

Mitochondrial donation: consent to sperm donation (PNT only)

MD (PNT only) Gender-neutral version

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?

If you are donating sperm and/or embryos created with your sperm for the treatment of others – specifically for use in mitochondrial donation treatment so that women can avoid passing on inheritable mitochondrial disease to their children.

What does mitochondrial donation involve?

Your sperm will be used to create embryos with donated eggs and/or the intended mother's eggs, by IVF or ICSI, so the intended mother can avoid passing on an inheritable mitochondrial disease to her child. The IVF-based technique used to achieve this is called pronuclear transfer (PNT).

What is PNT?

PNT allows women who have mitochondrial gene abnormalities to create embryos containing their nuclear genetic material (the genes which make us who we are) and donated mitochondria.

There are two stages to the technique. A woman may need to use donor sperm for both stages of the technique (eg, if she does not have a partner who can provide sperm for her treatment), or may only need donor sperm for the second stage of PNT (eg, if the intended father is genetically related to the egg donor providing the mitochondria).

On this form you can consent to donate your sperm for both stages of the technique or for the second stage only:

Stage one – your sperm will be used to create embryos with the intended mother's eggs. Both your and the intended mother's nuclear genetic material will be removed and transferred into embryos created in stage two below. Once your and the intended mother's nuclear genetic material is removed, the embryonic material created in stage one will be discarded. If you donate sperm for this stage you will be genetically related to the child. You will not have any financial or legal obligations to the child. Your identifying information will be passed on to any child born as a result of your donation upon request after they have reached 18 years old. For more information, see www.hfea.gov.uk/donation/donors/donating-your-sperm.

Stage two – your sperm will be used to create embryos with donor eggs. The genetic material will be removed, discarded, and replaced with the nuclear genetic material from the intended mother and sperm provider from the embryos created in stage one, above. If you only donate sperm for this stage you will not be genetically related to the child. No information that could identify you will be released to any child born following the mitochondrial donation treatment.

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

Before you fill in this form, you should have completed the 'Donor information form' if you are providing sperm for both stages of the technique and going to be genetically related to the child, or the 'Mitochondrial donation: PNT only sperm

For clinic use only (optional)

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HFEA centre reference

Other relevant forms

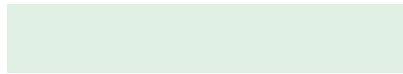
Date sperm were placed in storage

D	D	M	M	Y	Y
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Date sperm can remain in storage until

D	D	M	M	Y	Y
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Donor number



donor registration form' if you are providing sperm for stage two only and not going to be genetically related to the child.

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 have to fill in this form?

By law, you need to give your written consent if you want your sperm, or embryos created with your sperm, to be used or stored.

If your sperm 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. If you donate sperm for stage two only, once your nuclear genetic material has been removed and replaced with that of the intended parents, they will determine what happens to them, including how long they will be stored for.

You can make changes to or withdraw your consent to embryos created with your sperm in stage one at any point until the embryos have been transferred, used in training, or have been allowed to perish. For embryos created with your sperm in stage two, you can withdraw your consent at any point up until the nuclear genetic material has been removed from the embryos.

Why are there questions about using my sperm for training purposes?

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 for other purposes?

If you also want to donate your sperm for use in fertility treatment which does not involve PNT, you must complete a separate form 'Your consent to donating your sperm' (MD form).

Sperm 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 to research, speak to your clinic who will provide you with the relevant consent form(s).

What happens to my sperm or embryos if I die?

By consenting to the use of your sperm in PNT, you are also agreeing to your sperm or embryos 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 sperm 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 2.4). 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

1. About you

First name(s)

Surname

Date of birth

D	D	M	M	Y	Y
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NHS/CHI/HCN/passport number (please circle)

2. About your sperm donation

PNT - stage one

- 2.1. Do you consent to your sperm being used to create embryos outside of the body (eg, through IVF or ICSI, then PNT) and for those embryos to be used for the treatment of others? Do not complete this section if you are only providing sperm for stage two of PNT.**

This process will involve:

- your sperm being used to create embryos with the intended mother's eggs outside the body,
- the embryos undergoing the PNT process (This means that both your and the intended mother's nuclear genetic material will be removed and inserted into the embryos created in stage two. Once the nuclear genetic material has been removed from the embryos, the embryonic material will be discarded.) and the embryos (containing your and the intended mother's nuclear genetic material and donor mitochondria) to be used in the treatment of others (embryo transfer).

 Yes No

PNT - stage two

- 2.2. 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?**

This process will involve:

- your sperm being used to create embryos with donated eggs outside the body, and
- the embryos undergoing the PNT process (this means your and the egg donor's nuclear genetic material will be removed and discarded).

 Yes No

Page declaration signature

Date

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Donor number

2.3. How many families may have children using your donated sperm? Do not complete this section if you are only providing sperm for stage two of PNT.

The maximum number is 10 families. This is to minimise the possibility of two children from the same donor having a relationship with each other without knowing they are genetically related.

It is also based on the perceived interests of donor-conceived people and their parents in maintaining a relatively small number of siblings. Consenting to 10 families will help the greatest number of families and maximise the potential of your donation. You should think about how many families you are comfortable donating to and the long-term implications of donation.

families may have children using my donated sperm.

2.4. Do you have any restrictions that you would like to apply to questions 2.1 and 2.2 above?

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

Yes - specify your restrictions below then continue to section 3.

No - go to section 3.

3. Using sperm and embryos in training

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

Yes No

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

Yes No

Page declaration signature

Date

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Donor number

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4. Storing sperm and embryos

Sperm donated for the treatment of others needs to be stored.

4.1. Do you consent to your sperm being stored?

Yes No

4.2. Do you consent to embryos (containing your nuclear genetic material) being stored? Please note that embryos can only be stored if the female provider of the nuclear genetic material has also given her consent.

Yes No

If you have answered no to both 4.1 and 4.2, sign the page declaration on this page then go to section five. If you have answered yes to 4.1 or 4.2, or both, then continue below.

Sperm and embryo storage periods

In this section you must state how long you consent to your sperm and/or embryos containing your nuclear genetic material being stored for. You may want to think about how far in the future you want others to use your stored sperm and embryos – ask your clinic if you are unsure.

You can store for any period up to 10 years but in some cases where you, your partner, or the person to whom your sperm 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 sperm or embryos have been allocated to someone else's treatment, the patient (together with the clinic) will determine how long the sperm and embryos are stored for within the boundaries of what you have consented to in this form. If you are only providing sperm for stage two of the PNT process, once your nuclear genetic material is removed the intended mother and sperm provider will determine how long the embryos will be stored for.

4.3. For how long do you consent to your sperm, 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

Page declaration signature

Date

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Donor number

4.4. For how long do you consent to embryos being stored? Only complete this section if you answered yes to question 4.2. 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 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 would 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 if my sperm is used to create embryos with the intended mother's eggs (stage one of the PNT process) I can make changes to or withdraw my consent at any point until the embryos have been transferred, used in training, or have been allowed to perish.
 - I understand that if my sperm is used only to create embryos with the donor's eggs (stage two of the PNT process), I can make changes to, or withdraw, my consent at any point until my genetic material has been removed.
- 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

D	D	M	M	Y	Y
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If signing at the direction of the person consenting

If you have completed this form at the direction of the person consenting (because they are unable to sign for themselves 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.

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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 their direction.

Representative's name

Representative's signature

Relationship to person consenting

Date

Witness's name

Witness's signature

Date