PROPOSED TECHNICAL REQUIREMENTS
BLOOD AND BLOOD COMPONENTS

File 1

DRAFT

FOR CONSULTATION PURPOSES ONLY

ANNEX I

INFORMATION REQUIREMENTS

A. INFORMATION TO BE PROVIDED TO DONORS

1. Accurate but generally understandable educational materials about the essential nature of blood, the products derived from it, and the important benefits to patients of blood and plasma donations;

2. The reasons for requiring a medical history, physical examination, and the testing of donations; information on the risk of infectious diseases that may be transmitted by blood and blood products; the signs and symptoms of AIDS, and the significance of 'informed consent', self-deferral, and temporary and permanent deferral;

3. Information about protection of personal data: No unauthorised disclosure of the name of the donor, of information concerning his health, and of the results of the tests performed;

4. The reasons why they should not donate which may be detrimental to their own health;

5. The reasons why they should not donate which put recipients at risk, such as unsafe sexual behaviour, HIV /AIDS, hepatitis, drug addiction and the use and abuse of drugs;

6. The option of changing their mind about donating prior to proceeding further without any undue embarrassment or discomfort;

7. Information on the possibility of withdrawing or self-deferring at any time during the donation process;

8. The opportunity to ask questions at any time;

9. The undertaking that if test results show evidence of any pathology, they will be contacted by the blood collection centre;

10. Specific information on the nature of the procedures involved in the donation process and associated risks for those willing to participate in apheresis programmes, whether for plasma or cellular components.

B. INFORMATION TO BE OBTAINED FROM DONORS

1. Identification

Appropriate means of identification, providing

- name (first and surname),
- address,
- date of birth,

or alternative means allowing the donor to be uniquely identified.

2. Health history

Health and medical history

- any relevant factors that may assist in identifying and screening out persons whose donation could present a health risk to themselves or a risk of transmitting diseases to others, by way of a written questionnaire addressing the criteria listed in Annex II and a personal interview with a trained health care staff member. Abnormal conditions should be referred to the physician-in-charge who should have the final say on whether blood should be collected from a donor. If the physician is in doubt, the donor should be deferred.

3. Signature

- Signature, on the donor questionnaire, countersigned by the health care staff member conducting the interview under the responsibility of the responsible person, or subject to the approval of this responsible person;

- Signature on a separate attestation,

  - to acknowledge

    - that educational materials provided have been read and understood,
    - that opportunity to ask questions has been presented, and
    - that satisfactory responses have been received.

  - to agree that his / her blood or plasma donation could be used for patients needing transfusion or blood products in the country where the donation is made or in another country, to which it would be transferred in accordance with the provisions of the legislation of the country where the donation is made, particularly with regard to the destination of the donation; and

  - to indicate his / her informed consent of the wish to proceed with the donation process.

ANNEX II

REQUIREMENTS CONCERNING THE SUITABILITY OF BLOOD AND PLASMA DONORS AND THE SCREENING OF DONATED BLOOD

1. REQUIREMENTS FOR THE PROTECTION OF BLOOD AND PLASMA DONORS

a) Physical acceptance criteria

Age	18-65 years	60-65 years (first-time donor) - at discretion of responsible physician	17 years and not legally classified as a minor; otherwise written consent according to law	+ 65 years - with permission of responsible physician given annually
Body weight	≥ 50kg for either whole blood or plasma			
Blood pressure	Systolic ≤ 180 mm of mercury	Diastolic ≤ 100 mm of mercury		
Pulse	50 –100 beats per minute and regular	< 50 beats per minute Accepted if undergoes intensive sport training		
Haemoglobin (or haematocrit**)**	for females ≥ 12.5 g/100 ml	for males ≥ 13.5 g/100 ml	For apheresis plasma: males and females ≥ 12.5 g/100 ml	
Haematocrit	for females ≥ 38%	for males ≥ 40%	For apheresis plasma ≥ 38%	
Protein	For plasmapheresis 60 g/litre			

b) Donation criteria

Time interval	For whole blood > 8 weeks Maximum 6 donations per year for males, 4 for females	For apheresis plasma Normally > 2 weeks
Volume	Per whole blood donation ≤ 500 ml	

2. DEFERRAL CRITERIA FOR BLOOD AND PLASMA DONORS

2.1 Permanent Deferral Criteria

Prospective donors who have, or have a history of, any of the following:

- Auto-immune diseases if more than one organ is affected
- Cardiovascular diseases
- Central nervous system diseases
- Malignant diseases except after successful treatment for non-invasive cervical cancer and rodent ulcer
- Abnormal bleeding tendency
- Fainting spells (syncope) or convulsions
- Severe or chronic gastrointestinal, haematological, metabolic, respiratory, or renal disease not included in preceding categories
- Infectious diseases - persons suffering or having suffered from
  - Babesiosis
  - Hepatitis B (HBsAg confirmed positive)
  - Hepatitis C
  - Hepatitis, infectious (of unexplained aetiology)
  - HIV/AIDS
  - HTLV I/II
  - Leprosy
  - Kala Azar (leishmaniasis)
  - Q fever
  - Syphilis
  - Trypanosoma cruzi (Chagas' disease) – the blood of residents in an endemic area associated with poor living conditions may be used only for plasma fractionated products
- TSEs (or history thereof in genetic family)
- Alcoholism, chronic
- Cornea/dura mater transplantation recipient
- Diabetes, if treated with insulin
- Intravenous (IV) drug use
- Pituitary hormone of human origin (e.g. growth hormone) recipient
- Sexual behaviour that places them at high risk of transmitting infectious diseases, including
  - (a) persons who have had sex in return for money or drugs
  - (b) current sexual partners of people with HIV
  - (c) current sexual partners of people with HBV unless demonstrated to be immune
- Xenotransplant recipients
- Allergy – individuals with a documented history of anaphylaxis
- Malaria –if test results positive for individual who lived in endemic area for first five years of life, reject as a cellular donor.

2.2 Temporary Deferral Criteria

2.2.1 Ineligible for five years

– Acute glomerulonephritis (following complete recovery)

2.2.2 Ineligible for three years

– Epilepsy (off-treatment and without an attack)

2.2.3 Ineligible for two years

– Tuberculosis (after declared cured)
– Osteomyelitis (after declared cured)
– Toxoplasmosis (after recovery and absence of IgM antibodies)
– Brucellosis (after full recovery)
– Rheumatic fever (after an attack if no evidence of chronic heart disease)

2.2.4 Ineligible for one year

– Accidental exposure to blood or blood contaminated instruments
– Endoscopic examination
– Treatment involving use of catheters
– Transfusion with blood or blood components
– Tissue or cell transplant
– Major surgery
– Acupuncture (if not performed by a qualified practitioner)
– Tattoo
– Body piercing
– Drug allergy, in particular allergy to penicillin (after last exposure)
– Close contact with a case of hepatitis B or C
– Rabies vaccine (if post exposure)
– Tick-borne encephalitis vaccine (if post exposure)

2.2.5 Ineligible for nine months

– Pregnancy (after delivery)
– Abortion

2.2.6 Ineligible for six months

– Infectious mononucleosis (after recovery)
– Malaria (after return from last visit to endemic area and symptom free)

2.2.7 Ineligible for at least two weeks

– Prophylactic immunisations (following administration of vaccines with attenuated bacteria and viruses (four weeks)
– Minor infectious diseases (two weeks)
– Fever above 38º C, flu-like illness (following cessation of symptoms)

2.2.8 Ineligible for at least one week

– Minor surgery (without complications)

2.2.9 Ineligible for 72 hours

– Following administration of vaccines (desensitising)

2.2.10 Ineligible for 48 hours

- Treatment by dentist or dental hygienist
- Following administration of killed/inactivated viral/bacterial and rickettsial vaccines
- Rabies vaccine (prophylactic administration)

ANNEX III

STORAGE AND FREEZING

A. STORAGE

Blood product	Storage Temperature	Length of storage	Transportation temperature	Transportation time
Cryoprecipitate	-18 ºC — -25 °C Below -25 ºC	3 months 24 months	Similar to storage temperature	
Granulocytes	Not suitable for storage. If unavoidable: +20 °C — +24 °C	Administered as soon as possible after collection, with maximum storage of 24 hours.	Similar to storage temperature	
Plasma, cryoprecipitate-depleted	-18 °C — -25 °C Below -25 ºC	3 months 24 months	Similar to storage temperature	
Plasma, fresh frozen	-18 °C — -25 °C Below -25 ºC	3 months 24 months	Similar to storage temperature	
Plasma, thawed	Thawed between +30 °C — +37 °C	Transfused as soon as possible		
Platelets (single unit, concentrate recovered, buffy coat pool, apheresis)	+20 °C — +24 °C	5 days (with continuous gentle agitation) < 6 hours (after open system manipulation)	Similar to storage temperature (with continuous gentle agitation)	
Platelets, cryopreserved: apheresis	*Frozen platelets*: maintained at: -80 °C (in electrical freezer); -150 °C (in vapour phase liquid nitrogen). *Thawed platelets* To be stored at +20 °C to +24 °C with adequate agitation, if short term storage required.	Up to 12 months Beyond 12 months To be used immediately after thawing.	Similar to storage temperature	
Red cells	+2 °C — +6 °C	≤ 35 days (in adenine supplemented anticoagulant)	+2 °C — +10 °C	≤ 24 hours
Red cells in additive solution	+2 °C — +6 °C	According to anticoagulant and additive solution	+2 °C — + 10°C	≤ 24 hours

Blood product	Storage Temperature	Length of storage	Transportation temperature	Transportation time
Red cells in additive solution, buffy coat removed	+2 °C — +6 °C	According to anticoagulant and additive solution. Normally 35 days.	+2 °C — + 10°C	≤ 24 hours
Red cells, leukocyte-reduced	+2 °C — +6 °C	≤ 35 days with adenine supplemented anticoagulant. < 24 hours if prepared in open system	+1°C — +10°C	≤ 24 hours
Red cells, frozen by low glycerol method	-140 ºC — -150 ºC in vapour phase of liquid nitrogen +2 ºC — +6 ºC, after thawing	10 years < 24 hours, use as soon as possible after thawing	Storage conditions should be maintained	Frozen red cells: as short as possible. Thawed red cells: to be transfused within 24 hours of thawing
Red cells, frozen by high glycerol method	–60 ºC — –80 ºC in an electrical freezer +2 ºC — +6 ºC, after thawing	10 years < 24 hours, use as soon as possible after thawing	Storage conditions should be maintained	Frozen red cells: as short as possible. Thawed red cells: to be transfused within 24 hours of thawing
Red cells, washed	+2 °C — +6 °C	< 24 hours if prepared at low temperature < 6 hours if prepared at room temperature	+2 °C — +6 °C	Limited by the appropriate storage time
Whole blood (for transfusion as whole blood)	+2 °C — +6 °C	< 35 days with adenine supplemented anticoagulant	+2 °C — +10 °C	≤ 24 hours
Whole blood (for component preparation)	+1 °C — +6 °C +20 ºC — +24 ºC (if to be used for the preparation of platelets)	Up to 8 hours before use Up to 24 hours before use		

B. FREEZING

Blood product	Time of freezing
Plasma A	Frozen within 6 hours of phlebotomy
Plasma B	Frozen within 24 hours of phlebotomy
Plasma C	Frozen after 24 hours of phlebotomy
Platelets	Frozen within 24 hours
Red cells	Frozen within 7 days

ANNEX IV

QUALITY REQUIREMENTS FOR BLOOD COMPONENTS

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
Cryoprecipitate	Contains a major portion of Factor VIII, von Willebrand factor, fibrinogen, Factor XIII and fibronectin present in freshly drawn and separated plasma.	Blood donation testing requirements listed in Annex IV	
		Volume	10 — 25 ml
		Factor VIIIc *Sampling* -1% of all units. Every two months: a) pool of 6 units of mixed blood groups during first month of storage; b) pool of 6 units of mixed blood groups during last month of storage	> 70 I.U./unit
		Fibrinogen *Sampling* - 1% of all units; with a minimum of 4 units per month	> 140 mg/unit
Granulocytes, apheresis	Principal function is phagocytosis of bacteria.	Blood donation testing requirements listed in Annex IV	
		Volume	< 500 ml
		Granulocytes	> 10 X 10^9/unit
Plasma, cryoprecipitate-depleted	Content of albumin, immunoglobulins and coagulation factors comparable to fresh frozen plasma. Reduced levels of Factors V, VIII, XIII, von Willebrand factor, fibrinogen, & fibronectin.	Blood donation testing requirements listed in Annex IV. (unless plasma itself is the source)	
		Volume *Sampling* - all units	Stated volume ±10%
Plasma, fresh frozen	Contains normal plasma levels of stable coagulation factors, albumin & immunoglobulins; at least 70% of original Factor VIIIc, other labile coagulation factors, & naturally occurring inhibitors. European Community legislation applies if source material for fractionated products.	Blood donation testing requirements listed in Annex IV (unless plasma itself is the source)	
		Volume	Stated volume ±10%
		Appearance	Clear

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		Red Cells Leukocytes Platelets *Sampling*: 1% of all units with minimum of 4 units per month	< 6 X 10^9/l < 0.1 X 10^9/l < 50 X 10^9/l
		Factor VIIIc Sampling: every 2 months a) pool of 6 units of mixed blood groups during first month of storage b) pool of 6 units of mixed blood groups during last month of storage.	Minimum 70% of original value
Platelets, apheresis	Platelet content per procedure variable depending on method of preparation and machine used. Same applies to leukocyte and red cell contamination of product. Standard unit = 5-6 single units by PRP.	Blood donation testing requirements listed in Annex IV.	
		Volume	> 40 ml/60 X 10^9 platelets
		Platelet content *Sampling* – 1% of all units. minimum of 10 units per month. (90% of units sampled should fall within specified values).	> 200 X 10^9 platelets / donation
		Residual leukocytes - after leukocyte depletion *Sampling* – 1% of all units. minimum of 10 units per month. (90% of units sampled should fall within specified values.)	< 1.0 X 10^6 / standard unit
		Swirling *Sampling* - all units	+1 (score)
		HLA or HPA (when & as required)	Typing
		pH measured at the end of the recommended shelf life *Sampling* –1% of all units, minimum of 4 units per month	6.8 — 7.4
Platelets, cryopreserved: apheresis	Reconstituted unit of cryopreserved platelets is practically free of red cells and granulocytes.	Blood donation testing requirements listed in Annex IV	
		Volume	50 — 200 ml
		Platelet content	> 40% of original pre-frozen platelet content
		Residual leukocytes (before freezing)	< 0.2 X 10^6 per 60 X 10^9 platelets
Platelets, recovered from single unit by PRP	Amount of platelets in adult 'standard dose' equivalent to that obtained from 4-6 units of whole blood.	Blood donation testing requirements listed in Annex IV	

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		HLA or HPA (when & as required)	Typing
		Volume	40 — 60 ml
		Platelet content *Sampling* - 1% of all units: ≥ 10 units/month (75% of units sampled should fall within values specified).	≥ 60 X 10^9 platelets / single unit equivalent
		Residual leukocyte content - before leukocyte depletion - after leukocyte depletion *Sampling* - 1% of all units; ≥ 10 units / month (75% of units sampled should fall within values specified).	< 0.2 X 10^9 / single unit equivalent < 0.2 X 10^6 / single unit equivalent
		pH (at end of recommended shelf life) *Sampling* - 1% of all units; minimum 10 units per month	6.8 — 7.4
Platelet pool from buffy coat		Blood donation testing requirements listed in Annex IV	
		HLA or HPA (when & as required)	
		Volume	n.s.
		Platelet content *Sampling* - 1% of all units. Minimum 10 units / month (75% of units sampled should fall within values specified)	> 60 X 10^9 platelets / single unit equivalent
		Residual leukocyte content. - before leukocyte depletion - after leukocyte depletion *Sampling* - 1% of all units; ≥ 10 units / month (75% of units sampled should fall within values specified).	< 0.05 X 10^9 / single unit equivalent < 0.2 X 10^6 / single unit equivalent
		pH measured at the end of the recommended shelf life	6.8 — 7.4
Red cells	Contains all red cells from donated unit after centrifugation. No procedures taken to remove leukocytes or platelets.	Blood donation testing requirements listed in Annex IV	
		Volume *Sampling* – 1% of all units	280 ±50 ml
		Haematocrit (Hct) *Sampling* - 4 units per month	65 — 75%
		Haemoglobin *Sampling* - 4 units per month Haemolysis at the end of storage. *Sampling* - 4 units per month	≥ 45 g / unit < 0.8% of red cell mass
Red cells, buffy coat removed	All red cells from donated unit, except 10-30 ml, remain after centrifugation.	Blood donation testing requirements listed in Annex IV	

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		Volume *Sampling* – 1% of all units	250 ±50 ml
		Haematocrit (Hct) *Sampling* - 4 units per month	65 — 75%
		Haemoglobin *Sampling* - 4 units per month	> 43 g / unit
		Leukocyte content *Sampling* - 4 units per month (75% of units sampled should fall within specified values)	< 1.2 X 10^9 cells /unit
Red cells in additive solution	All red cells from donated unit remain after centrifugation. No procedures taken to remove leukocytes or platelets.	Blood donation testing requirements listed in Annex IV	
		Volume: to be defined for the system used. *Sampling* - 1% of all units	Defined volume ±10%
		Haematocrit (Hct) *Sampling* - 4 units per month.	50 — 70% (depending on additive solution, method of centrifugation, & quantity of remaining plasma)
		Haemoglobin. *Sampling* - 4 units per month. Haemolysis at the end of storage. *Sampling* - 4 units per month	≥ 45 g / unit <0.8% of red cell mass
Red cells in additive solution, buffy coat removed	All red cells from donated unit, except 10-30 ml, remain after centrifugation.	Blood donation testing requirements listed in Annex IV	
		Volume. *Sampling* – 1% of all units	To be defined for the system used
		Haematocrit (Hct) *Sampling* - 4 units per month	50 — 70% (depending on nature of additive solution, method of centrifugation, & amount of remaining plasma)
		Haemoglobin. *Sampling* - 4 units per month. Haemolysis at the end of storage *Sampling*: 4 units per month	≥ 43 g / unit < 0.8% of red cell mass
		Leukocyte content *Sampling*: 4 units per month (75% of units sampled should fall within specified values)	< 1.2 X 10^9 cells /unit
Red cells, cryopreserved		Blood donation testing requirements listed in Annex IV	
		Volume	> 185 ml
		Hb (supernatant) (Final suspending solution)	< 0.2 g / unit
		Haematocrit (Hct)	65 – 75%

Component	Properties	Parameter to be checked on all units (unless otherwise indicated)	Quality requirements
		Haemoglobin	≥ 36 g / unit
		Osmolarity. *Sampling* - 1% of all units with a minimum of 4 units per month	< 340 mOsm/L
		Leukocytes *Sampling* - 1% of all units with a minimum of 4 units per month. (75% of units sampled fall within values specified)	< 0.1 X 10^9 cells /unit
		Sterility. *Sampling* - 1% of all units:	Sterile
Red cells, leukocyte-reduced		Blood donation testing requirements listed in Annex IV	
		Volume	250 ±50 ml
		Residual leukocyte content *Sampling* - 1% of all units with a minimum of 4 units per month (validation with 100 filtrations for each kind of filter)	< 1 X 10^6 cells /unit
		Haematocrit (Hct) *Sampling* - 4 units per month	65 — 75%
		Haemoglobin. *Sampling* - 1% of all units with a minimum of 4 units per month. Haemolysis at the end of storage *Sampling* – 4 units per month	≥ 40 g / unit < 0.8% of red cell mass
Red cells, washed	Amount of residual plasma depends upon washing protocol.	Blood donation testing requirements listed in Annex IV	
		Volume	To be defined for the system used
		Haematocrit (Hct)	65 — 75%
		Haemoglobin Haemolysis at the end of the process	≥ 40 g / unit < 0.8% of red cell mass
		Residual protein of final supernatant	< 5 mg / unit (To ensure IgA content < 0.2 mg / unit).
Whole blood		Blood donation testing requirements listed in Annex IV	
		Volume. *Sampling* – 1% of all units with a minimum of 4 units per month	400 — 500 ml excluding anticoagulant
		Haemoglobin *Sampling* - 4 units per month	≥ 45 g/unit
		Haemolysis at end of storage *Sampling* - 4 units per month.	< 0.8% of red cell mass