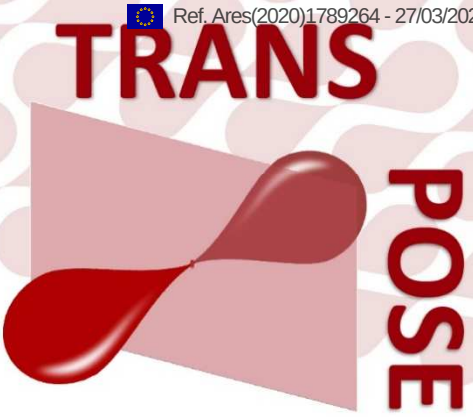

Co-funded by
the Health Programme
of the European Union

WP5 Deliverable D.5.3

Scope of the report:

Synopsis of criteria for the selection and protection of donors

Grant Agreement 738145

TRANSPOSE

TRANSfusion and transplantation PrOtection and SElection of donors

Document type: Deliverable D5.3

Version: 2.6

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Introduction to TRANSPOSE synopsis of criteria for donor selection

When selecting potential donors of Substances of Human Origin (SoHO) it is important that the selection criteria serves to protect donors as well as recipients. This synopsis presents suggestions for donor selection criteria that have all been assessed by means of a condensed risk assessment method with the inclusion of scientific evidence when available. For areas with lack of scientific evidence, suggestions are given based on expert evaluations by TRANSPOSE participants with proposals to gain scientific evidence. However, for donor selection criteria to remain up-to-date, it is important that the criteria are reassessed continuously, to include new insights and epidemiological data, and to implement measures after a renewed risk assessment. All establishments involved in the collection, processing and distribution of SoHO are advised to share new knowledge on and to participate in collaborations to ensure the health of future donors and recipients.

When going through the criteria some general considerations should be kept in mind. The criteria refer to minimum deferral time-periods as established by the TRANSPOSE consortium. However, these deferral periods can be adapted to suit regional or national guidelines or specifications. For instance, this can be important in case of differences in local or regional epidemiology or other circumstances, which might have an impact on the results of the risk assessment.
For some infectious diseases listed in the criteria, the term "treatment" is used. This refers to all interventions in relation to the infection in question, not just anti-microbial treatment, but also e.g. rehydration therapy and treatment for accompanying anaemia. It can be important to re-evaluate donor medical records to ensure that the donor still meets (and has always be compliant with) the donation criteria.

When selecting donors for donations of SoHO's that are further processed (e.g. for the preparation of medical products), the effect of the processing, including pathogen reduction steps, may be taken into consideration when assessing specific risks. It might be appropriate to include a shorter deferral or no deferral for donors depending on the nature of the risk.
Part of the donor selection criteria is the result of laboratory testing for certain infectious markers on samples taken from the donor at the moment of the donation. The cost-benefit ratio of such testing can also be considered. Using new technologies some previous testing methods may be omitted without compromising the safety of the donation but with great cost effectiveness for the donation establishments. Care should be taken that reduction of testing effort does not impact the safety profile of the products in a negative way. One example is testing for Hepatitis B, where it could be considered not necessary to test for HBsAg if a single donation (SD) nucleic acid testing (NAT) test is performed together with anti-HBc on all donors. Furthermore, deferral periods after infections should be related to the test regime and epidemiological situation of the establishment.
For some transfusion/transplantation related risks there is a lack of scientific evidence on frequency and seriousness of the risk, resulting in a deferral that is based on a theoretical risk, using the precautionary principle. Examples include:

- The presence of cardiac arrhythmias in the donor or a history of non-transmissible renal or central nervous system disease. However, the research of whether these patients can become blood donors is difficult in a blood donation setting due to ethical considerations. Instead further research into pathophysiology is needed and should be present before a risk assessment can be made.
- Donation frequency: especially for the donation of plasma is this parameter important. At this moment no clear scientific evidence that defines a safe upper limit for donation frequency exists. TRANSPOSE suggests that stakeholders collect relevant data.

- The deferral recommendations for travel and medication remain issues to be discussed and assessed. Further work is required to define a common list of travel and medication deferrals.

Abbreviations and medication listed in the document

α-thal: Alpha-thalassemia
anti-HBc: antibody to Hepatitis B core antigen
β-thal: Beta-thalassemia
BM: Bone marrow
BMI: Body Mass Index
BRCA1 and *2*: Genes encoding Breast Cancer type 1/2 susceptibility protein
CJD: Creutzfeldt-Jakob Disease
CNS: Central Nervous system
Denosumab: Recombinant human monoclonal IgG2-antibody
DHQ: Donor Health Questionnaire
G-CSF: Granulocyte-Colony Stimulating Factor
GOLD group: The Global Initiative for Chronic Obstructive Lung Disease (GOLD) uses a combined Chronic Obstructive Pulmonary Disease (COPD*)* assessment approach to group patients according to symptoms and previous history of exacerbations
HAV: Hepatitis A Virus
Hb: Haemoglobin, the following variants are also mentioned: Haemoglobin C / D / Punjab / E / Oman / S / SC / SS
HbA1c: Haemoglobin A1c – glycosylated haemoglobin
HBsAg: Hepatitis B surface antigen
HBV: Hepatitis B Virus
HCV: Hepatitis C Virus
HIV: Human Immunodeficiency Virus
IgG: Immunoglobulin G
IV.: Intravenous
IVF: In Vitro Fertilization
N/a: Not applicable = not necessary to include or consider
NAT: Nucleic Acid Testing
PBSC: Peripheral Blood Stem Cells
Raloxifene: A second generation selective oestrogen receptor modulator
SD NAT: Single Donations NAT testing
SoHO: Substances of Human Origin
T. cruzi: Trypanosoma cruzi
TP: Total protein
$T_{½}$: Half-life
vCJD: Variant Creutzfeldt-Jakob Disease

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
1. Lower limit for haemoglobin.		Female donors: 125 g/L.(7.8 mmol/L) Male donors: 135 g/L. (8.4 mmol/L)	Female donors: 120 g/L. (7.4 mmol/L) Male donors: 130 g/L. (8.1 mmol/L)	n/a although if evidence of anaemia may need to establish cause.	n/a although if evidence of anaemia may need to establish cause.	The responsible physician must be consulted to ensure that there is no identified pathology that could harm the recipient as well as ensure the safety of the donor.	The responsible physician must be consulted to ensure that there is no identified pathology that could harm the recipient as well as ensure the safety of the donor.	There must be haemoglobin testing of the CB unit after donation. For abnormal blood count parameters of the CB unit - please see below in item 2.
2. Upper limit for haemoglobin.		Donors with Hb level above the normal range in the population should be checked for pathology that could be transmitted through blood donation. They may proceed with donation if no such pathology has been identified. Plateletpheresis: If Hb above the upper limit as stated for plasma donation, then the donor can be referred to whole blood donation.	Female donors: 160 g/L. (9.9 mmol/L) Male donors: 180 g/L. (11.2 mmol/L) If above these limits, the donors can be referred to whole blood donation. If the Hb is continuously too high, the donor should be permanently deferred as plasma donation can result in too high haemoglobin and subsequent hyperviscosity with accordant risks to the donor.	n/a but donors with high haemoglobin above the normal population range should be checked and then can proceed with donation assuming no identified pathology that could harm the recipient.	n/a but donors with high haemoglobin above the normal population range should be checked and then can proceed with donation assuming no identified pathology that could harm either the donor or the offspring.	n/a but donors with high haemoglobin above the normal population range should be checked and then can proceed with donation assuming no identified pathology that could harm either the donor or the offspring.	Donors with high haemoglobin above the normal population range should be checked and then can proceed with donation assuming no identified pathology that could harm either the donor or the recipient.	After donation the responsible paediatrician should be informed if cord blood donation blood count parameters are not within the acceptable ranges. Cord blood donations with high haemoglobin or other blood count deviations should be assessed and can proceed with banking assuming no identified pathology that could harm the recipient.

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3. Donor circulating blood volume (assessed by weight and BMI).		If individuals weighing less than 50 kg are accepted, the volume of donation should be adjusted accordingly. There is no upper BMI limit, but donation needs possible and without additional risk for haematoma.	Donors should weigh a minimum of 55 kg and be taller than 150 cm. It should be strongly considered not to accept donors with a BMI below 20 or above 40, due to the risk of under- or overestimating blood volume. A nomogram including both height, weight and BMI should be applied for determining individualised maximal collection volume. Examples of nomograms are given in appendix 1.	Lower and upper donor weight limits for donation may be determined by the Tissue Establishment. The main risk is the manual handling for staff involved in the tissue retrieval. This has no impact on recipients.	n/a	The upper BMI limit should be 35. Consider nationally agreed safety guidelines for IVF.	BM: Excessive BMI might interfere with the BM collection.	n/a
4. Interval between donations.		Whole blood donation Female donors: A minimum donation interval of 91 days is advised. Male donors: A minimum donation interval of 56 days is advised.	Donation interval: Available data give very little evidence for any fixed upper level of annual plasmapheresis. No consensus could be reached on proposing an upper limit or to	n/a	n/a	One resting cycle (not induced) in between two donations.	The number of donations should be limited if feasible.	Once at birth.

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		It is advised to consider individualised donation intervals in the future based on the donor's Hb and iron levels and/or iron supplementation may be considered. <u>Plateletpheresis:</u> Shorter intervals can be accepted.	adhere to the current limit of 33 donations per year. Disagreements were expressed on proposing an upper limit of 60 donations per year based on a lack of scientific evidence that this limit is safe for donors. A minimum interval between donations of 96 hours is proposed. <u>IgG and TP levels:</u> • <u>New donors:</u> An IgG level minimum of 7.0 g/L and a TP minimum level of minimum 60 g/L, measured at day of first plasmapheresis is required in order for the donor to be considered for continued					

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			regular plasmapheresis. • <u>Repeat donors:</u> If IgG falls below 6.0 g/L or TP below 60 g/L, then deferral until recovery is confirmed by a repeat blood sample testing. Donation frequency should be individualised and based on IgG and TP recovery. <u>Testing frequency:</u> • <u>High frequency donors: (donors donating more often than every 14 days)</u>: IgG/TP should be controlled before the first and at every 5th subsequent donation to prevent iatrogenic immunodeficiency and					

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	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
			hypoproteinaemia. • <u>Low frequency donors (donors not donating more often than every 14 days):</u> IgG and TP level should be measured on a 6-monthly interval. All samples must be tested using a validated testing method. Current quick or bedside tests do not meet this criterion.					
5. Disability.	Accept if: • The donor can fully understand the screening questions and provide informed consent.			For mentally incapacitated donors, family members must be identified for providing amnestic information.	It should be confirmed that the disability is not hereditary.	It should be confirmed that the disability is not hereditary.	Consent by proxy should only be applied for family donors and includes minors and mentally incapable donors. Each donor must be informed properly at his/her own level of	Accept if single birth and both baby and mother meet the donor criteria. It should be confirmed that the disability is not hereditary and does not affect the stem cells.

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	• The quality of SoHO is not affected by the disability. • There is no increased risk of serious adverse reactions or events in the donor. • Insurance regulations must be included in assessment if relevant. •						understanding and give assent where possible.	
6. Hazardous Occupations/Jobs e.g. donors working with heavy machinery or as truck drivers.		The establishment should inform all donors of the risk of vasovagal reactions and instructed to follow the rules of their employer. The advice is 12-24 hours of restriction from jobs where delayed vasovagal events can have serious consequences for the donor or others..	As whole blood.	n/a	n/a	Consider whether anaesthesia is required for egg donation. The establishment's restriction from jobs should be followed.	<u>BM:</u> Follow the hospital restriction from jobs. <u>PBSC:</u> Due to expected spleen enlargement during GCSF mobilization, the donor is advised to refrain from hazardous duties (police, armed	n/a

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							forces), heavy lifting, or contact sports.	
7. Temperature.	There is no evidence for the value of checking the donor's temperature prior to SoHO donation. For pyrexia – please refer to the relevant section.							
8. Pre-donation assessment.	All donors should be pre-screened with a donor health questionnaire that correspond to the most important (depending on frequency, severity and imputability) donor criteria, preferably as close as possible to the donation event and in a validated language that ensures			Treating physicians or patient records should be consulted for pre-donation assessment. It is mandatory that all donors are assessed with a standard DHQ with the information obtained from the next of kin. Some donor				

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	the best possible understanding. It is mandatory that all donors are assessed in privacy so that there is the opportunity to exchange sensitive information in private communication with the donor physician that will help carry out the full donor assessment.			information and tests may not be accessible before donation e.g. autopsy report. Time of death and post-mortem blood samples should be included in the assessment.				
9. Age.	The lower age limit should at least be that of legal consent to medical treatment and potentially higher.			Age criteria need to be defined per tissue type that can be donated. Age might influence quality of the donated tissue and each Tissue Establishment must define their own age criteria for acceptance.	Consider upper age limit of 45 for product quality and safety.	Consider upper age limit of 35-45 years for product quality and safety.	Maximum age is established by the registry. <u>Related donors:</u> Donors under the legal age limit can be accepted, although consent would be required by the donor's parents or legal guardian.	

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10. Pregnancy, breastfeeding and termination of pregnancy.		Pregnancy: 6-months deferral post pregnancy. Breastfeeding: It is advised to consider a deferral of 30 days after cessation of breastfeeding. Termination of pregnancy: • Up to 12 weeks gestation: defer the donor the same number of weeks as the pregnancy plus an extra 12 weeks for RhD- donors. • 12 weeks plus gestation: Defer the donor for 6-months and an additional 30-days deferral after cessation of breastfeeding.	Pregnancy: 6-months deferral post pregnancy. Breastfeeding: In addition to the 6 months, it is advised to consider a deferral of 30 days after cessation of breastfeeding. Termination of pregnancy: • Up to 12 weeks gestation: 2-weeks deferral. • 12 to 24 weeks gestation: 6-weeks deferral. • 24 to 36 weeks gestation: 12-weeks deferral. • 36 weeks plus gestation: 6-months deferral and an additional 30-days deferral after	No deferral.	n/a	Pregnancy/ Termination of pregnancy: Minimum 6-months deferral post pregnancy. Breastfeeding: Deferral until cessation.	Pregnancy/termination: 6-months deferral. Breastfeeding: For donors donating by peripheral blood: mothers who wish to continue breast-feeding after donation should not breast-feed their infant (but may express and discard their milk) from the point of first G-CSF administration to one week following the last dose of G-CSF. For donors donating: mothers who wish to continue breast-feeding after donation should not breast-feed their infant (but may express and discard their milk) from the	n/a

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			cessation of breastfeeding.				point of administration of any sedating agent to 24 hours following the last dose of sedating anaesthetic or opiate analgesia. <u>Termination of pregnancy:</u> Consider a temporary deferral to ensure donor health.	
11. Donor policy after (possible) exposure to infectious agents. (With or without vaccination).	Donor must be deferred until the donor is well and until the risk of transmission to the recipient has passed. (See also specific criteria).							
12. Donor policy after vaccination with attenuated (live) vaccines. (without exposure).	Deferral for at least 4 weeks. For the Bacille-Calmette-Guérin (BCG) and smallpox vaccine: The skin lesion at							

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	the vaccination site must also be completely healed before donation can be accepted.							
13. Donor policy in case of vaccination with recombinant or dead vaccines. (without exposure).	No deferral except for HBV where a deferral of 1-4 weeks should be considered depending on the assay used, due to the risk of irrelevant reactive results..							
14. Medications known for teratogenic effect.	The reason why the medication is being taken should be evaluated. Need to identify a list of medications which are teratogenic grouped into the type of medications and a generic text. The half-life $t_{½}$ of specific medications needs to be considered when defining the deferrals for		<u>Plasma for fractionation:</u> The reason why the medication is being taken should be evaluated. To ensure product safety and recipient health, a 6-week deferral is generally should be considered after cessation of therapy with teratogenic drugs. For drugs with a half-life of	No deferral as tissue concentration is unlikely to be of significant quantity and the low likelihood of recipient being pregnant.	Deferral during treatment and possible wash-out period. The deferral period should be based on an assessment of half-life. Hereditary condition being treated needs to be excluded.	Deferral during treatment and possible wash-out period. The deferral period should be based on an assessment of half-life. Hereditary condition being treated needs to be excluded.	Risks of drug transmission need to be evaluated be treating physician.	Deferral during treatment possible wash-out period. The deferral period should be based on an assessment of half-life.

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	medicines which needs to be added to the list of "not acceptable medicines". Also, **the metabolism and active** metabolites of the medication must be evaluated as well as a possible wash-out period.		more than 3 weeks, a minimum deferral of $t_{½}$ x 2 should be applied. This also includes the active metabolites.					
15. Denosumab or Raloxifene: Osteoporosis medication.		Deferral for donation during medical treatment and wash-out period. Platelet apheresis: Donors with osteoporosis should be deferred due to citrate exposure that may aggravate the osteoporosis .	Deferral because of potential aggravation of osteoporosis by repetitive, long-term citrate exposure.	No deferral but bone quality must be evaluated if donating bone.	If a young donor already has osteoporosis the underlying diagnosis rather than the treatment would make them unsuitable for gamete donation as it raises concerns regarding a potential hereditary nature of the osteoporosis.	If a young donor already has osteoporosis the underlying diagnosis rather than the treatment would make them unsuitable for gamete donation as it raises concerns regarding a potential hereditary nature of the osteoporosis.	No deferral for PBSC donors, however the cause of osteoporosis must be established and evaluated if this could be a reason for deferral. The transplant centre should be informed. BM donors should be evaluated to prevent risk of fractures.	No deferral.

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16. Antihypertensive medication.	<u>New treatment:</u> Deferral for 2 weeks or until the donor's blood pressure is stable and within normal limits. <u>Stable treatment and blood pressure under control</u>: No deferral.		Defer if treatment with diuretics or angiotensin-converting enzyme inhibitor.		Consider hereditary nature of the hypertension. This depends on the level of hypertension and whether an underlying cause has been identified etc.	Consider hereditary nature of the hypertension. This depends on the level of hypertension and whether an underlying cause has been identified etc.	Evaluate the reason for medication.	
17. Antimicrobial drugs.	Not a reason for deferral if being taken for prophylaxis or long-term treatment (for example skin problems like acne) for a condition that does not lead to donor deferral. In cases of an acute infection, the deferral depends on the infection.							
18. Antihistamines.	No deferral.				Consider the reason for treatment and whether there	Consider the reason for treatment and whether		

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					is a hereditary element.	there is a hereditary element.		
19. Topical use of medicines.	In general, no deferral for topical treatment but it is important to assess the reason for the treatment as the diagnosis may give cause for deferral. Venepuncture area must be clear from dermatological conditions.			An evaluation must be performed in case of skin donation.	No deferral but consider the potential hereditary nature of the reason for treatment.	No deferral but consider the potential hereditary nature of the reason for treatment.		
20. Risk behaviour a. Sexual high-risk behaviour according to local definition and epidemiology b. Paid sex, sex workers, and IV. recreational drugs. c. Prophylactic pre- or post-exposure anti-retro-viral therapy d. Needle injury.	a. 6 months deferral. A shorter deferral can be accepted if NAT testing. b. 6 months deferral. A shorter deferral can be accepted if NAT testing. c. 6 months deferral after cessation of treatment. A						In consultation with transplant physician, deviation is possible if no **donor** risk.	

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	shorter deferral can be accepted if NAT testing. d. 6 months deferral. A shorter deferral can be accepted if NAT testing.							
21. New sex partner.	No deferral, unless national epidemiology supports otherwise.							
22. Sexual partners with HIV, HBV, HCV and HTLV.	6 months deferral. A shorter deferral can be accepted if NAT testing.						In consultation with transplant physician, deviation is possible if no **donor** risk.	
23. Hepatitis B household contacts.	6-months deferral from the last time that the donor lived with a Hepatitis B positive person (not just sexual contact). If NAT testing then the deferral can be shortened.		<u>Plasma for fractionation:</u> No deferral if effective pathogen reduction steps are in place					

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	If the donor is vaccinated and shown to be immune to Hepatitis B, then please see #13 for deferral period after vaccination.							
24. Acupuncture, piercings, tattoos and wound healing.	<u>If performed by a non-licensed person or studio or outside the EU:</u> 6 months deferral. A shorter deferral can be accepted if NAT testing. <u>If performed in a controlled/licensed studio within the EU and national data supports no risk of infection:</u> No deferral. <u>Wounds:</u> In general, wounds which require wound care should have a 1-week deferral post-healing.		<u>Plasma for fractionation:</u> No deferral if effective pathogen reduction steps are in place. One-week deferral after piercings and tattoos for wound healing				In consultation with transplant physician, deviation is possible if no **donor** risk.	

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	This includes tattoos and piercings.							
25. Surgery and endoscopy.	No deferral after endoscopy or surgery performed by a certified medical doctor, however the wellbeing and health status of the donor and impact on product quality must always be considered		<u>Plasma for fractionation:</u> The deferral period depends on the type of surgery and the wellbeing of the donor. No deferral for diagnostic endoscopies.					
26. Transfusion of blood components.	In countries considered at risk for vCJD, endemic malaria or T. cruzi a risk assessment must be carried out based on epidemiological data and available test. The donor can donate if negative in approved relevant tests.	<u>If risk of transfusion transmitted HIV, HBV, HCV</u>: 6 months deferral. A shorter deferral can be accepted if NAT testing.	As whole blood.	No deferral unless for deceased donors, where transfusion has caused haemodilution and no pre-transfusion blood samples are available.	Individual assessment. Depends on the reason for the transfusion.	Individual assessment. Depends on the reason for the transfusion.	In consultation with transplant physician, deviation is possible if no **donor** risk. Blood transfusion can induce antibodies, especially to HLA. Information should be forwarded to transplant centre.	No deferral. Blood samples from maternal donors with perinatal haemorrhage might have to be assessed for possible haemodilution.
27. Syphilis: a. Household contact with	a. Accept. b. Defer. c. Deferral minimum 3 months		<u>Plasma for fractionation:</u>	d. The quality/safety of the tissue			Donors with a risk of exposure can be accepted, when the benefits of the	

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individuals with syphilis. b. Current sexual contacts of individuals with active syphilis. c. Former sexual contacts of individuals with active syphilis. d. Previous syphilis infection.	with a negative test. d. Donor may be accepted based on a systematic risk assessment and testing strategies, if the donor is confirmed well treated, without symptoms and has a negative non-specific anti-treponemal test.		No deferral and no need for testing, however the donor must be well.	must be assessed.			medical treatment outweigh the possible risk. A non-specific anti-treponemal test must be negative.	
28. Creutzfeldt-Jakob Disease	<u>Patients with CJD and persons with family history of CJD:</u> Permanent deferral. If a donor with a family history of CJD has been tested and found to be negative for the relevant gene, then the donor can be accepted. <u>Persons with increased risk of CJD (recipients of dura</u>							

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	mater grafts, cornea or human pituitary derived extracts): Permanent deferral.							
29. Variant Creutzfeldt-Jakob Disease.	National and international data on the epidemiology of vCJD should be considered for risk-mitigating measures to prevent the transmission of vCJD through SoHO.						Donors with a risk of exposure to vCJD can be accepted when the benefits of the medical treatment outweigh the possible risk.	
30. Hepatitis A and E Virus.	6-months deferral following cessation of treatment and symptoms. This can be shortened to 3 months if HAV/HEV RNA confirms absence of viremia.		Plasma for fractionation: No testing needed if effective pathogen reduction steps are in place					

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
31. a. Herpes Simplex virus b. Varicella Zoster virus.	a. Herpes Simplex genital or oral: Accept if the lesion is healed. Herpes Simplex Encephalitis: 6-12 months after end of treatment and if well. b. Herpes Zoster: Accept if the lesions are healed.		Plasma for fractionation: a&b: No deferral if donor feels well.	If no active lesions or lesions are healing, donor can be accepted if no other underlying cause for concern. If history of ocular Herpes: Defer from eye donation of infected eye.	If no active lesions and no evidence of high-risk behaviour, the donor can be accepted.	If no active lesions and no evidence of high-risk behaviour, the donor can be accepted.	Generally, the donor can be accepted but it would be preferable to postpone the collection if active face or genital sores are present. After recovery as defined in the general section, the collection should be possible. Aciclovir or other antiviral locally may be used to shorten the recovery time and can be considered if sores become active after conditioning of the recipient has started and there are no risks for donor complications.	As general criteria.
32. Malaria.	Donors with previous residency in endemic malaria areas require a negative	Asymptomatic travellers with a negative malaria test: 4 month deferral.	Plasma for fractionation: Asymptomatic travellers:	The risk of transmitting malaria through processed tissues is extremely low.	Testing of whole blood	Testing of whole blood can be considered if this if found relevant.	Asymptomatic travellers with a negative malaria antibody test:	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	<u>malaria antibody test:</u> The definition and management of previous residency in malaria endemic areas must comply with the availability of malaria testing.	<u>Without test:</u> *At least* 6 months deferral. <u>Donors with a history of malaria:</u> The donor will require a negative malaria antibody test for reinstatement. The deferral period after treatment/last symptoms should be *at least* 4 months after cessation of symptoms and treatment.	No deferral. <u>Donors with a history of malaria:</u> 6-weeks deferral after cessation of symptoms and treatment, except for recurrent malaria due to donor protection.	Testing measures of whole blood can be considered for fresh, vascularised tissue or tissues containing residual RBC.	can be considered if this if found relevant.		The donor can be accepted after a 4-month deferral period. Deferral period for asymptomatic travellers without malaria antibody testing should be *at least* 6 months. <u>Donors with a history of malaria:</u> The donor will require a negative malaria antibody test for reinstatement. The deferral period after treatment/last symptoms should be *at least* 4 months. In all cases, where a malaria risk factor is identified, the transplant centre should be told: • The results of antibody testing (if performed).	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
							• The reported malaria risk factor, including the date of last exposure/ treatment cessation. • The interval between last exposure/treatment cessation and the date of testing (if performed), and the likely testing window period (typically 4 months for serological testing).	
33. Trypanosoma cruzi – Chagas disease.	<u>Defer donors if:</u> • known history of infection • born in South or Central		<u>Plasma for fractionation:</u> <u>Asymptomatic:</u> No deferral <u>If treated:</u>				A history of Chagas' disease may be acceptable if no evidence of acute or chronic infection, at the discre-	A history of Chagas' disease may be acceptable if no evidence of acute or chronic infection, at the discretion of the

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	America (including Southern Mexico) • Mother born in South or Central America (including Southern Mexico) • Transfused in South or Central America (including Southern Mexico) • has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more. <u>Accept donor if:</u> A minimum of 4 months has passed		6-week deferral after treatment to protect donor health. If organ affected, then permanent deferral.				tion of the requesting transplant centre. A history of being born or transfused with blood in a Chagas' endemic area should trigger serological testing to quantify risk.	requesting transplant centre. A history of being born or transfused with blood in a Chagas' endemic area should trigger serological testing to quantify risk.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	since last potential exposure and testing for T. Cruzi antibodies is negative, if no antibody tests are used the deferral should be prolonged to 6 months. A potential decision of not to test should be based on a national risk assessment							
34. Brucellosis.	Permanent deferral, however, if successfully treated and experts within microbiology or infectious diseases confirms no risk of transmission, then the donor can be accepted.		<u>Plasma for fractionation:</u> <u>Treated and recovered</u>: 6-weeks deferral following cessation of treatment and symptoms.				Donors with a risk of exposure can be accepted, when the benefits of the medical treatment outweigh the possible risk.	
35. Babesiosis.	Permanent deferral, however, if successfully treated and experts within micro-		<u>Plasma for fractionation:</u> <u>Treated and recovered</u>:				Donors with a risk of exposure can be accepted, when the benefits of the medical treatment	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	biology or infectious diseases confirms no recipient risk, then the donor can be accepted.		6-weeks deferral following cessation of treatment and symptoms.				outweigh the possible risk.	
36. Leishmaniasis.	Permanent deferral, however, if successfully treated and experts within microbiology or infectious diseases confirms no recipient risk, then the donor can be accepted.		<u>Plasma for fractionation:</u> <u>Asymptomatic travellers</u>: No deferral. <u>For symptomatic or diagnosed travellers:</u> No deferral, but the donor must be recovered.				Donors with a risk of exposure can be accepted, when the benefits of the medical treatment outweigh the possible risk.	
37. *Coxiella burnetii* - Q fever.	Permanent deferral, however, if successfully treated and experts within microbiology or infectious diseases confirms no recipient risk, then the donor can be accepted. Donors exposed to Q-fever through stay in an epidemic		<u>Plasma for fractionation:</u> <u>Chronic infection</u>: Permanent deferral. <u>Treated and recovered</u>: 6-weeks deferral following cessations of treatment and symptoms.				Donors with a risk of exposure can be accepted, when the benefits of the medical treatment outweigh the possible risk.	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	area may be accepted with a negative NAT test.							
38. Toxoplasmosis.	6-month deferral following cessation of treatment and symptoms.		Plasma for fractionation: Treated and recovered: 6 weeks following cessation of treatment and symptoms.					
39. Tuberculosis.	Defer the donor if it is less than 2 years from successfully completing treatment. In case of prophylactic treatment, deferral up to 3 months after cessation of treatment.			If contact with TB, the donor can be accepted if screened and given the all clear.	As tissues.	As tissues.	As tissues.	As tissues.
40. Chikungunya Virus.	Asymptomatic travellers: 28-days deferral. For symptomatic or diagnosed travellers: 28-days deferral following cessation of symptoms and		Plasma for fractionation: Asymptomatic travellers: No deferral. For symptomatic or diagnosed travellers:				If possible, delay the collection until 4 weeks after donor has returned from a risk area. If not possible, the treating physician must make a risk assessment.	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	treatment. The donor must be fully recovered. <u>Diagnosed non-travellers:</u> 28-days deferral following cessation of treatment and symptoms.		No deferral, but the donor must be recovered.					
41. Dengue Virus.	<u>Asymptomatic travellers:</u> 28-days deferral. <u>For symptomatic or diagnosed travellers:</u> 28-days deferral following cessation of symptoms and treatment. The donor must be fully recovered. <u>Diagnosed non-travellers:</u> 28-days deferral following cessation		<u>Plasma for fractionation:</u> <u>Asymptomatic travellers:</u> No deferral. <u>For symptomatic or diagnosed travellers:</u> No deferral, but the donor must be recovered.				If possible, delay the collection until 4 weeks after donor has returned from a risk area. If not possible, the treating physician must make a risk assessment.	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	of treatment and symptoms.							
42. Zika Virus.	<u>Asymptomatic travellers:</u> 28-days deferral. <u>Symptomatic or diagnosed travellers:</u> 28-days deferral following cessation of symptoms and treatment. The donor must be fully recovered. <u>Sexual contact with individuals with active infection:</u> 28-days deferral after sexual contact with a man diagnosed with ZIKV in the three months preceding or a woman diagnosed in the eight weeks preceding.		<u>Plasma for fractionation:</u> <u>Asymptomatic travellers:</u> No deferral. <u>For symptomatic or diagnosed travellers:</u> No deferral, but the donor must be recovered.		<u>Sexual contact with individuals with active infection:</u> 3-months deferral for both asymptomatic travellers and after cessation of symptoms. This also applies to sexual contact with individuals diagnosed with ZIKV as defined in the general section.	<u>Sexual contact with individuals with active infection:</u> 2-months deferral after return and 3- months after sexual contact with individuals diagnosed with ZIKV as defined in the general section.	If possible, delay the collection until 4 weeks after donor has returned from a risk area. If not possible, the treating physician must make a risk assessment.	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
43. West Nile Virus (WNV)	Asymptomatic travellers: 28-days deferral. for unless NAT test is available, then the donor can be accepted. Symptomatic donors or those with a diagnosis of WNV: 28-days deferral after cessation of treatment and symptoms.		Plasma for fractionation: Asymptomatic travellers: No deferral. For symptomatic or diagnosed travellers: No deferral, but the donor must be recovered.				If possible, delay the collection until 4 weeks after donor has returned from a risk area. If not possible, the treating physician must make a risk assessment.	
44. Transit stopovers.	**Airport Stopovers:** The definition of an Airport Stopover: ***A transit through an airport during which the traveller has not left the airport.*** When the donor's visit has consisted **only** of an airport stopover there is no need to refer to the							

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	Geographical Disease Risk Index.							
45. Dental treatment.		<u>Small dental procedures:</u> 60-minutes deferral (including root scaling and dental restoration). <u>Small surgery and tooth extraction:</u> 1-week deferral. <u>Acute oral infections (strongly bleeding gums) or due to treatment prescribed to oral infection:</u> A deferral should be considered.	As for whole blood.	No deferral.	No deferral.	No deferral.	No deferral. In case of active infection with systemic symptoms or recent surgery assess donor safety.	No deferral.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
46. Pyrexia.		Deferral if the donor currently has a fever (> 37.5°C/100°F or a subjective feeling of fever) for 2 weeks after cessation of fever and other symptoms.	<u>Plasma for fractionation:</u> The donor can donate as soon as possible after recovery providing that the donor fells well.	If the donor is pyrexial at the time of donation a full assessment is required to assess whether there is a medical contraindication to donation. For deceased donors the above applies to time of death.	Should not donate.	Should not donate.	If the donor is pyrexial at the time of donation, medical contraindication to donation must be excluded.	If the mother is pyrexial at the time of donation, this would normally be a contraindication to donation; if donation is considered essential the detail of the maternal history needs to be included in the history.
47. Osteomyelitis.	As the risk of relapse is highest within the first 12 months after treatment, a deferral period of 2 years should be considered.			<u>Bone donation:</u> Permanent deferral if osteomyelitis has affected the bone to be donated; otherwise 2-year deferral after successful treatment. <u>Cornea donation:</u> If corneas will be stored in organ culture they can be accepted.	Donation can be accepted if the donor has been successfully treated and there is no underlying condition that would lead to deferral.	Donation can be accepted if the donor has been successfully treated and there is no underlying condition that would lead to deferral.		

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
48. Pericarditis and myocarditis.		As the risk of relapse is highest within the first 12 months after treatment, deferral period of 2 years should be considered. The possibility of an underlying disease may have to be considered.	As whole blood.	If fully recovered, then the donor can be accepted. Product quality must be evaluated.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted after careful evaluation of underlying cause and possibility of exacerbation by donation.	If fully recovered, then the donor can be accepted.
49. Rheumatic fever.		2-years deferral after recovery and end of medical treatment. If persistent heart damage or chronic heart disease, then permanent deferral.	As whole blood.	If fully recovered, the donor can be accepted, except for heart valve donation if the heart valve to be donated has been affected. Living donors can be accepted if there is no risk to their health.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted	If fully recovered, then the donor can be accepted	If fully recovered, then the donor can be accepted
50. Bronchitis: a. Acute bronchitis. b. Chronic Obstructive pulmonary disease		a. The donor can donate if they are well with no fever, and if the donor has recovered from productive cough. b. <u>GOLD group A:</u> Can donate if asymptomatic and well. <u>GOLD group B-D:</u>	As whole blood.	a. No deferral. b. Accept, unless underlying pathology is cause for deferral.	a. 2-week deferral. b. Accept, unless underlying pathology is cause for deferral or is of a hereditary nature.	a. 2-week deferral. b. Accept, unless underlying pathology is cause for deferral or is of a hereditary nature.	As whole blood.	Deferral until maternal donor has no fever, is recovered from productive cough and feels healthy.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
		Permanent deferral.						
51. Common cold/Influenza.	Deferred if the donor has symptoms and is unwell and therefore does not fulfil the general requirement of donor eligibility. In case of avian or pandemic Influenza variants applicable guidelines must be followed.			No deferral.	No deferral.	No deferral, although donor health needs to be taken into consideration if requiring anaesthesia for donation to go ahead.		
52. Glandular fever.	2-weeks deferral after cessation of treatment and symptoms, including ensuring there are no palpable spleen or lymph nodes.		<u>Plasma for fractionation:</u> If fully recovered, the donor can be accepted provided there are no palpable lymph nodes or spleen enlargement.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted.	If fully recovered, then the donor can be accepted.
53. Allergy. a. Mild atopia, allergic rhinitis, hay fever, mild urticaria. b. Mild Respiratory allergic reactions.		a. All donors with mild allergy, also at the time of donation, can donate, if they feel well. b. Donors with acute allergies leading to a	As whole blood.	n/a	Donors with a mild form of allergy can be accepted; donors with a strong family history of allergy or with a	Donors with a mild form of allergy can be accepted; donors with a strong family history of allergy or with a	In cases of a relevant severe allergy in the donor or donor's family, the transplant centre must be informed. It must be ensured that the donor is	In cases of allergy in the donor or donor's family, the transplant centre must be informed. Maternal

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
c. Severe systemic allergic reactions.		mild respiratory crisis should not donate until the end of the crisis period and treatment. Evaluate the intake of oral or injected steroid medication. c. It should be considered to permanently defer donors with severe IgE-mediated allergy, particularly anaphylaxis to foods, drugs and latex due to risk of passive transfer of IgE with transfusion.			personal history of severe allergy should not be accepted for sperm donation.	personal history of severe allergy should not be accepted for oocyte donation.	not put at risk of being exposed to allergens during the donation process. Donors with multiple, severe allergies, particularly with a history of anaphylaxis should not donate if the agent is unknown and/or cannot be avoided or has multiple cross reactivity.	donors with multiple severe allergies, particularly with a history of anaphylaxis should not donate.
54. Autoimmune diseases (incl. CNS).	<u>If systemic immunemodulatory therapy is needed:</u> Defer until cessation. <u>Asymptomatic without severe complications:</u> No deferral. <u>Insulin-dependent Diabetes:</u> Deferral		<u>Plasma for fractionation:</u> <u>Autoimmune disease in general:</u> No deferral, however donors with potential pathogenic antibodies should be permanently deferred. <u>Diabetes type 1 and 2</u>: As plasma donation can change both the	Consider impact of the underlying condition and/or its treatment on the quality of the tissues – if no adverse effect on the tissue to be donated then no specific deferral.	Consider if there is a hereditary element to the condition.	Consider if there is a hereditary element to the condition.	Donors in remission of the listed diseases, who have not required systemic therapy for more than one year, may be considered for donation on an individual basis but should not receive granulocyte colony stimulating factor and thus should	Consider impact of the underlying condition and/or its treatment on the quality of the Cord blood donation – if no adverse effect on the cells to be donated then no specific deferral.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
			serum HbA1c and serum concentration of antidiabetic medication this may interfere with treatment and monitoring of the disease. For this reason, one should only accept donors where the diabetes is only strictly dietary controlled.				donate by bone marrow only. Risk of adoptive transfer of disease-causing cells should be discussed with the recipient, and risks of disease activation should be discussed with the donor.	
55. Malignancy.	<u>Premalignant conditions:</u> No deferral. <u>Non-haematological cancers, treated and cured:</u> A minimum deferral period of 5 years, after end of treatment and cessation of all symptoms could be considered. Risk of recurrence should be included in assessment.			<u>Avascular and acellular tissue:</u> No deferral. <u>Cornea:</u> Deferral of donors with a history of retinoblastoma, primary or metastatic ocular malignancies, metastatic malignant melanoma and haematological cancers. <u>All other tissue:</u> As general criteria.	Consider hereditary element of the malignancy and permanent deferral.	Consider hereditary element of the malignancy and permanent deferral.	<u>Premalignant conditions:</u> No deferral if associated malignancies can be excluded and if treatment of donor (e.g. mobilizing agents does not increase the risk of malignant deformation. <u>Previous cancer or malignant disease:</u> Deferral, except for: • Cured carcinoma in-situ.	<u>Premalignant conditions:</u> No deferral. <u>Maternal donors with previous cancer:</u> Deferral.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	<u>Malignancy of hematopoietic tissues and cells:</u> Permanent deferral.						• Successfully and completely treated basal cell carcinoma. <u>Known genetic predisposition:</u> Women with known positivity for *BRCA1* or *2* mutation, but no history of cancer are acceptable as donors. All such women should have a breast examination performed at or shortly before the pre-donation assessment. In the above cases, these conditions must always be communicated to the requesting transplant centre.	

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
56. Haemoglobinopathy traits and diseases		For donors with a Hb trait condition, the Hb needs to be in the acceptable range, which is already stipulated in the general criteria for suitable donors, unless the disease is known to affect the functional capacity of the red cell. Defer if: Thalassaemia major or intermedia, Sickle cell disease, High affinity haemoglobin, other clinically significant structural or functional haemoglobinopathies.	All known haemoglobinopathies, traits and diseases: Permanent deferral, as red cells are mechanically stressed during the apheresis procedure. Unknown status: In case of a high risk of these traits (by known family history or of an ethnic background with high incidence) then the donor physician must be made aware of the risk. A pre-donation assessment should then be performed.	The donor can be accepted if well and no adverse impact from the disease and/or its treatment on the quality and safety of the tissue to be donated.	Deferral.	Deferral.	Each donor with a haemoglobinopathy-thy should be assessed by a physician. Deferral: Thalassaemia major or intermedia, Sickle cell disease, High affinity haemoglobin and any other clinically significant structural or functional haemoglobinopathies. No deferral: Assuming the haemoglobin is within the normal sex-adjusted range, at the discretion of the transplant centre the following can be accepted: Alpha or beta thalassaemia trait Sickle cell trait HbC, HbD Punjab/Oman, HbE	Severe haemoglobinopathy must be assessed during pregnancy. Deferral: If the mother or father is homozygous or heterozygous for inherited haemoglobin disorders and the infant is affected. Discretionary: If the cord blood or infant/child is tested for the condition and the infant is shown to be unaffected or heterozygous (trait), accept and inform the transplant centre.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
							traits, other asymptomatic traits or compound heterozygous haemoglobinopathies e.g. HbC/a-thal trait. Donors with sickle cell trait must no receive G-CSF.	
57. Hemochromatosis.		<u>Accept if:</u> • The diagnosis is confirmed with known genotype. • The initial venesection programme for the donor has been completed and donor treatment is in the maintenance phase. • There are no significant complications of iron overload including cardiac or hepatic impairment. • The donor is not receiving iron chelation treatment or other iron depletion therapy.	As whole blood but keep upper Hb limits for plasma donors in mind as plasmapheresis by definition increases the Hb level	The donor can be accepted if there is no damage to the donated tissue.	Defer due to hereditary condition.	Defer due to hereditary condition.	No deferral. In cases of secondary organ damage the condition must be evaluated with donor safety in mind.	No deferral.

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
		• The donor complies other donor selection criteria. Note: The responsibility of donation as treatment of the donor as a patient **must** lie elsewhere.						
58. Renal Disease.		<u>Severe renal illness, chronic renal insufficiency:</u> Permanent deferral.	As whole blood.	If no impact on quality of tissue to be donated, then the donor can be accepted.	Defer if hereditary condition.	Defer if hereditary condition.	Deferral, if progressive disease and/or renal function is impaired.	As PBSC and BM.
59. Epilepsy.		<u>If not requiring treatment and no seizures:</u> 3-year deferral after last seizure or treatment.	As whole blood.	If the cause for epilepsy is fully investigated and there is no impact on the safety or quality of the tissue, the donor can be accepted.	Defer if likely hereditary element.	Defer if likely hereditary element and if requiring medical treatment.	<u>If not requiring treatment and no seizures:</u> 12-months deferral.	<u>If not requiring treatment and no seizures:</u> 12-months deferral.
60. Cardiovascular disease: a. Coronary heart disease. b. Cerebrovascular disease. c. Peripheral arterial disease.	In cases of diagnosed asymptomatic cardiovascular disease, individual risk assessment should be performed to ensure that donation does not pose a threat to			If quality of tissue to be donated is not adversely affected, then the donor can be accepted.	Defer if likely hereditary element.	Defer if likely hereditary element.		

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
	the health and well-being of the donor. a. Condition with ischaemic symptoms and abnormal narrowing and plaque in cardiac vessels: Permanent deferral. b. Condition with ischaemic symptoms or/and thrombosis in brain: Permanent deferral. c. Condition with ischaemic symptoms and abnormal narrowing and plaque in peripheral vessels: Permanent deferral.							
61. Stroke.	Permanent deferral.			Accept.				

Risk	TRANSPOSE synopsis of donor criteria							
	General criteria (except if stated otherwise for the individual SoHO)	**Whole blood (including plateletpheresis)**	**Plasmapheresis**	**Tissues**	**Medical assisted reproduction - sperm**	**Medical assisted reproduction - oocyte**	**Haemopoietic peripheral blood stem cells, granulocytes and bone marrow**	**Cord blood**
62. Chronic Fatigue Syndrome.	Should not donate.			Defer if not resolved.	Defer if not resolved.	Defer if not resolved.	Defer if not resolved.	

Appendix 1

Nomograms for determination of the collection volume of plasma by plasmapheresis

An example nomogram for female and male donors is included, to allow for individualization of the collection volume by the sex and BMI. Estimation on TBV is based on Pearson TC, Guthrie DL, Simpson J et al: Interpretation of red cell mass and plasma volume in adults: Expert panel of radionuclides of the International Council for Standardization in Haematology. Brit J Haematol 1995; 89:748-765

The nomogram must contribute to donor safety while being easy for staff to interpret and handle. The nomogram below includes BMI and identifies too low BMI (< 20), an adaptation to BMI > 30, and incremental volumes for BMI from 20 to 30. The maximum collection volume to be collected per donation is 850 ml (including anticoagulant).

Example nomogram for collection volume (incl. anti-coagulant) for women

Kg	55	60	65	70	75	80	85	90	95
150 cm	586	607	628	***638***	***638***	***638***	***638***	***638***	***638***
155 cm	599	622	643	663	***671***	***671***	***671***	***671***	***671***
160 cm	613	636	658	679	698	***705***	***705***	***705***	***705***
165 cm	627	650	672	694	714	734	***740***	***740***	***740***
170 cm	BMI<20	664	687	709	729	750	769	***775***	***775***
175 cm	BMI<20	BMI<20	701	723	745	765	785	803	***810***
180 cm	BMI<20	BMI<20	716	738	760	781	800	810	839
185 cm	BMI<20	BMI<20	BMI<20	753	775	796	816	836	***850***
190 cm	BMI<20	BMI<20	BMI<20	BMI<20	790	811	832	850	***850***
195 cm	BMI<20	BMI<20	BMI<20	BMI<20	BMI<20	826	848	***850***	***850***
200 cm	BMI<20	BMI<20	BMI<20	BMI<20	BMI<20	841	***850***	***850***	***850***

Example nomogram for collection volume (incl. anti-coagulant) for men

Kg	55	60	65	70	75	80	85	90	95	100
150 cm	654	684	712	***726***	***726***	***726***	***726***	***726***	***726***	***726***
155 cm	673	704	733	761	***772***	***772***	***772***	***772***	***772***	***772***
160 cm	692	723	754	782	809	***819***	***819***	***819***	***819***	***819***
165 cm	711	743	774	802	831	***850***	***850***	***850***	***850***	***850***
170 cm	BMI<20	762	794	823	***850***	***850***	***850***	***850***	***850***	***850***
175 cm	BMI<20	BMI<20	813	845	***850***	***850***	***850***	***850***	***850***	***850***
180 cm	BMI<20	BMI<20	833	***850***	***850***	***850***	***850***	***850***	***850***	***850***
185 cm	BMI<20	BMI<20	BMI<20	***850***	***850***	***850***	***850***	***850***	***850***	***850***
190 cm	BMI<20	BMI<20	BMI<20	BMI<20	***850***	***850***	***850***	***850***	***850***	***850***
195 cm	BMI<20	BMI<20	BMI<20	BMI<20	BMI<20	***850***	***850***	***850***	***850***	***850***
200 cm	BMI<20	BMI<20	BMI<20	BMI<20	BMI<20	***850***	***850***	***850***	***850***	***850***

(Source: EDQM, Draft for the 20th Ed of the Guide to the Preparation, Use and Quality Assurance of Blood Components. Modified according to the max volume of 850 ml and min BMI of 20, and weight of 55 kg)