Data Protection and Privacy Assurance

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Recording Consent Using Form 2B (FRM1570)

This guidance note is intended for use in conjunction with consent form 2B (FRM1570) which documents the patient's/donor's agreement to go ahead with the investigation or treatment you have proposed. Form 2B is not a legal waiver – if patients/donors, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients/donors are also entitled to change their mind after signing the form if they retain the capacity to do so.

Form 2B is intended to be an *aide-mémoire* to healthcare professionals, by providing a checklist of the kind of information patients/donors should be offered, and by enabling the patient/donor to have a written record of the main points discussed. Patients/donors should also be provided with a copy of the Patient/Family Information Leaflet (INF1750).

In no way, however, should the written information provided for the patient/donor be regarded as a substitute for face-to-face discussions with the patient/donor.

As the consenting healthcare professional, this guidance is intended to help you explain:

- the necessity for microbiological testing and provision of counselling if required.
- that once collected, cells will be tested and stored until required.
- that if the cells are no longer required, they will be discarded or used for research.

This guidance note is intended to be used in conjunction with the BSBMTCT *Guidance on Storage and Discard of Cryopreserved Cellular Therapy Products*, the Department of Health's *Reference Guide to Consent for Examination or Treatment* (which sets out the general legal and ethical principles for healthcare professionals seeking consent) and the Bone Marrow and Peripheral Blood Stem Cell Donor Selection Guidelines for Unrelated Donors (JPAC).

Part 1. Testing of Collected Cells

Microbiological testing is necessary to minimise disease transmission. Tests for some organisms and viruses are mandated. These include Hepatitis B, C & E, HIV 1 & 2, HTLV-1, HTLV-2 and Syphilis. If any of the tests for mandatory markers of infection are positive, patients/donors will be informed and further tests, counselling, and clinical follow-up arranged as necessary.

It is a standard requirement that these tests are completed within 30 days prior to stem cell and lymphocyte collections.

Blood samples and cell samples are stored frozen and may be retrieved at a future date should, for example, tests for new infectious agents be developed and mandated. In addition, tests are also necessary to assure the quality of collected and processed materials.

The patient, donor or guardian must either circle 'Yes' to indicate consent for testing *or* 'No' to withdraw consent in part 1 of form 2B.

Part 2. Storage and Discard of Collected Cells

It may be necessary to keep cryopreserved cellular therapy products (CTPs), including stem cells, lymphocytes and associated samples in long term storage. CTPs are not stored indefinitely and their need for storage is kept under continuous review. It is considered that a period of 5 years is a reasonable duration for storage, although they can be stored beyond this period at the discretion of the transplant physician or transplant programme director.

Conditions under which cells are considered unsuitable for clinical use should be explained to the person donating the CTP. The consent process should also include the actions to be taken when an intended recipient no longer requires the CTPs.

For allogeneic donors, the consent process should confirm their agreement that decisions around the discard of the CTPs stored will be between the patient and their clinical team without further input from the donor.

The patient, donor or guardian must either:

- Circle 'Yes' to **Option A** to indicate consent for cells to be discarded if no longer required or unsuitable for use

  OR

- Circle Yes to **Option B** to indicate the patient would like to be contacted at the time of planned discard

In the case of allogeneic donors, it should be explained that the patient will be asked at the time of discard, not them.

It is important that the patient/donor indicates yes to only one of the two options to avoid confusion.

Part 3. Options for Use of Waste Products or Cells that would Otherwise Be Discarded

This section shows options for which the patient/donor may wish to give consent. Stem cell donations generally require some form of processing before they can be transplanted or stored. This process generates residues or waste products. These residues may also be kept in long-term storage.

Stem cells, which, in the view of the transplant Consultant, are no longer required may be used for research (subject to ethical approval where appropriate and may involve the commercial sector, genetic testing or the use of human tissue in animals), for service development (the introduction of new procedures) or for education and training purposes (under the auspices of a bona fide institution).

There may be occasions when samples are exported for research purposes abroad. Cells will not be used for research without permission from the donor. The donor or donor's guardian will not benefit financially from any research. Donor identity will not be revealed when providing materials for research. Treatment will not be affected in any way should the patient/donor not wish to consent to the use of their cells for research.

The patient, donor or guardian must circle either 'Yes' for each potential use to indicate consent or circle 'No' to withdraw consent for one or more uses of waste products.

Part 4. Storage of Personal Information

The patient, donor or guardian must circle either 'Yes' to indicate consent to personal information being used in accordance with General Data Protection Regulations and all other privacy and data protection laws, or circle 'No' to withdraw consent.

Part 5. Signatures - To be completed by the patient, donor or guardian

The patient, donor or guardian MUST complete this section for the consent form to be valid.

Related Documents / References
Department of Health Reference Guide to Consent for Examination or Treatment
Reference guide to consent for examination or treatment (second edition) - GOV.UK (www.gov.uk)

JPAC
Bone Marrow and PBSC Donor Selection Guidelines for Unrelated Donors
Bone Marrow and Peripheral Blood Stem Cell (transfusionguidelines.org)

BSBMTCT guidance on Storage and Discard of Cryopreserved Cellular Therapy Products
DAT/ (bsbmtct.org)

NHSBT Documents
FRM1570 (2B) Consent for the Testing, Storage and Discard of Cellular Therapy Products
INF1750 Patient/Family information leaflet – Consent for Collection, Storage and Disposal of Cellular Therapy Products for Patients Undergoing Stem Cell Transplantation

Human Tissue Authority
Code A: Guiding Principles and the fundamental principals of consent Code E: Research Code G: Donation of Allogeneic bone marrow and peripheral blood stem cells for transplantation