

Title:

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

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### Forms / Work Instructions

New Donor Consent Form	Consent Form A
Family Donor Consent Form	Consent Form D
Platelet Donor Consent Form	Consent Form P
DR Consent Form	Consent Form DR
CT Consent Form	Consent Form CT
CT Information	Donor CT Information
Workup Information	Donor Workup Information

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

**4.0 NZBMDR** is funded to recruit people 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.

### 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 60<sup>th</sup> 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 should be adhered to regarding the donation of stem cells. However given that there may only be one appropriately HLA matched donor available for an individual patient, whether or not the transplant proceeds is at the discretion of the transplant physician in consultation with his/her 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 in the Republic of Ireland for a total period of 6 months or longer, between 1980 and 1996, are deferred from donating blood and will 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 will 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 STARLINK 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 STARLINK 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 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 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 must not 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.

### **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. Donors with a Class II status may be accepted at the discretion of the Medical Director of the Marrow Collection Centre, but any risk must be clearly understood by the prospective donor 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 should be approached 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 Family Consent Form D may be sent to the family by agreement with the Transplant Centre.

### **Refer: Information brochure and Family Consent Form D**

Timing of despatch of this letter is at the discretion of the Executive Officer of the ABMDR with the agreement of the Transplant Centre.

Family members up to the age of 59, who have already been tissue typed, may volunteer to join the registry at any time.

## **4.5 PLATELET and PLASMA DONOR RECRUITMENT**

NZBS platelet donors, up to the age of 59, who have been tissue typed may be approached to consider joining the NZBMDR.

Donors must have read the Information brochure. Form P, Platelet and Plasma Donor Consent , must be completed and forwarded to the NZBMDR. No further tissue typing is

required.

**Refer: Platelet and Plasma Donor Consent Form P**

## 4.6 DONOR INFORMATION

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 can Consent Form A be signed.

**Refer: Unrelated Donor Consent Form A  
Donor Information Brochure “ WE NEED YOUR HELP”**

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

Donors must be given information regarding the search process by phone and sent the Donor CT information (3 page document) before a CT sample is collected. Donors should be contacted no later than **eight weeks** after a confirmatory testing sample was drawn, to give them an update on the progress of the compatibility testing.

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

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

Donors must be given information by phone and sent the Donor Workup Information Document (4 pages) when workup is requested. If HPC, Apheresis has been requested the Information sheet on HPC, Apheresis collection together with the HPC, Apheresis DVD and booklet should also be sent to the donor.

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](http://www.fda.gov/cber/gdlns/donorimun) section 5

All women of child bearing age must be asked if there is a likelihood of pregnancy and offered a pregnancy test. If there is a possibility of pregnancy, the woman should have a pregnancy test.

If they decline to have the test this must be documented on Form 43. A full disclosure of risk must be given to the woman with regard to the possibility of foetal malformation and/or miscarriage if the donation proceeds whilst pregnant.

**Refer: Interpretation of Third Party Physical Exam at Workup Form 43  
Donor Workup Information, HPC, apheresis Information, HPC, apheresis DVD  
and booklet  
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 or alternatively they may be asked to donate lymphocytes if the recipient has had disease relapse.

For further information concerning this process refer Section 13.0

#### **4.7 INTERNATIONAL TRANSFER OF DONORS**

NZBMDR donors, who travel 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