

SECTION 5

**IVF TREATMENT &
EMBRYO
CREATION/USE
FORM**

Version 2008

Issue 3 – Published 11/09/2008

These guidance notes replace all previous versions

GUIDANCE NOTES ON COMPLETING HFEA FORMS T IVF Treatment & Embryo Creation/Use FORM

Version 2008/2

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Form submission	<p>An IVF Treatment & Embryo Creation/Use Form should be completed and sent to the HFEA after each one of the following events occurred:-</p> <ul style="list-style-type: none">• Ovarian stimulation starts with the intention of creating embryos <i>In Vitro</i>.• Gametes are mixed with the intention of creating embryos.• Embryos are used in treatment or removed from storage for any purpose.• Frozen embryos are moved into or out of storage other than for use in treatment.• Eggs are collected or embryos created are frozen and stored.• Eggs are collected or embryos created are donated for use in treatment or research.
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HFEA centre reference number	This is the unique number issued to each physical clinic/centre by the HFEA upon receipt of an initial licence application. The centre number must be included on all forms returned to the HFEA. Centre numbers should be quoted in the format of four numerics – i.e. 0000. The EDI system will automatically populate this field.
HFEA form number	<p>Each IVF Treatment & Embryo Creation/Use form has a single unique number to identify it, (top right hand corner starting with the letter T). If, after submitting a form, a correction needs to be made, it is essential that the unique form number of the form being corrected or updated be quoted on any new form in section 2. Original forms using duplicate form numbers will be rejected and returned to the centre.</p> <p>The EDI system will automatically populate this field with a unique number specific to your centre. Any paper forms supplied by the HFEA are unique, and it is the responsibility of the centre to ensure that where forms are generated from Electronic Patient Records systems, that form numbers are not repeated.</p>
1 This form	<div style="display: flex; justify-content: space-between;"> Is recording a new treatment <input type="radio"/> Replaces all details previously supplied <input type="radio"/> </div> <p>This form replaces form T <input style="width: 100px;" type="text"/></p>
Section 1	<p>This form:-</p> <p>If this form is recording a treatment for the first time, then please tick ✓ – RECORDING A NEW TREATMENT.</p> <p>If you wish to make changes or corrections to a previous form, then the number of the original form which is now being replaced must be supplied.</p> <p>Notifying Corrections To send a correction form the original form should be opened on EDI, and the 'EDIT' button along the bottom should be clicked. The EDI system will automatically populate the 'notifying correction to' form number.</p>
2 Form completed on	<input style="width: 100px;" type="text"/>

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Section 2	Form Completed On This is the date on which the treatment form is being completed.
3 Patient details Patient or donor number <input type="text"/> Patient surname <input type="text"/>	
Section 3	Patient or donor number The patient number (which may be the same as the donor number for egg donors) should remain constant throughout all treatments, and this number should always be quoted in the same format on any subsequent registration or treatment forms. Changes to Patient/Donor numbers should only be made through an appropriate Patient Registration or Donor Information Form. Patient Surname To ensure that the correct Patient Number has been supplied above, please enter the patients surname as specified on their Patient Registration form. If this information does not match, this form will be returned.
4 Is this patient a surrogate? <input type="radio"/> No <input checked="" type="radio"/> Yes	
Section 4	Is this patient a surrogate? If this patient is to be a surrogate mother, please tick <input checked="" type="checkbox"/> the Yes box.
5 Donor sperm from centre <input type="text"/> Sperm donor number <input type="text"/> Was this sperm imported into the UK? <input type="radio"/> No <input checked="" type="radio"/> Yes	

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Section 5	Donor sperm from Centre / sperm donor number: If a cycle involves embryo creation using donated sperm or the use of frozen embryos originally created using donated sperm then please enter the centre number and donor number of the relevant sperm donor in this section. The details provided must match those recorded on the relevant Donor Information form, or the form will be rejected. The sperm donor must be registered as male or the form will be rejected. Was this sperm imported into the UK? Tick <input checked="" type="checkbox"/> which box is applicable.
<p>6 Donor eggs/embryos from centre <input type="text"/></p> <p>Egg donor number <input type="text"/></p> <p>Were these eggs imported into the UK? No <input type="radio"/> Yes <input type="radio"/></p>	
Section 6	Donor eggs/embryos from Centre & egg donor number If a cycle involves embryo creation using donated eggs or the use of embryos originally created using donated eggs, please enter the centre number and egg donor number of the relevant donor in this section. The details provided must match those recorded on the relevant Donor Information form, or the form will be rejected. The egg donor must be registered as female or the form will be rejected. Were these eggs/embryos imported into the UK? Tick <input checked="" type="checkbox"/> which box is applicable.
<p>7 If donated or stored embryos are being used enter the embryo creation form number <input type="text"/></p> <p>OR If donated eggs are being used enter the egg collection/storage form number <input type="text"/></p>	
Section 7	Donated or stored eggs/embryos being used In order to link the previous treatment form used to collect/store eggs or create/store embryos to this treatment cycle, the centre number and form number of that treatment form must be entered here. This applies both to patients own and donated eggs/embryos.
<p>8 NHS funded treatment cycle? No <input type="radio"/> Yes <input type="radio"/> If yes, give name of commissioning organisation <input type="text"/></p>	

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Section 8	<p>NHS Funded Treatment Cycle?</p> <p>Please tick ✓ the appropriate box.</p> <p>If this is an NHS Funded Treatment Cycle, enter the name of commissioning organisation paying for treatment.</p> <p>If the treatment cycle is to be fully or part funded by the NHS, please record the organisation paying for this. This might be the Primary Care Trust or equivalent, for example.</p>
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9	Cycle None (natural cycle) <input type="checkbox"/> Stimulated <input type="checkbox"/>
	Start date of stimulation or last menstrual period (natural cycle) <input style="width: 80px;" type="text"/>

Section 9	<p>Cycle</p> <p>Please tick ✓ the appropriate box from the following choices:-</p> <ul style="list-style-type: none"> Stimulated None (for a natural cycle where no fertility drugs have been administered) <p>Start date of stimulation or last menstrual period (for natural cycle)</p> <p>Where stimulatory drugs have been given, please supply the date of the first drug administration (i.e. start of the administration cycle).</p> <p>Where no drugs have been administered (i.e. a natural cycle), please supply the date of the patient's last menstrual cycle.</p>
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Please complete sections 10, 11 and 12 (a or b) if the patients own eggs are being collected or used				
10	Main reason for intending to produce/thaw embryos and/or collecting eggs	Immediate patient treatment <input type="checkbox"/>	Frozen cycle <input type="checkbox"/>	For storing eggs <input type="checkbox"/>
	For storing embryos <input type="checkbox"/>	For research <input type="checkbox"/>	For donation <input type="checkbox"/>	

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Section 10	<p>Main reason for intending to produce/thaw embryos and/or collecting eggs</p> <p>Options include the following:</p> <ul style="list-style-type: none"> • Immediate patient treatment • Frozen cycle • For storing eggs • For storing embryos • For research • For donation (to treatment by others) <p>Tick ✓ the box which is most applicable.</p> <p>If the intention of a cycle for a particular patient is to achieve a live birth for that patient in that same cycle, then always tick the ‘Immediate Patient Treatment’ box. This is irrespective of whether some eggs or embryos may ultimately be donated (e.g. egg sharing), or some may be stored or given to research. If not all eggs or embryos are used at the time of treatment, but are stored for later use by the patient; this is secondary.</p> <p>If this form is notifying the use of frozen eggs or embryos, then the option ‘Immediate Patient Treatment’ in this section should not be ticked unless the cycle involves both fresh and frozen gametes/embryos.</p>
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11 Egg collection/abandonment date	<input style="width: 80px; height: 20px;" type="text"/>
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Section 11	<p>Egg collection/abandonment date</p> <p>Enter the date off egg collection or, if the cycle was cancelled/abandoned, the date that the decision was made.</p>
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12a	Egg collection was attempted Number of eggs collected <input style="width: 40px; height: 20px;" type="text"/> (enter 0 if no eggs were collected) If no eggs were collected, was this due to a poor response to drugs? <table style="display: inline-table; vertical-align: middle;"> <tr> <td style="text-align: center;">No</td> <td style="text-align: center;"><input type="radio"/></td> <td style="text-align: center;">Yes</td> <td style="text-align: center;"><input type="radio"/></td> </tr> </table>	No	<input type="radio"/>	Yes	<input type="radio"/>		
No	<input type="radio"/>	Yes	<input type="radio"/>				
12b	Egg collection was cancelled/abandoned Reason <table style="display: inline-table; vertical-align: middle; margin-left: 20px;"> <tr> <td style="text-align: center;">Under response</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Over response</td> <td style="text-align: center;"><input type="checkbox"/></td> <td style="text-align: center;">Other</td> <td style="text-align: center;"><input type="checkbox"/></td> </tr> </table>	Under response	<input type="checkbox"/>	Over response	<input type="checkbox"/>	Other	<input type="checkbox"/>
Under response	<input type="checkbox"/>	Over response	<input type="checkbox"/>	Other	<input type="checkbox"/>		

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Section 12a

Egg collection was attempted

Only complete this section if an attempt was made to collect the patients/donors own eggs. If this form is reporting the use of frozen or donated embryos/eggs, this section should be left blank.

Number of eggs collected

Please supply the number of eggs which were collected from the patient/donor. Please enter zero if no eggs were collected.

No eggs were collected

If no eggs were collected, please confirm whether this was a result of a poor response to the drugs administered.

Section 12b

Egg collection was NOT attempted

If egg collection was NOT attempted, please select the appropriate reason why from the following options:

- Under response (poor response)
- Over response (including OHSS)
- Other

13 Outcome of eggs collected from the patient/donor

Total collected

Mixed/injected

Freeze date

Discarded

Donated for use in research

Stored for future use by patient

Donated for use in treatment (fresh)

Donated for use in treatment (frozen)

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Section 13

Outcome of eggs collected from the patient/donor

If eggs were reported as collected in the last section, then please supply in this section:-

- Total number of eggs collected
- Total number of eggs mixed or injected with sperm
- Total number of eggs discarded
- Total number of eggs donated for use in research
- Total number of eggs donated for use in the **treatment of others (fresh)**
- Total number of eggs stored for future use **by the patient – please complete the freeze date section**
- Total number of eggs donated for use in the **treatment of others (frozen) – please complete the freeze date section**

Please ensure that all eggs are accounted for so that when added together, these fields equal the number reported as the total collected.

14 Reason why no embryos were transferred if embryos were developed and/or available after thawing

OHSS

Abnormal development

As a result of positive genetic test

Failed thaw

Other

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<p>Section 14</p>	<p>Reasons why no embryos were transferred if embryos were developed and/or available after thawing</p> <p>This section should only be completed where embryos were created but no transfer took place. If the gametes or embryos are being stored, or if the patient is donating all her eggs, then please leave this section blank. Otherwise, please tick ✓ the appropriate box from the following options:-</p> <ul style="list-style-type: none"> • Risk of OHSS • Abnormal development (of embryos) • As a result of a positive genetic test • Failed thaw • Other 																								
<p>15 If embryos were transferred supply transfer date</p> <p>Embryo transfer date <input style="width: 80px;" type="text" value="___/___/___"/></p>																									
<p>Section 15</p>	<p>Date of embryo transfer</p> <p>Where an attempt was made to transfer embryos to the patient please record the date in this section</p>																								
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%;">Egg mixing date</td> <td><input style="width: 40px;" type="text" value="___/___"/></td> <td><input style="width: 40px;" type="text" value="___/___"/></td> <td><input style="width: 40px;" type="text" value="___/___"/></td> <td><input style="width: 40px;" type="text" value="___/___"/></td> <td><input style="width: 40px;" type="text" value="___/___"/></td> </tr> <tr> <td>Gamete source</td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> </tr> <tr> <td>Treatment type</td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> </tr> <tr> <td>Source of partner sperm</td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> <td><input style="width: 80px;" type="text"/></td> </tr> </table>		Egg mixing date	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	Gamete source	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	Treatment type	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	Source of partner sperm	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>
Egg mixing date	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>	<input style="width: 40px;" type="text" value="___/___"/>																				
Gamete source	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>																				
Treatment type	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>																				
Source of partner sperm	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>	<input style="width: 80px;" type="text"/>																				

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Section 16

THE FOLLOWING SECTIONS ARE LIKELY TO CAUSE MOST PROBLEMS WITH THE RECORDING OF DATA. PLEASE FOLLOW THE INSTRUCTIONS LISTED BELOW CAREFULLY.

PLEASE NOTE: Where different techniques are used on different eggs/embryo's (such as ICSI or IVF), or where sperm from different people is mixed with/injected into the eggs, these treatments should be recorded on different columns across (not on different lines down as on previous treatment forms),

Egg mixing date - Fresh and Frozen Eggs

Please record the date on which the eggs were mixed with sperm in this field.

Gamete source

Please enter the source of the gametes used. Please enter one of the following:-

- Donated eggs, donated sperm
- Donated eggs, patient partners sperm
- Patient eggs, donated sperm
- Patient eggs, patient partners sperm

In circumstances where sperm from a partner is being mixed/injected at the same time as that from a donor, then these activities must be reported on two separate rows across this table.

Treatment Type

Please enter the treatment type which the fresh/frozen egg(s) will be subjected to. Please enter one of the following:-

- IVF
- ICSI
- GIFT (with donor eggs)Eggs thaw date

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	<p>Source or partner sperm</p> <p>This field only applies to partner sperm. Please choose from the following options:</p> <ul style="list-style-type: none">• Ejaculate fresh• Ejaculate frozen• Epididymal fresh• Epididymal frozen• Testicular fresh• Testicular frozen								
Use thawed egg	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Eggs thawed date	/ /	/ /	/ /	/ /	/ /	/ /	/ /		
Number of eggs thawed									

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Section 17	<p>This section should be completed for FROZEN eggs only</p> <p>Use thawed egg</p> <p>Where frozen eggs have previously been collected from the patient or donor and are thawed for use in this cycle please Tick ✓ this box. Please note that if the eggs are fresh then this field should be left blank.</p> <p>Eggs thawed date</p> <p>Where frozen eggs have previously been collected from the patient or donor and are thawed for use in this cycle, please record the date of thawing in this field. Please note that if the eggs are fresh then this field should be left blank.</p> <p>Number of eggs thawed</p> <p>Where frozen eggs have previously been collected from the patient or donor and are thawed for use in this cycle please record the number of eggs thawed for this cycle.</p> <p>In circumstances where the patients own thawed egg(s) are being mixed/injected at the same time as those from a donor, then the thawed eggs must be reported on two separate rows within this section</p>															
Number of eggs mixed Number of eggs fertilised normally Number of embryos developed	<table style="width: 100%; text-align: center;"> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> <tr> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> <td><input type="checkbox"/></td> </tr> </table>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
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<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>												

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Section 18

This section refers to the use of FRESH eggs and eggs THAWED in section 17

Number of eggs mixed – FRESH and FROZEN EGGS

Please record the number of eggs mixed with sperm in this field.

Where different techniques are used on different eggs (such as ICSI or IVF), or where sperm from different people is mixed with/injected into the eggs, the use of the eggs should be recorded on a different line and the associated number of thawed eggs mixed recorded in this field.

Number of Eggs fertilised normally

Please enter the number of eggs which have fertilised normally and with a single sperm.

Number of embryos developed

Enter the number of embryos (number of normally fertilised eggs reaching the 2 cell stage) created in this cycle. Where different techniques have been used to create the embryos (such as ICSI or IVF), or where sperm from different people is mixed with/injected into the eggs, the use of the eggs and embryos subsequently created should be recorded on a different line.

Embryo creation and usage	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Embryo(s) thaw date	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of thawed embryos	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of viable embryos	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Screening type	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Assisted hatching technique	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Number of embryos transferred	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Embryo stage at transfer	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
Elective single embryo transfer	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Number of embryos discarded	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>

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Section 19

Embryos Creation & Use section

This section deals with eggs that have been recorded as mixed in the last section where embryos were created, and those embryos which were previously created and then frozen/stored.

Date of embryo thaw (if applicable)

Where previously frozen embryos from the patient or donor have been thawed for use in this cycle please record the date of thawing.

Number of thawed embryos

Please supply the number of previously frozen/stored embryos which have been thawed for use in this cycle.

Number of viable embryos

Please supply the number of embryos that are suitable for transfer.

Screening Type

Please enter the screening type which the embryo(s) have been subjected to (if applicable). Only one option can be selected for each row and so multiple rows should be used where multiple screening types (and none) have been used. The choices include:-

- NONE (default)
- PGS
- PGD
- HLA

Assisted Hatching Technique

Please choose the assisted hatching technique which the embryo(s) have been subjected to (if applicable), from the following:-

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- NONE (default)
- ACID
- MECHANICAL
- LASER

Number of embryos transferred to patient

Enter the number of embryos (for each row used) which have been transferred to the patient in this cycle. Please refer to the latest Code of Practice or relevant Direction for the maximum number of allowed for the patient.

Embryo (development) stage at transfer

Select from the following options:

- 2PN
- Cleavage
- Blastocyst

Elective Single Embryo Transfer?

Where more than one viable, good quality embryo has been created or thawed (and survived), and a decision has been made to limit the number of embryos transferred to one (to reduce the risk of multiple pregnancies), please tick this box. If this box is ticked, but the total number of embryos transferred to the patient is greater than 1 (for multiple lines), the form will be rejected and returned to the centre.

Number of embryos discarded

Please record the number of embryos which were created fresh or thawed and subsequently discarded.

Embryo storage					
Embryo(s) freezing/donation date	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Number of embryos stored for patient use	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Dev. freeze stage	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Number of embryos donated Fresh	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Number of embryos donated Frozen	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>
Number of embryos donated to research	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>	<input type="text" value=""/>

GUIDANCE NOTES ON COMPLETING HFEA FORMS T IVF Treatment & Embryo Creation/Use FORM

Version 2008/2

Section 20

Embryos Storage Section

This section is to record the embryos which are to be stored for future use and/or donated for use in treatment and/or research.

Embryo(s) freezing/storage date

Where embryos are being frozen/stored, please record the date in this field.

Number of embryos being frozen/stored for future patient use

Where embryos are being stored for use in the patient's own future treatment, please supply the number in this field.

Developmental freezing stage (for embryos)

Where embryos are being stored for any reason, please record their stage of development at the freezing stage. Options are:-

- 2PN (Pro Nuclei)
- CLEAVAGE
- BLASTOCYST

No. of embryos donated for others Fresh

Please supply the number of embryos that are being donated for use by other patients in a fresh state.

No. of embryos donated for others Frozen

Please supply the number of embryos that are being donated for use by other patients in a frozen state

No. of embryos donated to research

Please supply the number of embryos that are being donated for use in research.