directive. However, in the UK inconvenience payments are not permitted. It will be for the PR to assure themselves that inconvenience	Donors of all gametes or embryos transferred must have only received reasonable expenses or compensation for loss of earnings. No inconvenience payments should have been made to the

embryo donation.	compensation may be granted.	payments have not been made, beyond payments for expenses and loss of earnings.	donor.
The gametes from an individual donor should not be used to produce children for more than 10 families.	The Directive makes no mention of this rule.	If this rule is extended to apply to exports under the new Regulations, it will be necessary to make the rule a specific licence condition. The rule would be unenforceable in the EEA without an agreement between EEA countries.	It was decided that it would be inappropriate to elevate the ten family rule (which is currently guidance) to a licence condition, without a proper re-evaluation of SEED policy. This evaluation will take place in 2008. However, all imported gametes will be subject to the SEED guidance limiting their use within the UK (although not within the wider EEA).

Revised Proposal

5. In order to align current policy with the new Regulations, the movement of gametes and embryos within the EEA will be treated as transfers.
6. It will be the responsibility of the Person Responsible (PR) to satisfy themselves that any transfer of gametes or embryos from within the EEA into the UK meets the following criteria;
 - a) The member state from which the transfer is being made has implemented the EUTCD.
 - b) The centre from which the transfer is being made is licensed or accredited under the laws and measures of the member state.
 - c) The gametes/embryos transferred meet UK requirements on screening, as set out in licence conditions and the 7th edition of the Code of Practice.
 - d) The donor of the gametes/embryos is identifiable, has consented to the transfer of their gametes/embryos to the UK and has been made aware of the legal position in the UK on identifying donors (including the implications for the donor).
 - e) The donor of the gametes/embryos must have only received reasonable expenses or reimbursement for loss of earnings. No inconvenience payments should have been made to the donor.
7. New guidance setting out the process for transferring gametes and embryos within the EEA has been drafted to reflect the change in policy (Annex A). This guidance has been included in the 7th edition of the Code of Practice. Two new forms have been drafted for centres to

register when a transfer has taken place within the EEA, one related to importing and the other to exporting. New Directions have also been drafted which require information to be supplied to the HFEA Register and specify the records to be kept by the centre (Annex C).

Recommendations

8. Members are asked to note the revised guidance included in the Code of Practice.

ANNEX A

GUIDANCE – COP7

1.1 Transferring gametes and embryos within Gibraltar and European Economic Area (EEA)

- 1.1.1 The Person Responsible receiving gametes or embryos transferred **from** an EEA country or Gibraltar is responsible for ensuring the following:
- a) The member state from which the transfer is being made has implemented the EUTCD.
 - b) The centre from which the transfer is being made is licensed or accredited under the laws and measures of the member state.
 - c) The gametes/embryos transferred meet UK requirements on screening, as set out in licence conditions and the 7th edition of the Code of Practice.
 - d) The donor of the gametes/embryos is identifiable, has consented to the transfer of their gametes/embryos to the UK and has been made aware of the legal position in the UK on identifying donors (including the implications for the donor).
 - e) The donor of the gametes/embryos must have only received reasonable expenses or reimbursement for loss of earnings. No inconvenience payments should have been made to the donor.
- 1.1.2 When importing gametes/embryos into the UK the form 'Notification of the transfer of gametes/embryos from within Gibraltar or the European Economic Area (EEA) into the UK (Imports)' should be filled in. In this form the PR will be required to make a declaration that they are assured that the centre from which the transfer is being made meets the requirements listed above.
- 1.1.3 When exporting gametes/embryos from the UK to Gibraltar or within the EEA the form 'Notification of the transfer of gametes/embryos to Gibraltar or the European Economic Area (EEA) from the UK (Exports)' should be filled in.
- 1.1.4 Completed forms should be returned to the HFEA no later than five working days after the transfer has taken place.
- 1.1.5 The PR is also responsible for ensuring that the donor is registered with the Authority. Records to be kept in respect of the gametes and donors of embryos being transferred are detailed in Directions 2007/01.
- 1.1.6 Before a patient considers obtaining gametes or embryos from Gibraltar or the EEA the centre should inform them that the donation/s must meet specified criteria, relating to UK standards.

ANNEX B



NOTIFICATION OF THE TRANSFER OF GAMETES AND EMBRYOS FROM WITHIN GIBRALTAR OR THE EUROPEAN ECONOMIC AREA (EEA) INTO THE UK (IMPORTS)

Centre Name	
Centre Address	
Person Responsible	
Nominal Licensee	

For HFEA use only

Date Received	
Centre Number	
Allocated Inspector	

Please use this form to register the transfer of gametes and embryos from within Gibraltar and the European Economic Area (EEA) into the UK.

This form is not for use when transferring gametes or embryos between premises in the UK.

It is important that this form is completed clearly and all abbreviations should be explained.

**Please return the completed form to:
Regulation Department
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF**

Please ensure that you are familiar with the Code of Practice guidelines on transferring gametes and embryos within the EEA.

A. INFORMATION ABOUT THE SUPPLYING CENTRE (WITHIN THE EEA)

Name of the centre _____

Address of centre _____

Name of contact _____ Telephone number _____

Email address _____ Fax number _____

Name of the Accrediting or Licensing body with whom the centre is registered _____

B. INFORMATION ABOUT THE GAMETES AND/OR EMBRYOS BEING IMPORTED

Number of persons from whom the gametes are to be transferred

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Details of gametes being imported (continue on separate sheet if necessary):

	Donor/patient number of each gamete provided	Volume/Quantity ¹	Name of Donor/Patient	Date of Birth	Please tick if gametes are donated
A					
B					
C					
D					
E					
F					
G					
H					

Details of embryos being imported (continue on separate sheet if necessary):

	Donor/patient number of embryos provided	Volume/Quantity ²	Name of Donor/Patient	Date of Birth	Please tick if embryos are donated
A	M1				
B	W1				
C	M2				
D	W2				
E	M3				
F	W3				
G	M4				
H	W4				

C. DECLARATION

I (the Person Responsible) have taken steps to assure myself that:

- The member state from which the transfer is being made has implemented the EUTCD.
- The centre from which the transfer is being made is licensed or accredited under the laws and measures of the member state.
- The gametes/embryos transferred meet UK requirements on screening, as set out in licence conditions and the 7th edition of the Code of Practice.
- The donor of the gametes/embryos is identifiable, has consented to the transfer of their gametes/embryos to the UK and has been made aware of the legal position in the UK on identifying donors (including the implications for the donor).

¹ Please specify vials/ampoules/straws/eggs etc as applicable.

² Please specify vials/ampoules/straws/eggs etc as applicable.

- The donor of the gametes/embryos must have only received reasonable expenses or reimbursement for loss of earnings. No inconvenience payments should have been made to the donor.

Please tick box below, as appropriate.

I have submitted completed Donor Information Form/s via EDI

I have submitted completed hard copy of the Donor Information Form/s (if EDI unavailable)

Both this form and any Donor Information Forms should be submitted to the HFEA within 5 working days of the transfer taking place.

Signed _____

Printed name _____

Position _____

Dated _____



NOTIFICATION OF THE TRANSFER OF GAMETES AND EMBRYOS FROM THE UK TO GIBRALTAR OR THE EUROPEAN ECONOMIC AREA (EEA) (EXPORTS)

Centre Name	
Centre Address	
Person Responsible	
Nominal Licensee	

For HFEA use only

Date Received	
Centre Number	
Allocated Inspector	

Please use this form to register the transfer of gametes and embryos from within the UK to Gibraltar or the European Economic Area (EEA).

This form is not for use when transferring gametes or embryos between premises in the UK.

It is important that this form is completed clearly and all abbreviations should be explained.

**Please return the completed form to:
Regulation Department
Human Fertilisation and Embryology Authority
21 Bloomsbury Street
London
WC1B 3HF**

Please ensure that you are familiar with the Code of Practice guidelines on transferring gametes and embryos within the EEA.

A. INFORMATION ABOUT THE RECEIVING CENTRE (WITHIN GIBRALTER OR THE EEA)

Name of the centre _____

Address of centre _____

Name of contact _____ Telephone number _____

Email address _____ Fax number _____

Nature of centre's activities _____

Director's Name _____

Name of the Accrediting or Licensing body with whom the centre is registered _____

B. INFORMATION ABOUT THE GAMETES AND/OR EMBRYOS BEING EXPORTED

Number of persons from whom the gametes are to be transferred

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Details of gametes being exported (continue on separate sheet if necessary):

	Donor/patient number of each gamete provided	Volume/Quantity ³	Name of Donor/Patient	Date of Birth	Please tick if gametes are donated
A					
B					
C					
D					
E					
F					
G					
H					

Details of embryos being exported (continue on separate sheet if necessary):

	Donor/patient number of embryos provided	Volume/Quantity ⁴	Name of Donor/Patient	Date of Birth	Please tick if embryos are donated
A	M1				
B	W1				
C	M2				
D	W2				
E	M3				
F	W3				
G	M4				
H	W4				

C. INFORMATION ABOUT THE GAMETE PROVIDERS, TO BE COMPLETED WHERE GAMETES OR EMBRYOS ARE TO BE EXPORTED FOR THE TREATMENT OF OTHERS.

1. Has written consent to the embryos' being exported to the above destination been given and not withdrawn by each person who provided the gametes?

Yes No

2. Has each person who provided the gametes been given a written notice saying the law governing the use of gametes and embryos, and the parentage of any resulting child, may not be the same abroad as it is in the UK?

Yes No

³ Please specify vials/ampoules/straws/eggs etc as applicable.

⁴ Please specify vials/ampoules/straws/eggs etc as applicable.

Please tick box below, if appropriate.

I have submitted completed Donor Information Form/s via EDI

I have submitted completed hard copy of the Donor Information Form/s (if EDI unavailable)

Both this form and any Donor Information Forms should be submitted to the HFEA within 5 working days of the transfer taking place.

Signed _____

Printed name _____

Position _____

Dated _____

Annex C



DIRECTIONS GIVEN UNDER THE HUMAN FERTILISATION AND EMBRYOLOGY ACT 1990

Records to be kept of gametes and embryos transferred within Gibraltar and the European Economic Area (EEA)

	Ref.D 2007/02
These Directions are:	GENERAL DIRECTIONS
Section of the Act providing for these Directions:	Sections 14A, 24(3A and 4A),
These Directions come into force on:	7 th June 2007
These Directions revoke Directions:	Ref. D. 1991/8
These Directions remain in force:	Until revoked

1. These Directions revoke Directions Ref. D 2001/1.
2. Whenever gametes or embryos are supplied by a UK centre to another centre within Gibraltar or the EEA, the UK centre should keep the original forms in accordance with Directions D.2007/01, but the following documentation should accompany the gametes or embryos to the recipient centre:
 - A copy of the consent form (where gametes are supplied) or forms (where embryos are supplied).
 - A copy of the Donor Information form (where donated gametes are supplied) and forms (where donated embryos are supplied).
 - A copy of the Patient and Partner Registration forms (where the gametes or embryos are supplied for own use).
 - The relevant Notification of Transfer form, notifying the Authority that a transfer has taken place. This form must be completed and signed by the Person Responsible.
3. Whenever gametes or embryos are transferred from a centre within Gibraltar or the EEA, the receiving centre should submit to the Authority:
 - A copy of the Donor Information form (where donated gametes are supplied) and forms (where donated embryos are supplied);

- A copy of the Patient and Partner Registration forms (where the gametes are supplied for own use).
 - The relevant Notification of Transfer form, notifying the Authority that a transfer has taken place. This form must be completed and signed by the Person Responsible.
4. The UK centre must hold the original forms in accordance with D2007/1.
 5. Recipient centres must be notified by the supplying centre if there are any changes to the information supplied.
 6. Completed forms should be returned to the HFEA no later than five working days after the transfer has taken place.