Template Patient/Family information leaflet – Consent for Collection, Storage and Disposal of Cellular Therapy Products for Patients Undergoing Stem Cell Transplantation

Information for patient / family

Written consent is required when we store any cells or tissues. The purpose of this information sheet is to explain what you are consenting for. It covers:
a) Collection and storage of cells
b) Disposal of cells when no longer required.

a) Collection and storage of cells

Cells for autologous (self) stem cell transplants are usually cryopreserved (frozen) and stored until the patient has had preparative tests and treatment for their transplant. Cells collected for transplants from family or unrelated donors are usually given to the patient as soon as possible after collection, although occasionally, they may be cryopreserved for operational reasons. Cells that have been cryopreserved will be stored until they are required. Most transplants go ahead soon after cells are collected but sometimes cells remain in storage. Cells will be discarded if the intended recipient dies or there are reasons which mean a patient is not suitable for a transplant (see examples below). If cells remain in storage, this hospital will review the need for continuing storage annually and at a minimum after 5 years. Although cryopreserved cells can survive for a long time, storage space is limited. Discarding cells that are no longer needed or suitable for transplants means that we will maintain our capacity for storing cells for our current patients.

b) Disposal of cells still in storage

At the time of review of need for continuing storage, the transplant physician responsible for your care will review the status of you and your illness to decide whether there is any possibility you will need the cells in the future. Circumstances where cells will not be needed include:

- if a disease appears to be cured
- if a disease has progressed such that further treatment with the stored cells will not be helpful.
- If a patient has become unsuitable for further treatment with the cells for any reason, for example significant health problems
- If a patient has died

Cells will usually be discarded in these circumstances but, if a clinical need is identified then cells may be retained for a longer period.

c) Disposal of cells unsuitable for clinical use

Sometimes cells that are stored are not suitable for the planned use. Examples of such circumstances include:

- If the cells cannot clearly be identified so it is unclear who donated them. This can happen with cells stored for long times
- Damaged storage bags. The bags are very brittle in storage and can crack. There could be a risk of cell loss or leakage
- Very low number of cells that are insufficient for a transplant
- Cells that do not appear to be capable of growing when laboratory tests are done on them.

If any issues affecting the suitability of cells is identified, the transplant physician responsible for your care would review the information on the donation and, in conjunction with the medical director of the cell storage facility, decide whether the cells could be used or not.

d) Communication around disposal

Standard practice is for decisions around ongoing storage or discard of cells to be made by the transplant physician responsible for your care. However, if you wish to be contacted at the time of planned discard of your cells, you can opt into this by indicating "yes" in section 2B of the consent form. If you wanted to continue to keep your cells in storage beyond this time, you would have the option of transferring the cells to a private storage facility. If this were the case, you would be responsible for arrangements and associated costs. If you wanted to retain the option of the cells being used in the future, such a private facility would need to have a licence from the Human Tissue Authority and accreditation from an international standards body called JACIE.

e) Potential use of the cells that would be discarded for research purposes

If you agree that donated material can be used for research purposes, any cells or samples that remain after essential diagnostic tests are completed or cells that would otherwise be discarded can be stored and used for various purposes. Section 3 of the consent form lists different areas where they may be used. Service development and training is useful to the hospital and any research done by this hospital or its research partners will already have the approval of the Research Ethics Committee. Researchers may be given access to some information about your health and diagnosis but will not be given any personal identification that will identify you. The European Union (EU) has issued a directive (95/46/EC) regulating collection and storage of personal data. The main purpose of the directive is to guarantee privacy as a patient contributing data to scientific research. Results from any research project will not be traceable back to you.

What are the possible risks of my cells being used for research?

There are no extra risks in collecting and storing samples for possible future tests or for research purposes, since the samples are being collected anyway for clinical purposes.

Are there any benefits?

In most instances there will be no direct benefit to you. Research projects using samples of cells or tissues have led in the past to improved understanding and treatment for patients undergoing stem cell transplantation. It is likely that future research projects will do the same.

What will happen to the results of projects using such stored samples?

The results of such projects, which are part of research and development to improve understanding and treatment of disease, may not be available to you or us at present. Eventually the results of such projects will be published in medical or scientific journals, but this may not happen for several years.

Do I have to take part?

No, you do not have to agree to storage of cells or tissues for research purposes. If you agree for storage for *clinical purposes* only (ie not for research purposes), the clinical records will be marked to that effect.

If you decide not to agree that samples can be used for research purposes this will not influence clinical management. You can also change your mind at a later date without any change to your treatment.

f) What should you do if you have any questions about stem cell storage or disposal or potential research uses?

If you have any concerns about this issue, you may contact the Stem Cell Transplant Nursing or Medical Team.