Mitochondrial donation: women’s consent to treatment and storage

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 having mitochondrial donation treatment to avoid passing on an inheritable mitochondrial disease to your child, using embryos created outside the body (in vitro) with your eggs. This may be by in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI).

What does mitochondrial donation involve?
Your eggs or embryos together with donated eggs, or embryos created outside the body with donor eggs will be used in technique(s) based on IVF, so you can avoid passing on an inheritable mitochondrial disease to your 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.

Before filling out this form please speak to your clinic about which technique will be used in your treatment.

What are MST and PNT?
MST and PNT allow eggs or embryos to be created containing your nuclear genetic material (the genes which make you who you are) and donated mitochondria.

In MST, the nuclear genetic material will be removed from your eggs and transferred into donated eggs once their nuclear genetic material has been removed. The eggs containing your nuclear genetic material and the donor’s mitochondria will be fertilised with your partner’s (or a donor’s) sperm to create embryos.

In PNT, your eggs will be fertilised with your partner’s (or a donor’s) sperm to create embryos. The nuclear genetic material within each embryo (which contains your genetic material) will then be transferred into embryos created using donated eggs and sperm from the sperm provider, from which the nuclear genetic material has been removed.

In both MST and PNT, the resulting embryos containing your and your partner’s (or a sperm donor’s) genetic material and the donor mitochondria will be transferred to your womb and hopefully implant and develop into a baby. You and the sperm provider, not the egg donor, 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?

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.

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 need 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 (which includes mitochondrial donation).

If following MST or PNT your eggs or embryos 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 transferred into the donor eggs or embryos, you (and the sperm provider) will determine what happens to them, including how long they will be stored for.

The eggs and embryos that have had your nuclear material removed will be discarded.

You are also legally required to record what you would like to happen to your eggs and embryos if you were to die or lose the ability to decide for yourself (become mentally incapacitated).

While this is perhaps not something you have considered, your clinic needs to know this so that they only allow your eggs and embryos to be used according to your wishes.

If you are unsure of anything in relation to this, please ask your clinic.

Why are there questions about using my eggs 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 and/or embryos?

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

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.
1. **About you**

First name(s) | Surname  
---|---

Date of birth | NHS/CHI/HCN/passport number (please circle)  
D D M M Y Y

2. **About your partner**

Your partner's first name(s) | Your partner's surname  
---|---

Your partner's date of birth | Your partner's NHS/CHI/HCN/passport number  
D D M M Y Y

3. **About your treatment**

3.1. **Do you consent to your eggs undergoing MST and embryos created from eggs following MST being used in your treatment?**

This process will involve:

- your eggs undergoing the MST process (this means that your nuclear genetic material will be removed from your eggs and transferred into ‘new’ eggs containing donor mitochondria but no donor nuclear genetic material. The eggs containing your mitochondria will be discarded.),
- the eggs, following the MST process (containing your nuclear genetic material and donor mitochondria), being used to create embryos outside of the body, and
- those embryos being used in your treatment (embryo transfer).

☐ Yes  ☐ No

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

This process will involve:

- your eggs being used to create embryos outside the body (those embryos will contain your and the sperm provider’s nuclear genetic material),
- those embryos (containing your nuclear genetic material) undergoing the PNT process (this means that genetic material will be removed from your embryos and transferred into ‘new’ embryos containing donor mitochondria but no donor nuclear genetic material. The embryonic material containing your mitochondria will be discarded.)), and
- those embryos (containing your nuclear genetic material and donor mitochondria), to be used in your treatment (embryo transfer).

☐ Yes  ☐ No

Page declaration signature  

Date  
D D M M Y Y
4. **Storing eggs and embryos**

You may wish to store any eggs and/or embryos before or after they have undergone MST or PNT so they can be used in future treatment. To be stored, eggs or embryos are frozen or ‘vitrified’. When considering how long to store for, you may want to think about how far in the future you might want/be able to use your stored eggs and embryos and the costs of storing – ask your clinic if you are unsure. You can store for any period up to 10 years but in cases where you or your partner are prematurely infertile, or likely to become prematurely infertile, you may store for longer, up to 55 years. Please note that any arrangements you need to make regarding the practicalities of storage with your clinic or funding body are separate from this consent. For example, your clinic may only continue to store your eggs and/or embryos for the period you have specified in this form if you, or your funding provider, continue to pay the storage fees.

4.1. Do you consent to your eggs (containing your nuclear genetic material and donated mitochondria, or your nuclear genetic material and mitochondria) being stored?

☐ Yes  ☐ No

4.2. For how long do you consent to these eggs being stored? Only complete this section if you answered yes to section 4.1.

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

4.3. Do you consent to embryos (containing your nuclear genetic material and donated mitochondria, or your nuclear genetic material and mitochondria) being stored? Please note that embryos can only be stored if the sperm provider (whose nuclear genetic material is being used) has also given his consent.

☐ Yes  ☐ No

4.4. For how long do you consent to these embryos being stored? Only complete this section if you answered yes to section 4.3.

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

4.5. Please note in the box below if you would like to specify different storage periods for eggs or embryos before or after they have undergone MST or PNT, or if you want to restrict your consent to only eggs or embryos at a certain stage (ie, pre or post MST or PNT). Your consent to store eggs or embryos prior to the MST or PNT process is not needed on this form if you have already completed the GS or WT form.
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. Using eggs and embryos in training

5.1. Do you consent to eggs surplus to your treatment being used for training purposes?

☐ Yes ☐ No

5.2. Do you consent to embryos (already created outside the body containing your nuclear genetic material) surplus to your treatment being used for training purposes? Please note that embryos can only be used if the sperm provider (whose nuclear genetic material is being used) has also given his consent.

☐ Yes ☐ No

6. In the event of your death or mental incapacity

As part of your consent, you also need to decide what you would like to happen to your eggs, or embryos containing your nuclear genetic material, if you die or lose the ability to decide for yourself (become mentally incapacitated). Please note your eggs or embryos may only be used within the storage period you consented to above. If you do not give your consent in the section below, your eggs or embryos must be allowed to perish in the event of your death or mental incapacity and cannot be used for treatment.

6.1. Do you consent to eggs being used for training purposes?

If you die

☐ Yes ☐ No

If you become mentally incapacitated

☐ Yes ☐ No

6.2. Do you consent to embryos (already created outside the body containing your nuclear genetic material) being used for training purposes? Please note that embryos can only be used if the sperm provider (whose nuclear genetic material is being used) has also given his consent.

If you die

☐ Yes ☐ No

If you become mentally incapacitated

☐ Yes ☐ No

Other uses for your eggs or embryos

If you are storing eggs or embryos following MST or PNT you may wish for them to be used in someone else’s treatment if you die or become mentally incapacitated, please speak to your clinic for more information. Depending on your circumstances, you will need to complete one of the following:

- ‘Your consent to donating your eggs’ (WD form),
- ‘Your consent to donating embryos’ (ED form), or
- ‘Women’s consent to the use and storage of eggs or embryos for surrogacy’ (WSG form).
7. **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 time of embryo transfer, use of eggs or embryos in training, or the eggs or embryos have been allowed to perish.
- 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

**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