

Mitochondrial donation: men's consent to treatment and storage

MMT

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 man and your partner is having mitochondrial donation treatment using embryos created outside the body (in vitro) with your sperm. This may be by in vitro fertilisation (IVF) or intracytoplasmic sperm injection (ICSI).

What does mitochondrial donation involve?

Your sperm will be used to create embryos with donated eggs and/or your partner's eggs, by IVF or ICSI, so your partner 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 partner's treatment.

What are MST and PNT?

MST and PNT allow eggs or embryos to be created for you containing your and your partner's 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 partner's eggs and transferred into donated eggs once their nuclear genetic material has been removed. Your sperm will then be used with these eggs to create embryos containing your and your partner's nuclear genetic material and donated mitochondria.

In PNT, your sperm may be used for two stages:

Stage one – your sperm will be used to create embryos with your partner's eggs. The nuclear genetic material will be removed and transferred into embryos created in stage two. Once the nuclear genetic material has been removed the embryonic material created in stage one will be discarded.

Stage two – either your sperm or donor sperm (for example, if you are genetically related to the egg donor) will be used to create embryos with donated eggs. The nuclear genetic material will be removed, discarded, and replaced with the nuclear genetic material removed from the embryos created in stage one, above.

In both MST and PNT, the embryos containing your and your partner's genetic material and the donor's mitochondria will be transferred to your partner's womb and hopefully implant and develop into a baby. You and your partner, not the donor, will be the genetic parents of the child.

For clinic use only (optional)

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HFEA centre reference

Other relevant forms

Date embryos were placed in storage

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

Date embryos can remain in storage until

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

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
 - 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 have to fill in this form?

By law, you need to give your written consent if you want your sperm, and embryos created using your sperm, to be used or stored. If your sperm or embryos created following MST or PNT are going to be stored, you must consent to this and state in writing how long you consent to them remaining in storage.

In MST once eggs containing your partner's nuclear genetic material have been fertilised with your sperm to create embryos, you (and your partner) will determine what happens to them, including how long they will be stored for.

In PNT embryos will be created from donated eggs and your (or donor) sperm.

The nuclear genetic material will be removed from those embryos and replaced with the nuclear genetic material from embryos created with your sperm and your partner's eggs. Once PNT takes place you (and your partner) will determine what happens to them, including how long they will be stored for. The embryos that have had their nuclear genetic material removed will be discarded.

You are also legally required to record what you would like to happen to your sperm 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 sperm 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 sperm and embryos for training?

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

What if I want to donate my sperm/embryos?

Unused sperm 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 sperm 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.

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1. About you

First name(s)

Surname

Date of birth

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

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

3. About your treatment

3.1. Do you consent to your sperm being used to create embryos outside of the body with eggs that have undergone MST for use in your partner's treatment?

This process will involve:

- eggs undergoing the MST process (this means that your partner's nuclear genetic material will be removed from her eggs and transferred into 'new' eggs containing donor mitochondria),
- your sperm being used to create embryos (containing your and your partner's nuclear genetic material and donor mitochondria) with the eggs that have undergone MST, and
- those embryos being used for your partner's treatment (embryo transfer).

 Yes

 No

PNT - stage one

3.2. Do you consent to your sperm being used to create embryos outside of the body with your partner's eggs (eg, through IVF or ICSI, then PNT) for use in your partner's treatment?

This process will involve:

- your sperm being used to create embryos with your partner's eggs,
- the embryos undergoing the PNT process (this means that your and your partner's nuclear genetic material will be removed and transferred into the embryos created in stage two. Once your nuclear genetic material has been removed from the embryos, the embryonic material will be discarded), and
- the embryos (containing your and your partner's nuclear genetic material and donor mitochondria) to be used in your partner's treatment (embryo transfer).

 Yes

 No

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PNT - stage two**3.3. Do you consent to your sperm being used to create embryos outside of the body with donor eggs and for those embryos to undergo the PNT process? Do not complete this section if donor sperm is used for this stage.**

This process will involve:

- your sperm being used to create embryos with donated eggs outside the body
- the embryos undergoing the PNT process (this means that your and the donor's nuclear genetic material will be removed, discarded, and replaced with your and your partner's nuclear genetic material from the embryos created in stage one), and
- those embryos (containing your and your partners nuclear genetic material and donor mitochondria) to be used in your partner's treatment (embryo transfer).

 Yes No
4. Storing sperm and embryos

You may wish to store any sperm and/or embryos before or after MST or PNT so they can be used in future treatment. To be stored, sperm 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 sperm 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 sperm 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 sperm being stored?
 Yes No
4.2. For how long do you consent to your sperm 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 and your partner's or donor's nuclear genetic material and your partner's or donor's mitochondria) being stored?
 Yes No
4.4. For how long do you consent to your 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

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

- 5.1. Do you consent to sperm surplus to your treatment being used for training purposes?**

Yes No

- 5.2. Do you consent to embryos (already created outside the body which contain your nuclear genetic material) surplus to your treatment being used for training purposes? Please note that embryos can only be used if the female provider of the genetic material has also given her 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 sperm, or embryos containing your nuclear genetic material, if you die or lose the ability to decide for yourself (become mentally incapacitated). Please note that if you would like your partner to use your sperm or embryos in the event of your death or mental incapacity, your partner should be named on this form. Your embryos may only be used within the storage period you consented to above. If you do not give your consent in the below section, your sperm 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 your sperm being used to create embryos outside the body for your partner's treatment? Please note that the egg provider also has to give her consent for embryos to be created.**

If you die Yes No If you become mentally incapacitated Yes No

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6.2. Do you consent to embryos (already created outside the body which contain your nuclear genetic material) being used for your partner's treatment? Please note that embryos can only be used if the female provider of the genetic material has also given her consent.

If you die Yes No If you become mentally incapacitated Yes No

6.3. Do you consent to your sperm being used for training purposes?

If you die Yes No If you become mentally incapacitated Yes No

6.4. Do you consent to embryos (already created outside the body which contain your nuclear genetic material) being used for training purposes? Please note that embryos can only be used if the female provider of the genetic material has also given her consent.

If you die Yes No If you become mentally incapacitated Yes No

Other uses for your sperm or embryos

If you are storing sperm or embryos following MST or PNT (containing your genetic material and donor mitochondria) 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 sperm' (MD form)
- 'Your consent to donating embryos' (ED form), or
- 'Men's consent to the use and storage of sperm or embryos for surrogacy' (MSG form).

Consent to birth registration

Complete section 6.5 if you consented to your sperm, or embryos created outside the body which contain your nuclear genetic material, being used in your partner's treatment after your death. If you have given your consent to your sperm or embryos (to be created outside the body which contain your nuclear genetic material) being used after your death, you may also wish to consent to being registered as the legal father of any child that is born as a result of your partner's treatment.

6.5. Do you consent to being registered as the legal father of any child born as a result of your partner's treatment after your death? By ticking yes, you consent to:

- My name, place of birth and occupation being entered on the register of births as the legal father of any child born from my partner's treatment. This register is kept under the Births and Deaths Registration Act 1953, or the Births and Deaths Registration (Northern Ireland) Order 1976, or the Registration of Births, Deaths and Marriages (Scotland) Act 1965.
- I also consent to information about my or my partner's treatment being disclosed to my partner and one of the following registrars:
 - the Registrar General for England and Wales
 - the Registrar General for Scotland
 - the Registrar for Northern Ireland.

Please note that being recorded in the register of births as the legal father of a child born from your partner's treatment does not transfer any inheritance or other legal rights to the child.

Yes No

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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 sperm or embryos in training, or the sperm 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 he is unable to sign for himself 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 his direction.

Representative's name

Representative's signature

Relationship to person consenting

Date

Witness's name

Witness's signature

Date