

29<sup>th</sup> September 2008



State Claims Agency

## The Procurement of Umbilical Cord Blood for Storage/Banking

The Clinical Indemnity Scheme (CIS) provides indemnity to scheduled hospitals/enterprises and, vicariously, practitioners in respect of claims for personal injuries brought by persons alleging negligence, statutory or at common law, in respect of the provision of, or failure to provide, professional medical services.

The procurement of umbilical cord blood for storage, with the intention of future human application, can only take place in a hospital/healthcare enterprise, if that hospital/healthcare enterprise is either:

- a. An authorised Tissue Establishment
- b. Has a procurement contract with a Tissue Establishment that satisfies the legislative requirements.

The relevant legislation concerning the procurement of umbilical cord blood is contained in **S.I. 158 of 2006** known as **European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006**. In Ireland, the Irish Medicines Board (IMB) is the competent authority for the implementation of this legislation.

A Doctor/Midwife/Nurse will be covered by the CIS, in respect of the procurement for storage of umbilical stem cells, **ONLY** in those circumstances where:

- a. The hospital/enterprise has applied for and received an authorisation from the IMB,  
**OR**
- b. The collection is on foot of a request by a Consultant Haematologist in respect of the treatment of a named individual and has been organised by the **Irish Blood Transfusion Service (IBTS)**. IBTS is an authorised Tissue Establishment for this purpose and an enterprise specified in Schedule 1, Part 1 of the National Treasury Management Agency (Delegation of Functions) Order 2003 [S.I. No. 63 of 2003].  
This may be referred to as a "directed" collection.

**AND**

Where the Doctor/Midwife/Nurse, in accordance with the relevant legislation, had received appropriate training, and was carrying out the described professional medical services with the express knowledge and consent of the hospital's/enterprise's management.

**N.B. CIS Cover applies, routinely, where a specimen of umbilical cord blood is taken for diagnostic, treatment or palliative purposes of the mother &/or infant e.g. Rhesus status, blood gases etc.**

Collection of umbilical cord blood for personal banking by a commercial organisation – sometimes called "non-directed" does **NOT** come within the provision of "professional medical services" as defined in the NTMA Delegation Order. *A Doctor/Midwife/Nurse who procures umbilical cord blood on foot of a contract with a third party (i.e. NOT for and on behalf of the enterprise) is NOT covered by the CIS for such procurement.*

This notice applies to enterprises/individuals covered under the Clinical Indemnity Scheme. For more information please go to: [www.stateclaims.ie/ClinicalIndemnityScheme/introduction.html](http://www.stateclaims.ie/ClinicalIndemnityScheme/introduction.html)  
Or e-mail: [info@stateclaims.ie](mailto:info@stateclaims.ie)

