

Mitochondrial donation: consent to donating your eggs

About this form

This form is produced by the Human Fertilisation and Embryology Authority (HFEA), the UK's independent regulator of fertility treatment and human embryo research. For more information about us, visit www.hfea.gov.uk.

Who should fill in this form?

Fill in this form if you are a woman donating eggs and/or embryos created with your eggs for use in other women's mitochondrial donation treatment so that they can avoid passing on inheritable mitochondrial diseases to their children.

What does mitochondrial donation involve?

You will be donating eggs (containing your mitochondria) to other women who have mitochondria containing gene abnormalities, for use in IVF-based treatment so that they can avoid passing on an inheritable mitochondrial disease to their child. The IVF-based techniques used to achieve this are called maternal spindle transfer (MST) and pronuclear transfer (PNT). On this form you can consent to MST, PNT or both.

What are MST and PNT?

In MST, your nuclear genetic material (the genes which make us who we are) will be removed from your eggs and replaced with the nuclear genetic material from the intended mother's egg. The nuclear genetic material removed from your eggs will be discarded.

Following MST, the eggs containing your mitochondria will be fertilised with the intended father's (or a donor's) sperm to create embryos which will be used in the intended mother's treatment. This means that the intended mother, not you, will be the genetic parent of any child that is born.

In PNT, your eggs will be fertilised with the intended father's (or a donor's) sperm to create embryos. The nuclear genetic material within these embryos will then be removed and discarded. It will be replaced with the nuclear genetic material removed from embryos created using the intended mother's eggs and father's (or donor's) sperm. This means that they, not you, will be the genetic parents of the child.

If you're unsure of anything, please ask your clinic for more information.

What do I need to know before filling in this form?

Before you fill in this form, you should have completed the 'Mitochondrial Donor Registration Form'. Make sure that your clinic has given you all the relevant information you need to make fully informed decisions. This includes:

- information about:
 - the different options set out in this form
 - the implications of giving your consent
 - the consequences of withdrawing this consent, and
 - how and when you can make changes to, or withdraw, your consent.
- an opportunity to have counselling.

For clinic use only (optional)

HFEA centre reference

Other relevant forms

Date eggs were placed in storage

D	D	M	M	Y	Y
---	---	---	---	---	---

Date eggs can remain in storage until

D	D	M	M	Y	Y
---	---	---	---	---	---

If you are unsure, or think that you have not been given all of this information, please speak to your clinic. There is a declaration at the end of this form which you must sign to confirm you have received this information before filling in this form. If you haven't your consent may be invalid.

If you are unable to complete this form because of physical illness, injury or disability you may direct someone else to complete and sign it for you.

Why do I have to fill in this form?

By law, you need to give your written consent if you want your eggs, or embryos created outside the body (in vitro) with your eggs, to be used or stored.

If your eggs or embryos containing your nuclear genetic material are going to be stored, you must consent to this and state in writing how long you consent to them remaining in storage. Once your nuclear genetic material has been removed and replaced with that of the intended mother and sperm provider, they will determine what happens to them, including how long they will be stored for.

Why are there questions about using my eggs and embryos for training purposes?

There may be some eggs or embryos left after treatment. This form allows you to consent to donate eggs or embryos (containing your nuclear genetic material) for training purposes, helping embryologists to learn about, and practice, IVF techniques.

What if I want to donate my eggs for other purposes?

If you also wish to donate your eggs for 'regular' egg donation (where your eggs are donated to someone to help them conceive rather than avoid passing on a mitochondrial disease), you must complete the 'Your consent to donating your eggs' (WD form). If you have entered into an egg sharing agreement, you must complete the 'Women's consent to treatment and storage form (IVF and ICSI)' (WT form).

Eggs can also be donated for research purposes, helping to increase knowledge about diseases and serious illnesses and potentially developing new treatments. If you would like to donate any eggs or embryos (before your nuclear genetic material is removed) to research, speak to your clinic who will provide you with the relevant consent form(s).

What if I want to withdraw my consent?

You can make changes to or withdraw your consent at any point up until your genetic material is removed from your eggs, or in PNT, the embryos created with your eggs. After this point you will no longer have any rights over the eggs or embryos and cannot withdraw consent to their use in treatment, storage or training.

What happens to my eggs or embryos if I die?

By consenting to mitochondrial donation, you are also agreeing to your eggs or embryos (before your nuclear genetic material is removed) being used and stored if you were to die or lose the ability to decide for yourself (become mentally incapacitated). If you do not want your eggs or embryos to be used for the purposes outlined in this form if this were to happen, you can state this as a restriction (at section 2.3).

Please note that the clinic can only act on these wishes if they are informed about your death or mental incapacity. If you're unsure of anything in relation to this, please ask your clinic.

When filling in this form, make sure you sign the declaration on every page to confirm that you have read the page and fully agree with the consent and information given. When you have completed the form you may request a copy of it from your clinic.

Donor number

Version 1, 29 October 2015

1. About you

First name(s)

Surname

Date of birth

NHS/CHI/HCN/passport number (please circle)

2. About your mitochondrial donation

2.1. Do you consent to your eggs undergoing MST and for embryos created from eggs following MST being used for the treatment of others?

This process will involve:

- your eggs undergoing the MST process (this means that your nuclear genetic material will be removed from your eggs and replaced with the intended mother's nuclear genetic material. Your nuclear genetic material will be discarded),
- the eggs, following MST (containing your mitochondria and the intended mother's nuclear genetic material) being used to create embryos outside of the body, and
- those embryos being used in the intended mother's treatment (embryo transfer).

 Yes

 No

2.2. Do you consent to your eggs being used to create embryos outside of the body which will undergo PNT and be used in the treatment of others?

This process will involve:

- your eggs being used to create embryos outside of the body (those embryos will contain your and the sperm provider's nuclear genetic material),
- the embryos undergoing the PNT process (this means that your nuclear genetic material will be removed from the embryo, discarded, and replaced with the intended mother's and sperm provider's nuclear genetic material), and
- those embryos (containing your mitochondria and the intended mother's and sperm provider's nuclear genetic material) being used in the intended mother's treatment (embryo transfer).

 Yes

 No

2.3. Would you like to apply any restrictions to your answers to 2.1 and 2.2 above?

You may want to put restrictions on who your eggs, or in PNT, embryos created with your eggs, can be used by (eg, a specified named recipient). Another example may be that you do not wish for your eggs or embryos to be used in the event of your death or mental incapacity. If so, please state on the next page. Please note that you can only place restrictions on eggs or embryos that still contain your nuclear genetic material (ie, before they have undergone the MST or PNT process).

Page declaration signature

Date

Donor number

Version 1, 29 October 2015

 Yes - specify your restrictions in the box below then continue to section 3. No - go to section 3.

3. Using eggs and embryos in training

3.1 Do you consent to your eggs (containing your nuclear genetic material) being used for training purposes?

 Yes No

PNT only

3.2. Do you consent to your embryos (containing your nuclear genetic material) already created outside the body with your eggs being used for training purposes?

 Yes No

4. Storing eggs and embryos

If your eggs or embryos are going to be stored before MST or PNT (eg, before your nuclear genetic material is removed), you must consent to this and state in writing how long you consent to them remaining in storage.

You can store for any period up to 10 years but in some cases where you, your partner, or the person to whom your eggs and embryos have been allocated, is prematurely infertile, or likely to become prematurely infertile, you may store for longer, up to 55 years.

A medical practitioner will need to certify in writing that the medical criteria for premature infertility have been met for storage to continue for more than 10 years. When the criteria have been met, the storage period will be extended by 10 years from the date the criteria are met.

The storage period can then be extended by further 10 year periods (up to a maximum of 55 years) at any time within each extended storage period if it is shown that the criteria continue to be met. For more information about this, please ask your clinic.

Once your nuclear genetic material has been removed from your eggs or embryos, the intended mother and sperm provider (together with the clinic) will determine how long the eggs or embryos will be stored for.

4.1. Do you consent to your eggs (containing your nuclear genetic material) being stored?

 Yes No

Page declaration signature

Date

D	D	M	M	Y	Y
---	---	---	---	---	---

Donor number

Version 1, 29 October 2015

4.2. For how long do you consent to eggs (containing your nuclear genetic material) being stored? Only complete this section if you answered yes to section 4.1. Please talk to your clinic if you're unsure of how long to store for.

- 10 years 55 years
- A specific period (up to 55 years). Specify number of years

PNT only

4.3. Do you consent to embryos (containing your nuclear genetic material) being stored?

- Yes No

4.4. For how long do you consent to embryos (containing your nuclear genetic material) being stored? Only complete this section if you answered yes to question 4.3. Please talk to your clinic if you're unsure of how long to store for.

- 10 years 55 years
- A specific period (up to 55 years). Specify number of years

The consent period will start from the date of storage. Remember you can always change the time period you consent to by completing this form again and specifying the new total time period you would like your eggs and embryos to be stored for. For example, if you consented to five years' storage on the original form and wish to consent for a further five years (10 years in total), you should complete another copy of this form but tick the box for 10 years. This second form would supersede the first form you completed.

5. Declaration

Please sign and date the declaration

- I declare that I am the person named in section one of this form.
- I declare that:
 - before I completed this form, I was given information about the different options set out in this form, and I was given an opportunity to have counselling
 - the implications of giving my consent, and the consequences of withdrawing this consent, have been fully explained to me, and
 - I understand that I can make changes to, or withdraw, my consent at any point until the nuclear genetic material has been removed from my eggs, or in PNT, embryos created with my eggs.
- I declare that the information I have given on this form is correct and complete.
- I understand that information on this form may be processed and shared for the purposes of, and in connection with, the conduct of licensable activities under the Human Fertilisation and Embryology Act 1990 (as amended) in accordance with the provisions of that act.

Your signature

Date

Donor number

Version 1, 29 October 2015

If signing at the direction of the person consenting

If you have completed this form at the direction of the person consenting (because she is unable to sign for herself due to physical illness, injury or disability), you must sign and date below. There must also be a witness confirming that the person consenting is present when you sign the form.

I declare that the person named in section one of this form is present at the time of signing this form and I am signing it in accordance with her direction.

Representative's name

Representative's signature

Relationship to person consenting

Date

Witness's name

Witness's signature

Date