Regulatory Survey ION-8362

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General

The information has been reviewed in year :	2023
Organisation name:	Thai National Stem Cell Donor Registry (TSCDR)
Organisation ION:	ION-8362
Country:	Thailand
Year the registry started operations:	2002

Products

		comment
Do you provide HPC, Marrow?	yes	
Do you provide HPC, Apheresis?	yes	
Do you provide HPC, Cord Blood?	yes	
Do you provide MNC, Apheresis?	yes	
Do you provide NC, Whole Blood?	yes	

Product quantity

Data valid for year	2022	
Number of products	**National**	**International**
HPC, Marrow products:	2	1
HPC, Apheresis:	44	29
HPC, Cord:	0	0

License

Organisation is licensed/accredited by the Competent Authority:	yes
Comment:	
Name of Competent Authority:	WMDA Qualified and ISO9001:2015
Date of last inspection:	1) WMDA 2018-03-27 2) ISO9001:2015 date of issue 2023-03-22/valid until 2026-03-21
Link to website of Competent Authority:	http://masci.or.th/
Can you provide the Legal documentation from the Competent Authority that your organisation is allowed to operate as a registry ?	yes
Is your registry WMDA Certified, WMDA Qualified or WMDA Accredited?	WMDA Qualified
The registry is accredited by any other organisation:	no
If yes, by which organisation?	

Affiliation

The registry works with the following number of affiliated donor centres:	1 (TSCDR is also donor centre)
The registry audits its donor centres:	We have an internal audit once per year
The registry works with the following numer of affiliated collection centres:	4
Ther registry audits its collection centres:	Every 4 years

The registry works with the following number of affiliated Cord Blood Banks:	1 (TSCDR have cord blood bank located at National Blood Centre)
The registry audits its Cord Blood Banks:	We have an internal audit once per year
The registry works with the following number of affiliated transplant centres:	6
The registry audits its transplant centres:	3 years for the first renewal, and every 5 years for the next renewal.
The registry works with the following number of affiliated IDM Testing Laboratories:	1 (TSCDR is also IDM testing Laboratory)
The registry audits its IDM Testing Laboratories:	We have an internal audit once per year
The registry works with the following number of affiliated HLA/other DNA markers testing laboratories:	1 (TSCDR is also HLA Laboratory)
The registry audits its HLA/other DNA markers testing laboratories:	We have an internal audit once per year
The registry would be able to provide a full list of name/addresses of each affiliated and their licence/accreditation status, on request:	yes
The Cord Blood Banks are FACT-NetCord accredited:	no
If yes, the following Cord Blood Bank(s) are accredited:	
The registry is able to provide a copy of all the certificates:	yes
Affiliated centres comply with WMDA Standards and applicable national regulations:	yes
The registry has requirements for affiliated centres in addition to WMDA Standards and applicable national regulations:	yes
If yes, what are these requirements?	Transplant center and collection center must be audits by TSCDR compliance with WMDA guideline.

Donor policy

All donors are unpaid volunteers:	yes
All donors are informed about donation process and associated risks:	yes
Donors sign a valid informed consent to donate in the presence of a medical doctor/health care personnel/registry staff:	yes
The registry has systems in place to protect and control access to donor/patient records:	yes
The registry maintains donor anonymity:	yes
The registry has detailed donor evaluation and exclusion criteria in place:	yes
The registry has donor evaluation and exclusion criteria that do meet or exceed the WMDA guidelines:	yes

IDM

IDM	Tested	Method	Days between test and sampling /workup
ALT/ASTALT/AST ratio, De-Ritis-Quotient	On request		
ChagasChagas, T. cruzi	On request	Trypanosoma cruzi Antibody (Quest diagnostic), Immunoassay	
CMV IgGCytomegalovirus (CMV) Antibody testing IgG	Yes	CMIA	
CMV IgMCytomegalovirus (CMV) Antibody testing IgM	Yes	CMIA	
CMV TotalCytomegalovirus Total	No		
EBV IgGEpstein-Barr Virus Antibody testing IgG	On request	EIA	
EBV IgMEpstein-Barr Virus Antibody testing IgM	On request	ELISA	

HAV (NAT)Anti-hepatitis A virus nucleic acid testing	On request	RT-PCR	
HBV (NAT)Hepatitis B nucleic acid testing	Yes	Individual NAT	
HBc AbHepatitis B core antibody testing	Yes	CMIA	
HBs AgHepatitis B Surface antigen testing	Yes	CMIA	
HCV (NAT)Hepatitis C nucleic acid testing	Yes	Individual NAT	
HCV AbHepatitis C antibody testing	Yes	CMIA	
HEV (NAT)Hepatitis E Virus nucleic acid testing	On request	RT-PCR	
HIV (NAT)Human Immunodeficiency Virus nucleic acid testing	Yes	Individual NAT	
HIV-1 AbHuman Immunodeficiency Virus HIV-1 antibody testing	Yes	CMIA with HIV Ag/Ab combination	
HIV-2 AbHuman Immunodeficiency Virus HIV-2 antibody testing	Yes	CMIA with HIV Ag/Ab combination	
HIV p24Human Immunodeficiency Virus p24 antigen testing	Yes	CMIA with HIV Ag/Ab combination	
HTLV-IHuman T-Lymphotropic Virus type I testing	Yes	Anti-HTLVI/II, CMIA	
HTLV-IIHuman T-Lymphotropic Virus type II testing	Yes	Anti-HTLVI/II, CMIA	
MalariaMalaria	On request	Malaria Ag screening, immunochromatography, Remark: On request at VT and mandatory testing at WU.	
HSVHerpes Simplex Virus	On request	HSV IgG and HSV IgM by ELISA, Multiplex Real-time PCR	
STSSerological tests for syphilis	Yes	CMIA	
STS FTA-ABSSerological test for syphilis	On request	IFA	
ToxoplasmosisToxoplasmosis	On request	CMIA, IFA, Realtime PCR	
VZVVaricella Zoster Virus	On request	ELFA, EIA, IFA, Real-time PCR, Immunofluorescent assay	
WNV-NATWest Nile Virus nucleic acid testing	On request	Real-time PCR	
Other tests performed	No		

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:	yes
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:	No
Are there any customs regulations to follow, or customs paperwork required, to export cell products from the organisation country? If yes, please specify:	No
Are there any import regulations to follow, or paperwork required, to import cell products into the organisation country? If yes, please specify:	No
Are there any export regulations to follow, or paperwork required, to export cell products from the organisation country? If yes, please specify:	No

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	no
- Voluntary National Reporting Scheme	yes
- 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:	More than 30 years