Regulatory Survey ION-5590

Testing

The physical and medical exam at donor workup is performed by a medical doctor:	yes
All donor testing (at workup) for infectious disease is performed in a laboratory certified/licensed by a Competent Authority:	yes
HLA typing for patient specific request is performed in an appropriately accredited laboratory:	yes
Sterility testing is performed on the adult donor product:	yes
Sterility testing is performed on the cord blood product:	no
Screening questionnaire to exclude communicable disease:	yes
Screening questionnaire to exclude donors with 'high risk' lifestyles:	yes
Donor reliability identified by a medical doctor:	yes
Donor clearance to donate is confirmed by a medical doctor, following as a minimum the donor exclusion criteria in Annex 1 of EU Directive 2006/17/EC : The party providing the cell product must exclude donors when: • They are pregnant; • They are breastfeeding; • There is the potential for transmission of inherited conditions; • There is evidence of any other risk factors for transmissible diseases on the basis of a risk assessment, taking into consideration *Donor travel and exposure history and local infectious disease prevalence*; • There is presence on the donor's body of physical signs implying a risk of transmissible disease(s); • There is a history of a disease of unknown aetiology; • There is a risk of transmission of diseases caused by prions; • There is systemic infection which is not controlled at the time of donation, including bacterial diseases, systemic viral, fungal or parasitic infections, or significant local infection in the tissues and cells to be donated; • There is history of chronic, systemic autoimmune disease that could have a detrimental effect on the quality of the Cell Product; • There is recent history of vaccination with a live attenuated virus where a risk of transmission is considered to exist; • There is ingestion of, or exposure to, a substance (such as cyanide, lead, mercury, gold) that may be transmitted to recipients in a dose that could endanger their health.	yes

Customs regulations

Are there any customs regulations to follow, or customs paperwork required, to import cell products into the organisation country? If yes, please specify:	
Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify:	
Are there any import regulations to follow, or paperwork required, to import cell products into the organisation country? If yes, please specify:	
Are there any export regulations to follow, or paperwork required, to export cell products from the organisation country? If yes, please specify:	

Reporting of Serious Adverse Events

Please indicate which of the following schemes for reporting Serious Adverse Events relating to either the Donor or the product the Registry participates in:	
- Mandatory National Reporting Scheme	

- Voluntary National Reporting Scheme	
- WMDA SEAR/SPEAR Reporting Scheme	yes
The registry will notify the receiving Registry within 24 hours of receiving information relating to any serious adverse event that could be considered to affect the patient receiving the product:	yes

Quality management

The registry does maintain Standard Operating Procedures for your work:	yes
The registry would be willing to provide these to WMDA or another registry upon request:	yes
The registry would be willing to provide WMDA or another registry, on request, with copies of any packaging the HPC product will arrive in:	yes
Donor records relating to the medical exam and HPC collection process are the following number(s) of year(s) retained:	30 years