Title: **SECTION 4.0 NZBMDR STANDARDS**
**DONOR RECRUITMENT, ENROLMENT & INFORMATION**

Authorised by: Executive Officer

Contributing Authors:
ABMDR

Dr Hilary Blacklock

Raewyn Fisher

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## SECTION 4.0 NZBMDR STANDARD DONOR RECRUITMENT, ENROLMENT & INFORMATION

**4.0** **NZBMDR** is funded to recruit males with Maori or Pacific Island ancestry. Other NZ Ethnic minority groups may also be recruited. People who have been tissue typed in another capacity such as platelet donors, or family members who have been tissue typed in the search for a family donor may also be approached to join the NZBMDR.

A signed consent form must be obtained at the time of recruitment

**Refer: Consent Form A – Unrelated Donor**

### 4.1 DONOR AGE CRITERIA

- New unrelated donors should only be enrolled by the NZBMDR if they are between the ages of 18 and 40 years.
- Previously tissue typed donors such as platelet donors, or family members who have been tissue typed in the search for a family donor will be enrolled up to the age of 59 years.
- Donors will be removed from the NZBMDR on their 60th birthday.
- Younger male donors are the preferred group for recruitment.

### 4.2 ELIGIBILITY FOR ENROLMENT AS A BONE MARROW DONOR

For the protection of recipients, criteria regarding infectious disease markers and the diagnosis of certain medical conditions as per NZBS A-Z Collection Standards should be adhered to regarding the donation of stem cells. However given that there may be only one acceptable HLA matched donor available for an individual patient the medical condition of an otherwise ineligible donor may be acceptable. Whether or not the transplant proceeds is at the discretion of the transplant physician in consultation with the patient.

- Donors should be eligible and willing to donate blood. Those unable to meet the blood donation criteria will usually not be enrolled on the NZBMDR.
- For those wishing to join the Registry but who are unable to meet the blood donation criteria due to the CJD restriction, the Donor Centre Director (via the NZBMDR Executive Officer) may give approval for them to enrol if this would enhance the diversity of the Registry.

### 4.2.1 Specific tests for infectious disease markers are defined in NZBMDR Standard - Infectious Disease Markers (refer: Section 6.0).

**Contraindications** to enrolment are:

- the risk or confirmation of HIV1/2 or the confirmation of HTLV I/II;
- Donors with a **diagnosis** of Creutzfeldt-Jakob Disease (CJD), Gerstmann Straussler Scheinker Syndrome (GSS), Fatal Familial Insomnia (FFI) or at risk of developing CJD, GSS or FFI must be deferred permanently;
- Donors with a family member with CJD, GSS or FFI must be deferred permanently.

- Donors with haemophilia or a related clotting disorder who have received treatment with clotting factor concentrate at any time must be permanently deferred.

### 4.2.2 NZBMDR Policy on variant CJD (vCJD) and Donor Deferral

Blood donors who have lived in or visited the United Kingdom (UK) (England, Scotland, Wales, Northern Ireland, Isle of Man and the Channel islands) or in France or the Republic of Ireland for a total period of 6 months or longer, between 1980 and 1996, are deferred from donating blood and should not be recruited as a new donor to the NZBMDR.

Donors who received a blood transfusion in the United Kingdom, France or the republic of Ireland from 1980 onwards are deferred from donating blood and should not be recruited to the NZBMDR as new donors.

Existing donors already on the registry, or donors who have transferred from overseas bone marrow donor registries and are deferred from donating blood because of the NZBS policy on vCJD, should have this information recorded on the MATCHPOINT database and will remain on the NZBMDR.

Donors who have previously been regular blood donors but are now excluded from donating blood because of the vCJD policy may be considered by the NZBMDR, if their joining will enhance the diversity of the registry. This information should be recorded on the MATCHPOINT database.

### 4.2.3 Other Causes for Ineligibility

Prospective donors who have had successfully treated basal cell carcinoma and squamous cell carcinoma or successful therapy for carcinoma in situ of the cervix, should be evaluated by a medical officer before being accepted as donors see NZBS Collection Standards manual
Donors with a history of any other diseases of malignant origin especially leukaemia, lymphoma or myeloma or other haematological conditions must be deferred permanently.

A donor with a diagnosis of one of the following must be removed from the Registry:

- Myeloproliferative diseases including polycythemia vera, thrombocythaemia and myelofibrosis.

- Other evidence of serious bone marrow dysfunction (e.g. refractory anaemias, chronic neutropenias, thrombocytopenia).

- Thalassaemia major, HbS and severe coagulopathy.

- **The Donor Centres must advise the Transplant Centres of any significant medical conditions affecting the donor. Instances where exceptions occur, such as residence in the UK between the years of 1980 and 1996, must be documented and communicated to the Transplant Centre.**

## 4.3 PROTECTION OF DONORS

Potential unrelated donors who have a condition which would place them at risk if undergoing a general anaesthetic, as defined by the American Society for Anaesthesiology Class I standards will only be available for a PBSC collection.

**Refer Attachment Section 4: Criteria for American Society for Anaesthesiology (ASA)**

This will be established at the time of the donor's physical examination by a third party haematologist and communicated to the Transplant Centre as this may negate a marrow collection if insufficient HPA, apheresis cells are collected .

## 4.4 FAMILY DONOR RECRUITMENT

Individuals who have been tissue typed as part of an extended family search may be approached by the relevant search centre to consider enrolling with NZBMDR. This is particularly important for those family members tissue typed for patients of minority ethnic groups, particularly those who do not have a Bone Marrow Donor Registry in their country of origin.

Apart from the obvious advantage of having these individuals on the registry, as genotyping and in some cases Class II typing have been performed, often many family members wish to make a commitment to the Registry.

### 4.4.1 Process

The Information Brochure and Form TR may be sent to the family members aged 18 to 59 by agreement with the Transplant Centre.

**Refer: Information brochure and Transfer Consent Form TR**

**PLATELET and PLASMA DONOR RECRUITMENT**

NZBS platelet and plasma donors, up to the age of 59, who have been tissue typed may be approached by NZ BS to consider joining the NZBMDR.
Donors must have read the Information brochure. Form TR must be completed and forwarded to the NZBMDR. DRB1* tissue typing may be required.

**Refer: Consent Form TR- Transfer of Previously tissue typed donors onto NZBMDR**

## 4.5 DONOR INFORMATION

A potential donor must be aware of the following before joining the registry

- NZBMDR donors are volunteer donors
- Donors must be willing to donate to any patient in need, from any part of the world
- Donors will not be paid for their donation but may be reimbursed for expenses such as travel and accommodation associated with the workup and collection. Expenses for one companion may also be reimbursed.
- Donors must be informed of their potential role in the donation of HPC, the risks involved in the donation and the tests required during the donor workup..
- Donors must be informed about the use of any medical intervention such as a general anaesthetic or the administration of GCSF and the known risks and side effects
- Donors must be informed about the possibility of a request for subsequent donations
- Donors must be informed that there is a follow-up process to ensure their complete recovery
- Donors must be informed that they can withdraw from the registry at any time but also be made aware of the implications of this action at certain periods of the search process
- Donors must be made aware of the privacy policy of the registry

It is essential that donors receive accurate and up to date information on the donation process. This will take place in three stages:

### 4.6.1 Stage 1 - At RECRUITMENT

The NZBMDR New Donor information brochure must be provided to potential donors at recruitment. Only after this has been read and understood should Consent Form A be signed.
Most NZBMDR donors join the registry when they donate a unit of blood at an NZBS collection site. Enrolment will be performed under the direction of NZBS staff that have training and experience in donor enrolment and donor management activities including Informed consent, confidentiality, and health screening.
All NZBS staff will have an information session with a staff member from NZBMDR at which they will be given information on the donation process.

**Refer:** **Unrelated Donor Consent Form A**
**Donor Information Brochure**

### 4.6.2 Stage 2 - At RECALL for repeat blood sampling

NZBMDR staff will give donors information regarding the search process by phone and send the Donor VT information (3 page document) before a VT sample is collected. Donors should be contacted no later than **eight weeks** after a verification testing sample was drawn, to give them an update on the progress of this testing.

**Refer:** **SOP 601 DR Consent**
**SOP 503 VT Consent**
**SOP 502 Collection of VT samples**
**Donor VT Information**

### 4.6.3 Stage 3 - At FINAL ASSESSMENT for donation

NZBMDR staff will give donors information by phone and send the Donor Workup Information Document (4 pages) when workup is requested. Prior to donation, donors must meet with an independent third party haematologist for an information session, medical assessment and to consent to the release of non identifying details to the Transplant Centre.
Potential donors with learning difficulties should be excluded from donating stem cells.
Refer: www.fda.gov/cber/gdlns/donorimun section 5

**All women of child bearing age must have a pregnancy test at workup.**
Female donors must be given full disclosure of risks associated with GCSF including the possibility of foetal malformation and/or miscarriage if the donation proceeds whilst pregnant. The result must be documented on Form 43

**Refer: Interpretation of Third Party Physical Exam at Workup Form 43**
**Donor Workup Information, HPC, apheresis Information, HPC**
**SOP 802 Donor Contact Call**

### 4.6.4 Information concerning requests for Second or Subsequent Donations

At the time of the final assessment of the donor (Work up), donors must be informed that they may be asked to donate stem cells (either HPC marrow or HPC apheresis) on a second or subsequent occasion if the patient has experienced graft failure.
Alternatively they may be asked to donate lymphocytes if the recipient has had disease relapse.
This information is contained in the donor workup information sheet which becomes part of the consent form signed by the donor at the medical assessment.

The transplant centre will be informed both from Form 43 and Form WU2 as to the willingness of donors to be contacted should a subsequent donation be requested

For further information concerning this process refer Section 13.0

## 4.7 INTERNATIONAL TRANSFER OF DONORS

NZBMDR donors, who travel and reside overseas for an extended period of time, may transfer to the Registry of their country of residence. Likewise, international donors residing for any length of time in New Zealand may be transferred either permanently or temporarily to the NZBMDR. To join the NZBMDR they must be able to complete the Blood Donor Declaration Form and Consent Form TR. Their recruitment to the NZBMDR would be subject to the Guidelines of the NZBMDR.

## CRITERIA FOR AMERICAN SOCIETY FOR ANAESTHESIOLOGY (ASA)

### CLASS I ANAESTHETIC RISK

"The donor has no organic, physiological, biochemical or psychiatric disturbance."

**Minimum Criteria for acceptance at Medical Director's discretion are those of ASA**

### CLASS II ANAESTHETIC RISK

"Mild to moderate systemic disturbance caused by pathophysiological processes such as non-limiting organic heart disease; mild diabetes; essential hypertension; anaemia; chronic bronchitis; morbid obesity; smoking" as described below.

Suggested criteria for exclusion of patients from the Bone Marrow Donor Register due to increased risks from anaesthesia:

1 **Personal or family history** of severe reactions to general anaesthesia. Include known susceptibility to malignant hyperpyrexia, porphyria etc.

2 **Cardiovascular disease:**

- Any history of angina, myocardial infarction, atrial fibrillation or ventricular arrhythmia
- Hypertension that is not well controlled
- Congenital and valvular heart disease
- Any episodes of congestive heart failure

3 **Pulmonary disease:**

- Asthma leading to hospitalisation in the past year
- Chronic airways disease with FVC or FEV <70% of predicted value, secondary polycythemia

4 **Haematologic function:**

- Chronic anaemia
- Polycythemia
- Coagulation disorders, including history of DVT in past year.

5 **Psychiatric disorders:**

- Treatment with anti-depressant drugs or major tranquillisers in the past year.

6 **Endocrine and Renal function:**

- Diabetes - all insulin dependent diabetics; those requiring hospital for control, or with history of hypoglycaemia episodes in the past six months
- Thyroid disease - unless stable on thyroid replacement
- Steroid treatment in the past year
- Renal impairment with elevated serum creatinine

7 **Gastrointestinal function:**

- Hiatus hernia
- Peptic ulcer, unless endoscopic evidence of healing or asymptomatic for 12 months
- History of hepatitis or jaundice in past year. Hep B Ag or HIV positive, abnormal liver function tests
- Obesity, >40% over ideal weight