Title: **SECTION 6.0 NZBMDR STANDARDS INFECTIOUS DISEASE MARKERS**

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Forms

Donor Infectious Disease Markers & History of Antigen Exposure at CT sample	Form 24CT
Donor Infectious Disease Markers at Workup (within 30 days of transplant)	Form 50

SECTION 6.0 NZBMDR STANDARDS INFECTIOUS DISEASE MARKERS

6.1 At recruitment to the Registry contraindications to enrolment due to infectious disease are:

- 1) the risk or confirmation of HIV1/2
- 2) the confirmation of HTLV I/II;

All prospective donors should understand and sign the NZBS Donor Session Record Form at the time of enrolment.
Donors **must** sign the NZBS Donor Session Record Form when a Confirmatory Typing sample is taken and at the 'Work up' stage prior to stem cell donation.

6.2 Human Immunodeficiency Virus

Refer to NZBS Collection Standards A-Z Guidelines
1) General Principals 1-6
2) AIDS/HIV page 6-8

6.3 Creutzfeldt-Jakob Disease (CJD), variant CJD (vCJD) and other Human Transmissible Spongiform Encephalopathies. See NZBS Collection standards pages 11-12

Before providing a donor to a Transplant Centre, NZBMDR must ensure that the donor has responded negatively to the following questions:

i] Have any of your blood relatives had Creutzfeldt - Jakob Disease (CJD), Gerstmann Straussler Sheinker Syndrome (GSS) or Fatal Familial Insomnia (FFI)?

ii] Were you ever treated with injections for infertility before 1985?

iv] Did you have neurosurgery or a brain operation between 1972 and 1989?

v] Have you had a cell, tissue or organ transplant?

vi] Have you lived in, or visited England, Scotland, Wales, Northern Ireland, the Channel Islands, the Isle of Man, France or the Republic of Ireland for a total period of 6 months or more, between 1st January 1980 and 31st December 1996 inclusive?

Vii] Have you received a Blood Transfusion in the United Kingdom, France or the Republic of Ireland from 1980 onwards?

If a positive response is obtained to questions I – v , the donor may only be accepted if further investigation proves the patient did not receive human pituitary extract or that there was no graft of cadaveric tissue such as dura mater or corneal tissue.
The transplant physician and patient must be made fully aware of any positive responses to questions vi – vii and agree to proceed with that donor.

6.4 Serological Evidence of HIV 1/2, HTLV I/II, HBV, HCV, CMV

Before Donor Clearance is given to provide a donor to a Transplant Centre, the Registry must have tested the donor for viral disease markers.
All results to be faxed or scanned and Emailed to the Transplant Centre
All donors must be tested and found **negative for HIV 1/2 antibody**.
All donors must be **negative for HTLVI/II and STS(syphilis)**.
All donors must be tested for **surface antigen to Hepatitis B** and **antibody to Hepatitis C and CMV. If the result is positive the Transplant Centre must be informed in writing**. **A decision to continue to transplant with a positive donor for Hepatitis B or Hepatitis C must be documented and signed by the Transplant Centre.**
Toxoplasmosis and EBV will be tested at workup

The Transplant Centre must be satisfied that the results of these tests are acceptable prior to actual transplant.

6.5 Donor Overseas travel and residence with exposure to blood borne disease including Chagas Disease, Zika and Malaria.

At the time of compatibility testing and before donor medical clearance is given at 'work-up', the donor must be asked for a list of the countries in which they have traveled, particularly in rural areas, during the past 3 years and countries in which they have resided.
If they have travelled or lived in rural South or Central America (including Southern Mexico), they may have been exposed to Chagas Disease. If 6 months has elapsed these donors must be tested for T Cruzi antibodies. If less than 6 months since exposure the transplant centre must be informed.

Donors who may have been exposed to malaria should be tested for malarial antibodies if 4 months has elapsed since exposure. If less than 4 months since exposure the transplant centre must be informed.

Risk of exposure to diseases carried in blood must be reported on Form 24CT and Form 50.

refer: NZBS Collection Standard Manual "Country List"

6.6 Timing of Tests for New Zealand Donors

6.6.1 HIV 1/2 should be tested at initial donor recruitment.

6.6.2 HIV 1/2, HBV, HCV, HTLVI/II, Serological Antibody Tests for Syphilis (STS) and CMV must be tested at the time of donor recall for final verification histocompatibility testing and recorded on Form 24VT (Donor Infectious Disease Markers)

At this stage of donor testing ABO Blood group and Rh factor must be tested unless the donor is a blood donor in which case the blood group will be recorded in Progesa. The blood group must be reported to the transplant centre with the IDM results

refer: Form 24VT

6.6.3 HIV Antigen testing is required by the USA and some other countries. If this test is reactive an HIV Antigen Neutralisation test must be performed.

The USA will accept Nucleic Acid Testing (NAT) instead of P24Ag HIV testing if the Gen-Probe Procleix Assay is used. This Assay is registered by the US Food and Drug Administration (FDA).

6.6.4 The NZBLOOD Donor Session Record Form should be completed to the satisfaction of the Donor Centre at the time of enrolment and verification typing and must be completed to the satisfaction of the Donor Centre prior to stem cell donation.

6.6.5 The donor workup, including full virology testing, must be performed within thirty (30) days prior to the transplant date. Nucleic Acid Testing (NAT) should be performed at this time. Virology results must be recorded on Form 50 (Donor Infectious Disease Markers at Workup) and Form 43 (Interpretation of Third Party physical Examination at Workup) must also be completed at this stage.

6.6.6 A list of the tests regularly performed is available. If the Transplant Centre requires other tests these may either be performed in New Zealand or a blood sample can be forwarded to the Transplant Centre.

refer: Form 50 and Form 43

In the event of postponement of the transplant it may not be necessary to repeat the third party haematological assessment however this will be a decision made by the Haematologist who conducted the workup on a case by case basis. Virology testing must be repeated within thirty days prior to the transplant date.

6.6.7 Form 50 (Donor Infectious Disease Markers at Work up) should be completed no later than five (5) days after testing.

6.6.8

It is a requirement of NZBS that the HPC product be tested for infectious serology on the day of collection.

If the courier will need to pick up the product before the test results are available a non-conformance form must be completed by the transplant physician

Refer: Form NZBS 111F019 Request for release of non-conforming product for use in a designated patient on clinical grounds

6.7 Indeterminate Virology Results

Information must be made available to the Transplant Centre in writing concerning any unusual history or abnormal virology results. The Transplant Centre would then make the final decision about whether or not to proceed with the donor.

The Institute of Environmental Science and Research Ltd (ESR) should be contacted on a case by case basis for interpretation of indeterminate results.

6.8 Counseling of donors identified with abnormal test results

Hepatitis C testing by PCR should be performed when supplementary tests are indeterminate.
All donors identified as having abnormal test results must be contacted by the professional body identified in SOP 806.
Follow up tests or treatment should be arranged by this body in consultation with the donor.
NZBMDR is to be informed with appropriate details and information about temporary or permanent unavailability of the donor. This information is to be recorded in the donor's file.
The Transplant Centre must be informed in writing if issues of donor health pertain to the safety of the patient or to the removal of the donor from the Registry

6.9 Records

All records must be kept for 100 years.