Change Notification for the UK Blood Transfusion Services

Date of Issue: 18 July 2025 **Implementation:** to be determined by each Service

No. 14 – 2025

Interpreters

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue – Deceased Donors	TL-DSG Tissue – Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Third-Party Interpreters	○	○	○	○	○	○	●
2. Disabled Donor	○	○	○	○	○	●	○
3. Communication Difficulties	○	○	○	○	○	●	○
4. DSG Preliminaries: General Principles	○	○	○	○	○	●	○

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Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	~~deleted text~~

1. Changes apply to the **Red Book**

Chapter 3: Care and selection of whole blood and component donors (including donors of pre-deposit autologous blood)

(no changes to 3.1 – 3.3)

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).

~~*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.*~~

«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.»

(no changes to 3.5 – 3.17)

2. Changes apply to the **Whole Blood and Components DSG**

Disabled Donor (Revised entry)

Obligatory	~~*1.*~~ **All donors must:** a) Fully understand the donation process. b) Give their informed consent to the process and to the testing of their blood for infections that may affect its suitability for use. c) Be able to use the bleed facilities provided without risking their own safety or the safety of others (donors must not be bled in a wheelchair). ~~***2. Third party interpreters:***~~ ~~*If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the donor and the qualified health professional, they must:*~~ ~~*a) Understand the requirements of the Blood Safety and Quality Regulations (BSQR) relevant to the donation process.*~~ ~~*b) Not be personally known to the donor.*~~
Discretionary	**Donors with difficulty in reading:** Ensure by questioning the donor that they: a) Understand and fully complete the tick-box questionnaire. b) Give valid consent to donation and to the testing of their blood for diseases that may affect its suitability for use.
See if Relevant	Central Nervous System Disease Urinary Catheterisation Neurobehavioral Disorders Spina Bifida
Additional Information	The Services are aware of their duties under Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for disabled individuals. Potential donors with a disability are advised to seek advice from their local Blood Service Help Line before attending a donor session to see if their needs can be met. It is however important to note the following. Some donors, especially those with spinal cord injuries can have significant problems with regulating their blood pressure and as such may be at a greater risk of vasovagal events following blood donation. People who are in wheelchairs are more at risk if they suffer a delayed vasovagal event in the chair, and are alone, as they could remain upright and may suffer prolonged cerebral hypoxia. This can result in permanent brain injury or in extreme circumstances death. For this reason, donors must not donate from a wheelchair. Some potential donors may have indwelling shunts and/or catheters in situ which will mean that they are not eligible to donate.

	To comply with Part 2 of the Blood Safety and Quality Regulations 2005 (BSQR) every donor must: «a)» Be provided with accurate educational materials, which are written in terms which can be understood by members of the general public (Part A 1-13). «b)» Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional (defined in the BSQR as a doctor, a nurse or a donor carer) trained and qualified in the requirements of the BSQR (Part B 15). «c)» Provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history (Part B 16 (a) - (f)). A qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood Service. To facilitate comprehension, it is permissible to use alternative formats (e.g. audio, Braille, computer or alternative language) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardised way of assessing comprehension so this will be a personal judgement made by the qualified health professional. «Guidance on the use of interpreters is presented in Chapter 3 of the Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK (Red Book).» ~~***Use of third party interpreters***~~ ~~*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 however be present during any exchange of confidential information, unless they are not personally known to the donor and understand the requirements of that part of the BSQR relevant to the donation process. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the donor, may accompany the donor through other parts of the donation process that do not include the exchange of confidential information.*~~ ~~***Rationale***~~ ~~*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. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the relevant aspects of the BSQR this may make the interpretation of information incomplete and potentially put both the donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.*~~ To comply with both the BSQR and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.
Information	Part of this entry is a requirement of the Blood Safety and Quality Regulations 2005.
Reason for Change	«The guidance on third party interpreters has been moved to Chapter 3 of the Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK (Red Book).» ~~*The See if Relevant section has been revised.*~~

3. Changes apply to the **Whole Blood and Components DSG**

Communication Difficulties (revised entry)

Obligatory	~~1.~~ **All donors must:** a) Fully understand the donation process. b) Give their informed consent to the process and to the testing of their blood for diseases that may affect its suitability for use. ~~***2. Third party interpreters:***~~ ~~*If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the donor and the qualified health professional, they must:*~~ ~~*a) Understand the requirements of the Blood Safety and Quality Regulations (BSQR) relevant to the donation process and provide an accurate and truthful translation and interpretation of all information provided to enable the Blood Service to comply with these regulations.*~~ ~~*b) Not be personally known to the donor.*~~ ~~*c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor.*~~
See if Relevant	Central Nervous System Disease Disabled Donor Neurobehavioral Disorders
Additional Information	The Blood and Tissue Services are aware of their duties under «the Equality Act» ~~*Race Relations and Disability Discrimination Legislation*~~ and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. Potential donors with such difficulties are advised to seek advice from their local Blood Service Help Line before attending a donor session to see if their needs can be met. It is however important to note the following. **To comply with Part 2 of the Blood Safety and Quality Regulations 2005 (BSQR) every donor must:** a) Be provided with accurate educational materials, which are written in terms which can be understood by members of the general public (Part A 1-13). b) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional (defined in the BSQR as a doctor, a nurse or a donor carer) trained and qualified in the requirements of the BSQR (Part B 15). c) Provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history (Part B 16 (a) - (f)). A qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement

	and any other information provided by the Blood Service. To facilitate comprehension, it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor must be able to clearly demonstrate they have understood this material. At present there is no standardised way of assessing comprehension so this will be a personal judgement made by the qualified health professional. «Guidance on the use of interpreters is presented in Chapter 3 of the Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK (Red Book)» ~~***Use of third party interpreters***~~ ~~*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 however be present during any exchange of confidential information, unless they are not personally known to the donor, understand the requirements of that part of the BSQR relevant to the donation process and provide an accurate and truthful interpretation of all information, including personal and confidential information, provided to enable the Blood Service to comply with these regulations. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the donor, may accompany the donor through other parts of the donation process that do not include the exchange of confidential information.*~~ ~~***Rationale***~~ ~~*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. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the potential donor in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the relevant aspects of the BSQR and the need to provide an accurate and truthful interpretation of all information, including personal and confidential information, provided by the donor this may make the interpretation of information incomplete and potentially put both the donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.*~~ To comply with both the BSQR and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.
Information	Part of this entry is a requirement of the Blood Safety and Quality Regulations 2005.
Reason for Change	«The guidance on third party interpreters has been moved to Chapter 3 of the Guidelines for the Blood Transfusion and Tissue Transplantation Services in the UK (Red Book).» ~~*This has been updated to clarify the role of a third party interpreter and to bring it in line with the Tissue donor Guidelines.*~~

4. Changes apply to the **Whole Blood and Components DSG**

Preliminaries:

General Principles

These guidelines apply to donors giving whole blood or blood components (red cells, platelets, plasma and granulocytes) for therapeutic use.

Donors are selected firstly to ensure that they do not come to harm from giving their donation and secondly to ensure that their donation is unlikely to harm any recipient. The ultimate responsibility for the selection of donors rests with the respective **National Medical Director**.

The immediate responsibility is with the **Qualified Healthcare Professional** in clinical charge of an individual donor session. When it is not clear from these guidelines if an individual donor is suitable, no donation should be taken until it has been discussed and agreed with a **Designated Clinical Support Officer**.

Only persons in good health should be accepted as donors. The prospective donor must be evaluated for their fitness to donate on the day by a suitably qualified person who has undergone appropriate training to use this document to select or defer donors. They must verify their assessment by signing the donation record.

Special note must be taken of the content of the Blood Safety Entry in the **A-Z Topics**.

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 aspects of their medical history, hence great care must be taken over privacy and confidentiality. ~~*This means that third party interpreters can only be used as described in the A–Z Topic entry on* ***Communication Difficulties***.~~

(no further changes to this section)