HEALTH HOLDING

HAFER ALBATIN HEALTH CLUSTER MATERNITY AND CHILDREN HOSPITAL

Department:	Laboratory and Blood Bank		
Document:	Internal Policy and Procedure		
Title:	Donor Pre-Donation Education, Identification, Selection, Registration and Consent		
Applies To:	All Blood Bank Staff		
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1. PURPOSE:

1.1 Proper selection of blood donor (questionnaire and examination).
1.2 Blood donor educational materials.
1.3 Highlighting the blood donor medical history questionnaire.
1.4 Donor deferral; causes and duration.

2. DEFINITONS:

2.1 **Deferral:** The act of putting off to a future time. It may be temporary or permanent.
2.2 **Transfusion Transmitted Diseases (TTD):** They are diseases caused by infections resulting from the introduction of a pathogen into a person through blood transfusion.

3. POLICY:

3.1 Prospective donor's history should be evaluated and the donor examined by a qualified person before whole blood collection.
3.2 Acceptance criteria for the donors have to be determined.
3.3 Deferral criteria and period of deferment have to be determined.
3.4 Insurance that donor receives appropriate information/education before donation process.
3.5 The donor must sign a consent form giving permission to draw blood.
3.6 The process of selecting blood donors aims to minimize the risk of harm to blood recipients by preventing donations by individuals who have:
  3.6.1 Evidence of disease transmissible by blood transfusion.
  3.6.2 Conditions thought to compromise the suitability of the blood or blood component.
3.7 Also, the process of selecting blood donors aims to minimize the risk of harm to blood donors, so the blood donor must be:
  3.7.1 Able to tolerate the collection procedure without experiencing significant complications.
  3.7.2 Provided with high standards of care and assurance of their health and safety.
  3.7.3 Aware of his / her rights and responsibilities.
3.8 Donation of paid donors is not allowed.
3.9 Therapeutic venesection is not done in the blood bank of MCH. It could be done in generalised hospitals.
3.10 Apheresis is not available in the blood bank of MCH.

4. PROCEDURE:

4.1 **The donor selection process involves:**
  4.1.1 Pre-donation information before an individual registers for blood donation (Donor education).
  4.1.2 Registration and donor identification.
  4.1.3 Check history of previous donation, transfusion transmitted disease (TTD) results and deferred donors' record.
  4.1.4 Donor medical history questionnaire and consent.

4.1.5 Proper physical examination.

4.2 Every morning, Technicians/ specialists of the donation area do quality control of Fresenius Kabi compo lab machine and record the results in their quality control records, and check of the shaker & balance of blood collection device Also, they must be sure that all 'donor selection' needs are available.

4.3 Pre-donation information (educational materials) to prospective blood donors:

4.3.1 Pre-donation information/education materials including:

4.3.1.1 Educational materials regarding the donation process. They include:

4.3.1.1.1 Availability of qualified and trained medical staff throughout the process.

4.3.1.1.2 The blood bank responsibility to ensure donor health, safety, and confidentiality.

4.3.1.1.3 The importance of voluntary non-remunerated blood donation, particularly regular donation, to maintain an adequate supply of safe blood for patients who require transfusion.

4.3.1.1.4 Nature and use of blood and its components; and the importance of maintaining healthy lifestyles.

4.3.1.1.5 The steps in the blood donation process and the rationale for each step, assurance of the safety of the donation process and potential adverse donor reactions, such as fainting or hematoma.

4.3.1.1.6 Basic information about blood group serology and tests performed on donated blood. Possible consequences for donors and the donated blood in the event that the test results show unusual red cell serology or rare blood groups.

4.3.1.1.7 The donor's rights and responsibilities.

4.3.1.2 Educational materials regarding infectious diseases transmitted by blood transfusion (i.e. Transfusion-Transmitted Diseases "TTD"). These include:

4.3.1.2.1 The importance of the safety of donated blood for transfusion recipients, which can be achieved through donor adherence to donor selection criteria relating to their health and risk for TTD.

4.3.1.2.2 The purpose of blood screening for TTD is to ensure blood safety and not to provide testing for individuals who seek to know their infection status.

4.3.1.2.3 Common TTD, including HIV, HBV, HCV and syphilis, and routes of their transmission.

4.3.1.2.4 The infectious disease tests that will be performed on his/her donation; possible consequences for donors and the donated blood in the case of abnormal TTD test results; the mechanisms for confirmatory testing, information and the notification process for positive tests, about any reporting requirements to health authorities; assurance of confidentiality; and referral for further investigation, counselling, treatment and care.

4.3.1.3 Importance of providing accurate information because of the limitations of the tests to detect early infections.

4.3.1.3.1 Increase the donors' trust in the blood bank and encourage them to inform the blood bank of any recent behaviours that increased the risk of a TTD and medical conditions that may affect their suitability to donate or the safety of the subsequent donations.

4.3.1.4 Importance of withdrawing themselves from the donation process if they believe that their blood is not suitable for transfusion.

4.3.1.4.1 This could be at any time before, during or after donation,(without any undue embarrassment or questioning) especially if they:

4.3.1.4.1.1 Are suffering from an infection, disease or health condition that may make them unsuitable to donate blood.

4.3.1.4.1.2 Have engaged in behaviours that put them at high risk for TTD.

4.3.1.4.1.3 Have travelled to a country or region that puts them at high risk for TTD.

4.3.1.4.1.4 Are known carriers of infections: e.g. HBV.

4.3.1.4.1.5 Are seeking to know their infection status for HIV or other TTD.

4.3.1.5 Donors acknowledge that the educational materials have been read and understood.

4.4 **Registration and donor identification:**

4.4.1 The interview should be inaudible to the rest of the staff and the other donors.

4.4.2 All potential donors must be provided with information about HIV, HBV, HCV, and other TTD so that those at risk will refrain from donation.

4.4.3 Acceptable form(s) of identification include Saudi national I.D/Iqama or other government-issued identification documents such as driver's license or visitor card from Absher .

4.4.4 The information obtained from the donor during registration must fully identify the donor (e.g. full name, ID number, date and place of issue, address, phone number).

4.4.5 Current information must be obtained and recorded for each donation; single use donation form is used for recording the information.

4.4.6 Registration is recorded in hematos system for blood banks by the phlebotomist through donor access then go to donor reception then secretarial ,then select the MCH code 2007 at the facility option then enter the ID number and date of birth in then the data well downloaded from absher then select yes after confirmation of full name , nationality ,phone number and address of HFR then print the questinaire and consent give to donor to answer it and sign the consent ,then will go medical reception button to add medical data regarding questinaire Blood pressure ,pulse ,tempreture,arms condition ,etc ,after that will v

Collect the blood according to standard proceduers then will write in hematos the volume of collected bag ,time ,duration of collection ,shaker used

the Donor History Questionnaire (DHQ) and consent Form Registration makes a record of the donor identification so that the donor can be contacted in future, if necessary.

4.4.7 Linking the donor identification information to existing donor history is done on each donor encounter.

4.4.7.1 history of previous donation, transfusion transmitted disease (TTD) results and deferred donors' record will appear automatically in hematos during the secertrial registration.

4.5 **Donor medical history questionnaire (DHQ) and consent:**

4.5.1 The medical history is obtained in privacy according to the Donor History Questionnaire (DHQ) and Consent Form approved from the Ministry of Health.

4.5.2 All donors must fill the information and answer all questions in the Donor History Questionnaire Form.

4.5.3 The document is self-administered by the donor, but blood bank may choose to use direct oral questioning, self-administration, or a combination of both methods.

4.5.4 The donor medical history and medical examination are confidential.

4.5.5 The donor must sign a consent form to ensure:

4.5.5.1 Receiving explanation of the donation procedure.

4.5.5.2 Being informed about the risks of the procedure.

4.5.5.3 Being informed about the tests performed and the risks of transmission of infectious diseases.

4.5.5.4 Being informed about the donor confidentiality and the requirement to report test results to health authorities.

4.5.5.5 Being informed that there are circumstances in which blood/blood components are released for transfusion before the completion of infectious disease testing.

4.5.5.6 Having read and understood the information presented to him/her.

4.5.5.7 Having the opportunity to ask questions and having them answered.

4.5.5.8 Permission to draw blood.

4.5.5.9 For minor donors (Below age of 18), parents or guardians must agree about donation and sign the consent on their behalf.

4.5.6 In the past 8 weeks, have you donated blood or its components?

4.5.6.1 Frequency of whole blood donation is every 8 weeks for one unit, but not more than five whole blood units in a year.

4.5.7 Have you ever been rejected as a blood donor? Why?

4.5.7.1 If the answer is yes, blood bank staff should know the reason and carefully re-evaluate the whole issue of donation.

4.5.8 Donors should be deferred permanently if they have history of:

4.5.8.1 Bleeding abnormalities/ blood clots.
4.5.8.2 Cancer.
4.5.8.3 Chagas disease (Trypanosoma cruzi) or babesiosis.
4.5.8.4 Diabetes who require insulin; Complications of diabetes with multi-organ involvement.
4.5.8.5 Epilepsy.
4.5.8.6 Heart diseases/chest pain.
4.5.8.7 Hepatitis.
4.5.8.8 Human growth hormone or bovine insulin.
4.5.8.9 Kidney diseases.
4.5.8.10 Leishmaniasis.
4.5.8.11 Lung diseases.
4.5.8.12 SARS.
4.5.8.13 Positive HIV serology (AIDS patients).
4.5.8.14 I.V. drug users or used intranasal cocaine.
4.5.8.15 Family member with Creutzfeldt-Jacob's disease.
4.5.8.16 Dura matter transplant or reside in UK for 6 months.
4.5.8.17 Tegison (Etretinate) medication for psoriasis.
4.5.8.18 T.B.
4.5.8.19 Stroke.
4.5.8.20 Symptoms of AIDS;

4.5.8.20.1 Prolonged fever or diarrhoea.
4.5.8.20.2 Enlarged lymph nodes, unexplained weight loss (more than 5 kg), night sweats, persistent cough, and/or white spots in mouth.

4.5.9 Donors should be deferred for three years if they have:

4.5.9.1 Been from countries with endemic malaria.
4.5.9.2 Been diagnosed and treated from malaria.
4.5.9.3 Been diagnosed and treated from brucellosis.
4.5.9.4 Soriatane (Acitretin) medication, because of its long acting teratogenic effect.

4.5.10 Donors should be deferred for one year (12 months)if they suffer from or they have, had:

4.5.10.1 Himself or his spouse received blood or organ transplant.
4.5.10.2 Rabies shots.
4.5.10.3 Been a nurse for kidney dialysis unit.
4.5.10.4 Been a rape victim.
4.5.10.5 Been incarcerated in a prison more than 72 hours.
4.5.10.6 Been a patient in mental hospital.
4.5.10.7 Tattoo.
4.5.10.8 Acupuncture.
4.5.10.9 Ear or nose piercing.
4.5.10.10 Needle stick.
4.5.10.11 Stab wound.
4.5.10.12 Contact with AIDS or hepatitis patients.
4.5.10.13 Received Anti HB immunoglobulin.
4.5.10.14 Body fluid splash to mucous membrane.
4.5.10.15 Gonorrhea, after treatment.
4.5.10.16 Syphilis, after treatment.
4.5.10.17 Been travelled to malaria endemic area without symptoms.
4.5.10.18 Been treated with anti-malarial treatment as a prophylaxis.
4.5.10.19 Animal bite.

4.5.10.20 Been outside the kingdom for leisure trips (not married, or without his family; 'to be assessed').
4.5.10.21 If they have had any surgery or severe illness (to be assessed).
4.5.10.22 Have sex with haemophilia A or B or taking money or drug for sex.
4.5.11 Donors should be deferred for 6 months (after last dose) if they had taken "Avodart" medication.
4.5.12 Female donors should be deferred if pregnant and for 6 weeks if delivered a baby.
4.5.13 Donors should be deferred for four weeks if they have had:
4.5.13.1 Low hemoglobin (less than 12.5 g/dl).
4.5.13.2 High pulse rate (more than 100 beat/ minute).
4.5.13.3 Low pulse rate (less than 50 beat/ minute).
4.5.13.4 High blood pressure (more than 180 mm Hg for systole and/or more than100 mm Hg for diastole).
4.5.13.5 Vaccination; the following live attenuated viral and bacterial vaccines: German measles (rubella), Chicken pox (varicella zoster).
4.5.13.6 Acutane medicine for acne.
4.5.13.7 Propecia or Prozac, or Proscar (for prostate) medications.
4.5.13.8 German measles (rubella), or Chicken pox (varicella zoster)
4.5.13.9 Travel to endemic area or contact with SARS patient.
4.5.14 Donors should be deferred for two weeks if they:
4.5.14.1 Have received the following live attenuated viral and bacterial vaccines: Measles (rubeola), Mumps, Polio (Sabin/oral), Typhoid (oral), Yellow fever.
4.5.14.2 Have Plavix and Ticlid (deferral for platelet donors; does not affect whole blood donation).
4.5.15 Donors should be deferred for one week if they have had:
4.5.15.1 Mild fever.
4.5.15.2 Common cold or flu.
4.5.15.3 Sore throat.
4.5.15.4 Dental extraction.
4.5.15.5 Antibiotics.
4.5.16 Donors should be deferred for 72 hours they have had:
4.5.16.1 Aspirin, feldene or any aspirin-containing medication, if we intend to separate platelet concentrate.
4.5.17 The confidential unit exclusions (CUE):
4.5.17.1 Refer to "Confidential Self Unit Exclusion And Handling Post Donation Information" chapter (LB-IPP-229).
4.5.18 No deferral with the following (toxoids, or synthetic or killed viral, or bacterial) vaccines;
4.5.18.1 Hepatitis A, Hepatitis B, Influenza, Polio (Salk/injection), Pneumococcal polysaccharide, Diphtheria, Cholera, Tetanus, or Typhoid (by injection) vaccines.

4.6 **Physical examination (Accepted criteria):** The prospective donor's history is evaluated and the donor is examined.
4.6.1 General appearance: The donor should look healthy, not excessively nervous or under effect of drugs or alcohol.
4.6.2 Age:
4.6.2.1 Between 18 and 65 yrs.
4.6.2.2 Below age of 18 and above age of 65 can donate after been evaluated by medical director.
4.6.2.3 Below age of 18 (minor donors) should submit a written agreement for donation from his father or his guardian on their behalf.
4.6.3 Weight:
4.6.3.1 Should not be less than 50 kg.
4.6.4 Temperature:
4.6.4.1 Oral temperature should not exceed 37.5°C (99.5°F).
4.6.5 Pulse:
4.6.5.1 Should be regular and between 50-100 beat/min.
4.6.6 Blood pressure (B.P.):

4.4.6.1 Systolic B.P. between 100-180 mmHg
4.4.6.2 Diastolic B.P. between 60-100 mmHg

4.6.7 Arm inspection:
4.6.7.1 Both arms should be free of lesions, multiple needle puncture marks, sclerotic veins, boils, purulent wounds and severe skin infections.
4.6.7.2 Mild skin disorders as acne and psoriasis, which are not in antecubital area, are accepted for donation.

4.6.8 Hemoglobin (Hb) Evaluation:
4.6.8.1 Perform Hb determination by blood haemoglobin photometer (Fresenius Kabi compo lab), based on dry chemistry photometric assay, or by any available method for Hb estimation.
4.6.8.2 Accepted Hb level for routine donor: 12.5-18.0 g/dl.
4.6.8.3 Hb photometer system components:
4.6.8.3.1 The system consists of disposable microcuvettes with reagent in dry form and a single purpose designed photometer.
4.6.8.3.2 The microcuvette is used for measuring the sample as reaction vessel and as measuring cuvette, and no dilution required.
4.6.8.3.3 Reading of Hb takes place in the photometer which follows the reaction and presents the result only when the reaction has stopped.
4.6.8.3.4 The photometer is calibrated at the factory against the Hb-cyanide-(HiCN) method which is the international reference method for the determination of the total Hb concentration in blood.
4.6.8.3.5 Photometer, transformer (battery eliminator), and control cuvette are delivered with machine.
4.6.8.3.6 The photometer may be powered with batteries.
4.6.8.4 Control cuvette:
4.6.8.4.1 It is an optical interference filter used to verify that the calibration is stable (e.g. not changing from day to day)
4.6.8.4.2 When checking the value received, it shouldn't deviate from the assigned value on the control cuvette card by more than ± 0.3 g/dl.
4.6.8.4.3 In case of control cuvette is not available, whole blood control samples could be used instead by comparing with the results from calibrated automatic blood cell counter.
4.6.8.5 Sample collection:
4.6.8.5.1 Make sure that the patient sits comfortably; The hand should be warm and relaxed. The patient's fingers should be straight but not tense, to avoid stasis.
4.6.8.5.2 Use the middle finger or the ring finger for sampling. Avoid fingers with rings for sampling.
4.6.8.5.3 Clean the puncture site with disinfectant and allow it to dry.
4.6.8.5.4 Using your thumb, slightly press the finger from the top of knuckle to the tip. This stimulates the blood flow towards the sampling point.
4.6.8.5.5 Whilst lightly pressing towards the fingertip, it is better to prick at the side of the fingertip. Not only the blood flow is best at this point but it also causes the least pain. The middle part of the fingertip may be used.
4.6.8.5.6 Wipe away the first two or three drops of blood. This stimulates the blood flow. If necessary, Re-apply light pressure again until another drop of blood appears. Avoid milking.
4.6.8.5.7 Make sure that the drop of blood is big enough to fill the cuvette completely. Introduce the cuvette tip into the middle of the drop.
4.6.8.5.8 Fill the cuvette in one continuous process.
4.6.8.6 Measuring procedure:
4.6.8.6.1 Wipe off the excess blood on the outside of the cuvette tip.

4.6.8.6.2 The filled cuvette should be visually inspected for air bubbles. Small air bubbles around the edge don't influence the results.

4.6.8.6.3 Place the filled cuvette in the cuvette holder immediately and push it into measuring position.

4.6.8.6.4 The filled cuvette should be analysed immediately and at the latest 10 minutes after it has been filled.

4.6.8.6.5 After 15-45 seconds, the result is displayed.

4.7 If donor is accepted to donate, he/she is directed to donation room. The phlebotomist in the donor room receives the donor form and asks the donor to rest on the donor chair to start the donation process. This process may be done in the same place where examination was done according to the availability of separate donation room.

5. MATERIALS AND EQUIPMENT:

5.1 **Records and forms:**

- 5.1.1 Donor History Questionnaire (DHQ) and consent Form
- 5.1.2 Blood Donor Education materials
- 5.1.3 Whole Blood Donation Record.
- 5.1.4 Deferred Donors Record.
- 5.1.5 The confidential unit exclusions (CUE) File.
- 5.1.6 Daily Hemoglobin Photometer Calibration form

5.2 **Equipment:**

- 5.2.1 Protective medical gloves.
- 5.2.2 Alcohol swab.
- 5.2.3 Sterile lancets.
- 5.2.4 Cotton.
- 5.2.5 Sharps disposal container.
- 5.2.6 Sphygmomanometers
- 5.2.7 Thermometers.
- 5.2.8 Balance
- 5.2.9 Blood Hb level estimation using Hb photometer (e.g. Fresenius Kabi compo lab) and:
  - 5.2.9.1 Fresenius Kabi compo lab machine
  - 5.2.9.2 Fresenius Kabi compo lab cuvettes.
  - 5.2.9.3 Control cuvette.

6. RESPONSIBILITIES:

6.1 **Technician/ specialist/ staff of donation area:**

- 6.1.1 Should follow what is stated in the policy (3) and procedure (4).

6.2 **Responsibilities of blood bank counsellors:**

- 6.2.1 Explaining blood donors' rights and responsibilities to respond accurately to the donor questionnaire.
- 6.2.2 Assessing the risk and severity of the conditions for which donors are being counselled.
- 6.2.3 Providing donor information materials that are factual, culturally appropriate and in a language and form that is easy to be understood by all donors.
- 6.2.4 Manage donors who are deferred temporarily or permanently for health reasons, high risk for infection or positive test results consistent with infection by:
  - 6.2.4.1 Providing information on the reasons for deferral and where to seek medical advice, if necessary.
  - 6.2.4.2 Providing counselling to donors who have been deferred for health reasons or risk for infection.
  - 6.2.4.3 Providing post-donation counselling to all donors deferred for infection.
- 6.2.5 Obtain written informed consent from donors prior to blood donation.

6.2.6 Informing and notifying test results (both negative and positive), when asked, and counselling donors on how to protect their health and prevent the transmission of infection.
6.2.7 Encouraging healthy lifestyles for donors who are not infected.
6.2.8 Correctly documenting interventions and services using standard protocols.
6.2.9 Ensuring that all documentation and records are kept for the defined time period, while maintaining confidentiality.
6.2.10 All responsibilities of counsellors could be done by the donation area staff.

6.3 **Rights and responsibilities of the blood donors:**

6.3.1 Rights:

6.3.1.1 Right to clear information, including the purpose of donor selection, and the consequences of failure to provide the relevant information to the blood bank.

6.3.1.2 Right to withdraw from blood donation at any time during the procedure for any reason, including doubts as to their suitability as a blood donor, without any need to explain this decision.

6.3.1.3 Right to maintain confidentiality and privacy.

6.3.2 Responsibilities:

6.3.2.1 Responsibility to provide the blood bank with all relevant information to the best of their knowledge about health conditions that may pose risks for their health and about activities or behaviours that increase their risk for a TTD.

6.3.2.2 Responsibility to self-defer from blood donation if they believe they are unsuitable to donate; no donor should use blood donation as a means to obtain medical check-ups, to know their HIV status or to be tested for other TTD.

6.3.2.3 Responsibility to inform the blood bank after donating blood if they have any doubts about their suitability or in the event of a change in health status within 28 days after blood donation.

7. APPENDICES:

7.1 Donor History Questionnaire (DHQ) and consent Form Arabic and English
7.2 Blood Donor Education materials Arabic and English
7.3 Daily Hemoglobin Photometer Calibration form

8. REFERENCES:

8.1 The Unified Practical Procedure Manual For Blood Banks In The Arab Countries, 1434-2013.
8.2 The Standard Policy For Blood Banks In The Kingdom Of Saudi Arabia, 1st edition, 1435-2014.
8.3 National Standards For Clinical laboratories and Blood Banks, 1st edition, 2015.
8.4 AABB Technical manual, 18th edition, 2014.
8.5 AABB Standards for Blood Banks and Transfusion Services, 30th edition, 2016.
8.6 World Health Organization In collaboration with Centres for Disease Control and Prevention and International Federation of Red Cross and Red Crescent societies 2014: Blood donor counselling: implementation guidelines.
8.7 Good Manufacturing Practice for Blood Establishments, Version 2.0, May 2019, Saudi FDA.

9. APPROVALS:

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