Department of Health

NATIONAL BLOOD SERVICE

VOLUME 1

Standard Operating Procedures

SAFETY IN BLOOD DONATIONS

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Authors: Drs Mathias, Paua
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Towards 100% voluntary non-remunerated blood donation in Papua New Guinea

This Standards Operating Procedure Manual is owned by the National Department of Health and is prepared to be used by all staff working in all Blood Transfusion Services in public hospitals and private facilities in Papua New Guinea for the purpose of maintaining standard best practice in ensuring staff, Donor safety and Blood safety.

It is in the best interest of the staff and the donors and for the sake of Promoting Blood Safety that each member of the BTS staff must take the time to read through and understand this document before they commence their work in BTS.

I trust that you will find this document easy to understand and it will prove a useful guide to you daily in your work

Any suggestions and queries on this document can be forwarded to the address given below.

_____

Dr Merrilyn Mathias
Date:24 October, 2023

The Manager
National Blood Service
Department of Health,
P.O.Box 807,
Waigani, NCD
Phone: 325 1066 ext 32.
Email; mlmathias9@gmail.com

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CONTENTS

I Introduction

All blood donor programme managers, laboratory managers and OICs are encouraged to collect blood only from donors who are at low risk population and are regular voluntary non-remunerated blood donors (VNRBD).This will enable a safe, adequate and timely blood supply for all patients in Papua New Guinea (PNG).This manual is designed to help blood bank nurses, laboratory scientists and managers of Blood Centres in PNG and to ensure work is done in a standardised and quality-assured manner.

There is also a Volume 2 standard operating procedure (SOP) manual for use in the Blood Banking bench or the laboratory.We are currently updating this document and will soon be made available to your laboratories. Staff from the blood centres and the laboratories will have some shared work practices and concerns, thus, you are encouraged to be familiar with the two SOPs.

This document is from the National Blood Service, Department of Health, Papua New Guinea and should be adhered to by all blood services in the country regardless of whether the hospital is under government or church-run or private as per the National Blood Policy of Papua New Guinea.

Most of you are working in less than ideal circumstances with problems in central and mobile locations, transport and communication. Despite this, it is essential that the public see you as caring professional people doing their best to provide cheerful and clean surroundings, dealing safely and quickly in the business of collecting blood so that the donor is willing to come back again and again.

The National Blood Service has finally formulated the National Blood Guidelines for the Clinical Use of Blood which when approved can be used as a guide by all categories of health workers especially clinicians directly involved in blood transfusion. Most of the reference is based on the World Health Organisation (WHO) handwork book and CD on

the Clinical use of blood, and is a very useful tool. There is also a distance-learning programme on Safe Blood and Blood Products, which was introduced in 2008. You are all encouraged to take part in the Introductory Module, Module 1 and 2.

In this edition we have included and incorporated new updates on:

1. Voluntary Counselling and Testing (VCT) of a rejected/deferred blood donor
2. SOP for testing of Hepatitis B and C and Syphilis using Rapid Diagnostic Tests (RDT)
3. Referral Pathways for a donor with Transfusion Transmissible Infections (TTI)

In the last page of this manual you will find a table prepared for you to enter the names of your staff that have taken the time to read this document. Please ensure that these staff members read and understand the manual and that they sign and date when they have done so. Whenever new procedures are introduced you will be sent new SOPs and these must also be signed and dated.

On that note, we will also encourage you to counsel and test clients or those 'rejected donors' who present to the blood centre to donate. We are collaborating with the HIV/AIDS Program at the National Department of Health of assess the prevalence of HIV in the 'normal healthy' population and this is a very helpful avenue to do just that. You will be made aware of this once this is adopted. A staff will be assigned for this purpose.

Also attached, an updated Donor Information paper and Donor Questionnaire. You will find theses very useful in your donor interviews and assessments. Give these to donors to read each time they visit the Blood Centre. Use these when you are conducting an interview as well.

For information on Preparation, Storage and Issue of Blood and Blood Components refer to Volume 2 of this SOP series on Blood Banking in PNG.

The Annexure comprises 9 different forms altogether including the Activity summary (1-4) that you are required to fill monthly, the Donor Patient Usage Data Sheet and the Data on Blood Needs that you can fill to estimate the monthly and annual blood product requirements for your health facility.

Finally, please ensure that you collect the promote best safe practice in your place of work to ensure that the blood you collecting is from a trustworthy individual and is safe for transfusion

We hope that this manual will prove useful in your activities in blood services at your location

Best wishes.

II Standard Operating Procedures

SOP.1: Optimum Quality Assurance

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
SP 01	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the criteria to ensure that the minimum standard of best practice is applied daily and routinely in a blood donation center in promoting quality in the daily tasks being attended to at a Blood Centre.

2. Responsibility

The Officer In Charge or the Unit Manager is responsible for practice of minimum standards for the sake of staff and donor safety in all processes of donor selection, screening, bleeding and follow-up.

3. Materials required

NBTS Quality Standards Checklist
Quality Standards Manuals
Vol 1 SOP Safety in Blood Donations
Vol 2 SOP Laboratory Safety in Blood Banking
WHO Manuals on Blood Safety
CME materials on blood safety
Relevant SOPs on Infection Control and Prevention
Guidelines on HIV Counseling and Testing

4. Procedure

I. Blood centres should be organized in such a way to ensure donors/clients and staff safety is promoted by adapting to safety cleanliness and hygiene.

II. Infection Control measures should be in place to ensure minimum transmission of any infections and other infectious materials

   a. Hand hygiene- washing of hands with soap and water or sanitising with an antiseptic solution or gel
   b. Cough etiquette- cover mouth with elbow when coughing or cough into a cloth
   c. Safe disposal of used items in appropriate bins - gloves, face masks, and other soiled materials used while carrying out the routine procedures

III. Regularly (twice a year), the OIC should take the team through the SOPs Quality Management Checklist, Infection Control and Blood Donor Management and Care of the venue

IV. Any new member that joins the team should be adequately informed of all the requirements of the Blood Centre and given SOPs to familiarise themselves with. For the first month, the OIC or a senior staff provide supervision and ensure they understand and can work on their own with ease.

V. There should be proper labelling of areas of donor and staff sitting rooms, interviews rooms and bleeding rooms and should be visible to everyone.

VI. Continuous medical education (CME) sessions should be conducted weekly or fortnightly to build basic knowledge base in team members. Appoint each member to take the responsibility each time.

VII. Adequate recording and reporting mechanisms should be in place and visible to all staff/team members

VIII. In order to provide safe blood and blood products, there are certain checks that need to be carried out on a regular basis. More often in cases of spills, effective cleaning and maintenance minimises the risk of infection.

IX. Venue/Centre: Floors in collection area should not be carpeted. These areas must be mopped daily. Ideally use a solution that contains 1% hypochlorite solution. Most household bleaches are acceptable.

X. Protective clothing (face masks, gloves and safety glasses) must be worn at all times when you are performing procedures.

XI. Donor beds: Clean these with alcohol/chlorhexidine solutions daily and placed 1.5m to 2m apart.

XII. Bench tops, table-tops must be cleaned daily.

XIII. Blood mixers if available must be cleaned daily.

XIV. Used blood bags must be incinerated daily or in a rural district hospital setting, thrown into a deep pit which is inaccessible to humans or animals.

XV. Ideally all districts and provincial hospitals should have an incinerator to manage all the wastes especially

SOP. 2: The Centre or Mobile Venue

Number	Author	Reviewed	Effective Date	Authorised by
SP 02	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
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2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the requirements for a blood donation center to be adequately organized in order to provide a place of comfort and safety to the donor and also the staff and in ensuring safe blood is collected for the recipient.

2. Responsibility

The donation room staff is responsible in ensuring that the donation venue is properly organized in the 'new normal' sitting arrangements, and other requirements and ensure that client and staff safety is not compromised during the process of donor interview and bleeding.

3. Materials required

- ✓ Blood Donor Information Paper (See Annexure)
- ✓ Blood Donor Questionnaire (See Annexure)
- ✓ Vol 1 SOP Safety in Blood Donations
- ✓ Safe Blood and Blood Products Module 1; Safe Blood Donation (WHO)
- ✓ National Guidelines on HIV Counselling and Testing
- ✓ WHO Guidelines on Blood Centres

4. Procedure

I. Make sure the Blood Service is easily located and accessible by blood donors.

II. A clerk should be at the entrance waiting for donors and making sure they feel welcomed.

III. Make sure that there are appropriate posters such as the large HIV/AIDS poster, blood donation and blood appeal posters displayed in the appropriate language (s) so that they are easily seen as soon as the donor enters.

IV. Offer them the information paper or a pamphlet to read regarding information on blood donation and about the benefits of blood

5. Requirements of an Interview room at a Blood Center

i. The National Guidelines on HIV Counselling (NGHC&T) and testing clearly outlines the requirements of an interview room. The NDOH HIV C&T Unit can also accredit this room.

The minimum requirements for stand-alone C&T sites are per the NGHC&T:

ii. Visible location that is accessible to all populations;
iii. Clear signage indicating what services are provided;
iv. At least a well ventilated and private counselling rooms;
v. Counselling rooms should be large enough for at least three chairs and a small desk;
vi. Reception area where clients or patients can wait to receive C&T services;
vii. Office for management duties such as reporting;
viii. Office should be large enough for locked filing cabinet for data storage
ix. Office should also contain separate locked cabinet or refrigerator for storage of test kits and supplies
x. Resources vary from place to place. This is especially true of mobile sites and finding suitable mobile sites can be difficult. All venues have some things in common.

6. Requirements of a bleeding room at a Blood Center

i. At a minimum they should satisfy the following requirements;
ii. The area should be large enough to accommodate comfortably the required number of beds. Beds must placed 1.5m apart and be at a sufficient height to use scales for weighing the unit of blood during donation.
iii. The temperature should be comfortable without excess draughts.
iv. There should be adequate toilet facilities for men and women nearby.
v. There should be facilities for staff hand washing or a place where such a facility can be set up. In mobiles you can provide water and appropriate disinfectant for hand washing.
vi. There must be a suitable means of displaying advice to donors, HIV/AIDS and other transfusion transmissible infections (TTIs) particularly before they enrol.
vii. There must be privacy for particularly interviews and counselling for HIV (and weight, blood pressure and haemoglobin measurements).
viii. There must be areas where donors can comfortably fill in questionnaires and declaration forms, an area for refreshments, and a bed for faints.

Note:

Apart from the above points, mobile areas must be safe for staff and donors, have reliable communication, and adequate lighting. Blood storage (e.g. eskies), thermometers and transport must be available.

7. Mobile Site Requirements

Blood collection at mobile sites or venues provides an appropriate and convenient venue for blood donors. The mobiles can be large (more than 50 donors) or small (<50). Can be indoors or outdoors. Preferably under a shade tree or a tent.

Make sure you give yourselves enough time to set up and this should be included in your timing in your programmes. Masks, gloves and safety glasses and appropriate footwear are very important part of collection.

Requirements

i. Mobile beds; 6 or more for large and 3 for small mobiles. Have a spare bed for faints etc.
ii. Table and chairs, eskies
iii. Donor Information Paper and Questionnaires (see Annexure)
iv. Blood bags and other accessories
v. Tent/s if outdoors
vi. Blood mixers if available with electrical extension cords (make sure these are safe to use; get them checked by an electrician)
vii. Masks, gloves and safety glasses
viii. Sample bottles (Plain tubes and EDTA for low haemoglobin)
ix. Skin swabs (alcohol & chlorhexidine)
x. Cotton wool (5 per pack)
xi. Plaster/Band aid
xii. Water for drinking & cups etc
xiii. Water for washing hands
xiv. Disinfections-soaps for hand washing, hand sanitizers
xv. Donors refreshment (varies from place to place and amount you bring)
xvi. Staffing for Major Centres:
    a. Large mobile; 8 nurses, 4 CHW, 2 clerk, 2 driver & 2 for refreshment
    b. Small mobile; 2 nurses, 2 CHW, 2 clerk, 1 for refreshment, 1 driver

SOP 3: The role of Staff members at Blood Donor Sessions

Number	Author	Reviewed	Effective Date	Authorised by
SP 03	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
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2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the important role of a staff member at a blood center in promoting standard best practice.

2. Responsibility

The donation room staff is responsible for determining the suitability of donor for blood donation. He /She should confirm that the potential donor meets the criteria after careful evaluation of health history questionnaire and examination including the results of pre-donation screening tests.

3. Materials required

- ✓ Donor Information Paper
- ✓ Blood Bank SOP
- ✓ Donor Questionnaire
- ✓ Blood Donor Record Cards
- ✓ Vol 1 SOP Safety in Blood Donations
- ✓ Safe Blood and Blood Products Module 1;
- ✓ Safe Blood Donation (WHO)

4. Procedure

I. The role of designated trained staff members at blood donor sessions is to conduct careful interview and assessment of the potential donor.

II. The staff member is also responsible for the comfort and safety of the donor in ensuring that blood is collected blood safely in a proper and recognised manner

III. Their individual duties may vary according to the number of donors bled at a session and number of staff present, and depend on their experience and seniority.

IV. In some centres, laboratory staff members perform this duty. Regardless of who collects blood, however, share the responsibility to ensure that;

- Donors are appropriately screened to make sure that they are suitable as blood donors and that donation will not harm either the donor themselves or the recipients of their blood
- Appropriate counselling and care is provided for donors before, during and after they donate blood.
- Blood donated by each donor is collected into an appropriate blood collection bag
- Blood bags and sample tubes are correctly labelled for each donor
- Accurate and complete records are maintained
- Work is performed to a high quality standard

SOP 4: The Counselling and Interview and Assessment of the Potential Blood Donor

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
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1. Purpose

This SOP describes the criteria for a potential blood donor to be accepted for blood donation, for ensuring safety of donor as well as recipient.

2. Responsibility

The blood center staff is responsible for determining the suitability of donor for blood donation. He/ She should confirm that the potential blood donor has met the criteria after taking into account relevant clinical, social and sexual history that may affect the safety of the blood that is to be donated. The staff member also ensures that the results of pre donation screening tests have met the criteria for donation.

3. Materials required

Documents:

- Blood donor information paper
- Blood donor questionnaire
- Donor card
- Vol 1 SOP Safety in Blood Donations
- Safe Blood and Blood Products Module 1; Safe Blood Donation

Devices: BP machine, weighing scale,

4. Procedure

- Refer to the attached Donor Information paper, Questionnaire & **Declaration Form**
- **This must be done in privacy.**

If at a mobile site where privacy is difficult to maintain, place the interview area a few meters away from the collection and the donor examination area so that the donor and the interviewer can communicate comfortably without any disturbance.

At interview and counselling, ensure the donor has read and understood the questionnaire. This must be done carefully and sensitively. A large number of donors cannot read very well and some not at all. You may have to explain the questionnaire to them and help fill it. Note that the AIDS notice is a set of statements, not questions. The donor decides whether to continue with enrolment after having understood the questionnaire and notices.

A: Procedure of the Interview

1. Counselling/interview sessions should not take long; approximately 5 minutes per donor.
2. Get the donors to identify themselves by name, date of birth (if known) and address to confirm
3. Ask them a few general questions especially in relation to their sex history, drugs taken or current health status.
4. Having taken the donor through the interview, the BTS staff must be able to assess the donor considering their past medical and social history and history of body tattooing etc and be able to either allow the donor to proceed to the next stage or defer the donor Temporarily or Permanently.
5. Get them to sign the declaration form of which they have to be sure of. Show them a legal documentation of consequences of lying.
6. If the donor passes this stage, then the donor will now give their consent to have their blood checked/screened, Hepatitis and Syphilis.

B: Defer the donor for the period mentioned as indicated in the following table:

Conditions	**Period of Deferment**
Abortion	6months
History of blood transfusion	6months
Surgery	12months
Typhoid fever	12months after recovery
History of Malaria duly treated	3 months (endemic) 3 months in a (non endemic area)
Tatoo	6 months
Breastfeeding	12 months after delivery
Immunization(cholera, tetanus, Diptheria, Gammaglobulin)	15 days
Rabies vaccination	1 year after vaccination
Hepatitis immunoglobulin	12 months
Hepatitis in family or close contact (spouse)	12months

C: Defer the donor permanently if suffering from any of the following diseases:

1. Cancer
2. Heart disease
3. Abnormal bleeding tendencies
4. Unexplained weight loss
5. Diabetes
6. Hepatitis B infection
7. Chronic nephritis
8. Signs and symptoms, suggestive of HIV/AIDS
9. It is important to ask donors if they have been engaged in any risk behavior.
10. Liver disease
11. Tuberculosis
12. Polycythemia Vera
13 Asthma
14. Epilepsy
15. Endocrine disorders
16. Schizophrenia
17. Leprosy

Allow sufficient time for discussion in the private room/cubicle. Try and identify result-seeking donors and those with refer them to VCTC (Voluntary Counseling and Testing Center). Reassure the donor that strict confidentially is maintained.

D: Frequency of Types of Donations

Whole Blood donors may donate every 90 days.

Plasma donors may donate once in 4 weeks.

Platelet donors may donate a maximum of 24 times per year.

Other specialized donations are subject to other rules.

D: Summary of Criteria For Selection of Blood Donors

Accept only voluntary /replacement donors if they meet the following criteria;

I. The interval between whole blood donations should be no less than 12 week

II. The donor shall be in good health, mentally alert and physically fit.

III. Age: in the age group of 18 to 60 years. Absolute minimum age is 16 years to 17 years

IV. with parental/guardian consent.

V. Weight: not less than 55 kilograms for male and 48 kilograms for female.

VI. For those donors with small stature with weight of 48kg to 55kg, use the 350ml bag to collect only 300mls of blood.

VII. Blood pressure: The systolic and diastolic blood pressures are within normal limits. i.e.100/60- 140/90 (If you are worried about high or low BP, refer to a doctor for assessment)

VIII. Temperature and Pulse: 60-100 regular

IX. Hemoglobin shall not be less than 13.5 g/dl for male and12.5 g/dl for female and Hematocrit > 38%.

X. The donor shall be free from any skin disease, skin punctures or scars at the site of phlebotomy.

E: Attending to a donor:

I. Weigh the donor.

a) The minimum acceptable weight is 50 kg for males and 48 kg for females.

b) Exceptions are allowed in some places where people are smaller in stature; males with weight of 48kg can be allowed to donate as long as they pass all the requirements. Donors 48kg to 50kg can donate 300mls of blood whilst 50kg and over can donate 450mls.

c) If the donor is underweight, record this down and defer the donor temporarily.

II. **Measure their blood pressure**. Acceptable blood pressure is systolic 100-140 and diastolic 60-90mmHg.

a) If BP is too high allow the donor to rest and repeat after 30 mins. If repeat BP reading is normal, then allow them to continue.

b) If BP is still high, then refer to a medical officer and defer Temporarily.

c) If BP is too low, give them a glass or two of water to drink and repeat BP reading after 30mins, if normal, allow to continue, if still low, record in the Temporary deferral column and defer.

III. **Measure their pulse** by placing your hand on the wrist and reading the pulse for a minute.(Pulse of 60-100/min is acceptable).

a) If pulse is rapid, allow the donor to rest for at least 30mins and recheck pulse. If normalise, you can allow them to donate blood.

b) If not normal, then refer or ask your medical officer to see them and assess to exclude any other underlying medical condition

SOP 5: Hemoglobin check

Number	Author	Reviewed	Effective Date	Authorised by
SP 05	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
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2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the procedure involved in assessing the hemoglobin of a client to determine eligibility for blood donation for blood donation.

2. Responsibility

The donation room staff is responsible for testing the blood of a client to measure their hemoglobin level. The staff will then decide if the hemoglobin meets the criteria to be able to donate blood.

3. Materials required

Hemoglobinometer and cuvettes

Alcohol swab and cotton wool

Lancets

4. Procedure

I. Check the donor's haemoglobin (Hb). Safety glasses are to be worn during Hb check

II. Hemoglobinometer (Hemocue) can be used for Hemoglobin check.

4. Haemoglobin measurement using an Hemoglobinometer

i. Switch on the Hemoglobinometer and ensure that the battery or the power supply is adequate. It will give you a beep when ready to use.

ii. Clean the puncture site at the end of the finger and a little to the side.

iii. Puncture firmly with a sterile lancet/needle and ensure blood flows freely.

iv. Wipe off the first drop of blood then collect blood into an anti-coagulated Hemocue micro-cuvettes

v. Place the cuvette into the slot in the hemoglobinometer and wait for it to give you the Hemoglobin reading.

vi. Haemoglobin reading of 12.5g/L and above will be allowed to proceed with the donation. *(Note: Any Hb less than 12.5g/L should not be allowed to bleed for safety reasons.) Any Hb above 18.5g/L who are should not be allowed to donate. Please refer to SMO/Medical officer for further investigation.*

vii. If the donor is not accepted because of low Haemoglobin, record this down on the donor deferral list and supply iron tablets to the donor.

viii. Ask him to return in a month's time and repeat haemoglobin check.

ix. Refer to a doctor or the Medical Team to manage if haemoglobin reading does not improve after a month on treatment.

SOP 6. Point of Care Testing of a Rejected Donor (VCT)

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
SP 07	Dr Merrilyn Mathias	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
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2	2018	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the procedure involved in POCT of a rejected donor who has not met the criteria for donation however, upon counseling, this person voluntarily consents to undergo testing for the other TTIs by voluntary counseling and testing

2. Responsibility

I. The blood donor counselor at the blood center is responsible for the counseling of these rejected blood donors and ensure that they are aware of the procedure involved and that they give their consent to have their blood samples tested for HIV, Syphilis, Hepatitis B and C.

II. NBTS in collaboration with the HIV program of the Public Health Wing at NDoH is training BTS staff in the provinces to ***counsel and test*** these rejected blood donors only upon their consent.

3. Materials required

Donor Information Paper
Donor Questionnaire
Donor cards, Daily record sheet,
SD-Bioline HIV/Syph RDT Kit, Dual Pack
Lancet, alcohol swab, cotton wool

4. Procedure

I. These clients are to be taken onto a separate interview room and counselled for 5-10mins.

II. The counsellor should take the client through the process of understanding the importance and reason for the testing. Testing should ONLY be done once a verbal and written informed consent is obtained for HIV, Syphilis, Hepatitis B and C testing.

III. The client has the right to refuse the tests even after counselling is offered and should NOT at any one time be coerced into testing.

(Also refer to the Guidelines on HIV Counselling and Testing for further information)

Note:

NBTS is aware that hospitals are doing TTIs screening of donors on site prior to collections. Thus we recommend that;

- Each hospital should have their own hospital policy in mandatory testing or screening of blood either before or after collection considering your specific situations. We concur that per WHO recommendation, ALL screening of transfusion transmissible infections should be done in the laboratory
- NBTS recommends that BTS staff members should not be allowed to SCREEN any donors unless they are certified as counsellors or available to counsel donors and there are laboratory personnel available to do screening at the interview site.
- NBTS or the Department of Health will not be held accountable for any repercussions that may arise as a result of non-compliance to the above by a BTS staff.
- Screening on site will only take place once the donor is properly counselled and consented

- They are not to discuss results with anyone except the individual donor at any one time.
- Confidentiality must be maintained right throughout testing.
- Please refer to the Manual on Laboratory Standards for Blood Banks in Papua New Guinea for the procedures on screening of the above infections
- Each hospital will have their own policy on pre-screening of TTIs before bleeding. This decision will be done after certain considerations such as local prevalence of TTIs, manpower verses workload, the effectiveness of excluding high-risk donors and the total local BTS wastage

Notes on Rapid Diagnostic Tests

I. The rapid diagnostic test kits (RDTs) used here are for the screening of infections in the blood.

II. These tests are for *in vitro* use, and are read visually. They are qualitative immunoassay for the detection of HIV 1 & 2 antibodies, Hepatitis B Surface Antigen, Hepatitis C antibody and Syphilis antibodies

III. The screening test is intended as an aid to detect these infections from infected individuals and donations.

IV. Screening for HIV **must only** be done in the laboratory on donated blood so as to protect the donor.

V. Refer to **SOP 12** for further management of the clients found to be TTIs positive or reactive.

VI. A flow chart titled Donor Referral Pathway is also available as a guide to assist you in the management of these clients. Use this to chart your own pathway if your setting is a bit different.

VII. Refer to the Annexure at the end of this document.

SOP 7: Keeping of Daily Record of Donor Information

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
SP 08	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
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2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the importance of maintaining daily records for the purpose of reporting and improvement

Note: After 10 years, donor records cards should be moved into the archives. Do not throw away donor records cards.

2. Responsibility

The Officer in Charge as the Team Leader and other senior staff should ensure that all routine activities are monitored and recorded daily in the daily worksheet

3. Materials required

Donor cards, Daily record sheet, Donor records,

4. Procedure

i. All potential donors attending with the intention to donate blood must be recorded. This information will be included in the Part 1 of the statistics template.

ii. All donor deferrals must be recorded and their reasons for deferral noted down. Reasons such as low haemoglobin, underweight, recent illnesses, on short-term treatment, will be classified as Temporary deferrals.

iii. High risk behaviour, certain chronic illness that require long term medications such as high blood pressure, diabetes, asthma who are on medications, etc should be deferred Permanently. Consult the Manager NBTS if you have further queries. All these information will be recorded in Part 1 as above.

I. **Donor Record Card-**this is both an enrolment and a record card.

II. All regular or repeat donors must have their cards checked for previous results of transfusion transmissible infections (TTI) before any collection is made.

III. This will abolish unnecessary duplication and require the donor to sign each time he/she donates that he/she is in good health and has agreed to statement regarding testing for HIV/AIDS, Hepatitis B and C Syphilis.

IV. **Note**: In centres where the donor is counselled and other infections are screened before testing, they will only get to fill the donor record card when they are cleared to donate.

V. **A Donor Patient and Usage Data Worksheet**: this will make it easier to follow units through to use or destruction and to identify donors and patients involved.

VI. A standard system of labelling bags and specimen bottles should be followed; this will permit a more orderly approach.

VII. Enrolment

a) When a donor is cleared to donate and is to be registered, make out a new card for him/her.
b) If he/she is a regular donor, find his/her old record card if possible.
c) Note that on the bottom of the back of the new card you have to state how many donations have been given before and you will need the old card to answer this.

d) If he/she is a new donor enter the current date under "Date of Enrolment"; if he/she is a regular donor, enter his/her original enrolment date.

e) Retain his/her previous card (s). Ask the donor for a pocket card if they have one.

- Enter the current date on the back of the card. After the donor has read and understood the statements about general health and AIDS, he/she then signs the card. The donor signs this portion each time he/she donates.

- When you have completed the card, enter the appropriate personal data on the usage sheet using the designated place name abbreviations. Enter the unit number on this sheet and on the record card.

- This card can be used for 4 donations. When it is full you will have to fill out a new one, update the total number of donations on the back and clip it to the old card (s).

f) We note that most of the smaller centres are not using these cards for your donor record. We encourage you to do so.

SOP 08: Donor Identification, Blood Bag Labelling, Venepuncture and Collection

Number	Author	Reviewed	Effective Date	Authorised by
SP 10	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the criteria for which a donor upon meeting the bleeding criteria, is given number with a blood bag labeled and is managed at the blood donation station or room

2. Responsibility

The donation room staff is responsible for ensuring that the potential client meets the criteria for donation and takes this client through the donation process. She/He is responsible for the comfort and safety of the donor and at the same time ensure that the blood is collected into the relevant bag.

3. Materials required

- Donor Card
- Relevant blood bag (labeled and given a number)
- Sphygmomanometer (BP machine)
- Alcohol swab

Blood bags

i. Blood bags

These are the disposable biomedical transparent flexible poly vinyl chloride(PVC) containers, designed to collect, process and store the whole blood and blood components.

ii. Parts of blood bag system

The blood bag system consists of blood donor bag, donor tube (consists of needle with needle cover), puncturable and non-sealable transfusion pot and clamp.

iii. Types of blood bags

Single bag: Used for whole blood collection

Double bag: Used to separate packed cells and Plasma

Triple bag: Used to separate packed cells, plasma and platelets

Quadruple bag: Used to separate packed cells, plasma, platelets and cryoprecipitate

Fig: Double bags 350mls with a sample pouch (closed system)

Fig: Triple bags 450mls

iv. Volume of blood bags

Available in 350mls and 450 ml capacity

For 350mls bag, collect no less than 300mls and for the 450mls bag collect no less then 400mls.

v. How are the blood bags stored

After collection, the blood units should be stored standing upright in baskets or lying flat on shelf. The bags should never be packed tightly nor should be stored near the freezer compartment/ in the door of the refrigerator.

vi. Shelf life of platelets

Platelets can be stored up to 5 days under room temperature (22^0C) with continuous agitation

4. Procedure

I. Blood bags and specimen bottles should be labelled with identical numbers before collection (centre or mobile). Each year, start with a new number that will include the year and the number of the blood centre. In larger centres, you will decide whether the collection is from the centre or a mobile site.

II. Each blood bank has been allocated a number and this number will be used in the labelling system with the year of collection. Refer to the Annex on Blood Banks numbering system.

Example: Port Moresby General Hospital BTS No is 1, year 2021. The first blood bag for 2021 in Port Moresby BTS is 21-01-001, the 2nd is 21-01-002, etc. Then depending on whether it is a centre collection or mobile collection, this should be clearly marked as 'C' or 'M'

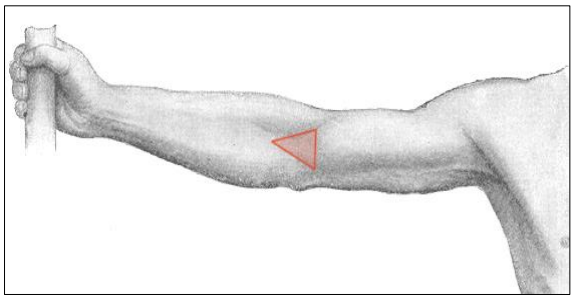
III. Get the blood bags, sample tubes ready and place them within reach. Place the empty bag on the scales and make a loose knot in the line about 20 centimeters from the needle.

IV. Check the identification of blood bag and sample tubes against donor verbally by asking for name, date of birth (if known), and address.

V. Wear your gloves and safety glasses

VI. Identify the most prominent vein in the cubital fossa (see diagram) by inflating your blood pressure cuff to about 60-80 mmHg.

Figure 10.1 Ante-cubital fossa



VII. Clean the cubital fossa area with alcohol/chlorhexidine starting from the site of puncture outward. Do not touch the site. If you do, swab again, using a new swab.

VIII. Insert the needle into the vein and start your collection. Some donors may request for local anaesthetic. (Note 1)

IX. Mix the blood thoroughly throughout the collection, evenly distributing the anticoagulant to avoid clotting. You can use a volunteer for this purpose or better still a blood mixer if available.

X. Stop collection at 450+/- 50 mls or when 12 minutes is up, regardless of whether 450 mls is reached or not.

XI. Use of Blood Bags

a. **Old bags-Open system**: If you are using old bags, collect your samples at the end after you have clamped off (open system); When 450 ml has been

collected, release the cuff, clamp the line x2 about 10 cm from the needle and cut between the clamps. Release the line to the needle and collect a minimum of 10 ml into specimen bottle. Then remove the needle and apply pressure on the site. Tighten the knot in the line to the bag and remove the clamp.

b. **New bags-Closed system**: Set up the donor as described. The sample pouch is attached to the bag via a separate line. Once the vein is punctured, the blood flows directly into the sample pouch. Clamp the line when full and release the clamp on the line to the collection bag proper, this will allow blood to flow into the bag. When the bag is full, clamp the line and release the cuff before pulling out the needle. Note that you will need to use this bag few times to be familiar.

XII. Enter volume and signature. If at any stage donation is aborted, enter this under "Notes" on the record card giving date and reason.

XIII. If this is a new donor, let him lie down for 5 minutes before going to refreshment area.

Note 1: The donor must not be left alone during collection. If he/she becomes unwell during collection, withdraw the needle, apply pressure and keep the donor resting until recovery.

Note 2:

Local anaesthetic (LA) is not mentioned here. LA is no longer used as it is a potential source of infection and cross-infection unless done carefully and aseptically. Needles nowadays are very sharp and the insertion to the vein is less painful.

Note 3:

Ensure that all needles are disposed of in a suitable hard-walled plastic container (sharps container). These can be obtained from your pharmacy.

Note 4:

At the end of a session, all cards must be checked for entry under "Notes" and any entry copied on to the usage data sheet if not already done so. If no suitable product is obtained, put a cross immediately in the spaces under "Product" and "Patient Name" on the usage sheet. If no blood is taken at all put lines through "Group" and "Status" as well.

5. Autologous Donations

i. If a doctor requests that a patient should donate a unit for the patient' own use (autologous transfusion), the patient must satisfy all the requirements of a normal donor and there must be at least 3 days between collection and the surgery for which it is required.

ii. If he/she fails these requirements, they should be deferred and the managing clinician notified so other options can be considered such as being transfused from other donated blood from the blood bank.

iii. Immediately after the blood has been collected, tie an "Auto Transfusion" label and label it with the patient's name, requesting doctor's name and expected date of use. Store it in the cold room or refrigerator in an area clearly labelled "Autologous".

iv. These units will be processed, labelled, and cross-matched and issued in the same way as other units

v. If the screened unit that is infection free is not used for the patient, it can be cancelled and reallocated to be used by the blood bank for other patients **only** if the patient and his/her unit satisfied all the normal donor requirements.

SOP 09: Welfare of the Donor

Number	Author	Reviewed	Effective Date	Authorised by
SP 10	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP the manner in which a donor is treated in ensuring his/her safety and the safety of others during and after the blood collection.

2. Responsibility

The donation room staff is responsible for ensuring that the donor is comfortable and is not feeling apprehensive during the process of bleeding.

3. Materials required

Donor Questionnaire
Donor Information Paper
Donor identification (Donor Card, Donor ID)

4. Procedure

Ideally, all donors should be given a glass (2-3 in hot climates) of water to drink before donating blood. After collection, ensure that the donor feels well and accompany him to the recovery area. All donors should rest for a minimum of 10 minutes after donation and should take a drink. Some donors may be reluctant to do so but try to persuade them. If they refuse outright there is nothing else you can do.

Advice donors that they should not smoke, drink alcohol or do heavy manual work for about 30 minutes after recovery. If bleeding starts again from venepuncture site, he

should raise his arm and apply pressure. If he feels faint then he should rest and if this persists return to the blood bank.

Note: Refreshment is important to replace volume and gives them time to recover before walking out the door. Before the donor leaves, give a short advice on what to expect and what to do if anything happens.

5. Faint Management

If a donor faints, lie them down on the bed or floor in 'feet up' position. Make sure they drink a lot of water and reassure them before they leave. Do not panic, as this can discourage donor & other donors waiting to give blood.

SOP 10: Packing of Whole Blood for Transport to Blood Centre

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
SP 11	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the process of adequate packaging of a blood product for transportation to the laboratory in maintaining adequate safety measures and temperature control

2. Responsibility

The donation room staff is responsible for ensuring that the blood unit that has been donated in stored in appropriate temperature and conditions ready for transportation the laboratory.

3. Materials required

Vol 1 SOP Blood and Blood Donor Safety
WHO Manual on safe blood Donation
Temperature regulated Blood shipper
Cooler/Esky

4. Procedure

i. Ideally blood must be transported in a temperature that is between +2^{o}C- +6^{o}C (up to 10^{o}C is acceptable).
ii. Fresh whole blood for platelet production should be transported separately in room temperature (kept between +20^{o}C and +24^{o}C.
iii. The transit time for blood and blood components should not exceed more than 24hours

iv. A thermometer must be placed at all times in the shipper (esky)

The instructions given below are for a 125-litre esky. (Not required in a temperature regulated blood shipper)

v. Use room temperature bricks on both sides of the narrower end and cover with large pad.

vi. Place 2 ice bricks on each side of the wider aspect of the esky and cover with large pad or card-board with holes.

vii. Place a plastic bag inside and then your blood packs with labels facing down.

viii. If you have temperature control monitors, place one inside and the other one to monitor outside temperature. The difference should be 10^{o}C. The ideal temperature should be +2 ^{o}C and +6^{o}C.

ix. Packing of a small esky will differ in the way you place your blood packs.

x. Check the temperatures when you reach your destination and record these readings.

SOP 11: Storage and Labelling of Blood and the Use of Enrolment and Donor Patient and Usage Data

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
SP 13	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the process of storage and in labeling of blood upon arrival in the laboratory

2. Responsibility

It is the responsibility of the blood donor team bringing the blood in and the laboratory staff to ensure that the blood units have arrived safely in the laboratory and is stored in the appropriate section and within the right temperature.

3. Materials required

Blood fridge (Temp range 2ºC-6ºC) or a cold room, Temperature control chart, shippers (eskies), thermometer

4. Procedure

I. All donated blood except bloods for platelets concentrates should be kept in **quarantine** in temperatures ranging from 2ºC-6ºC. Make sure this area is labelled **QUARANTINE**.

II. These blood units should be labelled after the laboratory has done the grouping and completed screening for TTIs.

- **Note:** Whole blood units that will be used to make platelet concentrates should be kept at room temperature.

- Labelling is available as follows:-

Label	**Type of label**	**Comments**
*A, B, AB, O	Stickers	If available, otherwise label with a ballpoint pen
Rhesus (D) Negative	Stickers	As above
Haemolysin	Stickers	Emergency O sticker
HIV	(NEG) Stickers	If sticker is available. Otherwise, label with a ballpoint pen
Hepatitis B Surface Ag Negative	(NEG) Stickers	As above
Hepatitis C Negative	(NEG) Stickers	As above
Auto-transfusion	Tie-on label	
VDRL/TPHA	(NEG) Stickers	As above
Gerbich Negative	Stickers	As above
Packed red cells	Stickers	As above

i. After labelling, units are stored in the normal use area.

ii. After cross-match, the units are labelled with a 'tie-on label' giving details of the patient for whom they have been matched. This also applies to FFP, Cryoprecipitate and Platelet concentrate.

iii. The record cards will be completed as soon as possible with appropriate stickers.

iv. The stickers are either blood group labels or similarly coloured labels are placed on the top right hand side of the card as you face donor personal data.

v. On the top left -hand side put a red sticker or mark with red ink if the donor is HIV positive, orange sticker or mark Hepatitis B and C and pink VDRL/TPHA. Enter the results of tests done.

vi. Do not enter any comment where a test has not been done. For most donors this will mean a comment against group and hepatitis only.

The **Usage Data Sheet** has several specific features (see the example).

I. **On the Donor Side**

i. Under "Group" enter the ABO group. If Rhesus or Gerbich has been done enter that result under this heading also. (N.B. All expatriate donors and recipients and those of mixed racial origin must have Rhesus grouping done). Gerbich antigen testing will soon be reintroduced into blood banking once available.

ii. Under "Status" record if IR*, HbsAg+, HCV+, VDRL+/TPHA+, or, Haemolysin+ otherwise simply write OK.
(*IR for HIV initially reactive not confirmed)

iii. Under the "Product" state how the unit was processed for components. A unit may be used simply for Whole Blood (WB) or Red Cell Concentrate (RCC) and the plasma discarded. The plasma may be used for Fresh Frozen Plasma (FFP) or Cryoprecipitate (CRYO) or Platelet Concentrate (PC).

II **On the patient side**

i. When blood (i.e. WB or RCC) or a component (i.e. FFP, CRYO or PC) is requested enter the patient data against the appropriate unit number.

ii. WB or RCC is cross-matched so if these are being issued enter the cross-match (XM) date.

iii. In larger institutions the same WB or RCC may be cross-matched for subsequent patients if not used for the original patient and there are 4 lines so allowing up to 4 XMs for the same unit.

iv. Sometimes more lines are needed for one unit especially if it has been made into components. So at the bottom, there are two extra lines for any one donation on the page that requires extra space. The bag number will have to be written in: use asterisks as shown.

v. If you know the blood or component has been used enter the date used and under "FATE" state what the component was. If the unit had been cross-matched for another recipient, put a line through the "Date Used" against the originally intended recipient. Always state what the fate of the blood or component is e.g. OD for Out Of Date, etc

vi. Finally the bottom line is a quick means of keeping a statistical tally that will help you with your monthly returns.

Although these changes will allow us to keep a close watch on all our donations, it may be desirable in some places to keep a separate note book recording some special points such as Group O donors who are willing to donate in an emergency, or donors who are Gerbich negative or Rhesus negative.

SOP 12: Management of Donors/Clients with Reactive Results for Transfusion Transmittable Infections (TTIs)

Number	**Author**	**Reviewed**	**Effective Date**	**Authorised by**
SP 14	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

1. Purpose

This SOP describes the management of a donor found to have a TTIs either post donation or via the VCT describes the referral pathways for HIV and other TTIs.

2. Responsibility

The responsibility lies with the OIC Pathology, the BTS manager, the NUM and the trained counselor. They are is responsible making sure that the donor/client is and notified and brought into the center for counseling and appropriate referral.

3. Materials required

HIV and TTI referral pathway flowchart
Donor results
Lab request forms

4. Procedure

4.1. TTIs from Donor Blood

i. In the laboratory, the scientist on the TTI bench screens the blood units for these diseases; HIV 1 and 2, Hepatitis B and C, Syphilis.
ii. All samples should be labelled with donor numbers with no names given, for screening. This maintains confidentiality of donors and also reduces bias from the technician performing the test.

iii. Any positive or equivocal reaction must be double checked by a senior medical laboratory technical staff member in Blood Transfusion Service in duplicates.

iv. ALL units, which are initially reactive for any transfusion transmittable infections must be withdrawn and discarded.

v. If the supplemental tests are positive, the donor will be labelled 'Repeat reactive' or Positive. (This applies mainly to HIV after confirmatory testing.)

vi. All documentation of final results from the local laboratory should be entered by the Senior Laboratory staff. A record book must be kept in the laboratory for this purpose.

vii. Each TTI-positive donor must be called up for follow-up and counselling and appropriate referral. This maintains the confidentiality of our Blood Donors.

4.2 TTIs from A Client (Donor Rejects)

Clients found to have either TTIs from the VCT group can be managed through the same referral pathway as depending on whether it HIV or one of the others

4.3 Referral Pathway of Donors and clients with TTIs ;

Unlike in the past, hospitals are now using other new and improved testing platforms to screen for TTIs such as the Maglumi. An algorithm

However, for those laboratories using the RDTs in TTI screening; if

i) **Positive for Hepatitis B surface antigen (Two bars if using RDT)**

Counsel first and refer to a medical officer or the Medical Consultation clinic for further advice and management.

ii) **Positive for Hepatitis C virus antibody (Two bars if using RDT)**

Counsel first and refer to a medical officer of the Medical Consultation clinic for further advice and management

iii) **Positive for TPHA (Two bars if using RDT)**

TPHA is tested simultaneously with VDRL. Refer to the Referral Pathways flowchart.

Note that if:

a) TPHA Positive and VDRL Positive: Active Syphilis so counsel and refer to STI/HIV clinic for further counselling and treatment

b) TPHA Positive and VDRL Negative: Exposure, may mean previous infection and treatment or can refer to medical clinic to investigate for Yaws

C) TPHA Negative and VDRL Positive; False reaction

Counsel first and refer collect blood VDRL to do confirmatory testing the Outpatient Department or the STI/HIV clinic for further advice and VDRL for treatment.

vi) **Initial Reactive (IR) for HIV I/II (if using RDT)**

Call the donor into the centre and counsel the donor. In facilities without a proper trained nurse counsellor, refer to a social worker, who will counsel the donor and then refer to the HIV/STI clinic (White House).

Collect another blood sample for confirmatory testing. This donor can be counselled and asked to return after 6 months for repeat testing if the test is 'Negative'. If the test is 'Confirmed' Positive, counsel and refer to the STI/HIV clinic (White House) for further counselling and testing. Confidentiality must be maintained.

Note: Any donors with confirmed positive results for HIV, HBsAg and HCV should be permanently deferred**.**

III Administration

Number	Author	Reviewed	Effective Date	Authorised by
SP III	Dr Ralph Tozer	M Mathias/P Paua	Oct, 2023	Dr Merrilyn Mathias
Version	**Year**	**Review Period**	**Location**	**Date**
2	1994	June-Oct, 2023	NBTS, NDOH	24.08.2023

Admin.1: Ordering

The ordering form included all requirements for nursing and technical procedures in the blood bank. It is essential therefore that you liaise closely with each other so that a comprehensive order is made for both. Your ordering system should be such that you have two months supply available at the time you make your order. Check your stocks and ensure that you do not order more than you need for that period of time. Some centres have ordered excessively in the past and have stock going out of date.

This method, frequency and placement of orders are being reviewed. When this has been completed, a new sheet with precise information will replace this one. For the time being, carry on as you have been doing before.

Admin.2: Despatching

When transporting units of blood ensure that the units do not come into direct contact with ice packs or ice itself.

Place an insulating layer of cardboard, newspaper or some other material between the bags and the refrigerant.

Ensure that whatever method you adopt on the general packaging is acceptable to the air-line. (Refer to IATA standards and SOP on Packaging and Transport)

Admin.3: Records

All recording practices are being reviewed. In recent training workshops, the new recording systems have being reviewed and introduced.

Admin.4: Publicity

Some centres are finding it difficult to attain much publicity. This issue has being discussed extensively in the recent training workshops for regular voluntary non-remunerated blood donation. Some Centres might get help from local Red Cross office. You should use what you can of the newspaper, radio and television.

Every year worldwide, World Blood Donor Day is celebrated on June 14. This day should be used to acknowledge and encourage your donors locally. This is a good time to thank the donors by giving them small gifts and recognising long-term and regular blood donors.

In Headquarters, we are devising and providing more publicity and will distribute material as soon as possible. This will come in forms of Posters and Information on Blood Donation for you to use at your centres and mobiles.

Note: Sign after you have read the SOPs

Staff member	Position/No	Date commenced	Date read	Signature

Authorised by:

_____

Dr. Merrilyn Mathias
Manager
National Blood Service
24.08.2023