



CONSENT VARIATION FORMS

Version 2010

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GUIDANCE NOTES ON COMPLETING HFEA CV (Consent Variation) Forms

Version 2010/1

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Consent Variation Form –Type CV

When to use this form

This form should be used for the following:

- ❖ When patients and partners who were registered before 1 October 2009 but treated after 1 May 2010 complete a CD form (N.B: for patients registered and treated after 1 October 2009, clinics should submit a correction to their original registration form rather than completing this CV form)
- ❖ When parents consent to or object to the disclosure of information about their child but only when that differs from their preferences regarding disclosure of their own data

Generally, parental consent/dissent recorded on a CD form also will apply to data about a child born as a consequence of this treatment. If a patient/partner objects to the disclosure of their own data in the CD form, this preference will automatically be applied to data about any child born as a consequence of their treatment.

However, in some cases, patients and their partners may be content for their own data to be disclosed for research purposes but be opposed to the disclosure of any information about their child.

In such cases, clinics will need to receive in writing any expression of dissent from disclosure. This should be stored with the original CD form in compliance with Directions 0012 - Retention of records. It may be helpful to advise parents and guardians to formulate any letter of dissent as follows:

I {insert full name} do not consent to personally identifying information about {insert child's name} born {insert date of birth} being disclosed under section 33D of the Human and Fertilisation and Embryology Act 1990 (as amended).

{Signed and dated}.

Centres are advised to give the patients as much information as possible about this issue before patients provide them with notification of their withdrawal of consent.

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 numbers – i.e. 0000. The EDI application will automatically populate this field.

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HFEA form number	Each Consent Variation form has a single unique number to identify it (top right hand corner starting with the letter CV). If, after submitting a form, a correction needs to be made, it is essential that the original form number be quoted on any new form in section 2. Original forms using duplicate form numbers will be rejected and returned to the centre. Numbers supplied by the HFEA are unique. It is the responsibility of the centre to ensure that, where forms are generated from Electronic Patient Records systems, form numbers are not repeated. The EDI application will automatically populate this field.
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Consent Variation	Centre <input type="text"/>	Form CV <input type="text"/>	
1 This form:	<input checked="" type="radio"/> Is recording a new variation: <input type="radio"/> Replaces all details previously supplied		
This form replaces form CV	<input type="text"/>		

Section 1	<p>This form</p> <p>If the submission is for a new consent or parents are change the consent applied to their child, please tick the 'Is recording a new variation' button.</p> <p>If you wish to make changes or corrections to a previous CV form, please tick the 'Corrects all details previously supplied' button and record the number of the original form to which the correct applies in the box supplied.</p>
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2 Form completed on	<input type="text"/>
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Section 2	<p>Form completed on</p> <p>Please enter the date this form is being completed on.</p>
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3 Purpose of form:	Vary consent for: <input type="radio"/> Patient <input type="radio"/> Partner <input type="radio"/> Child		
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Section 3	<p>Purpose of form</p> <p>Please confirm whether this form is recording consent information for a patient, a partner or a child born as a consequence of treatment.</p>
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4 Patient/Partner number

Patient/Partner surname

If a child, enter the child's DOB

Section 4

Patient/Partner number

The Patient or Partner number allocated to the individual whose consent is being recorded or changed. This number should relate to the number under which the patient or partner has been registered with the HFEA.

Patient/Partner surname

Please enter the patient/partner surname as specified on their HFEA Registration form.

If a child, enter the child's DOB

If the form is being submitted to record a change in consent for a child born as a result of treatment then enter the child's Date of Birth. If parents are asking to change consent for twins the form will automatically apply to both. If parents are asking to change consent for children born at different times then a new CV form is required for each separate birth date.

5 Consent Variation

Generic Consent for Research Yes No

Consent for non-contact research Yes No

Consent for contact research Yes No

Section 5

Consent Variation

Complete this section with details of what the patient/partner has completed in section 4.1 and 4.2 on the CD form or indicate if a patient/partner has written to the centre to object to the disclosure of information about their child.

Comments

Comments Use the section if there is any additional information you wish to send to the Authority about this form.

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SAMPLE FORM - DO NOT COPY OR USE

Consent Variation	Centre	<input style="width: 100%;" type="text"/>	Form CV	<input style="width: 100%;" type="text"/>
1 This form:	<input checked="" type="radio"/> Is recording a new variation <input type="radio"/> Replaces all details previously supplied			
This form replaces form CV	<input style="width: 100%;" type="text"/>			
2 Form completed on:	<input style="width: 100%;" type="text"/>			
3 Purpose of form:	<input type="radio"/> Patient <input type="radio"/> Partner <input type="radio"/> Child			
Vary consent for:				
4 Patient/Partner number	<input style="width: 100%;" type="text"/>			
Patient/Partner surname	<input style="width: 100%;" type="text"/>			
If a child, enter the child's DOB	<input style="width: 100%;" type="text"/>			
5 Consent Variation				
Generic Consent for Research	<input type="radio"/> Yes <input type="radio"/> No			
Consent for non-contact research	<input type="radio"/> Yes <input type="radio"/> No			
Consent for contact research	<input type="radio"/> Yes <input type="radio"/> No			
Comments	<div style="border: 1px solid #ccc; width: 100%; height: 100%;"></div>			

HFEA: Consent Variation Form (71) - 1 May 2010