Guidelines for the Blood Transfusion Services

3.4: Informed consent

http://aws-lon-jpac.targetservers.uk/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 consenter 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).

3.4.1: Use of third party interpreters

There is concern that the use of third parties during any exchange of confidential information between the donor and the qualified health professional may compromise the confidentiality of the donor and the safety of the blood supply. It is permissible for any third party to act as an enabler by helping to reassure the donor and to assist in establishing effective communication between the donor and the qualified health professional.

The third party must not participate in the health screening interview, including any exchange of confidential information, unless they are not personally known to the donor, and they are an accredited trained interpreter or a member of blood service staff with appropriate language skills. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent.

Professional interpretation services may be delivered remotely (e.g. telephone, video) instead of face to face. If blood services wish to use an interpretation service for verbal communication or translation service for written information, these must meet relevant health care standards. Services should ensure that:

- Interpretation is also available for pre-session and post-donation donor enquiries and follow up of adverse events and abnormal results.
- Any written information for the donor can be provided in the correct language using an appropriate translation service.