The IMB has been involved in the SOHO V&S Project (Vigilance and Surveillance of Substances of Human Origin) funded by the European Commission as an associated partner for the last three years. The main aim of this project was to support EU Member States in the establishment of effective vigilance and surveillance systems for tissues and cells used in transplantation and assisted reproduction. More details on the project can be found at [www.sohovs.org](http://www.sohovs.org).

Further project outputs have been finalised, these are, Clinical User guidelines on Tissues and Haematopoietic Stem Cells. These guidelines are addressed to health care professionals who, working in different organisations responsible for human application (ORHA) in the EU such as hospitals, clinics, doctors’ and dentists’ surgeries (offices) are involved in processes associated with the management and use of tissues and cells. They aim to define the roles and responsibilities of these health professionals in relation to supporting vigilance and safety of tissues and cells for transplantation.

The guidelines have been divided in 2, wholly self-contained parts.

[**Part 1: Tissues**](file:///I:\Tissues%20&%20Cells\SOHO%20V&S\Clinical%20User%20Guide\SOHOV&S%20Vigilance%20Guidance%20for%20Healthcare%20Professionals%20-%20Part%201%20Tissues.pdf)

Part 1 addresses all types of tissues, including:

* musculo-skeletal tissues (bones, tendons, ligaments, menisci, etc.)
* skin
* cardiovascular tissues (heart valves, blood vessels etc.)
* amniotic membrane
* ocular tissues (corneas in particular).

Part 1 focuses on the key role of physicians in:

* maintaining traceability
* recognising, reporting and investigating serious adverse events and reactions
* recall and look back management procedures where there is a need to contact all patients who received grafts from a particular donor, from a particular processing batch or from a particular centre.

Part 1 is also addressed to ORHA personnel who are responsible for ordering, receiving and storing of tissues prior to clinical application. It provides guidance on:

* choosing a tissue supplier
* the management of tissues, including ordering, receiving, storage, handling and disposal
* management of recalls, where the supplying tissue establishment requests the immediate return of distributed tissue for safety reasons

[**Part 2: Haematopoietic Stem Cells**](file:///I:\Tissues%20&%20Cells\SOHO%20V&S\Clinical%20User%20Guide\SOHO%20V&S%20Vigilance%20Guidance%20for%20Healthcare%20Professionals%20-%20Part%202%20HPCs.pdf)

Part 2 addresses all types of haematopoietic stem cells (HSC) including:

* bone marrow
* peripheral blood stem cells (PBSC)
* cord blood

Part 2 focuses on the key role of HSC transplant physicians and supporting personnel in:

* maintaining HSC traceability
* recognising, reporting and investigating serious adverse reactions and events associated with HSCs
* recall and look back management procedures where there is a need to contact the patient(s) who received cells from a particular processing centre

Part 2 is also addressed to ORHA personnel who are responsible for ordering, receiving and storing of HSCs prior to clinical application. It provides guidance on:

* the management of HSC products, including ordering, receiving, storage, handling and disposal
* management of recalls where the supplying centre requests the immediate return of distributed HSC for safety reasons.

Please review these guidelines and forward to associated hospitals and clinics as necessary.