

G

Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation



Guide for the general public to Code of Practice G



A guide for the public to Code of Practice G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation

This guide is intended to be read alongside [Code of Practice G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation](#).

This guide is primarily for those who are giving consent on behalf of another person who does not have capacity to give consent. In this guide, the term 'you' is used to refer to the person giving consent on behalf of another person. The person who does not have capacity to consent is referred to as the 'donor'.

Commonly used terms

Tissue and organs

Organs

Where we use the term organ, or organs, in this guidance, it refers specifically to a whole solid organ, or organs, including:

- Kidney
- Liver
- Heart
- Brain
- Eyes

The general definition of what constitutes an organ in this context is a body part which has a specific vital purpose.

Tissue

Where we use the term tissue, this refers to all other various human materials that are not whole solid organs.

Tissue and Organs

When we refer to "tissue and organs", this is to make it clear there is a combination of both.

The role of the HTA

[The Human Tissue Act 2004](#) (the Act) sets out the legal requirements for lawful donation of allogeneic bone marrow and peripheral blood stem cells (PBSC) for transplantation in England, Wales and Northern Ireland. In Scotland this is set out in [the Human Tissue \(Scotland\) Act 2006](#).

We are responsible for ensuring bone marrow and PBSC donations are carried out in a way that is lawful and with informed consent.

We are only responsible for giving approval in cases where the donor is unable to consent for themselves and consent is instead provided by someone else. This is when a donor is:

- a child who lacks competence to consent, or
- an adult that lacks capacity.

In cases where the donor has capacity to give consent, this can go ahead without our involvement or approval.

Consent

You should receive the information you need to reach a decision that is right for the donor. This information should be clear and suitable to help you understand as much as you need to about bone marrow and PBSC donation. It should also include information on any material risks. A material risk is one which:

- you reasonably think is significant to making a decision, and
- your clinician would reasonably think you or the donor would consider significant.

Information you should receive

Before you give consent to donate, a medical practitioner should explain the medical procedure of donation and any associated medical treatments. This includes any information on short or long-term risks, and any reasonable alternatives.

You should also receive information telling you:

- donation is voluntary - neither you nor the donor should be pressured into donating;
- the likelihood of success for the transplant - transplantation is not always successful;
- the donor may need to donate bone marrow and PBSC again;
- you have the right to withdraw your consent at any time - you should also be told what this might mean for the donor and the person receiving bone marrow or PBSCs; and
- it is illegal for you or the donor to seek or receive payment or reward for donating bone marrow or PBSC for transplantation.

Court referral

Cases involving adults without capacity to consent to donate bone marrow or PBSCs must be referred to a court for a decision. Donation can only proceed if the court decides that the donation is in the donor's best interests. This must happen before the case is referred to the HTA.

Court directions are not normally needed for cases involving children. However, in certain circumstances the case may be referred to the court for a decision. For example, if there is disagreement between parents.

The HTA Assessment process

If the donor has been assessed by a clinician as not having capacity to consent, a referral will be made to an HTA Accredited Assessor (AA). Accredited Assessors are trained by the HTA to assess potential bone marrow and PBSC donations from adults who lack capacity and children who lack competence to consent. The donation process is organised by a Stem Cell Coordinator, who arranges the interviews and keeps participants informed.

Accredited Assessors

AAs act as a representative of the HTA. They will interview:

- the potential donor,
- the person giving consent on behalf of the donor, and
- the person receiving the donated PBSCs or bone marrow.

The interviews are carried out with all three people both together and separately where possible.

AAs are responsible for acting as a checking point. First of all, they will check that a clinician has confirmed that the donor does not have capacity to consent. They will then make sure the donor and the person giving consent on their behalf have been told about the medical procedure, including the risks involved. The AA will also check that the donor and the person giving consent are aware that they can withdraw consent.

The purpose of the interviews is to ensure:

- donors are not forced to do something against their wishes;
- no reward has been offered or asked for; and
- the person giving consent on the donor's behalf has the capacity to make an informed decision.

When children are involved, the AA will interview the donor and recipient in a way which reflects the child's level of understanding.

Our decision

Following the interviews, the AA will submit a report to us which will include the information above. The AA will also report on any difficulties they had interviewing the donor, the person giving consent and the person receiving the donation.

Once we receive the report, we will decide whether the requirements are met. The Stem Cell Coordinator will tell the donor, the person giving consent, and the recipient whether the donation can go ahead.

How capacity is assessed

Adults who may lack capacity to consent

An adult's capacity to consent to donate bone marrow or PBSC is assessed by clinicians in line with [the Mental Capacity Act 2005](#). To have capacity to consent, a person must be able to do all of the following things:

- understand the information they are given that is relevant to making a decision;
- remember the information long enough to make a decision;
- use the information to make a decision; and
- communicate their decision.

Anyone unable to do one or more of the above may be considered to lack capacity to consent.

There are certain circumstances where a donor without capacity may give consent to donate. Please refer to [Code of Practice G: Donation of allogeneic bone marrow and peripheral blood stem cells for transplantation](#) for more information.

Children under 18

Legally, for the purposes of bone marrow and PBSC donation, a child is anyone under 18 years of age. However, anyone aged 16 or 17 will be presumed to have capacity to consent unless there is evidence to suggest otherwise. This means you will be considered legally capable to consent to medical treatment once you can understand the treatment.

If there is evidence to suggest that a person lacks capacity to consent, they may be assessed in the same way as an adult who potentially lacks capacity. This means that their capacity may be assessed against [the Mental Capacity Act 2005](#). Alternatively, their parents may be able to give consent on their behalf.

Children under 16

For children under 16, capacity to consent is assessed by a clinician in line with "Gillick competence". This means you will be considered legally capable to consent to medical treatment once you can understand the treatment.

Your parents cannot give consent on your behalf if you are capable of making the decision. This does not mean that your parents cannot or should not be involved. However, you must make the decision.

If a child does not have capacity, parents can give consent on their behalf.

Scotland

In Scotland, the consent requirements are set out in [the Human Tissue \(Scotland\) Act 2006](#). This means the legal requirements are different. In Scotland, all donors aged 16 and under must receive our approval. We will decide whether each case can go ahead based on criteria set out by the Scottish Parliament.

Further information

If you have any concerns about the services you've received, please contact us on either 020 7269 1900 or by using our [online form](#). For more information on bone marrow and PBSC donation, please refer to [our website](#).