

Giving consent for the collection and transplantation of stem cells – paediatric donor information

About consent

This factsheet explains important aspects of the consent process for stem cell/bone marrow donors. Consent refers to the freely given agreement to a treatment or a procedure that is proposed by a healthcare team, based on a full understanding of what is going to happen. Therefore, in order to give consent, the doctor and nurse will give you and your child (in the case of paediatric donors) information about the proposed treatment and the risks and benefits involved. They will also explain what effects giving or withholding consent would have.

The Human Tissue Authority (HTA) regulates and offers guidance to healthcare professionals on issues surrounding the collection, storage and use of human tissue for treatments. The HTA is concerned that the interests of all donors are protected. In the case of stem cell donation, it is important that there is a process in place to safeguard children. The Royal Marsden takes these regulations very seriously.

The consent process

- The doctor will explain the details of the procedures and the risks and benefits involved
- We will provide written information about the procedure and HTA assessment (where relevant) to take away and read
- You can ask any questions and take time to think about the procedure and you can contact your healthcare team with any questions
- Only when the parents or guardians and patient (if old enough) are happy to go ahead, will a written consent form be signed by the patient and/or the person with parental responsibility
- You can see the consent form beforehand and we will give you a copy to take home
- Young people aged over 16 years must be the person to give consent (unless they do not have the capacity to make the decision). Children and young people aged under 16 years will need to undergo an assessment of their capacity and competence to understand the information presented to them. This will determine whether they are able to provide consent to the donation of their stem cells or whether a separate HTA assessment and approval process is required.
- In cases where an HTA assessment and approval is required, there will be a separate appointment with an HTA accredited assessor
- Following the appointment with the HTA accredited assessor they submit a report to the HTA and the team awaits HTA approval before proceeding with the donation.



Parental responsibility

Mothers of their children hold parental responsibility unless the child is given up for adoption. Mothers may also share parental responsibility with a Local Authority. If the parents of a child are married to each other or if they have jointly adopted a child, then they both have parental responsibility. For unmarried parents, a father can acquire parental legal responsibility for his child through one of these three routes:

- By jointly registering the birth of the child with the mother (for children born after 1st December 2003 in England and Wales)
- By a parental responsibility agreement with the mother
- By a parental responsibility order, made by a court (see www.gov.uk/parental-rights-responsibilities).

Consenting to the donation of stem cells for a brother or sister

For donations of stem cells made by a child under 16 years for their sibling, it is important to be sure that the donor is medically and emotionally fit for the process and that everybody concerned understands the process. Informed consent must be given in order to undergo the procedure. Parents or guardians with parental responsibility will give consent on behalf of patients under 16 years although it is usual for older children to be involved in the process. There will be a separate requirement for an HTA assessment and approval for younger donors as outlined above.

The doctor will meet with the donor and the person who holds parental responsibility, and a full discussion will take place to cover the processes involved, including the reasons, risks and benefits associated with harvesting the stem cells prior to the consent being signed. Discussion will include talking about blood tests that will be needed such as tissue typing and virology testing, as well as the donation procedure itself. The doctor will assess the donor's competence to give consent, and this will determine the need for an HTA assessment and HTA accredited assessor interview. The HTA assessor will need to be sure that the explanations were clear and understood by everyone concerned and that consent was freely given.

- The HTA decision is usually made within five working days
- Once approval has been given it is valid for six months.

We will provide a separate HTA information leaflet explaining the role of the HTA.

Withdrawal of consent

Whether you are consenting for donation or transplantation of stem cells, you will be able to withdraw your consent at any time if you no longer wish the procedure to go ahead. The doctor and nurse will explain the implications of this.

Contact details

Paediatric Stem Cell Transplant Coordinator, Tel:

020 8661 3659

Human Tissue Authority, Website:

www.hta.gov.uk

