

Guidelines for the Blood Transfusion Services

3.4: Informed consent

<http://www.transfusionguidelines.org/red-book/chapter-3-care-and-selection-of-whole-blood-and-component-donors-including-donors-of-pre-deposit-autologous-blood/3-4-informed-consent>

3.4: Informed consent

For consent to a procedure to be legally valid the donor must as a matter of good principle have been told the nature and purpose of the procedure as well as being warned of any substantial or unusual adverse event risk. Therefore, informed consent must be obtained by a trained person, fully conversant with the procedure. A consent form must be signed by each donor before donation.

Leaflets or equivalent material about donation appropriate to the procedure should be available at the session and should be studied by prospective donors to assist in the process of obtaining fully informed consent. In obtaining donor consent, the consentor must satisfy themselves that the donor has gone through the material provided and has understood the following information:

- The purpose of the donation and the use of the product (clinical, research or other).
- A description of the procedure and its likely duration.
- An explanation that a voluntary donor can withdraw consent at any stage of the procedure or of an apheresis programme.
- A description of the common risks and discomfort involved in the procedures. These include:
 - for all donors:
 - dizziness and fainting
 - haematoma formation
 - other venepuncture-related injuries, including nerve damage, arterial puncture and tendon injury
 - for donors of components by apheresis:
 - citrate toxicity
 - red cell loss if the procedure has to be aborted and it is considered unsafe to return the red cells
 - chilling on reinfusion.
 - rare complications, such as anaphylaxis, haemolysis and air embolism

It is the responsibility of session staff to ensure that donors clearly understand the nature of the donation process and the associated risks involved as explained in the available literature. The donors must also understand the health check and other medical information presented to them. Donors are asked about confidential and sensitive aspects of their medical history and lifestyle. It is therefore important that blood collection sessions have facilities that offer privacy for donor interviews and that donors are assured of the confidentiality of any information they provide. For the donor's consent to be valid the donor must have capacity to consent. Capacity is defined in the Mental Capacity Act 2005.²

The five principles of this act state that:

- The person must be assumed to have capacity unless you can establish that they have not.

- No-one should be treated as being unable to make a decision unless the Blood Service has made all practical steps to ensure that they are able to make that decision without success.
- The person may not be deemed unable to make a decision just because they appear to make an unwise decision.
- Any act done or decision made under the Act on behalf of a person who lacks capacity must be done in the best interests of that person.
- One must always consider whether you can do the same thing in a way that is less likely to infringe that person's rights and freedom of action.

We must therefore presume that every donor that we deal with has capacity to make decisions. To have capacity the person must, with the appropriate help and support, be able to understand, retain, use and/or weigh up the information they are given to make the decision or to communicate their wishes. Just because a person is of a certain age, or has a disability, communication difficulty or medical condition we cannot assume that they lack capacity. Thus staff who consent donors must understand and apply these principles. All donors, be they 17 or 70, should have capacity when they sign their consent and it is the duty of the attending carers and healthcare professionals at the session to ensure that they do have that. Since the Family and Law Reform Act 1969 children have capacity to give consent in medical matters from the age of 16. (Applies to England and Wales. Equivalent legislation applies in Scotland and Northern Ireland.) Third-party interpreters should not be used except as laid down in the current JPAC *Donor Selection Guidelines*¹ as there is no guarantee of understanding or the accuracy of information provided to or given by the interpreter, particularly if they are a friend, family member or are otherwise known to the donor. Blood Service staff gain sensitive medical and personally identifiable information about donors. They must not disclose information to a third party about a donor without the donor's consent. This includes members of their family and includes the fact that they have attended for donation. All services should have a procedure in place for management of third party information relating to a donor and their eligibility to donate. All members of staff should be clear that they must protect a donor's personal information. Potential donors who are unable to read the literature should be informed of its contents by a suitably trained member of staff.