

Key Change From Previous Revision:

Policy placed in new format.

Equality screen completed.

HTA directions and references updated.

Changes to directed donation storage information re. suitability for future transplantation and storage for up to 20 years.

1 STATEMENT

This document sets out the general policies for discard and disposal of both directed and unrelated/public cord blood units at Belfast Cord Blood Bank (BCBB), which shall be in keeping with the following Regulations and Best Practice Guidelines:

- The Human Tissue Act 2004
- The Human Tissue (Quality and Safety for Human Application) Regulations, 2007
- Human Tissue Authority Directions
- Human Tissue Authority Codes of Practice.
- Current Edition Guidelines for the Blood Transfusion Services in the United Kingdom.

2 OVERVIEW

Discard /disposal of cord blood donations must be in keeping with the Human Tissue (Quality and Safety for Human Application) Regulations 2007, HTA's Codes of Practice, EU Directives on Tissue and Cells and the current Guidelines for the Blood Transfusion Services in the United Kingdom.

It is essential that a full audit trail is available for all cord blood donations, from the donor to the issue and transportation of tissue for transplantation or discard.

3 RESPONSIBILITY

Belfast Cord Blood Bank Consultant, Nursing, Biomedical Scientist And Quality Assurance Staff

4 POLICY

4.1 Unsuitable units:

Cord blood donations which are unsuitable for processing and banking will be discarded. These units are discarded with the reason recorded on the Donor Management IT system. The consent form must be retained. The Computer records will indicate the reason for discard, the components discarded and date of discard. The method of disposal and decontamination shall meet UK laws, current codes, rules and regulations for the disposal of non-hazardous and bio-hazardous materials (NIBTS Waste Management Policy, HP:006).

4.2 Record retention:

Raw data which are critical to the safety and quality of tissues and cells must be kept for 10 years after the use, expiry date or disposal of tissues or cells.

The minimum data to ensure traceability from donor to recipient as required by Directions 003/2010 must be kept for 30 years after the use, expiry or disposal of tissues or cells.

4.3 Directed Donations:

Generally, the Belfast Cord Blood Bank will undertake to store directed donations which are deemed to be potentially suitable for future transplantation use, for a period of up to 20 years. This period may be reviewed in the light of new scientific information in the area of stem cell transplantation, or as part of Belfast Cord Blood Bank Contingency planning, in the event of a threat to storage capabilities or cessation of activities. Provision for storage of directed cord units will be an integral part of any contingency plans held by the Belfast Cord Blood Bank.

In the case of a directed cord blood unit which is to be discarded prior to this period, there shall be written communication with the donor's clinician (and family if applicable, or appropriate) to ascertain that there is no further requirement to store the cord blood unit prior to its discard.

5 EQUALITY SCREENING OUTCOME

This policy has been drawn up and reviewed in light of the statutory obligations contained within Section 75 of the Northern Ireland Act (1998). In line with the statutory duty of equality, this policy has been screened against particular criteria. If at any stage of the life of this policy there are any issues within the policy which are perceived by any party as creating adverse impacts on any of the groups under Section 75, that party should bring these to the attention of the Head of HR & Corporate Services.

6 TRAINING REQUIREMENTS

All Belfast Cord Blood Bank staff should have read and understood this policy.