Guidance for Healthcare Professionals in Consenting for the Testing, Storage, and Discard of Stem Cells and Lymphocytes

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Recording Consent Using Form 2B

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 check-list 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. 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 note 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 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 *Tissue Donor Selection Guidelines – Bone Marrow and PBSC Donors* (UKBTS and NIBSC).

The patient, donor or guardian must sign in either the Yes box to indicate consent or in the No box to withdraw consent in parts 1 and 2 of form 2B. Part 3 must also be completed.

Part 1. Testing, Storage and Discard of Collected Cells

Microbiological testing is necessary to minimise disease transmission. Tests for some organisms and viruses are mandated. These include Hepatitis, 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.

It may be necessary to keep stem cells, lymphocytes and associated samples in long term storage. Stem cell donations are not stored indefinitely; their need for storage is kept under continuous review. Stem cells which, in the view of the transplant consultant, are no longer required may be discarded. Cells will not be discarded without permission from the donor.

Part 2. Options

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.

Applicable documents:

Department of Health
Reference Guide to Consent for Examination or Treatment

UKBTS & NIBSC
Tissue Donor Selection Guidelines Bone Marrow and PBSC Donors

NHSBT
MPD634 *The Use of SCI Referral Forms and Information Sheets*

MPD622 *Donor/Patient Consent to HPC, Apheresis and HPC, Marrow Collections*

MPD625 *Selection, Evaluation and Consent of Potential Progenitor Cell Donors*

MPD615 Discard *or Non-Clinical Issue of CMT products or components*

MPD565 *Guidelines for the Use of Donated Material*

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