

SECTION 7

PREGNANCY OUTCOME FORM

Version 2007

Issue 1 – Published 22/02/07

These guidance notes replace all previous versions

GUIDANCE NOTES ON COMPLETING HFEA FORMS

O Pregnancy Outcome Form

Version 2007/1



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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 three numerics – i.e. 000.
HFEA form number	Each Pregnancy Outcome form has a single unique number to identify it, (top right hand corner starting with the letter O). 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 1. Original forms using duplicate form numbers will be rejected and returned to the centre. 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.

Pregnancy Outcome	Centre: <input type="text" value="9004"/>	Form O <input type="text"/>	
1 This form	<input type="checkbox"/> Is reporting a new outcome <input type="checkbox"/> Replaces all details previously supplied		
This form is notifying corrections to form O	<input type="text"/>		

Section 1	<p>This form:-</p> <p>Tick ✓ which box is applicable. If all or none of the boxes are ticked ✓, the form will be rejected and returned to the centre.</p> <p>If this form is providing information about a pregnancy outcome for the first time, then please tick ✓ – IS REPORTING A NEW OUTCOME</p> <p>To make updates or corrections to a previously reported pregnancy outcome form, fill out a new form and tick ✓ the REPLACES ALL DETAILS PREVIOUSLY REGISTERED box. The number of the original form which is now being replaced must be supplied in section 1. If the form number stated in section 1 is not found on the HFEA Register, the form will be returned.</p> <p>Notifying Corrections</p> <p>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>
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2 Form completed on <input style="width: 100px;" type="text"/>	
Section 2	Form Completed On This is the date on which the form is being filled out at the clinic.
3 Patient number <input style="width: 150px;" type="text"/> Patient surname <input style="width: 350px;" type="text"/>	
Section 3	Patient 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 ID 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 rejected.
4 This form is reporting additional sacs to those recorded on form <input style="width: 50px;" type="text"/>	
Section 4	This form is reporting additional sacs to those recorded on form Details for a maximum of 3 gestational sacs can be recorded on a single pregnancy outcome form. To report additional details, please record these on an separate Pregnancy Outcome form, and enter the form to which the additional details relate in this field.
5 This outcome is a result of the following treatment type IVF <input type="checkbox"/> Donor insemination <input type="checkbox"/> Date of successful treatment cycle to which outcome relates <input style="width: 80px;" type="text"/>	
Section 5	The outcome is a result of the following treatment type: Tick <input checked="" type="checkbox"/> which box is applicable from the choice of IVF or Donor Insemination.

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	<p>If the IVF option is ticked, then an IVF Treatment & Embryo Creation and Use form (T type) must have previously been supplied to the HFEA for treatments which took place on the date specified below, or the form will be rejected.</p> <p>If the Donor Insemination option is ticked, then a Donor Insemination form (I type) must have previously been supplied to the HFEA for treatments which took place on the date specified below, or the form will be rejected.</p> <p>Date of successful treatment cycle to which outcome relates:</p> <p>Please supply the date of the treatment activity which produced this successful outcome as recorded on the relevant I or T type form.</p> <p>ALTERNATIVELY</p> <p>Please enter the IVF Treatment (T) or Donor Insemination (I) form number which created this pregnancy outcome.</p>
<p>6 Number of gestational sacs with detected fetal pulsation <input type="text"/></p>	
<p>Section 6</p>	<p>Number of gestational sacs with detected fetal pulsation</p> <p>Please fill in the number of gestational sacs in which a pulsation was seen. This must be recorded in all cases including miscarriage.</p>
<p>7 Pregnancy terminated <input type="checkbox"/> Reason <input type="text"/></p>	
<p>Section 7</p>	<p>Pregnancy terminated</p> <p>If the pregnancy has been deliberately terminated, tick ✓ the box and supply a reason. A typical reason might be to protect the health or life of the patient.</p>
<p>8 Lost to follow up <input type="checkbox"/> Reason <input type="text"/></p>	
<p>Section 8</p>	<p>Lost to follow up</p> <p>If, after extensive efforts (as specified in the HFEA Code of Practice) your clinic has been unable to obtain outcome details from the patient, then tick ✓ the Lost to follow up box. Please provide a brief reason why this is the case.</p>

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9 Pregnancy outcome	Gestational SAC	Gestational SAC	Gestational SAC
	Sac number <input type="text"/>	Sac number <input type="text"/>	Sac number <input type="text"/>
	Gestation weeks <input type="text"/>	Gestation weeks <input type="text"/>	Gestation weeks <input type="text"/>
	Miscarriage <input type="checkbox"/>	Miscarriage <input type="checkbox"/>	Miscarriage <input type="checkbox"/>
	Ectopic pregnancy <input type="checkbox"/>	Ectopic pregnancy <input type="checkbox"/>	Ectopic pregnancy <input type="checkbox"/>
	Heterotopic pregnancy <input type="checkbox"/>	Heterotopic pregnancy <input type="checkbox"/>	Heterotopic pregnancy <input type="checkbox"/>

Section 9

Pregnancy outcome

Changes to this form mean that **outcomes are now reported by gestational sac** (as opposed to fetal heart). Since a gestational sac may contain several foetuses (for example with monozygotic twins), the sac number has not been defaulted. Instead, the relevant sac number needs to be entered.

Please tick ✓ the appropriate pregnancy outcome for each gestational sac. It is also important that you record the number of weeks gestation for all cases including miscarriage, termination, etc. Failure to do so will result in the form being returned. If more than 3 gestational sacs are observed, please complete a second Pregnancy Outcome form and relate the details to this first form by entering the form number in section 4.

If the outcome type is recorded as a live birth for any of the fetal hearts, then relevant details must be entered in section 12.

10	Embryo reduction <input type="checkbox"/>	Embryo reduction <input type="checkbox"/>	Embryo reduction <input type="checkbox"/>
Reason	<input type="text"/>	<input type="text"/>	<input type="text"/>

Section 10

Embryo Reduction

If any of the embryo are terminated tick ✓ the box and provide the reason for this clinical intervention.

11 Baby Born	Baby 1	Baby 2	Baby 3
	Live birth <input type="checkbox"/>	Live birth <input type="checkbox"/>	Live birth <input type="checkbox"/>
	Still birth <input type="checkbox"/>	Still birth <input type="checkbox"/>	Still birth <input type="checkbox"/>
	Neonatal death <input type="checkbox"/>	Neonatal Death <input type="checkbox"/>	Neonatal Death <input type="checkbox"/>
	Weight (grams) <input type="text"/>	Weight (grams) <input type="text"/>	Weight (grams) <input type="text"/>
	Male <input type="checkbox"/> Female <input type="checkbox"/>	Male <input type="checkbox"/> Female <input type="checkbox"/>	Male <input type="checkbox"/> Female <input type="checkbox"/>
	Date of delivery <input type="text"/>	Date of delivery <input type="text"/>	Date of delivery <input type="text"/>
	NHS Number <input type="text"/>	NHS Number <input type="text"/>	NHS Number <input type="text"/>

Section 11

Baby born

Complete all fields within this section if there was a live birth,

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a stillbirth or a neonatal death. Information about each baby must be provided including:-

- Weight of the baby in metric units,
- Sex of the baby,
- Date of delivery, and
- NHS Numbers should be supplied for all babies.

If the baby was born after 24 weeks gestation and the baby is classed as a stillbirth, you must still report all the information above.

If the baby was born before 24 weeks of gestation this is classed as a miscarriage, and only the number of weeks gestation need to be supplied.

12	Baby's forename(s) <input type="text"/> Registered surname <input type="text"/>	Baby's forename(s) <input type="text"/> Registered surname <input type="text"/>	Baby's forename(s) <input type="text"/> Registered surname <input type="text"/>
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Section 12	<p>Baby's forename</p> <p>Please enter each of the baby's forenames.</p> <p>Baby's registered surname</p> <p>Please supply the surname of the baby with which it will be registered.</p>
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13	Congenital abnormalities <input type="radio"/> No anomaly observed <input type="radio"/> Uncertain - further review required <input type="radio"/> Yes - anomaly observed	Congenital abnormalities <input type="radio"/> No anomaly observed <input type="radio"/> Uncertain - further review required <input type="radio"/> Yes - anomaly observed	Congenital abnormalities <input type="radio"/> No anomaly observed <input type="radio"/> Uncertain - further review required <input type="radio"/> Yes - anomaly observed
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Section 13	<p>Congenital abnormalities</p> <p>Tick ✓ which box is applicable. If all or none of the boxes are ticked ✓, the form will be rejected and returned to the centre.</p>
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14	Baby's town of birth <input type="text"/> Country of birth <input type="text"/>
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Section 14

Town of birth

Please enter the town (or district) where the birth took place.

Country of birth

Please enter the associated country where the birth took place.

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SAMPLE FORM - DO NOT COPY OR USE



HFEA EDI (Training Centre 9004) - [Pregnancy outcome (New entry)]

File Forms Reports Utilities Window Help

Pregnancy Outcome Centre: Form O

1 This form

This form is notifying corrections to form O

2 Form completed on

3 Patient number

Patient surname

4 This form is reporting additional sacs to those recorded on form O

5 This outcome is a result of the following treatment type IVF Donor insemination

Date of successful treatment cycle to which outcome relates

Alternatively IVF Treatment Form T OR Treatment Form I

6 Number of gestational sacs with detected fetal pulsation

7 Pregnancy terminated Reason

8 Lost to follow up Reason

	Gestational SAC	Gestational SAC	Gestational SAC
<p>9 Pregnancy outcome</p> <p>Sac number <input type="text"/></p> <p>Gestation weeks <input type="text"/></p> <p>Miscarriage <input type="radio"/></p> <p>Ectopic pregnancy <input type="radio"/></p> <p>Heterotopic pregnancy <input type="radio"/></p> <p>10 Embryo reduction <input type="checkbox"/></p> <p>Reason <input type="text"/></p>	<p>Sac number <input type="text"/></p> <p>Gestation weeks <input type="text"/></p> <p>Miscarriage <input type="radio"/></p> <p>Ectopic pregnancy <input type="radio"/></p> <p>Heterotopic pregnancy <input type="radio"/></p> <p>Embryo reduction <input type="checkbox"/></p> <p>Reason <input type="text"/></p>	<p>Sac number <input type="text"/></p> <p>Gestation weeks <input type="text"/></p> <p>Miscarriage <input type="radio"/></p> <p>Ectopic pregnancy <input type="radio"/></p> <p>Heterotopic pregnancy <input type="radio"/></p> <p>Embryo reduction <input type="checkbox"/></p> <p>Reason <input type="text"/></p>	<p>Sac number <input type="text"/></p> <p>Gestation weeks <input type="text"/></p> <p>Miscarriage <input type="radio"/></p> <p>Ectopic pregnancy <input type="radio"/></p> <p>Heterotopic pregnancy <input type="radio"/></p> <p>Embryo reduction <input type="checkbox"/></p> <p>Reason <input type="text"/></p>
<p>11 Baby Born</p> <p style="text-align: center;">Baby 1</p> <p>Live birth <input type="radio"/></p> <p>Still birth <input type="radio"/></p> <p>Neonatal death <input type="radio"/></p> <p>Weight (grams) <input type="text"/></p> <p>Male <input type="radio"/> Female <input type="radio"/></p> <p>Date of delivery <input type="text" value="__/__/__"/></p> <p>NHS Number <input type="text"/></p> <p>Baby's forename(s) <input type="text"/></p> <p>Registered surname <input type="text"/></p> <p>12 Congenital abnormalities</p> <p>No anomaly observed <input type="radio"/></p> <p>Uncertain - further review required <input type="radio"/></p> <p>Yes - anomaly observed <input type="radio"/></p>	<p style="text-align: center;">Baby 2</p> <p>Live birth <input type="radio"/></p> <p>Still birth <input type="radio"/></p> <p>Neonatal Death <input type="radio"/></p> <p>Weight (grams) <input type="text"/></p> <p>Male <input type="radio"/> Female <input type="radio"/></p> <p>Date of delivery <input type="text" value="__/__/__"/></p> <p>NHS Number <input type="text"/></p> <p>Baby's forename(s) <input type="text"/></p> <p>Registered surname <input type="text"/></p> <p>12 Congenital abnormalities</p> <p>No anomaly observed <input type="radio"/></p> <p>Uncertain - further review required <input type="radio"/></p> <p>Yes - anomaly observed <input type="radio"/></p>	<p style="text-align: center;">Baby 3</p> <p>Live birth <input type="radio"/></p> <p>Still birth <input type="radio"/></p> <p>Neonatal Death <input type="radio"/></p> <p>Weight (grams) <input type="text"/></p> <p>Male <input type="radio"/> Female <input type="radio"/></p> <p>Date of delivery <input type="text" value="__/__/__"/></p> <p>NHS Number <input type="text"/></p> <p>Baby's forename(s) <input type="text"/></p> <p>Registered surname <input type="text"/></p> <p>12 Congenital abnormalities</p> <p>No anomaly observed <input type="radio"/></p> <p>Uncertain - further review required <input type="radio"/></p> <p>Yes - anomaly observed <input type="radio"/></p>	
<p>14 Baby's town of birth <input type="text"/></p> <p style="text-align: right;"><input type="button" value="Print Form"/></p>			