# United Kingdom Blood Transfusion Services (UKBTS)

# Cord Blood Donor Selection Guidelines (TDSG-CB)

# Edition 203 - Published 01 June 2010

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## Introduction

These guidelines form a constituent part of Chapter 22 (haemopoietic progenitor cells) of the Guidelines for the Blood Transfusion Services in the United Kingdom, 8th Edition, 2013.

The criteria are reviewed regularly to ensure that the stem cells obtained are of the highest quality and of sufficient quantity to meet the needs of recipients.

The Joint Professional Advisory committee (JPAC) of the UKBTS is responsible for this document. JPAC receives professional advice from the Standing Advisory Committees (SACs) that form part of its structure and from other relevant expert groups.

Users of these guidelines must ensure that they have the latest version and that recent changes have been implemented (usually within three months) by their national service.

Latest Updates lists alterations to the guidelines made since publication of this edition.

Advice on these guidelines can be obtained from:

**Dr L Williamson, Medical and Research Director**
**National Health Service Blood & Transplant (NHSBT)**
E-mail lorna.williamson@nhsbt.nhs.uk

**Prof M Turner, Medical & Scientific Director**
**Scottish National Blood Transfusion Service (SNBTS)**
E-mail marcturner@nhs.net

**Dr SP Field, Medical Director**
**Welsh Blood Service (WBS)**
E-mail stephen.field@wales.nhs.uk

**Dr K Morris, Medical Chief Executive Officer**
**Northern Ireland Blood Transfusion Service (NIBTS)**
E-mail kieran.morris@nibts.hscni.net

Comments about the content of these guidelines, including notification of errors, omissions and suggestions for improvements, should be sent to the Chair of SAC-Tissues and Cellular Therapy Products:

**Dr Akila Chandrasekar**
NHSBT Tissue Services
14 Estuary Bank
Speke
Liverpool L24 8RB

Preferably by e-mail to akila.chandrasekar@nhsbt.nhs.uk with TDSG-CB in the subject line.

This section was last updated in TDSG-LD Edition 203, Release 16 Issue 01

# Contents

## Document and Change Control

These guidelines are under the continuing review of the Standing Advisory Committee for Tissues and Cellular Therapy Products (SAC-TCTP) and for Transfusion Transmitted Infection (SAC-TTI). This is to ensure that they are accurate and up to date. All changes have the approval of the Joint UKBTS Professional Advisory Committee (JPAC).

**Change Notification.**
A Change Notification Letter notifies changes to the **Medical Director** and the **Quality Manager** of each of the four national services. The **Professional Director of JPAC** is responsible for this notification. All changes will have the approval of the JPAC.

Implementation of changes is the responsibility of the individual Services.

**Document version terminology.**
A version shall be any of the following:
Extensive revisions of this document are known as '**Editions**'.
Changes following the issue of 'Change Notification Letters' are known as '**Releases**'.
Changes to the website, which do not involve a change to the medical or scientific content, are given an '**Issue**' number.

Edition Date, Release Date and Issue Date is the date on which an Edition, Release or Issue is first published on the UKBTS website.

**Changes to printed versions.**
The **Quality Manager** of each Blood Service will effect changes to the document. They will be informed when a new electronic version is released. The **Quality Manager** is responsible for ensuring that there is an effective Document Control and Document Change procedure in operation within their Blood Service to ensure that only up to date versions are in use and that all authorized copies, both electronic and paper, are traceable.

**Individual users** of these guidelines are responsible for ensuring that they are using an up-to-date version.

**Changes to the website versions.**
The website will always display the up to date version. Any errors should be notified to the publisher, **Caroline Smith@nhsbt.nhs.uk**, preferably by e-mail to caroline.smith@nhsbt.nhs.uk

This section was last updated in TDSG-CB Edition 203, Release 03.

## General Principles

This document provides guidance for the selection of cord blood donations. It must be read in conjunction with Chapter 22 (haemopoietic progenitor cells) of the Guidelines for the Blood Transfusion Services of the United Kingdom - 8th Edition, 2013, which lists the general, and some specific aspects of donor selection.

Cord Blood is taken from the placenta of newborn infants. As placentae are normally treated as a waste product there is no risk to the infant or the mother. To ensure the donated material is safe to use it is important to exclude risk factors in the mother. On occasions tests may need to be performed on the cord blood but no additional testing of the infant should be required. Unless stated specifically, all guidelines apply to the mother of the infant whose cord blood is collected.

Mothers are selected firstly to ensure that their baby's cord blood stem cells are unlikely to harm any recipient. The ultimate responsibility for the selection of mothers rests with the respective **National Medical Director**.

The immediate responsibility is with the **Qualified Healthcare Professional** who must ensure that the mother fulfils the respective selection guidelines. When it is not clear from these guidelines if an individual is acceptable, cord blood should not be released for issue without discussion with a **Designated Medical Officer**.

The mother must be evaluated by a **Qualified Healthcare Professional** who has undergone appropriate training to use this document, to assess the suitability of their infant's cord blood for donation. They must verify their assessment by signing and dating the donation record.

Special note must be taken of the content of the **Tissue Safety Entry** in the **A-Z**.

It is the responsibility of the **Qualified Healthcare Professional** to ensure that the mother clearly understands the nature of the donation process. They must also understand the health questions and other information presented to them. The mother is asked about confidential aspects of their medical history, hence great care must be taken over privacy and confidentiality. This means that third party interpreters can only be used, as described in the **A-Z** entry on **Communication Difficulties**.

When there is a recognized risk to a recipient, the guidelines **must** be followed.

The following terms may be used:

**Including**
Lists any other terms which may be covered by the Guideline.

**Definition**
Where additional clarity is required, a definition is provided.

**Obligatory**
This will indicate how the mother **must** be dealt with by the use of several terms:

**Must not donate**
The mother **must** not be accepted if any of the statements apply to them, **unless** a 'discretion' clearly applies. Often the exclusion will depend on time related factors. If a donation cannot be taken, the mother **must** be clearly advised why.

**Refer to Designated Medical Officer**
Is used when there is a need to seek further advice. The **Designated Medical Officer** is a suitably trained person authorized to undertake this task by the **National Medical Director**.

**Discretionary**
Gives reasons why a mother may be permitted to donate. The statements are conditional. All statements that **must** be fulfilled come before the final statement that they may be accepted. If the mother fulfils these requirements, as well as all others that apply, then they can be accepted.

**See if relevant**
Is used when an **A-Z** entry may or may not need to be consulted. This will depend upon the information provided by the mother.

**Additional Information**
This provides background information as to why a particular action or actions is required.

**See**
Means that the specified **A-Z** entry **must** be consulted.

**Reason for Change**
This indicates the background to any changes made to the entry since the last Edition or Release.

Some or all of these terms may be used under each subject heading or sub-heading.

This section was last updated in TDSG-CB Edition 203, Release 02

## Medication

The underlying illness suffered by a mother, rather than the properties of any drug they have taken, is the usual reason for them not being eligible.

In general, traces of drugs in cord blood are harmless to any recipient. However, mothers treated with certain drugs are deferred for periods associated with the pharmacokinetic properties of the drug. Examples are some drugs used to treat acne and psoriasis. All such drugs have their own entry in the **A-Z** section.

This section was last updated in TDSG-CB Edition 203, Release 02.

## Use of Alphabetical Listing (A-Z)

Any medical condition, or possible contraindication to donation, elicited at any point during donation, processing or storage, must be managed according to the **A-Z** section of these guidelines. Any donated cord blood, which, as a result, is unsuitable for clinical use, **must** be clearly labelled as unfit for use.

Any new health risks identified by this process should be notified to the Standing Advisory Committee on Stem Cells, so they can be considered for incorporation into future revisions of these guidelines.

If late information is provided by the mother, or through any other source, that the donation is medically unfit, this must be recorded and reported to the **Designated Medical Officer**.

**Donations must not be accepted from mothers who exhibit health risks that are not listed in this guidance, without referral to, and acceptance by, the Designated Medical Officer.**

This section was last updated in TDSG-CB Edition 203, Release 02.

## A-Z Index

## Accident

*Including* Trauma

*Obligatory* **Must not donate if:**
a) Not recovered.

b) Still under follow-up.

c) Has a plaster-cast.

*See if Relevant* Neurosurgery
Surgery
Tetanus Immunization
Transfusion

*Additional Information* An unhealed wound or sore is a risk for bacteria entering the blood. Bacteria in blood can be a serious threat to anybody receiving stem cells. This is because the bacteria can multiply to dangerous levels. A plaster-cast can hide a wound or sore.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Acitretin

Neotigason

*See* Acne
Psoriasis

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Acne

*Obligatory* **Must not donate if:**
a) Has ever taken Etretinate (Tigason).

b) Pregnancy commenced within 24 months of the last dose of Acitretin (Neotigason).

c) Pregnancy commenced within four weeks of the last dose of Isotretinoin (Roaccutane) or Alitretinoin (Toctino).

d) There is secondary infection

*Discretionary* Therapy with topical treatments, oral tetracycline, erythromycin and Dianette (cyproterone acetate and ethinyloestradiol), accept.

*Additional Information* Etretinate (Tigason), Acitretin (Neotigason), Isotretinoin (Roaccutane) and Alitretinoin (Toctino) can cause birth defects in babies exposed to them while inside the womb. It is important to allow time for the drug to be cleared from the donor. It takes longer to clear some drugs than others.

Secondary infection of acne is usually obvious with swelling and redness of affected spots. There is a risk of bacteria entering the blood. This could be a serious threat to anybody receiving tissues. This is because the bacteria can multiply to dangerous levels.

*Reason for Change* To include information on Alitretinoin (Toctino).

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 16

## Acupuncture

*See* Complementary Therapy

*Reason for Change* To replace the entry for acupuncture with a link to complementary therapy. The acupuncture entry was virtually a duplicate of the entry for complementary therapy. By using a link it will make future changes to the guidelines simpler.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 16

## Addiction and Drug Abuse

*Obligatory* **Must not donate if:**
a) The mother has ever injected, or been injected with, drugs; even a long time ago or only once. This includes bodybuilding drugs.

b) The mother is adversely affected by any drug, including alcohol, which may affect the process of obtaining valid consent.

*Discretionary* a) May be acceptable if injected drugs were prescribed by the mother's physician for a condition that would not lead to exclusion.

b) Previous use of non-parenteral drugs does not necessarily require exclusion.

*See if Relevant* Tissues Safety Entry

*Additional Information* Injecting drugs has been linked with the passing on of many infections, including hepatitis and HIV. It can be many years before any infection shows itself. Former drug users often do not realize that they can still pass infection on to others many years after they last used drugs themselves.

Anyone obviously affected by alcohol or other drugs that can affect the mind, cannot give valid consent or fully understand why they are being asked certain questions.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## African Trypanosomiasis

(Sleeping Sickness)

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Age

*Obligatory* **Must not donate if:**
Mother is under seventeen years of age.

*Additional Information* This takes account of national laws on age of consent.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## AIDS

*See* HIV
Tissues Safety Entry

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Alcoholism

*See* Addiction and Drug Abuse

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Alitretinoin

*Obligatory* Must not donate if less than four weeks from the last dose of Alitretinoin (Toctino).

*See if Relevant* Acne
Dermatitis

*Additional Information* Alitretinoin is a drug analogous to Tretinoin and Isotretinoin used to treat acne and refractory eczema.

Treatment with retinoids such as Alitretinoin can cause birth defects for babies exposed to them before birth. It is important to allow time for the drug to be cleared from the donor. A one month deferral for donation is recommended in the drug information sheet.

*Reason for Change* New Entry.

## Allergy

*Discretionary* Accept.

*See if Relevant* Steroid Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Alternative Therapies

*See* Complementary Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Anaemia

*Obligatory* **Must not donate if:**

a) Mother or Father homozygous or heterozygous for inherited haemoglobin disorder or enzymopathy.

**Inform Transplant Centre if:**
b) Cells are from a baby that has an inherited disorder.

*Discretionary*

**1.** a) If the cord blood is tested for the relevant condition and is shown to be unaffected, accept.

b) For X linked disorders, if father affected and male baby, accept. If mother affected and female baby, accept.

c) For non-X linked disorders, if baby heterozygous (trait), accept.

**2. History of anaemia:**
This should be assessed regarding its cause, current status and what treatment has been received.

**3. Iron deficiency:**
If not under investigation and the underlying cause is not a reason to exclude, accept.

**4. Other types:**
Accept or exclude according to the guidelines.

5. In other cases:
**Refer to a Designated Medical Officer**.

*See if Relevant*

Haemoglobin Disorders
Haemolytic Anaemia
Malignancy

**If treated with blood components or products or by plasma exchange or filtration:**
Transfusion

*Additional Information*

A successful transplant will mean the recipient will produce the same blood as the donor. This would be unacceptable for a homozygous (major) form of blood disorder but would probably be acceptable for a heterozygous (minor form, or trait).

By informing the transplant centre, details can be passed on to the person receiving the transplant. This can avoid unnecessary problems in the future. For example searching for the cause of small red cells or anaemia in a person who has had a transplant from a donor with thalassaemia minor (trait).

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Animal Bite

(Non-Human)

*Obligatory*

**Must not donate if:**
a) Ever bitten by a non-human primate

b) Any wound is infected or not healed.

*See if Relevant*

Human Bite
Infection - General
Rabies Immunization

*Additional Information*

Animal bites may result in many different infections. Allowing all wounds to heal and for any obvious infection to have resolved should avoid problems. Rabies, and similar diseases, have long incubation periods and do not show as a wound infection. There is no evidence that these infections have ever been transmitted through a cord blood donation. These diseases appear to be confined to the nervous system during their incubation periods. There is evidence that they have been transmitted through organ, tissue and ocular transplants. For this reason there are different rules for material that may contain nervous system tissue.

*Reason for Change*

There have been minor changes to make it clear that the reference is to non-human animals and to introduce guidance concerning bites from non-human primates.

*Update Information*

This entry was last updated in

TDSG-CB Edition 203, Release 02

## Ankylosing Spondylitis

*Discretionary* Accept.

*See* Autoimmune Disease

*Reason for Change* A link to 'Autoimmune Disease' added.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Anthrax

### Infection

*See* Infection - Acute

### Exposure

*Discretionary* Even if on prophylactic antibiotics, accept.

*Additional Information* Anthrax infection most commonly affects the skin through direct contact with infected material such as animal hides. If spores have been inhaled there is no evidence that there is any spread to the bloodstream until the person has developed signs of infection. For this reason it is considered safe to accept exposed mothers provided they have not shown signs of infection, even if they have been given prophylactic antibiotics.

### Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Anti-Androgens

*Including* Androgen Antagonists

*See* Dutasteride (Avodart)
Finasteride (Proscar)

*Reason for Change* To include a link for 'Anti-Androgens'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Antibiotic Therapy

*Additional Information* Treatment with antibiotics is not of itself a reason for deferral but the reason for the treatment may be. When treatment is being given to prevent infection, rather than to treat it, see if there is

a relevant entry. If not, discuss with a **Designated Medical Officer**.

*See* Infection - General

*Reason for Change* Additional Information has been added for clarity.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Antidepressant Therapy

*See* Mental Health Problems

*Reason for Change* The entry has been replaced with a link to Mental Health Problems.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Antifungals

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Antivirals

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Arthritis

*See if Relevant*
Ankylosing Spondylitis
Autoimmune Disease
Osteoarthritis
Psoriasis
Rheumatoid Arthritis

*Reason for Change* A link has been added for Autoimmune Disease.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Arthropod Borne Encephalitis

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Asthma

*Obligatory*
**Must not donate if:**
Taking, or has completed, oral or parenteral steroids within the last seven days.

*See if Relevant*
Infection - General
Steroid Therapy

*Additional Information*
Steroid therapy can hide the signs and symptoms of infection. Stem cells from an infected donor could be dangerous to the person receiving them.

*Update Information*
This entry was last updated in
TDSG-CB Edition 203, Release 02

## Autoimmune Disease

*Obligatory*
Must not donate if:
The mother has needed treatment to suppress the condition in the last 12 months.

*See if Relevant*
**If treated with immunoglobulin or plasma exchange or filtration:**
Transfusion

*Additional Information*
Treatment to suppress the condition may be with steroids, immunosuppressive drugs, antimetabolites, antibodies directed against parts of the immune system as well as other therapies. These will affect the mother's immune system. This may make her more susceptible to certain types of infection and also will make some infections more difficult to diagnose.

*Reason for Change*
Additional Information has been added to clarify treatment that may have been used to suppress the condition.

Autoimmune disease will not be transmitted through cord blood or amniotic membrane.

*Update Information*
This entry was last updated in
TDSG-CB Edition 203, Release 02

## Babesiosis

*Obligatory*
**Must not donate.**

*Update Information*
This entry was last updated in
TDSG-CB Edition 203, Release 02

## Basal Cell Carcinoma

*Obligatory*
**Must not donate if:**
a) Still receiving treatment.

b) Any wound has not healed.

*Additional Information*
Although basal cell carcinoma is a form of cancer it only spreads locally. As it does not spread by the blood stream it is not a risk to people receiving donated material.

An unhealed wound is a risk for bacteria entering the blood. Bacteria can be a serious threat to anybody receiving donated material. This is because the bacteria can multiply to dangerous levels.

*Update Information*
This entry was last updated in
TDSG-CB Edition 203, Release 02

## BCG

*Obligatory* **Must not donate if:**
Immunized in this pregnancy.

*Additional Information* BCG is an immunization with live bacteria. We do not want to pass BCG, or other infections, on to people receiving donated material.

*See* Immunization - Live

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## BCG Immunization

*See* BCG

*Reason for Change* The 'See' entry has been changed from 'Immunization - Live' to 'BCG',",Update Information"
This entry was last updated in
TDSG-CB Edition 203, Release 02

## Bilharzia

*See* Infection - Acute

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Bipolar Disorder

*See* Mental Health Problems

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Bleeding Disorder

*Including* Carriers

### Affected Individual

*Obligatory* **Must not donate if:**
a) Treated with blood derived coagulation factor concentrates.

b) There is a history of excessive bleeding or bruising which may be due to a condition that could be transmitted by stem cells (e.g. some platelet disorders).

*Discretionary* **Carrier state:**
This does not necessarily prevent donation:
**Refer to a Designated Medical Officer** who will liaise with the haematologist that investigated the mother.

*See if Relevant* Transfusion

*Additional* Mothers who have received blood derived coagulation concentrates (these are made

*Information* from the blood of many hundreds of individual donors) may have been put at risk of infections that can be passed through donations.

### Family Members, Carers and Sexual Partners of Individuals Treated with Blood Derived Coagulation Factor Concentrates

*Obligatory* **Must not donate if:**
a) Treated with blood derived coagulation factor concentrates.

b) A sexual partner, or former sexual partner, of a person treated with blood derived coagulation factor concentrates.

c) Has had an inoculation injury with blood derived coagulation factor concentrates.

*Discretionary* If six months or more from last sexual contact or inoculation injury, accept.

*See if Relevant* Inoculation Injury
Transfusion

*Additional Information* **Blood derived coagulation concentrates:**
These are made from the blood of many donors. They may put recipients at risk of infections that can be passed through blood. This risk may be shared by their sexual partners.

Waiting six months from the last sexual contact or inoculation injury helps to ensure that the infections tested for by the Blood & Tissues Services will be picked up.

*Reason for Change* This entry has been extensively rewritten to improve clarity.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 03

## Blind Mother

*See* Disabled Mother

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Blood Pressure - High

*Obligatory* If the mother has had severe hypertension in pregnancy:
**Refer to a Designated Medical Officer.**

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Blood Transfusion

*See* Transfusion

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Body Piercing

*Including* Permanent and Semi-permanent Makeup

*Obligatory* **Must not donate if:**
Less than four months after last piercing.

*Discretionary* If it is less than four months since the last body piercing, discuss with the designated medical officer who will decide if the donor may be accepted following a documented risk assessment and discussion with the transplant centre. In this scenario a negative NAT for HBV, HCV and HIV is mandatory as an extra safety check.

*Additional Information* Piercing has passed infection from person to person. Waiting four months helps to ensure that the infections tested for by the Blood & Tissue Services will be picked up.

The deferral period has been reduced from 6 to 4 months to reflect updated JPAC Standing Advisory Committee on Transfusion Transmitted Infections guidance on infection risk. (JPAC paper 09-34). This guidance presumes that a validated NAT test for hepatitisC is negative, if this test is stopped for any reason the guidance will change.

*Reason for Change* To allow a risk assessment to be performed when the donor is the best match for the recipient.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 16

## Bone Graft

*See* Surgery
Tissue and Organ Recipients

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Borrelioses

*See* Infection - Acute

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Botulism Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Brain Surgery

*See* Neurosurgery

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Brain Tumour

*See if Relevant* Malignancy
Neurosurgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Breast Biopsy

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Breast Lump

*Obligatory* **Must not donate if:**
a) Malignant.

b) Not fully investigated and cleared of malignancy.

*See if Relevant* Malignancy

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Bronchitis

### Acute

*See* Infection - Acute

### Chronic

*See if Relevant* Infection - General
Steroid Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Brucellosis

Undulant Fever

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cancer

*See* Malignancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Candida

*See* Thrush - Oral
Thrush - Vaginal

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cannabis

*See* Addiction and Drug Abuse

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cardiac Surgery

*See if Relevant* Cardiovascular Disease
Endocarditis
Surgery
Transfusion

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cardiomyopathy

*Obligatory* **Must not donate if:**
Not recovered from infective causes.

*Reason for Change* This is a new entry

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cardiovascular Disease

*See if Relevant* Cardiomyopathy
Endocarditis
Myocarditis

*Reason for Change* Additional links have been added.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Catarrh

### Acute

*See* Infection - Acute

### Chronic

*See if Relevant* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Central Nervous System Disease

*Obligatory*

**Must not donate if:**
a) Dementia.

b) History of CNS disease of suspected infective origin (e.g. multiple sclerosis (MS), optic neuritis, transverse myelitis, Creutzfeldt-Jakob disease (CJD)).

c) Neurodegenerative conditions of unknown aetiology (e.g. Parkinson's disease).

*Discretionary*

a) Individuals who have had Bell's palsy more than four weeks ago and have discontinued any treatment for the condition for at least seven days, even if they have residual paralysis, accept.

b) If a definite diagnosis of transient global amnesia has been made, accept.

*See if Relevant*

Neurosurgery
Prion Associated Diseases
Rabies

*Additional Information*

Often the exact cause of a degenerative brain condition only becomes known after death. For this reason, when there is any doubt as to the underlying cause of a brain condition, it is considered safest not to accept a donation. It is thought that degenerative brain disease in the form of vCJD has been transmitted by blood transfusion.

Transient global amnesia is a temporary and isolated disorder of memory. Affected individuals are usually over 50 years of age and there is an association with migraine. There is no association with cerebrovascular disease.

*Reason for Change*

Additional advice for donors with a history of optic neuritis, transverse myelitis, Bell's Palsy or transient global amnesia has been added.

A new section Additional Information has been added.

*Update Information*

This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-CB Edition 203, Release 16

## Cervical Carcinoma in Situ

*Obligatory*

**Must not donate if:**
Undergoing investigation or treatment.

*Discretionary* a) If investigation and treatment is concluded, accept.

b) If just having regular review of smears, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cervical Cone Biopsy

*See* Cervical Carcinoma in Situ

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cervical Dysplasia

*See* Cervical Carcinoma in Situ

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Chagas' Disease

South American Trypanosomiasis

*Obligatory* **Must not donate.**

*See if Relevant* South American Trypanosomiasis Risk

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Chicken Pox

### Herpes Zoster (Varicella Zoster)

*Obligatory* **Must not donate if:**
Has had chicken pox or shingles during this pregnancy.

*See* Infection - Acute

### Contact

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Chiropody

*Obligatory* **Must not donate if:**
There are open wounds or infection.

*See if Relevant* Fungal infection:
Infection - Chronic

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Chlamydia

*See if Relevant* Lymphogranuloma Venereum

*See* Infection - Acute

*Reason for Change* A link to 'Lymphogranuloma Venereum' has been added.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Cholecystitis

*See* Gall Bladder Disease

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Cholera Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Chondromalacia

*Discretionary* Accept.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Christmas Disease

*See* Bleeding Disorder

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Chronic Fatigue Syndrome

*See* Post Viral Fatigue Syndrome

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Cirrhosis

*Obligatory* **Must not donate if:**
a) Complicated by hepatoma.

b) Infectious or autoimmune cause.

*Discretionary* If the cause is genetic, accept.

*See if Relevant* Alcoholism
Autoimmune Disease
Malignancy

*Reason for Change* Additional links have been added.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Clinical Trials

*Obligatory* **Must not donate if:**
Participating in a clinical trial. This includes the use of drugs of any kind (oral, parenteral, transcutaneous, etc.) and applies to healthy individuals participating as volunteers - for example in 'phase 1' clinical trials.

*Discretionary* If a **Designated Medical Officer** has examined and agreed the trial protocol, accept.

*See if Relevant* Complementary Therapy
Transfusion

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Coagulation Factor Concentrates

*See* Bleeding Disorder

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Coeliac Disease

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Colitis

*Obligatory* **Must not donate if history of:**
a) Crohn's disease.

b) Ulcerative colitis.

*See if Relevant* Infection - General
Inflammatory Bowel Disease
Malignancy.

*Reason for Change* A link has been added for 'Malignancy'.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Colostomy

*Obligatory* **Must not donate if:**
For malignancy or inflammatory bowel disease.

*Discretionary* If the reason for the colostomy is not of itself a reason to exclude and the stoma is healthy, accept.

*See if Relevant* Surgery

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Communication Difficulties

*Obligatory* **1. All mothers must:**
a) Fully understand the donation process.

b) Give their informed consent to the process and to the testing of their blood for diseases that may affect the suitability of their baby's stem cells/tissues for use.

**2. Third party interpreters:**
If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the mother and the qualified health professional, they must:

a) Understand the importance of providing an accurate and truthful translation of the information provided, to enable the tissue/cell establishment to comply with regulatory requirements

b) Not be personally known to the mother.

c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor.

*See if Relevant* Disabled Donor

*Additional Information* The Services are aware of their duties under Race Relations and Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language is not English, or who have other difficulties in communicating. **Every mother must:**
a) Be provided with accurate educational materials, which are written in terms which can be understood by members of the general public.

b) Complete a health and medical history questionnaire and undergo a personal interview performed by a health professional.

c) Provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history.

A qualified health professional may assist a mother in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the information leaflets, the health and medical history questionnaire and consent statements. The mother must be able to clearly demonstrate they have understood this material. At present

there is no standardized way of assessing comprehension so this will be a personal judgement made by the health professional.

**Use of third party interpreters.**
It is permissible for any third party to act as an enabler by helping to reassure the mother and to assist in establishing effective communication between the mother and the health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the mother and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the mother, may accompany the mother through other parts of the donation process that do not include the exchange of confidential information.

**Rationale.**
There is concern that the use of third parties during any exchange of confidential information between the mother and the health professional may compromise the confidentiality of the mother and the safety of any donated material. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the mother in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the need to accurately and truthfully communicate all the information, including personal and confidential information, provided by the person giving consent, this may make the interpretation of information incomplete and potentially put both the mother and the donated material at risk. There is also a requirement to communicate the results of any testing performed by the Blood/Tissue Services that may be of relevance to the mother or her baby's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain confidentiality, should be taken into account when deciding if an individual mother may be accepted.

*Reason for Change*

1. To clarify that interpreters and translators do not need to understand all the regulatory requirements of the Human Tissue Act, but are aware of the importance of providing a truthful and accurate translation to enable the tissue/cell establishment to comply with regulatory requirements.

2. To clarify that interpreters and translators have a duty of confidentiality.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 19.

## Complementary Therapy

*Obligatory*

**1. Must not donate if:**
a) The condition for which treatment was given is not acceptable.

b) Less than four months from colonic irrigation or colonic hydrotherapy

**2. Therapies involving penetration by needles:**
**Must not donate if:**
Less than four months from completing treatment.

*Discretionary*

a) If oral or topical complementary medicines only and reason for which treatment was given is acceptable, accept.

b) For all other therapies (to include faecal microbiota therapy):

**1. Performed within the NHS**
If performed by a suitably qualified NHS healthcare professional on NHS premises, accept.

**2. Performed outside of the NHS**
If performed by a Qualified Health Care Professional registered with the:
General Medical Council (GMC),

Nursing and Midwifery Council (NMC),
General Dental Council (GDC),
The General Chiropractic Council (GCC),
The General Optical Council (GOC),
The General Osteopathic Council (GOsC),
or The Health and Care Professions Council (HCPC) (which regulates: Arts therapists, Biomedical Scientists, Chiropodists/ Podiatrists, Clinical Scientists, Dieticians, Hearing Aid Dispensers, Occupational Therapists, Operating Department Practitioners, Orthoptists, Paramedics, Pharmacists, Practitioner Psychologists, Physiotherapists, Prosthetists and Orthotists, Radiographers, Social Workers in England and Speech and Language Therapists), accept.

*Additional Information*

Equipment that has been reused has passed infection from person to person. Therapists who are subject to discipline from statutorily constituted professional authorities are unlikely to re-use needles.

This guidance presumes that a validated NAT test for hepatitis C is negative, if this test is stopped for any reason the guidance will change.

When there is any doubt about infection being passed on, waiting four months means infections are more likely to be picked up by the tests used by Blood & Tissue Services.

JPAC considers statutory registration of practitioners to afford the best overall guarantee that tissues and cells donated by individuals who have undertaken complementary therapy is safe. In the absence of statutory regulation of complementary therapy, there is currently no single body to which all therapists are accredited, and so to continue with the approval of one or more organisations would necessarily mean that others of possibly equal merit were excluded from approval.

Voluntary registration with a non-statutory body cannot provide assurance as to how high the standards of an organisation's members are or how diligent the non-statutory regulator is in enforcing them or the practitioner in applying them. Practitioners who choose not to join a voluntary register are still able to practise legally and to use the relevant title, as will a practitioner who has been removed from the register by the registering body.

There is no way of policing the enforcement by voluntary associations of the standards they require of their members as the organisations are not subject to supervision by the Council for Regulatory Healthcare Excellence (CHRE). Nor is there currently any external, independent consideration of "fitness to practise" cases referred to voluntary regulators. While statutory regulation cannot guarantee the absence of risk, its primary aim is to deliver enhanced patient safety and public protection. Statutory "protection of title" means that donor centres can safely assume that a person who practises in the name of the registered profession is actually registered.

*Reason for Change*

Pharmacists have been added to the list of professions regulated by the Health and Care Professions Council.

*Update Information*

This entry was last updated in
TDSG-LD Edition 203, Release 19

## Cone Biopsy

*See* Cervical Carcinoma in Situ

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Congo Fever

*Obligatory* **Must not donate if:**
Less than twelve months following recovery or from return to the UK, if occurred abroad.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Contact with Infectious Disease

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Contagious Pustular Dermatitis

Orf

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Corneal Transplant

*Obligatory* **Must not donate.**

*See if Relevant* Prion Associated Diseases

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Coronary Thrombosis

*Including* Heart Attack
Myocardial Infarct

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cortisone (Periarticular)

*See* Steroid Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cortisone Tablets

*See* Steroid Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Creutzfeldt-Jakob Disease

*See* Prion Associated Diseases

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Crimean Fever

*See* Viral Haemorrhagic Fever

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 18

## Crohn's Disease

*See* Inflammatory Bowel Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cystitis

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Cytomegalovirus

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Deaf Mother

*See* Disabled Mother

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Deep Vein Thrombosis

*Discretionary* If the underlying cause does not exclude, accept.

*See if Relevant* Malignancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Dementia

*Obligatory* **Must not donate.**

*Update Information* This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-CB Edition 203, Release 02

## Dental Treatment

*Obligatory* **Must not donate if:**
a) Less than seven days since root canal treatment, dental capping or having a tooth removed.

b) Less than 24 hours since a filling, scale and polish or other superficial treatments.

c) All wounds are not healed.

d) There is any infection.

*Discretionary* If inspection or dental impressions only, accept.

*See if Relevant* Surgery
Infection - General

*Additional Information* Dental extractions and other treatments can result in bacteria getting into the blood stream. The waiting times after treatment are to allow healing and for any bacteria that have entered the blood stream to be cleared.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Depression

*See* Mental Health Problems

*Reason for Change* The previous link has been replaced with one to 'Mental Health Problems'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Dermatitis

*Obligatory* **Must not donate if:**
Mother has infected perineal dermatitis.

*See if Relevant*

Alitretinoin
Allergy
Infection - General
Steroid Therapy

*Reason for Change* To add a link to Alitretinoin.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 16

## Diabetes Insipidus

*Discretionary* If the underlying cause does not exclude, accept.

*See if Relevant* Neurosurgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Diabetes Mellitus

*Obligatory* **Must not donate if:**
Uncontrolled infection.

*Discretionary* Accept.

*See if Relevant* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Diarrhoea

*Including*
D & V
Entero-colitis
Food Poisoning
Gastric Flu
Gastro-enteritis

*Obligatory* **Must not donate if:**
a) Chronic or associated with inflammatory bowel disease.

b) Less than two weeks since full recovery.

*See if Relevant* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Dilatation and Curettage

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Diphtheria

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Diphtheria Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Diphtheria Tetanus Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Diphtheria Tetanus Pertussis Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Disabled Mother

*Obligatory*

**1. All mothers must:**
a) Fully understand the donation process

b) Give their informed consent to the process and to the testing of their blood for diseases that may affect the suitability of their baby's stem cells/tissues for use

**2. Third party interpreters:**
If they are to be present at any part of the selection procedure were there is an exchange of confidential information between the mother and the qualified health professional, they must:
a) Understand the requirements of the Human Tissue Act (HTA) relevant to the donation process
b) Not be personally known to the mother.

*Discretionary*

**Mothers with difficulty in reading:**
Ensure by questioning the mother that they:
a) Understand and fully complete the tick-box questionnaire

b) Give valid consent to donation and to the testing of their blood for diseases that may affect its suitability for use.

*See if Relevant* Self-Catheterization
Spina Bifida

*Additional Information* The Services are aware of their duties under Disability Discrimination Legislation and will, whenever and wherever reasonable, try to provide facilities for individuals whose first language

is not English, or who have other difficulties in communicating. **Every mother must:**

be provided with accurate educational materials, which are written in terms which can be understood by members of the general public

complete a health and medical history questionnaire and undergo a personal interview performed by a health professional

provide written informed consent to proceed with the donation process which must be countersigned by the qualified health professional responsible for obtaining the health history.

A health professional may assist a mother in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. audio, Braille, computer or alternative language) for the information leaflets, the health and medical history questionnaire and consent statements. The mother must be able to clearly demonstrate they have understood this material. At present there is no standardized way of assessing comprehension so this will be a personal judgement made by the health professional.

**Use of third party interpreters.**
It is permissible for any third party to act as an enabler by helping to reassure the mother and to assist in establishing effective communication between the mother and the health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the mother and understand the requirements of that part of the HTA relevant to the donation process. Confidential parts of the process include the evaluation of the health and medical history questionnaire, the medical interview and the obtaining of valid consent. Any third party, with the permission of the mother, may accompany the mother through other parts of the donation process that do not include the exchange of confidential information.

**Rationale.**
There is concern that the use of third parties during any exchange of confidential information between the mother and the health professional may compromise the confidentiality of the mother and the safety of any donated material. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the mother in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the individual's eligibility to donate. If a third party is not fully aware of the relevant aspects of the HTA this may make the interpretation of information incomplete and potentially put both the mother and the donated material at risk. There is also a requirement to communicate the results of any testing performed by the Blood/Tissue Services that may be of relevance to the mother or her baby's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain confidentiality, should be taken into account when deciding if an individual mother may be accepted.

*Reason for Change* This is a revised entry to clarify the use of interpreters by the Blood & Tissue Services.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Disease of Unknown Aetiology

*Obligatory* **Must not donate.**

*Additional Information* When the cause of an illness is not clear, there is an unknown risk to any recipient of donated material.

*Reason for Change* This is a new entry.

*Update Information* This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Diverticulosis

*Discretionary* Accept.

*See if Relevant* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Drug Abuse

*See* Addiction and Drug Abuse

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Drug Treatment

*Obligatory* The taking of some drugs may make a mother ineligible.
This could be due to the underlying disease or to the medication.

**See:**
Any specific entry for the disease or the drug.

*Discretionary* Self-medication with some drugs e.g. vitamins, aspirin, sleeping tablets, need not prevent a donation being accepted, providing the mother meets all other criteria.

*See if Relevant* Addiction and Drug Abuse

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## DTP Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Duodenal Ulcer

*See* Peptic Ulcer

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ear Piercing

*See* Body Piercing

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ebola Fever

*See* Viral Haemorrhagic Fever

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 18

## Eczema

*See* Dermatitis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Electrolysis

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Elliptocytosis

*See* Hereditary Elliptocytosis

*Reason for Change* This entry has been changed to Hereditary Elliptocytosis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Emphysema

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Encephalitis

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Endocarditis

*Obligatory* **Must not donate if:**

Active infection.

*See if Relevant* Infection - General

*Reason for Change* This new entry replaces the previous entry for 'Subacute Bacterial Endocarditis'. It recognizes that the cause of endocarditis is not always bacterial and the course is not always subacute.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Endometriosis

*Discretionary* Accept.

*See if Relevant* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Epilepsy

*Obligatory* **Must not donate if:**
a) Mother has taken drugs with known haematological toxicity during this pregnancy.

b) Recent onset and not fully investigated.

c) Secondary to malignancy or degenerative neurological disease.

*See if Relevant* Malignancy
Neurosurgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Episcleritis

*See* Inflammatory Eye Disease

*Reason for Change* To include an entry for 'Episcleritis'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Etretinate

Tigason

*Obligatory* **Must not donate if:**
Has ever taken Etretinate (Tigason).

*See if Relevant* Acne
Psoriasis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Eye Disease

*Obligatory* **Must not donate if:**
a) Active ocular inflammation.

b) History of malignancy.

c) Ocular tissue transplanted.

*See if Relevant*
Autoimmune Disease
Glaucoma
Infection - General
Malignancy
Ocular Surgery
Ocular Tissue Recipient
Steroid Therapy
Tissue and Organ Recipients

*Reason for Change* A link has been added for 'Malignancy'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Eye Drops

*Obligatory* **Determine what they are being used to treat.**
**See:**
Is there a relevant entry.

*See if Relevant*
Autoimmune Disease
Glaucoma
Infection - General
Steroid Therapy

*Additional Information* Eye drops are used to treat a wide range of conditions, some of which would prevent the person from donating. It is important to know exactly why the drops are being used.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Factor V Leiden

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Febrile Episodes

*See* Pyrexia

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Fertility Treatment

*See* Infertility

*Reason for Change* The text had been removed to ensure that the entry for fertility treatment and the entry for infertility are identical at all times.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 13 Issue 02

## Fever

*See* Pyrexia

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Fibroids - Removal

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Filariasis

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Fits

*See* Epilepsy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Food Allergy

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Food Poisoning

*See* Diarrhoea

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Foreign Travel

*See* Travel

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Fungal Infection

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Fungal Infection of Nails

*See* Infection - Chronic

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## G6PD Deficiency

*Obligatory*

**1. Must not donate if:**
Mother or Father affected by clinically significant disease.

**2. Inform Transplant Centre if:**
Infant affected and cord blood accepted.

*Discretionary*

a) If infant shown to be unaffected, accept.

b) If father affected and male infant, accept.

*Additional Information* This is an X linked red cell enzyme deficiency that is variable in its severity. Suitability as a donor should be discussed with a **Designated Medical Officer**.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Gall Bladder Disease

*Obligatory*

**Must not donate if:**
a) Symptomatic.

b) Associated with an inherited haemolytic anaemia e.g. spherocytosis.

*Discretionary*

a) If recovered or has asymptomatic gallstones, accept.

b) If infant shown to be unaffected by any haemolytic process, accept.

*See if Relevant*

Haemolytic Anaemia
Infection - General
Malignancy
Surgery

*Reason for Change* A link has been added for 'Haemolytic Anaemia' and for 'Malignancy'.

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Gastrectomy

*See if Relevant* Malignancy
Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Gastrointestinal Disease

*Obligatory* **Must not donate if:**
a) Ulcerative colitis or Crohn's disease.

b) Malignant.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Genital Herpes Infection

*See* Herpes - Genital

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Genital Warts

*Discretionary* Accept.

*See if Relevant* Sexually Transmitted Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## German Measles

*See* Rubella

*Reason for Change* The entry now links to 'Rubella'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Giardiasis

*Discretionary* Accept.

*Additional Information* This is a local intestinal infection that does not affect donation.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Gilbert's Disease

*See* Gilbert's Syndrome

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Gilbert's Syndrome

*Discretionary* Accept.

*Additional Information* Gilbert's syndrome is an inherited defect in bilirubin metabolism. It is harmless but can cause jaundice in the mother and her baby.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Glandular Fever

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Glaucoma

*Obligatory* **Must not donate if:**
Received transplant of sclera during glaucoma surgery.

*See if Relevant* Ocular Tissue Recipient
Surgery
Tissue and Organ Recipients

*Additional Information* If surgery was performed after 1997 and the sclera was supplied through UK Transplant, this information will be stored on the National Transplant Database.

*Reason for Change* A link has been added for 'Ocular Tissue Recipient'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Goitre

*See* Thyroid Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Gonorrhoea

*See* Sexually Transmitted Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Gout

*Discretionary* Even if on treatment, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Grand Mal

*See* Epilepsy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Granuloma Inguinale

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Grave's Disease

*See* Thyroid Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Growth Hormone

*Obligatory* **Must not donate if:**
Has ever received human pituitary derived growth hormone.

*Discretionary* If treated exclusively with recombinant-derived growth hormone, accept. In the UK this has been since 1987.

*See if Relevant* Prion Associated Diseases

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Guillain-Barré Syndrome

*Obligatory*

**Refer to a Designated Medical Officer:**
**Must not donate if:**
a) Less than 24 months from resolution.

b) There has been any recurrence of symptoms.

c) The doctor who managed the mother cannot confirm a typical monophasic Guillain-Barré syndrome that recovered completely within 12 months.

*See if Relevant*

**If treated with immunoglobulin or plasma exchange:**
Transfusion

*Reason for Change*

A link has been added to 'Transfusion'.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Haematological Disease

*Obligatory*

**Must not donate if:**
a) Malignant.

b) Clonal disorder such as primary polycythaemia (rubra vera), essential thrombocythaemia or monoclonal gammopathy of unknown significance (MGUS).

*Discretionary*

If polycythaemia or thrombocytosis is secondary to a non-malignant/clonal condition, accept.

*See if Relevant*

Anaemia
Haemoglobin Disorders
Immune Thrombocytopenia
Therapeutic Venesection

*Additional Information*

Clonal disorders result from the proliferation of a single cell. Because they have the potential to become malignant they are treated in the same way as malignancy.

*Reason for Change*

Monoclonal gammopathy of unknown significance (MGUS) has been added as an example of a clonal disorder.

'Additional Information' has been added.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Haematuria

*Obligatory*

**Must not donate if:**
a) Due to infection.

b) Due to malignancy.

*See if Relevant*

Kidney Disease

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Haemochromatosis

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Haemoglobin Disorders

*Obligatory*

**1. Must not donate if:**
Mother or Father homozygous or heterozygous for inherited haemoglobin disorders.

**b) Inform Transplant Centre if:**
Cells are from the cord of a baby that has an inherited disorder.

*Discretionary* If the cord blood is tested for the condition and the infant is shown to be unaffected or heterozygous (trait), accept.

*See if Relevant*
Anaemia
Sickle-Cell Trait
Thalassaemia Trait
Transfusion

*Reason for Change* A link has been added to 'Transfusion'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Haemolytic Anaemia

*Obligatory*

**See:**
a) Is there an entry for the condition?

b) If not: **Refer to a Designated Medical Officer**.

*See if Relevant*
Autoimmune Disorder
G6PD Deficiency
Haemoglobin Disorders
Hereditary Elliptocytosis
Hereditary Spherocytosis
Pyruvate Kinase Deficiency
Transfusion

*Reason for Change* A note to Refer to a Designated Medical Officer if there is no entry for the cause of the condition has been added.

Additional links have been added.

To include an entry for haemolytic anaemia.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Haemophilia

*See* Bleeding Disorder

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Haemophilus Influenzae Type B Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Haemorrhoids

*Including* Piles

*Discretionary* Accept.

*See if Relevant* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hand, Foot and Mouth Disease

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hashimoto's Disease

*See* Thyroid Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hay Fever

*See* Allergy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Head Injury

*See* Accident

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Headache

### Occasional

*Discretionary* Accept.

### Regular

*Obligatory* **Must not donate if:**
Not investigated.

*Discretionary* If investigated and diagnosis does not contra-indicate donation, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Heaf Test

*Obligatory* **Must not donate until:**
Healing.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Health Care Worker

### History of Inoculation Injury

*See* Inoculation Injury

### No Inoculation History

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Heart Operation

*See* Cardiac Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Henna Painting

*Discretionary* Accept.

*See if Relevant* Body Piercing

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hepatitis

*Obligatory* **Note:**
Hepatitis has a number of causes including infection and hypersensitivity to drugs. Our concern is with viral hepatitis.

*Discretionary* If fully recovered from non-viral hepatitis, accept.

*See if Relevant*
Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis E
Hepatitis of Unknown Origin

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Hepatitis A

### 1. Affected Individual

*Obligatory* **Must not donate if:**
Less than 6 months from recovery.

*Discretionary* If fully recovered, and documented HAV RNA negative, anti HAV IgG positive after recovery, accept.

*See if Relevant* Travel

*Additional Information* Hepatitis A is spread by the faecal - oral route and by sewage-contaminated food and water. It can also be spread sexually. There is no long term infection with the virus but there are many reports of transmission by transfusion. Infection may be symptom free but can be serious and occasionally fatal. The Blood Services do not test for this infection

*Reason for Change* The obligatory deferral has been reduced from 12 to 6 months and a discretion to accept on full recovery added. Additional Information has been updated.

### 2. Current or Former Sexual Partner of Affected Individual

*Obligatory* **Must not donate if:**
Less than 6 months from recovery of current sexual partner, or from last sexual contact if a former sexual partner.

*Discretionary* If shown to be immune, accept.

*Additional Information* There is a risk of transmitting the infection through sexual activity. Infection may be symptom free but can be serious and occasionally fatal. The 6 month exclusion allows any infection to run its natural course and for any risk of passing the infection on through donation to have passed.

*Reason for Change* The obligatory deferral has been reduced from 12 to 6 months.

### 3. Person Currently or Formerly Sharing a Home with an Affected Individual

*Obligatory* **Must not donate if:**
Less than 6 months from recovery of the last affected person in the home, or from the last contact if no longer sharing.

*Discretionary* If shown to be immune, accept.

*Additional Information* Because hepatitis A is spread by the faecal - oral route household contacts may easily become infected. Infection may be symptom free but can be serious and occasionally fatal. The 6 month exclusion allows any infection to run its natural course and for any risk of passing the infection on through donation to have passed.

*Reason for Change* The obligatory deferral has been reduced from 12 to 6 months.

### 4. Immunization

*Obligatory* **Known exposure.**
**Must not donate if:**
Less than six weeks after vaccine or intramuscular immunoglobulin was given.

*Discretionary* **No known exposure:**
Accept.

*See if Relevant* Hepatitis B - Post Immunization
Travel

*Additional Information* Hepatitis A immunization is advised before travel to parts of the world where other infections relevant to donating such as malaria are common. The donor should be asked about any relevant travel history.

Hepatitis A immunization may be combined with Hepatitis B immunization.

*Reason for Change* The 'Additional Information' has been extended.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 24

## Hepatitis A Immunization

*See* Hepatitis A - Post Immunization

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Hepatitis B

### Infected Individual

*Obligatory* **Must not donate.**

*See if Relevant* Tissues Safety Entry

## History of Infection

*Obligatory* **Must not donate.**

*Discretionary* If more than 12 months from recovery, obtain history and blood samples and: **Refer to Designated Medical Officer.**

*Additional Information* Only accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative or, HB core antibody positive, HBsAg negative, and HBV-DNA negative.

## Current Sexual Partners of Infected Individuals

*Obligatory* **Must not donate.**

*Discretionary* Obtain history and blood samples and: **Refer to Designated Medical Officer.**

*See if Relevant* Hepatitis B - Post Immunization - 1. Known Exposure

*Additional Information* Only accept if HB core antibody positive, HBsAg negative and HBV-DNA negative.
or
if more than 12 months from the date the donor was immunised and all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative.

## Former Sexual Partners of Infected Individuals

*Obligatory* **Must not donate.**

*Discretionary* Obtain history (including time from last sexual contact) and blood samples and: **Refer to a Designated Medical Officer.**

*See if Relevant* Hepatitis B - Post Immunization - 1. Known Exposure

*Additional Information*

**a) If less than six months from last sexual contact:**
Only accept if HB core antibody positive, HBsAg negative and HBV-DNA negative.
or
if more than 12 months from the date the donor was immunised and all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative.

**b) If more than six months from last sexual contact:**
Only accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative or, HB core antibody positive, HBsAg negative and HBV-DNA negative. No evidence of current infection, with or without natural immunity

## Current or Former Sexual Partners of Person who has recovered from hepatitis B infection

*Obligatory* **Must not donate if less than 12 months from last sexual contact.**

*Discretionary* Obtain history (including date the partner cleared the HBV infection and the date HBV immunisation of the donor commenced) and blood samples and **Refer to Designated Medical Officer**.

*See if Relevant* Hepatitis B - Post Immunization,- 1.Known Exposure

*Additional Information* Only accept if
more than 12 months from the date the partner was stated to have recovered from / cleared HBV
or

more than 12 months from the date that the donor received the first dose of a course of HBV vaccine
AND either
all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative
or
HB core antibody positive, HBsAg negative and HBV-DNA negative

### Person Sharing Home

*Obligatory* **Must not donate if less than 12 months from last sexual contact.**

*Discretionary* Obtain history (if no longer sharing, include the time since sharing ceased) and blood samples and: **Refer to a Designated Medical Officer.**

*See if Relevant* Hepatitis B - Post Immunization - 1. Known Exposure

*Additional Information* **If still sharing or less than six months since last sharing:**
Only accept if HB core antibody positive, HBsAg negative and HBV-DNA negative.

**If has not shared for more than six months:**
Accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative or, HB core antibody positive, HBsAg negative and HBV-DNA negative No evidence of current infection, with or without natural immunity.

*Reason for Change* To remove the requirement for anti-HBs levels to be >100 iu/l for acceptance of stem cell donations from donors who are anti-HBc-positive provided the HBV DNA result is negative.

*Update Information* This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 16

## Hepatitis B - Post Immunization

### Known Exposure

*Obligatory* **Must not donate.**

*Discretionary* If more than 12 months from immunization obtain history and blood samples and: **Refer to a Designated Medical Officer.**

*Additional Information* Only accept if negative for all markers (i.e. HBsAg, HBV-DNA and HB core antibody) or, HB core antibody positive, HBsAg negative and HBV-DNA negative.

Immunization post exposure may be with specific anti-HB immunoglobulin as well as with HBsAg.

May be combined with hepatitis A immunization.

*Reason for Change* To remove the requirement for anti-HBs levels to be >100 iu/l for acceptance of stem cell donations from donors who are anti-HBc-positive provided the HBV DNA result is negative.

### No Known Exposure

*Obligatory* If less than seven days from when the last immunization was given:
**Refer to a Designated Medical Officer.**

*See if Relevant* Hepatitis A - Post Immunization

*Additional Information* Sensitive assays for HBsAg may be positive following recent immunization. Full screening for Hepatitis B may be required.

May be combined with hepatitis A immunization.

*Update Information* Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 16

## Hepatitis C

### Affected Individual

*Obligatory* **Must not donate.**

*Discretionary* If the individual has been told that he/she is HCV antibody negative, then samples should be taken to determine eligibility.

*See if Relevant* Tissues Safety Entry

*Additional Information* Hepatitis C is a serious viral infection that can lead to chronic liver disease, liver cancer (hepatoma) and chronic fatigue syndrome. It has also been linked with malignant lymphomas and autoimmune disease. The infection is very easily spread by transfusion.

Individuals who are chronically infected are sometimes referred to as 'carriers'. They often have no, or minimal, symptoms associated with their infection.

Many cases are linked to previous drug use and, before the introduction of HCV screening of blood donations, to transfusion.

Individuals who have had Hepatitis C infection in the past, and have been told that they have been successfully treated, will usually remain HCV antibody positive for many years. As a negative HCV antibody screening test is required before their donation can be issued, their cells cannot be used.

*Reason for Change* 'Additional Information' has been added.

### Current Sexual Partners of HCV Positive Individuals

*Obligatory* **Must not donate.**

*Discretionary* If the mother's HCV positive partner has been successfully treated for hepatitis C infection and has been free of therapy for twelve months and continues in sustained remission, accept.

*See if Relevant* Tissues Safety Entry

*Additional Information* Confirmation of the success of treatment of the HCV positive partner is not required.

*Reason for Change* There is now sufficient evidence to establish that individuals who have a sustained virological response to treatment for hepatitis C infection (defined as remaining hepatitis C RNA negative six months after cessation of treatment) are likely to have been cured" and that the chance of relapse is less than 1%. (Data from the Pegasys Study presented at the 38th annual Digestive Diseases Week conference, Washington, USA, 21 May 2007 by Shiffman et al [abstract ID #444]).

In the United Kingdom sexual transmission of HCV from an infected individual to a

sexual partner is low, but not zero.

As the treated individual would have a very low (<1%) risk of relapse of infection and sexual transmission of the hepatitis C virus is rare, the transmission of hepatitis C from a successfully treated individual to a sexual partner is most unlikely."

### Former Sexual Partners of HCV Positive Individuals

*Obligatory* **Must not donate if:**
Less than 12 months from last sexual contact.

*Discretionary* If less than 12 months from last sexual contact and the mother's former HCV positive partner has been successfully treated for hepatitis C infection and has been free of therapy for twelve months and continues in sustained remission, accept.

*See if Relevant* Tissues Safety Entry

*Reason for Change* The discretionary entry has been amended to be consistent with '2. Current sexual partners of HCV positive individuals' above.

### Person Sharing Home

*Discretionary* Accept.

*See if Relevant* Sexual Partners of HCV Positive Individuals above.

*Additional Information* Hepatitis C is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood route. For these reasons household contacts do not need to be deferred.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 11 Issue 01

## Hepatitis E

### Infection

*Obligatory* **Must not donate if:**
Less than 12 months from recovery.

*See if Relevant* Travel

*Additional Information* Hepatitis E is similar to Hepatitis A in the way that it is spread (faecal - oral route and sewage-contaminated food and water). It can affect non-human animals and has been found in pigs in the UK. There have been reports of transmission by transfusion.

### Sexual Partner of Confirmed Case

*Obligatory* **Must not donate if:**
Less than 12 months from recovery of partner.

### Person Sharing Home

*Obligatory* **Must not donate if:**
Less than 12 months from recovery of last affected person in the home.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Hepatitis of Unknown Origin

### Affected Mothers

*Obligatory* **Must not donate if:**
Less than 24 months from recovery.

*Discretionary* a) If more than 12 months, but less than 24 months from recovery, obtain history and blood samples and refer to a **Designated Medical Officer**.

b) If more than 24 months from recovery, accept.

*Additional Information* If more than 12 months and less than 24 months from recovery:
c) If negative for all markers of hepatitis B, accept.

d) If HB core antibody is positive and HBsAg is negative and HBV-DNA is negative, accept.

### Sexual Partner of Affected Individuals

*Obligatory* **Must not donate if:**
Less than 12 months from recovery of partner.

### Person Sharing Home

*Obligatory* **Must not donate if:**
Less than 12 months from recovery of the last affected person in the home.

*See if Relevant* Sexual Partner of Affected Individuals above.

*Additional Information* Most hepatitis of unknown origin will have been due to hepatitis A or hepatitis E (or non-viral causes). Additional testing for those who give a history of hepatitis between 12 and 24 months before donation will exclude the rare case of HBV which may have delayed clearance of infection and therefore will still present a risk through donation.

*Reason for Change* Clarification regarding hepatitis B markers has been added to the additional information.

To remove the requirement for anti-HBs levels to be >100 iu/l for acceptance of stem cell donations from donors who are anti-HBc-positive provided the HBV DNA result is negative.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 16

## Hepatitis of Viral Origin

*See* Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis E
Hepatitis of Unknown Origin

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Hereditary Elliptocytosis

| | |
|---|---|
| *Obligatory* | **1. Must not donate if:**<br>Either parent has significant haemolysis.<br><br>**2. Inform Transplant Centre if:**<br>Cells are from a infant with/or at risk of hereditary elliptocytosis. |
| *Discretionary* | Even if a parent has significant haemolysis, if the cord blood is tested for the condition and the infant is shown to be unaffected, accept. |
| *Additional Information* | Hereditary elliptocytosis is a variably inherited but usually dominant condition. Suitability as a donor should be discussed with a **Designated Medical Officer**. |
| *Reason for Change* | This entry replaces the previous entry for 'Elliptocytosis'. |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Hereditary Spherocytosis

| | |
|---|---|
| *Obligatory* | **1. Must not donate if:**<br>Either parent has significant haemolysis.<br><br>**2. Inform Transplant Centre if:**<br>Cells are from a infant with/or at risk of hereditary spherocytosis. |
| *Discretionary* | Even if a parent has significant haemolysis, if the cord blood is tested for the condition and the infant is shown to be unaffected, accept. |
| *Additional Information* | Hereditary spherocytosis is a variably inherited but usually dominant condition. Suitability as a donor should be discussed with a **Designated Medical Officer**. |
| *Reason for Change* | The entry has been brought into line with the guideline for 'Hereditary Elliptocytosis'. |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Herpes - Genital

| | |
|---|---|
| *Obligatory* | **Must not donate if:**<br>a) Fresh lesions.<br><br>b) Primary infection occurred during this pregnancy. |
| *Discretionary* | If lesions are healing, provided there is no history of other Sexually Transmitted Diseases, accept. |
| *See if Relevant* | Sexually Transmitted Disease |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Herpes - Oral

| | |
|---|---|
| *Obligatory* | **Must not donate if:**<br>a) Fresh lesions.<br><br>b) Primary infection occurred during this pregnancy. |
| *Discretionary* | If lesions are healing, accept. |

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Herpes Simplex

*See if Relevant* Herpes - Genital
Herpes - Oral

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Herpes Zoster

*See if Relevant* Infection - Acute
Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## HIV

*Including* AIDS

### Infection

*Obligatory* **Must not donate.**

*See if Relevant* Tissues Safety Entry

### Current Sexual Partners of Confirmed Case

*Obligatory* **Must not donate.**

*See if Relevant* Tissues Safety Entry

### Former Sexual Partners of Confirmed Case

*Obligatory* **Must not donate if:**
Less than 12 months from last sexual contact.

*See if Relevant* Tissues Safety Entry

*Update Information* This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-CB Edition 203, Release 02

## Homeopathy

*See* Complementary Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Homosexual and Bisexual Individuals

### Female

*Discretionary* Accept

*Additional Information* There is no evidence that there is an increased risk of sexually transmitted infections in homosexual or bisexual females compared to heterosexual females.

*Reason for Change* This is a new entry, combining the previous entries for 'Homosexual' and 'Bisexual' individuals. 'Additional Information' has been added.

### Female sexual partners of men who have sex with men

*Discretionary* There is no specific restriction regarding donation for females with a male partner who has had a history of male-sex-with-male behaviour, but it should be documented to facilitate an in depth discussion should the donor be a potential match for a patient. This ensures that the current practice of individual risk/benefit assessment prior to donation is continued.

*See if Relevant* Tissue Safety Entry

*Additional Information* The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland

Men who have sex with other men have a higher chance of having an undiagnosed infection, which could be passed to their female partner. During 2012 and 2013, SaBTO commissioned a subgroup to review the donor selection criteria and risks associated with the donation of tissues and cells by men who have had sex with men.

This review considered advances in the sensitivity of testing procedures currently in use in the UK, the prevalence of transfusion transmissible infections in men who have had sex with men, the current level of compliance with the donor selection guidelines and, where applicable, the additional processes used to reduce the risk of transmission of viral infection. This review recommended that the 12 month deferral for females who have a male partner with a history of male-sex-with-male behaviour should be removed for potential cord blood donors.

*Reason for Change* To remove the 12 month deferral regarding donation for donors who have a male partner with a history of male-sex-with-male behaviour.

## Hormone Replacement Therapy

*Obligatory* **Must not donate if:**
a) Used for malignancy.

b) A recipient of human gonadotrophin of pituitary origin.

c) A recipient of human pituitary growth hormone.

*Discretionary* a) If treated with gonadotrophins that were exclusively non-pituitary derived, accept.

b) If treated with growth hormone that was exclusively recombinant, accept.

*See if Relevant* Prion Associated Diseases
Thyroid Disease

*Reason for Change* The discretionary entry has been re-worded for clarity.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## HTLV

### Infection

*Obligatory* **Must not donate.**

*See if Relevant* Tissues Safety Entry

### Current Sexual Partners of Confirmed Case

*Obligatory* **Must not donate.**

*See if Relevant* Tissues Safety Entry

### Former Sexual Partners of Confirmed Case

*Obligatory* **Must not donate if:**
Less than 12 months from last sexual contact.

*See if Relevant* Tissues Safety Entry

*Update Information* This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-CB Edition 203, Release 02

## Human Bite

*See* Inoculation Injury

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Human Pituitary Extract

*See* Pituitary Extract - Human

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Huntington's Chorea

*See* Huntington's Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Huntington's Disease

*Obligatory* If the diagnosis is uncertain:
**Refer to a Designated Medical Officer.**

*Discretionary* If diagnosis can be confirmed, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hydatid Disease

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hydatidiform Mole

*See* Pregnancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hydrocephalus

*Obligatory* **Must not donate if:**
Has an indwelling shunt.

*See if Relevant* Neurosurgery
Spina Bifida

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hypertension

*See* Blood Pressure - High

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hyperthyroidism

*See* Thyroid Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hypnotics

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Hypothyroidism

*See* Thyroid Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Idiopathic Thrombocytopenic Purpura (ITP)

*See* Immune Thrombocytopenia

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ileostomy

*Obligatory* **Must not donate if:**
a) For malignancy

b) Inflammatory bowel disease.

*Discretionary* If the reason for the ileostomy is not of itself a reason to exclude and the stoma is healthy, accept.

*See if Relevant* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Immune Thrombocytopenia

*Obligatory* **Must not donate if:**
Mother received treatment for the condition in the 12 months before this pregnancy.

*See if Relevant* **If treated with immunoglobulin or plasma exchange:**
Transfusion

**If treated with immunosuppressive therapy:**
Immunosuppression

*Reason for Change* The links have been revised.

There is no evidence that this condition can be transmitted through cord blood or amniotic membrane.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Immunization

### Non-exposed

*See* Immunization - Live
Immunization - Non-Live

If you do not know if an immunization is live or not, see the specific entry for the type of immunization or:
**Refer to a Designated Medical Officer.**

### Post Exposure

*Obligatory*

**1. BCG:**
**See**
BCG

**2. Hepatitis A:**
**Must not donate if:**
Less than six weeks from exposure.

**3. Hepatitis B:**
**See**
Hepatitis B - Post Immunization

**4. Rabies:**
**See**
Rabies

**5. Smallpox:**
**See**
Smallpox Immunization

**6. Tetanus:**
**See**
Tetanus Immunization

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Immunization - Live

### No Exposure

*Obligatory* **Must not donate if:**
Immunized during this pregnancy.

*See if Relevant* BCG
Smallpox Immunization

*Additional Information* Live immunizations use living viruses or living bacteria that will stimulate the immune system but do not normally cause a severe illness. They may however cause severe illness in people who are already unwell and have a weakened immune system.

*Update Information* This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-CB Edition 203, Release 02

## Immunization - Non-Live

### No Exposure

*Obligatory* **Hepatitis B:**
If less than seven days from when the last immunization was given:
**Refer to a Designated Medical Officer.**

*Discretionary* Other non-live immunizations, accept.

*See if Relevant* Immunization - 2. Post Exposure

*Additional Information* Sensitive assays for HBsAg may be positive following recent immunization. Full screening for Hepatitis B may be required.

"Non-Live" immunizations do not use material that can cause infection. This means there is no risk to people receiving stem cells.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Immunodeficiency

*See* Immunosuppression

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Immunoglobulin Therapy

*Obligatory* **Must not donate if:**
a ) Immunosuppressed.

b) Mothers with recovered immunodeficiency:
**Refer to a Designated Medical Officer.**

*Discretionary* a) If the intravenous or subcutaneous human immunoglobulin was given before 1980, accept.

b) Routine ante- and post- natal use of anti-D immunoglobulin, accept.

c) If single dose prophylactic immunoglobulin has been given, accept.

*See if Relevant* Hepatitis A
Hepatitis B
Rabies
Tetanus Immunization

*Additional Information* Immunoglobulin used before 1980 is unlikely to be affected by vCJD.

Single dose immunoglobulin is unlikely to pose a significant risk for transmitting vCJD.

*See* **If treated with intravenous or subcutaneous human immunoglobulin:**
Transfusion

*Reason for Change* A link to 'Transfusion' has been added.

*Update Information* The advice reflects advice from the MSBTO committee of the DH.

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Immunosuppression

*Obligatory*

**Must not donate if:**
a ) Immunosuppressed.

b) Mothers with recovered immunodeficiency:
**Refer to a Designated Medical Officer.**

*See if Relevant*

Autoimmune Disease
Immunoglobulin Therapy
Steroid Therapy

*Reason for Change*

Additional links have been added.

*Update Information*

This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Infection - Acute

*Obligatory*

**See:**
Is there is a specific entry for the disease you are concerned about?

**Must not donate if:**
a) evidence of active infection
b) less than two weeks from recovery
c) less than 7 days from completing systemic antibiotic, antifungal or antiviral therapy.

*Discretionary*

Cold sores, genital herpes and common upper respiratory tract infections such as colds and sore throats but not influenza, if recovering, accept.

*See if Relevant*

Congo Fever
Crimean Fever
Ebola Fever
Herpes - Genital
Herpes - Oral
Lassa Fever
Marburg Fever
MRSA (Methicillin Resistant Staphylococcus Aureus)
Steroid Therapy
West Nile Virus

*Additional Information*

Many infections can be spread by donated material. It is important that the mother does not pose a risk of giving an infection to a recipient. Waiting two weeks from when the infection is resolved and seven days from completing systemic antibiotic, anti-fungal or antiviral treatment makes it much less likely that there will still be a risk of the infection being passed on.

There is no evidence that cold sores, genital herpes and common upper respiratory infections such as colds and sore throats can be passed on by donated material but it is still necessary to wait until any such infection is obviously getting better before allowing anyone to donate.

*Reason for Change*

To align the guidance with that for BM and PBSC donors.

*Update Information*

Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 16

## Infection - Chronic

*Obligatory* **Must not donate.**

*Discretionary*

**1. Acne:**
Most donors with acne can be accepted.

**2. Chronic superficial fungal infections:**
a) If on local therapy only, accept.

b) If more than seven days from completing systemic antifungal therapy, accept.

**3. Typhoid and Paratyphoid**
If more than seven days from completion of antibiotic course and last symptoms, accept.

*See if Relevant*

Acne
Steroid Therapy

*Additional Information* Typhoid and paratyphoid are gastrointestinal infections which rarely have a chronic carrier state. It is usually caught while travelling. It is passed by the faecal-oral route and is not transfusion transmitted.

*Reason for Change* To add an entry for typhoid and paratyphoid

*Update Information* Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 15

## Infection - General

*Obligatory* **See:**
Is there a specific entry for the disease?

*See if Relevant* Decide if the infection is of short duration with no long lasting carrier stage, e.g. flu:
Infection - Acute

Or if lasting a long time (more than a few weeks) and possibly with long lasting carriage of the infecting organism, e.g. malaria or typhoid
Infection - Chronic

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Infection - Tropical

*Obligatory* **Must not donate if:**
Filariasis or Leishmaniasis

*See if Relevant*

Congo Fever
Crimean Fever
Ebola Fever
Lassa Fever
Marburg Fever
Malaria
South American Trypanosomiasis Risk
**Other infections, see:**
Infection - General

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Infectious Diseases - Contact with

*Obligatory*

**See:**
Is there a specific entry for the disease with which there has been contact?

**Must not donate if:**
Within the incubation period for the condition or, if this is not known, less than four weeks from last contact.

*Discretionary*

If there is a definite history of past infection with the disease with which contact has occurred, accept.

*See if Relevant*

Hepatitis
Meningitis
Sexually Transmitted Disease
Tuberculosis

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Infertility

*Obligatory*

**Must not donate if:**
a) Has ever been given human gonadotrophin of pituitary origin.

b) Has received donated eggs or embryos since 1980.

c) If donor knows that they have ever been treated with Metrodin HP®.

*Discretionary*

If treated exclusively with non-pituitary derived gonadotrophins, accept.

*See if Relevant*

Fertility Treatment
Prion Associated Diseases

*Additional Information*

The use of human gonadotrophin of pituitary origin (follicle-stimulating hormone (FSH) and luteinizing hormone (LH)) had stopped in the UK by 1986. The situation in other countries varied so specific dates cannot be given.

There is a concern that transfer of tissues (eggs or embryos) between individuals might lead to the spread of vCJD.

Metrodin HP® was withdrawn by the Committee on Safety of Medicines in 2003 and following advice from the Medicines and Healthcare products Regulatory Agency the precautionary principle has been applied to withdraw donors who have been treated with this product. Donors treated for infertility after 2003 in the UK will not have been treated with this product.

*Reason for Change*

To add additional information to clarify when the use of human gonadotrophin of pituitary origin (follicle-stimulating hormone (FSH) and luteinizing hormone (LH)) ceased in the UK.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 19

## Inflammatory Bowel Disease

*Including*

Crohn's Disease
Ulcerative Colitis

*Obligatory*

**Must not donate.**

*Additional Information*

The cause of these conditions is not fully understood and may include infection. Lesions caused by the disease can increase the risk of bacteria entering the blood stream.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Inflammatory Eye Disease

*See if Relevant* Autoimmune Disease

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Influenza Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Inherited Diseases

*Obligatory* **See:**
Is there a specific entry for the condition? If not:
**Refer to a Designated Medical Officer.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Injected Drugs of Misuse

*See* Addiction and Drug Abuse

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Inoculation Injury

*Including* Human Bite

*Obligatory* **Must not donate if:**
a) With material containing abnormal prions.

b) Less than four months after the date of an inoculation injury, or contamination of mucosa or non-intact skin with blood or body fluids.

*See if Relevant* Animal Bite

*Additional Information* This guidance presumes that a validated NAT test for hepatitis C is negative, if this test is stopped for any reason the guidance will change.

*Reason for Change* The deferral period has been reduced from 6 to 4 months to reflect updated JPAC Standing Advisory Committee on Transfusion Transmitted Infections guidance on infection risk. (JPAC paper 09-34).

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 06

## Inoculations

*See* Immunization

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Irritable Bowel Syndrome

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Isotretinoin

Roaccutane

*See* Acne

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## ITP

*See* Immune Thrombocytopenia

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Japanese Encephalitis Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Jaundice

*Obligatory* **Must not donate if:**
a) Jaundiced or has a history of jaundice.

b) If the cause of the jaundice was viral see the specific entry for that condition.

c) If the cause of the jaundice was not known, treat as **Hepatitis of Unknown Origin**.

*Discretionary* a) If fully recovered from a non-viral cause of jaundice (this includes, but is not limited to, physiological jaundice of the newborn, gall stones and drug reactions), accept.

b) If due to Gilbert's Syndrome, accept.

*See if Relevant*

Gall Bladder Disease
Gilbert's Syndrome
Hepatitis A
Hepatitis B
Hepatitis C
Hepatitis E
Hepatitis of Unknown Origin

*Additional Information*

Many things can cause jaundice. The concern is with infectious causes that might be passed on by donation.

*Reason for Change*

In 'Obligatory' the link to Hepatitis B' has been changed to 'Hepatitis of Unknown Origin'.

There have been other minor changes to improve clarity and to avoid the unnecessary exclusion of donors.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Kala-Azar

*Obligatory*

**Must not donate.**

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Kidney Disease

### Acute Nephritis

*Obligatory*

**Must not donate if:**
Less than 12 months since recovery.

*Discretionary*

**1. All tissues:**
a) Self-limiting renal disease e.g. single attacks of glomerulonephritis, pyelitis, from which recovery has been complete, do not necessarily disqualify the donor.

b) If there is doubt about the diagnosis refer to a **Designated Medical Officer**.

*Additional Information*

If the donor is well and has not received treatment to suppress the condition in the last 12 months it is unlikely that their donation will pose a risk to the recipient.

*Reason for Change*

To align the guidance with that for blood donors, the deferral period following an attack of 'Acute Nephritis' has been reduced from five years to 12 months

### Chronic Nephritis

*Obligatory*

**Must not donate.**

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 16

## Kidney Donor

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Kidney Recipient

*See* Tissue and Organ Recipients

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Kidney Stones

*See if Relevant* Infection - General

*See* Renal Colic
Kidney Disease

*Reason for Change* Addition of See Kidney Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 25

## Laminectomy

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Laser Treatment

*Obligatory* **Must not donate if:**
For malignancy.

*Discretionary* a) If for Basal Cell Carcinoma, treatment is completed and fully recovered, accept.

b) If for Cervical Carcinoma in Situ, treatment is completed and a follow up smear did not show abnormal cells, accept.

c) If for cosmetic purposes, accept when healed.

d) If laser refractive surgery to the cornea, accept when healed.

*See if Relevant* Basal Cell Carcinoma
Cervical Carcinoma in Situ

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Lassa Fever

*See* Viral Haemorrhagic Fever

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release18

## Legionnaire's Disease

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Leishmaniasis

*Including* Kala-Azar

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Leptospirosis

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Lesbian

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Leukaemia

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Listeriosis

*See* Infection - Acute

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Lyme Disease

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Lymphogranuloma Venereum

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Malaria

*Obligatory* **Must not donate if:**
a) The mother has ever had malaria.

b) The mother has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area.

c) The mother has lived in any malarial endemic area for a continuous period of six months or more at any time of life.

d) Less than 12 months after last leaving a malaria endemic area.

*Discretionary* **1a) Mothers who have had malaria diagnosed in the past:**
If more than three years have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved and a validated test for malaria antibody is negative, accept.

If the donor (with a history of malaria) has revisited a malaria endemic area and at least four months have passed since return and a validated test for malaria antibody is negative, accept.

**1b) Mothers who have EVER had an undiagnosed fever that could have been malaria while in a malaria area or within four months of leaving a malaria endemic area:**
If at least four months have passed since the donor returned from the malaria endemic area, or from the date of recovery from symptoms (undiagnosed fever) that may have been caused by malaria, whichever is later, and a validated test for malaria antibody is negative, accept.

**NB.** this may have to be increased to six months if the area is also identified as a risk area for T. cruzi or a tropical virus; the longest stipulated deferral period must be applied

**1c) Mothers who have EVER been resident in a malaria endemic area for six months or more:**
If at least four months have passed since the date of the last potential exposure to malaria, and a validated test for malaria antibody is negative, accept.

**1d) For all other mothers:**
If at least four months and less than 12 months have passed since return from a malaria endemic area, and a validated test for malaria antibody is negative, accept.

If travel to a malaria endemic area is more than 12 months prior to donation and the mother has never been diagnosed with malaria, has never had an undiagnosed fever while abroad or within four months of leaving a malaria endemic area and has not lived in a malaria endemic area for a continuous period of six months or more at any time of life, the mother can be accepted without the need for malaria antibody testing.

If the malaria antibody is positive obtain details of exposure and treatment and discuss with the **Designated Medical Officer.** A risk assessment must be documented and, if accepted, the details must be discussed at selection with the transplant centre.

*See if Relevant* Geographical Disease Risk Index for countries with a current endemic malaria risk.

*Additional Information* Cases of malaria transmission have occurred many years after the mother was last at risk of becoming infected with malaria. This is mainly a problem in people who have had repeated episodes of infection with malaria. This is uncommon, but before allowing someone who has had, or may have had malaria to give a donation, it is safer to test for malaria antibodies rather than to wait a specific length of time. Malaria may be fatal.

Some countries have malaria as well as tropical viral risk. Both risks have to be considered if the mother had symptoms after travel or stay.

*Reason for Change* The 'Discretionary' entry has been expanded for clarity.

The interval since last leaving a malaria endemic area for malaria antibody testing has been reduced from 6 to 4 months.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 26

## Malaria - Contact in UK

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Malignancy

*Obligatory* **Must not donate.**

*Discretionary* a) If this was a basal cell carcinoma (rodent ulcer) and treatment is completed and all wounds are healed, accept.

b) If the potential donor has a non haematological (non-clonal) premalignant condition (e.g. polyposis coli, prostatic intraepithelial neoplasia PIN or Barrett's oesophagus) that is being regularly monitored, or has had a similar condition cured and has been discharged from follow-up, accept.

c) If the potential donor has a carcinoma in situ (e.g. cervical or vulval carcinoma in situ, ductal carcinoma in situ of the breast DCIS, or Bowen s disease) that has been cured and has been discharged from follow-up, accept.

d) If the potential donor has had lentigo maligna refer to clinical support to ensure that they have not had lentigo maligna melanoma.

e) Potential donors with a high risk of cancer due to family history or following genetic tests, even if had or having prophylactic surgery or on prophylactic medication (e.g. Tamoxifen), accept.

*See if Relevant* Basal Cell Carcinoma
Cervical Carcinoma in Situ
Surgery
Transfusion

*Additional Information*

Many malignancies spread through the blood stream and by invading surrounding tissues. Viruses that can be spread by blood and tissue donation can also cause some malignancies. For these reasons it is considered safer not to accept blood from people who have had a malignancy. However, because basal cell carcinoma (rodent ulcer) and other Carcinomas in situ do not spread through the blood, people who have had successful treatment may donate. Cervical carcinoma in situ would be defined as cured if treatment is complete and a follow up smear did not show abnormal cells. Regular screening smears are not defined as follow up.

Premalignant conditions are very common, particularly in older donors. Regular monitoring should prevent donors with invasive malignancy from being accepted.

Lentigo Maligna is a common skin condition of the elderly and should be considered a carcinoma in situ and the donor may be accepted once it has been cured. However Lentigo Maligna melanoma is a true malignant melanoma and the donor must be permanently deferred if they have had this condition.

*Reason for Change* Clarification for in situ carcinoma, premalignant conditions and donors at high risk of cancer added.

*Update Information* This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 16

## Malignant Hypertension

*See* Blood Pressure - High

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Malignant Melanoma

*See* Malignancy

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Mantoux Test

*Obligatory* **Must not donate unless:**
Negative and no further investigations planned.

*See if Relevant* Tuberculosis

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Marburg Fever

*See* Viral Haemorrhagic Fever

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 18

## Marfan's Syndrome

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Mastectomy

*See if Relevant* Malignancy

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Measles

### Affected Individual

*See* Infection - Acute

### Contact

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Measles Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Measles Mumps Rubella (MMR) Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Measles Rubella Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Medication (Drugs)

*See* Drug Treatment

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ménière's Disease

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Meningitis

### Affected Individual

*See* Infection - Acute

### Contact

*Discretionary* Even if on prophylactic antibiotics, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Meningococcal Meningitis Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Mental Health Problems

*Obligatory* **Must not donate if:**
Not able to fully understand and consent to the donation process and to the testing of their blood for diseases that may affect its suitability for use.

*See if Relevant* Communication Difficulties

*Additional Information* Many people have mental health problems that can be controlled with regular medication. Providing individuals are well on the day of donation and have the mental capacity to give full informed consent, there is no reason why they cannot donate whether on medication or not. Individuals who are over anxious, depressed, manic or psychotic cannot always give valid consent, or fully understand why they are being asked certain questions.

*Reason for Change* To ensure that all donors with mental health conditions can donate if they are well enough to do so and have the mental capacity to give full informed consent.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 16

## Migraine

*See if Relevant* Headache

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Mitral Valve Prolapse

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Molar Pregnancy

Hydatidiform Mole

*See* Pregnancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## MRSA

Methicillin Resistant Staphylococcus Aureus

*See if Relevant* Infection - General

*Additional Information* Staphylococcus aureus is a widely occurring skin commensal. The carrier status or exposure of the mother is not relevant to donation.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Multiple Sclerosis

*Obligatory* **Must not donate.**

*Additional Information* As the cause of multiple sclerosis is not certain and there is a possibility that there is an underlying infectious agent, donation is not permitted.

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Mumps

### Affected Individual

*See* Infection - Acute

### Contact

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Mumps Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Muscular Dystrophy

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myalgic Encephalomyelitis

*See* Post Viral Fatigue Syndrome

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myasthenia Gravis

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myelodysplastic Syndrome

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myeloproliferative Syndrome

*Obligatory* **Must not donate.**

*Reason for Change* This entry has been added to clarify the eligibility of donors with this condition.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myocarditis

*Obligatory* **Must not donate if:**
a) Not recovered.

b) Occurred during this pregnancy.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myomectomy

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Myxoedema

*See* Thyroid Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Needle-Stick Injury

*See* Inoculation Injury

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Neotigason

Acitretin

*See* Acne
Psoriasis

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Nephrectomy

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Nephritis

*See* Kidney Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Neurofibromatosis

*Obligatory* **Must not donate if:**
History of malignant change.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Neurological Conditions

*See* Central Nervous System Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Neurosurgery

*Obligatory* **Must not donate.**

*Discretionary* a) If carried out in the UK after 1992, providing the reason for the surgery is not itself a reason for exclusion, accept.

b) If burr hole surgery only, accept.

c) If it can be shown that Dura Mater was not used during surgery and there is no evidence of malignancy, the mother may be accepted by a **Designated Medical Officer**.

*See if Relevant* Malignancy
Prion Associated Diseases
Surgery

*Update Information* This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in TDSG-CB Edition 203, Release 02

## Night Sweats

*Obligatory* **Must not donate if:**
Unexplained.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Non-Specific Urethritis

### Acute

*See* Infection - Acute

### Chronic

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Nonsteroidal Anti-Inflammatory Drugs (NSAID)

*Obligatory* Assess reason for treatment and see relevant entry.

*Discretionary* If medication is self prescribed and the mother meets other criteria, accept.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## NSAID

*See* Nonsteroidal Anti-Inflammatory Drugs (NSAID)

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## NSU

*See* Non-Specific Urethritis

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Ocular Surgery

*See if Relevant* Eye Disease
Laser Treatment
Malignancy

Ocular Tissue Recipient

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ocular Tissue Recipient

*Obligatory* **Must not donate if:**
Has received a corneal, scleral or limbal tissue graft or limbal or corneal epithelial cells.

*Additional Information* If the surgery was performed after 1997 and the tissue was supplied through UK Transplant, this information will be stored on the National Transplant Database.

*See* Prion Associated Diseases

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Operations

*See if Relevant* Transfusion

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Orf

Contagious Pustular Dermatitis

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Organ Donor

*Discretionary* Accept.

*See if Relevant* Transfusion

*See* Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Organ Recipient

*See* Tissue and Organ Recipients

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Oseltamivir

*See* Tamiflu®

## Osteoarthritis

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Osteomalacia

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Osteomyelitis

*Obligatory* **Must not donate if:**
Less than two years from completing treatment and cure.

*Additional Information* Sometimes it is difficult to be certain that all infection has been eliminated. Waiting two years minimizes the risk of any infection being passed on by a donation.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Osteoporosis

*See if Relevant* Steroid Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ovarian Cyst

*Obligatory* **Must not donate if:**
Malignant.

*See if Relevant* Malignancy
Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Paget's Disease of Bone

*Including* Osteitis Deformans

*Discretionary* Accept.

*Additional Information* Paget's disease of bone is very common in the UK affecting about 1 in 20 adults aged over 50 years. The cause is not known. Many people with the condition have no symptoms and so will be accepted by the blood and tissue services. There is no evidence that it is spread by donation. It is most commonly treated with painkillers and bisphosphonates. The use of these drugs is accepted for other conditions, so there seems no reason why individuals with Paget's disease of bone on treatment should not be accepted, provided that they are otherwise acceptable.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pain Killers

*Obligatory* Assess reason for treatment and see relevant entry.

**Must not donate if:**
Taken for a serious long-term illness.

*See if Relevant* Nonsteroidal Anti-Inflammatory Drugs (NSAID)

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Paratyphoid

*See* Chronic Infection

*Reason for Change* To replace the entry for paratyphoid with a link to chronic infection. By using a link it will make future changes to the guidelines simpler.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 16

## Peptic Ulcer

*Including* Gastric and Duodenal Ulcer and Erosions

*Obligatory* **Must not donate if:**
Associated with malignant change.

*See if Relevant* Surgery
Transfusion

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pericarditis - Viral

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Peritonitis

*See* Infection - General
Surgery

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Peritonsillar Abscess

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Permanent Make-Up

*See* Body Piercing

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Perthes' Disease

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Petit Mal

*See* Epilepsy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pituitary Extract - Human

*Including* Adrenocorticotrophic Hormone, Follicle Stimulating Hormone, Gonadotrophin, Growth Hormone, Luteinising Hormone, Thyroid Stimulating Hormone.

*Obligatory* **Must not donate if:**
Has ever received injection(s) of Human Pituitary Extract.

*See if Relevant* Growth Hormone
Prion Associated Diseases

*Additional Information* Human Pituitary Extracts have been contaminated with abnormal prions and have led to the spread of Creutzfeldt-Jakob Disease (CJD). They have been used to treat growth hormone deficiency and infertility. They have also been used in diagnostic tests to see if other endocrine glands such as the thyroid and adrenal work normally. They have not been used in the UK since 1985 and it is thought that all those exposed to these extracts have been notified of their

increased risk of CJD. It is uncertain as to when their use stopped in other countries.

Donors that have been given only synthetic pituitary hormones or gonadotrophin made from urine may be accepted.

*Reason for Change* Additional information has been added for clarity.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Platelet Disorder

*Obligatory* **Must not donate if:**
a) Causes excessive bleeding or bruising and could be transmitted by stem cells.
b) Has thromboctocytosis.

*See if Relevant* Haematological Disease
Immune Thrombocytopenia
Thrombocytosis

*Additional Information* Maternal platelet counts in excess of 500 x $10^9$should be repeated. If found to be persistently raised the mother should not be accepted and referred for investigation.

*Reason for Change* Thrombocytosis' and relevant links have been added.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pleurisy

*See if Relevant* Infection - General
Malignancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pneumococcal Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pneumonia

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Pneumothorax

### Spontaneous

*Discretionary* Accept.

### Traumatic

*See* Accident

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Polio Contact

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Polio Injected Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Polio Oral Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Polycythaemia

*Obligatory* **Must not donate.**

*Discretionary* If confirmed as secondary polycythaemia, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Polymyalgia Rheumatica

*See* Autoimmune Disease

*Reason for Change* To include Polymyalgia Rheumatica under Autoimmune Disease.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Porphyria

*Obligatory* **Must not donate if:**
Suffers from porphyria.

*Discretionary* If the potential donor suffers from Acute Intermittent Porphyria (AIP), Varigate Porphyria (VP) or Hereditary Coproporphyria (HCP), accept.

*See if Relevant* Hepatitis

*Additional Information* Porphyria Cutanea Tarda (PCT) is almost always an acquired condition associated with underlying liver disease, usually hepatitis of viral or unknown origin.

Erythropoietic Protoporphyria (EPP) and Congenital Erythropoietic Porphyria (CEP) have porphyrins in the red cells causing the red cell life span to be reduced.

*Reason for Change* This is a new guideline.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 10

## Post Viral Fatigue Syndrome

*Including* Myalgic Encephalopathy (ME) and Chronic Fatigue Syndrome (CFS)

*Obligatory* **Must not donate if:**
a) Not resolved.

b) Affected during this pregnancy.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Pregnancy

*Obligatory* **Must not donate if:**
a) Resulted in a malignant (invasive) Hydatidiform mole.

b) Resulted in a non-malignant (non-invasive) Hydatidiform mole and treatment and follow up is ongoing.

*See if Relevant* Surgery
Transfusion

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Prion Associated Diseases

*Including* Sporadic, Familial and Variant Creutzfeldt-Jakob Disease (CJD), Gerstmann-Strãussler-Scheinker Disease and Fatal Familial Insomnia

*Obligatory* **Must not donate if:**
**1.** Diagnosed with any form of CJD, or other human prion disease.

**2.** Identified at increased risk of developing a prion associated disorder.
This includes:
a) Individuals at familial risk of prion-associated diseases (have had two or more blood relatives develop a prion-associated disease or have been informed following genetic counselling they

are at risk).

b) Individuals who have been told that they have been put at increased risk from surgery, transfusion or transplant of tissues or organs.

c) Individuals who have been told that they may be at increased risk because a recipient of blood or tissues that they have donated has developed a prion related disorder.

d) Recipients of dura mater grafts.

e) Recipients of corneal, scleral or other ocular tissue grafts.

f) Recipients of human pituitary derived extracts.

g) **Since January 1st 1980**Recipients of any allogeneic human tissue.

*Discretionary* If the mother has had two or more blood relatives develop a prion-associated disease and, following genetic counselling, they have been informed that they are not at risk, accept. This requires confirmation by a **Designated Medical Officer**.

*See if Relevant* Pituitary Extract - Human
Tissue and Organ Recipients
Transfusion

*Additional Information* See the Position Statement on Creutzfeldt-Jakob Disease available in the JPAC Document Library.

*Reason for Change* To reflect guidance from the Committee on the Microbiological Safety of Blood Tissues and Organs. There is the same concern over a possible second wave of cases of vCJD from accepting donors who have received tissue or organ transplants, as there is over donors who have been previously transfused.

*Update Information* This is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 21

## Proctitis

*Obligatory* **Must not donate if:**
a) Due to ulcerative colitis.

b) Crohn's disease.

c) Requiring treatment.

*Discretionary* If due to other causes and not on treatment, accept.

*See if Relevant* Inflammatory Bowel Disease
Radiation Therapy

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Prostitutes

*Obligatory* **Must not donate.**

*See if Relevant* Tissues Safety Entry

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Psoriasis

*Obligatory* **Must not donate if:**
a) Has ever taken Etretinate (Tigason).

b) Less than 24 months from the last dose of Acitretin (Neotigason).

c) Generalized or severe.

d) Associated with arthropathy.

e) There is secondary infection.

*Discretionary* If mild and only using topical treatment, accept.

*Additional Information* Psoriasis is primarily a skin condition caused by an autoimmune process. About one in ten people with psoriasis may develop joint problems (psoriatic arthropathy). Sometimes the disease is treated with powerful drugs to suppress the underlying autoimmune process. This may alter the body's defence mechanisms to infection. In such cases donations should not be taken.

*See* Autoimmune Disease

*Reason for Change* There has been an increase in the deferral period after using acitretin (Neotigason®) from 12 to 24 months.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 13

## Psychiatric Problems

*See* Mental Health Problems

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Pulmonary Embolism

*Discretionary* Accept.

*See if Relevant* Malignancy

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Pyelonephritis

*See* Infection - General

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Pyrexia

### Not Related to Travel in Malarious Areas

| | |
|---|---|
| *Obligatory* | **Must not donate if:**<br>Less than two weeks from an episode of pyrexia. |
| *Discretionary* | If related to a common cold or other upper respiratory tract infection from which the mother is now recovered or recovering, accept. |
| *See if Relevant* | Infection - General |
| *Additional Information* | A raised temperature may be a sign of an infection, which could be passed on through a donation. Waiting two weeks from when the temperature returns to normal reduces the risk of infection being transmitted by the donation.<br><br>There is no evidence that common colds and upper respiratory tract infections can be passed on by donation but it is still necessary to wait until any such infection is obviously getting better before allowing donation. |

### Related to Travel in Malarious Areas

| | |
|---|---|
| *See* | Malaria |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Pyruvate Kinase Deficiency

| | |
|---|---|
| *Obligatory* | **Must not donate if:**<br>Mother and father have symptomatic disease. |
| *Discretionary* | Unless mother and father both have symptomatic disease, accept. |
| *Additional Information* | This is an autosomal recessive red cell enzyme deficiency that is variable in its severity. This means it only has relevance if both parents have symptomatic disease. |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Q Fever

| | |
|---|---|
| *Obligatory* | **Must not donate.** |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Quinsy

| | |
|---|---|
| *See* | Infection - Acute |
| *Update Information* | This entry was last updated in<br>TDSG-CB Edition 203, Release 02 |

## Rabies

### Infection

*Obligatory* **Must not donate.**

*See if Relevant* Animal Bite

### Immunization - Post Exposure

*Obligatory* **Must not donate until:**
At least 12 months post exposure and fully cleared by treating physician.

### Immunization - Non-exposed

*Discretionary* If non-exposed, accept.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Radiation Therapy

*Obligatory* **Must not donate if:**
a) For malignancy other than basal cell carcinoma.

b) For other treatments:
**Refer to a Designated Medical Officer.**

*See if Relevant* Basal Cell Carcinoma
Malignancy

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Radionuclides

*Obligatory* **1. Radioactive iodine therapy:**
**Must not donate if:**
a) For malignancy.

b) Administered in this pregnancy or the preceding six months.

2. Other treatment or investigation:
**Refer to a Designated Medical Officer.**

*See if Relevant* Malignancy
Thyroid Disease

*Additional Information* In general those used for diagnostic purposes are cleared within 24 hours. Some, e.g. radioactive iodine, have long half-lives and affected mothers must not be accepted.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Raynaud's Syndrome

*Obligatory* **Must not donate if:**
Part of a multisystem disorder.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Recipients of Normal Human Immunoglobulin

*See if Relevant* Hepatitis A
Immunosuppression
Immunoglobulin Therapy

*See* Transfusion

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Relapsing Fever

*See* Infection - Acute

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Relenza®

*Approved Name* Zanamivir

*Obligatory* **Must not donate if:**
a) Taking Relenza® as treatment for influenza.

b) At any time in the seven days prior to, or while taking Relenza®, has had symptoms of influenza, (a temperature of greater than 38°C, or a history of fever and two or more of the following symptoms: cough, headache, runny nose, diarrhoea/vomiting).

*Discretionary* If taking Relenza® as prophylaxis, they have not been advised to be confined to home and have not had any symptoms of influenza, accept.

*See if Relevant* Infection - Acute

*Additional Information* Relenza® is a viral neuraminidase inhibitor (neuraminidase is an enzyme that helps the virus spread from cell to cell). It is used to treat influenza and for post-exposure prophylaxis of influenza. It appears to be a very safe drug with little evidence for teratogenic (potential to cause birth defects) or mutagenic (potential to cause malignancy) effect.

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in:
TDSG-CB Edition 203, Release 04.

## Renal Colic

*Obligatory* **Must not donate if:**
a) Symptomatic.

b) Under investigation.

*See if Relevant* Infection - General

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Renal Disease

*See* Kidney Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Respiratory Disease

*See if Relevant* Infection - General
Steroid Therapy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Resurfacing of Hip

*See* Surgery
Tissue and Organ Recipients

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Retinitis Pigmentosa

*Discretionary* Accept.

*See if Relevant* Disabled Mother

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Rheumatic Fever

*Discretionary* Accept.

*See if Relevant* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Rheumatoid Arthritis

*Discretionary* If mild and the only treatment is NSAIDs, accept.

*See* Autoimmune Disease

*Reason for Change* This entry is now linked to 'Autoimmune Disease'.

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Ringworm

*Obligatory* **Must not donate if:**
On systemic treatment.

*Discretionary* If on local treatment only, accept.

*See if Relevant* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Risk Factors

*See* Tissues Safety Entry

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Roaccutane

Isotretinoin

*See* Acne

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Rodent Ulcer

*See* Basal Cell Carcinoma

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Rubella

### Acute Infection

*See* Infection - Acute

### Contact

*See* Infectious Diseases - Contact with

### Congenital

*Obligatory* **Must not donate if:**
Baby has congenital rubella.

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Rubella Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Salpingitis

*See if Relevant* Sexually Transmitted Disease

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Sandfly Fever

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Sarcoidosis

### Acute

*Obligatory* **Must not donate if:**
a) Not recovered.

b) Less than five years from both finishing all treatment and full recovery.

*Discretionary* If more than five years since finishing all treatment and full recovery, accept.

*Additional Information* Acute sarcoidosis is normally a self limiting disease and does not require treatment in about 90% of cases. The cause is not known but there appears to be an immune defect that can run in families. Because of the uncertainty with this condition, only potential donors who have fully recovered and been off all treatment for at least five years may donate.

*Reason for Change* To align the guidance with that for blood donors, new guidance to accept donors who required treatment but who have made a full recovery and have been off all treatment for at least five years has been added.
'Additional Information" has been added.

### Chronic

*Obligatory* **Must not donate.**

*Additional Information* Chronic sarcoidosis can cause a range of problems, particularly with the lungs but also with the heart, that may pose risks for a potential donor. The treatments used may also cause immunosuppression. For these reasons people with this condition should not donate.

*Reason for Change* 'Additional Information' has been added.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 16

## SARS (Severe Acute Respiratory Syndrome)

*Obligatory* **Must not donate if:**
a) Less than 21 days from leaving a country to which the Department of Health (DH) has advised deferring travel, because there is, or is thought to be, ongoing transmission of SARS.

b) Less than 21 days from last contact with a person with SARS.

c) Less than three months since recovery from SARS or possible SARS.

*Discretionary* If more than 21 days has passed since return from a SARS endemic area, or from the last contact with a person affected by SARS and the donor has remained well, accept

*Additional Information* Since 2004 there have not been any known cases of SARS reported anywhere in the world. Although the threat of SARS to public health seems to have passed, international health officials continue to remain vigilant. The World Health Organization (WHO) monitors countries throughout the world for any unusual disease activity.

*Reason for Change* Under 'Additional Information' the extant entry states "DH advice can be found at: www.dh.gov.uk/PolicyAndGuidance/HealthAdviceForTravellers/fs/en under 'Latest health updates'." The site that this link used to go to no longer exists.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Schistosomiasis

*See* Infection - Acute

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Sclera Recipient

*See* Ocular Tissue Recipient

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Scleritis

*See* Inflammatory Eye Disease

*Reason for Change* To include an entry for 'Scleritis'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Self-Catheterization

*Obligatory* **Must not donate.**

*Additional Information* Mothers who need to self-catheterize are likely to have bacteraemia following the procedure. Bacteria in a donation can lead to severe and even fatal reactions.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Semi-Permanent Make-Up

*See* Body Piercing

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Sexually Transmitted Disease

### Infection

*Obligatory*

**See:**
Is there is a specific entry for the disease?

**Must not donate if:**
Less than 12 months from completing treatment.

*See if Relevant*

Tissues Safety Entry
Chlamydia
Genital Warts
Herpes - Genital
Syphilis

### Sexual Partner

*Obligatory*

**See:**
Is there is a specific entry for the disease with which there has been contact?

**Must not donate if:**
a) Mother required treatment and it is less than twelve months since completing that treatment.

b) Mother did not require treatment and it is less than 12 months from the last sexual contact with the infected partner.

*Discretionary* Donor did not require treatment and it is more than 12 months since the infected partner has completed treatment, accept.

*See if Relevant*

Tissues Safety Entry
Chlamydia

Genital Warts
Herpes - Genital
Syphilis

*Reason for Change* Further discretionary advice has been added to allow acceptance of donors whose partners have completed treatment over 12 months ago for syphilis.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 08

## Shingles

### Affected Individual

*See* Herpes Zoster

*Reason for Change* The links have been changed for clarity.

### Contact

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Sickle-Cell Disease

*See* Haemoglobin Disorders

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Sickle-Cell Trait

*Obligatory* **Inform Transplant Centre if:**
Cells are from a baby that has sickle-cell trait.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Skin Cancer

*See* Malignancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Skin Disease

*Obligatory* **Must not donate if:**

a) The condition is infected or infectious.

b) Malignant.

*Discretionary* If malignancy was a Basal Cell Carcinoma and treatment is completed, accept.

*See if Relevant*
Acne
Dermatitis
Infection - General
Malignancy
Psoriasis

*Reason for Change* Malignancy' has been added to 'Obligatory' and additional links have been included.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Sleeping Sickness

(African Trypanosomiasis)

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Smallpox Immunization

### Immunized Individual

*Obligatory* **Must not donate if:**
Inoculated during pregnancy.

*Additional Information* Smallpox immunization is with live virus. We do not want to pass the virus on to people receiving stem cells.

### Contacts

*Obligatory* **Must not donate if:**
Secondarily inoculated during this pregnancy.

*Discretionary* If no new skin lesions, accept.

*Additional Information* Close contacts of vaccinees (household or direct bodily contact) may become secondarily infected from direct skin contact with an infected inoculation site or from virus on clothing, bedding, dressings etc. If infection occurs, a new skin rash, blister or sore appears at the site of contact, which could be anywhere on the body. The rash represents a secondary vaccination site and presents exactly the same potential risk to patients and staff as that of a person who has been intentionally immunized.

*Update Information* This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Snake Bite

*Obligatory* **Must not donate until:**
Recovered.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## South American Trypanosomiasis

*Obligatory* **Must not donate.**

*See if Relevant* South American Trypanosomiasis Risk

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## South American Trypanosomiasis Risk

*Obligatory* **Must not donate if:**
a) Mother was born in South America or Central America (including Southern Mexico).

b) Mother's mother was born in South America or Central America (including Southern Mexico).

c) Has had a transfusion in South America or Central America (including Mexico).

d) Mother has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.

*Discretionary* a) For situations other than transfusion, if at least six months from the date of the last exposure, a validated test for T. cruzi antibody is negative, accept.

b) If transfused before 1st January 1980 and a validated test for T. cruzi antibody is negative, accept.

*See if Relevant* Geographical Disease Risk Index for countries with T. cruzi risk
Transfusion

*Additional Information* Infection with T. cruzi is very common in many parts of South or Central America and is often symptomless. It can be passed from an infected mother to her unborn baby and by transfusion. The insect that passes the infection on is only common in rural areas and the greater time that an individual has spent living in housing conditions with thatched roofs or mud lined walls which harbour the insect vector, the greater their risk of becoming infected. Testing is available and should be performed if there is a possibility of infection. Waiting six months from the last time of exposure allows time for the antibodies that are tested for to develop.

Camping or trekking in the jungle in South or Central America (including Southern Mexico) is not considered of high enough risk to merit exclusion.

*Reason for Change* 'Additional Information' has been added.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 16

## Spherocytosis

*See* Hereditary Spherocytosis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Spina Bifida

*Obligatory* **Must not donate if:**
a) Has an indwelling shunt.

b) Uses a catheter.

c) Has a pressure sore.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Spinal Surgery

*See if Relevant* Neurosurgery
Surgery
Transfusion

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Splenectomy

*Obligatory* **Must not donate if:**
a) For malignancy.

b) For a myeloproliferative disorder.

c) For immune thrombocytopenia (ITP).

d) For haemolytic anaemia.

*Discretionary* a) If for trauma, when recovered accept.

b) If taking prophylactic antibiotics, accept.

c) Discretions are available to accept donors with **Haemolytic Anaemia** and **Immune Thrombocytopenia**.

*See if Relevant* Immune Thrombocytopenia
Malignancy
Surgery
Transfusion

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Squamous Cell Carcinoma

*See* Malignancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Steroid Therapy

*Obligatory* **Must not donate if:**

a) Regularly taking steroid tablets, injections or enemas, or applying creams over large areas.
b) The mother has needed treatment to suppress an autoimmune condition in the last 12 months.
c) Less than seven days after completing a course of oral or injected steroids for disorders associated with allergy.
d) The mother has infected perineal dermatitis

*Discretionary* a) If occasional use of creams over small areas of skin for minor skin complaints, accept.
b) If using steroid inhalers for prophylaxis, accept.
c) The short term administration of steroids to the mother to induce fetal lung maturation is not an exclusion to donation, accept.

*See if Relevant* Autoimmune Disease
Skin Disease
Tissue and Organ Recipients

*Additional Information* Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation.

*There is no evidence that the short-term use of steroids to induce fetal lung maturation can mask or increase the risk of maternal infection.*

*Reason for Change* To allow mothers who receive short term administration of steroids to induce fetal lung maturation to donate.

*Update Information* Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Stroke

*Discretionary* Accept.

*See if Relevant* Disabled Mother

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Subacute Bacterial Endocarditis

SBE

*See* Endocarditis

*Reason for Change* This entry is replaced by the entry for 'Endocarditis'. It recognizes that the cause of endocarditis is not always bacterial and the course is not always subacute.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Surgery

*Definition*

**Major Surgery:**
Any surgical procedure that required an inpatient stay of more than five nights or involved the use of a flexible endoscope.

*Obligatory*

**Must not donate if:**
a) For malignancy.

b) All wounds are not healed.

c) There is any infection.

d) Normal mobility has not been regained.

e) Less than six months from major surgery.

f) Less than seven days from other surgery.

g) Requiring post-operative treatment, or attending hospital regularly.

*Discretionary*

**1.** If for Cervical Carcinoma in Situ (CIN) or Basal Cell Carcinoma and all other criteria are fulfilled, accept.

**2. Major surgery:**
a) If more than four months from the procedure and NAT for HCV is performed, accept.

b) If less than four months from the procedure, discuss with the **Designated Medical Officer** who will decide if the mother may be accepted on a balance of risks. The risk analysis must be discussion with the Transplant Centre.

*See if Relevant*

Basal Cell Carcinoma
Cervical Carcinoma in Situ
Neurosurgery
Ocular Surgery
Tissue and Organ Recipients
Transfusion
Xenotransplantation

*Additional Information*

Surgery may place the mother at risk of infection, either from unhealed wounds or due to infection risks from infected staff or equipment. Although these risks are very small it is important to wait long enough for the risks to have gone or until the tests performed by the Blood & Tissues Services can pick up any infection that they test for that may have been transmitted to the mother by surgery.

*Reason for Change*

The 'Discretionary" entry has been modified and a link to 'Ocular Surgery' has been added.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Syphilis

*Obligatory*

**Must not donate.**

*Discretionary*

If fully treated in the past and confirmatory tests exclude recent infection, discuss with a **Designated Medical Officer**.

*Additional Information*

The interpretation of syphilis testing is often difficult. The advice of an experienced microbiologist may be required before a decision on safety can be made.

*Reason for Change*

The 'Discretionary' entry has been modified.

'Additional Information' has been added.

*Update Information*

Part of this advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in

TDSG-CB Edition 203, Release 02

## Syphilis Sexual Contact

*See* Sexually Transmitted Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Systemic Lupus Erythematosus

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Tamiflu®

*Also Known As* Oseltamivir

*Obligatory* **Must not donate if:**

a) Taking Tamiflu® as treatment for influenza.

b) At any time in the seven days prior to, or while taking Tamiflu®, has had symptoms of influenza, (a temperature of greater than 38°C, or a history of fever and two or more of the following symptoms: cough, headache, runny nose, diarrhoea/vomiting).

*Discretionary* If taking Tamiflu® as prophylaxis, they have not been advised to be confined to home and have not had any symptoms of influenza, accept.

*See if Relevant* Infection - Acute

*Additional Information* Tamiflu® is a viral neuraminidase inhibitor (neuraminidase is an enzyme that helps the virus spread from cell to cell). It is used to treat influenza and for post-exposure prophylaxis of influenza. It appears to be a very safe drug with little evidence for teratogenic (potential to cause birth defects) or mutagenic (potential to cause malignancy) effect.

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in: TDSG-CB Edition 203, Release 04.

## Tamoxifen

*Obligatory* **Must not donate:**

a) If used for malignancy.

b) While taking tamoxifen for non-malignant conditions.

*See if Relevant* Infertility

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Tattoo

*See* Body Piercing

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Temporal Arteritis

*See* Autoimmune Disease

*Reason for Change* The entry has been changed for consistency from 'Must not donate' to 'See Autoimmune Disease'.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Tetanus Immunization

*Obligatory* **Must not donate if:**
Less than four weeks from exposure.

*Discretionary* If non-exposed, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thalassaemia Major

*See* Haemoglobin Disorders

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thalassaemia Trait

*See* Haemoglobin Disorders

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Therapeutic Venesection

*Obligatory* **Must not donate.**

*Discretionary* If for haemochromatosis or confirmed secondary polycythaemia, accept.

*See if Relevant* Haemochromatosis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Threadworms

*Discretionary* Even if on treatment, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thrombocytosis

*Obligatory* **Must not donate if:**
Due to a myeloproliferative disorder.

*Additional Information* Platelet counts in excess of 500 x 10e9/l should be repeated. If found to be persistently raised the donor should not be accepted and referred for investigation.

*Reason for Change* This entry has been added to clarify the eligibility of donors with this condition.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thrombosis

*Discretionary* If the underlying cause does not exclude, accept.

*See if Relevant* Malignancy

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thrush - Oral

*Obligatory* **Must not donate if:**
a) Unexplained.

b) Related to immunodeficiency.

c) Less than seven days after completion of treatment.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thrush - Vaginal

*Obligatory* **Must not donate if:**
a) Related to immunodeficiency.

b) Less than seven days after receiving systemic therapy.

*Discretionary* If not related to immunodeficiency, even if using local therapy, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Thyroid Disease

*Obligatory* **Must not donate if:**
a) Under investigation.

b) Malignant.

c) Radioactive iodine administered in this pregnancy or the preceding six months.

d) Less than 24 months from stopping treatment with anti-thyroid tablets.

*See if Relevant* Autoimmune disease
Surgery

*Reason for Change* The reference in 'Discretionary' to treatment with thyroxine has been removed.

A link to 'Autoimmune Disease' has been added.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Thyroxine

*See* Thyroid Disease

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tick-Borne Encephalitides

*See* Infection - Acute

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tick-Borne Encephalitis Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tigason

Etretinate

*Obligatory* **Must not donate if:**
Has ever taken Etretinate (Tigason).

*See if Relevant* Acne
Psoriasis

*Reason for Change* The entry has been changed to be the same as for Etretinate.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tissue and Organ Recipients

*Obligatory*

**Must not donate if:**
**1. At any time:**
a) Has needed immunosuppression.

b) Dura mater transplanted.

c) Ocular tissue transplanted.

d) Xenotransplant performed.

**2. Since January 1st 1980:**
**Refer to a Designated Medical Officer** if the mother has received an allogeneic tissue transplant.

*Discretionary*

**1.** a) If an allogeneic tissue transplant was performed before January 1st 1980 and there is no other reason to exclude the mother, accept.

b) If at anytime a non-stored autologous tissue or organ has been transplanted, accept.

**2. Mother who has received an allogeneic tissue transplant since January 1st 1980**
The full transplant/transfusion history must be recorded and remain part of the documentation associated with the donation. The donation may only be issued after a documented risk assessment has been performed by the **Designated Medical Officer**. This must take into account the availability of alternative donors, the risks of vCJD transmission and the expected benefits of using a particular donation.

*See if Relevant*

Immunosuppression
Ocular Tissue Recipient
Prion Associated Diseases
Xenotransplantation

*Additional Information*

The transfer of tissues or organs between individuals and species has lead to the spread of infection. The above guidelines are intended to minimize these risks.

There is now a concern that this could also happen with vCJD. This is because in the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD.
In view of this, people who have received a tissue or organ transplant since 1980 are now required to have a risk assessment performed. This date is before BSE, which is believed to have caused vCJD, was prevalent. The **Designated Medical Officer** should consider the availability of alternative donors and discuss the risks and benefits with the physician of the intended recipient. This risk assessment should be shared with the recipient, or their next of kin as appropriate.

*See*

Surgery
Transfusion

*Reason for Change*

To reflect guidance from the Committee on the Microbiological Safety of Blood Tissues and Organs. There is the same concern over a possible second wave of cases of vCJD from accepting donors who have received tissue or organ transplants, as there is over donors who have been previously transfused.

The term 'Xenotransplant' has replaced 'Animal tissue' under **Must not donate if:**.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tissue Recipient

*See*

Tissue and Organ Recipients

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tissues Safety Entry

*Obligatory*

Information must be provided so that those at risk do not donate.

**1. You must not donate if:**
You think you need a test for HIV/AIDS, HTLV or hepatitis.

**2. You must never donate if:**
a) You are HIV positive
b) You are HTLV positive
c) You are a hepatitis B carrier
d) You are a hepatitis C carrier
e) You have ever received money or drugs for sex
f) You have ever injected, or been injected with, drugs; even a long time ago or only once. This includes bodybuilding drugs and injectable tanning agents. You may be able to give if a doctor prescribed the drugs. Please ask.

**3. You must not donate for at least 12 months after sex (even if you used a condom or other protective) with:**
A partner who is, or you think may be:
a) HIV or HTLV positive
b) A hepatitis B carrier
c) A hepatitis C carrier
d) A partner who has ever received money or drugs for sex
e) A partner who has ever injected, or been injected with, drugs: even a long time ago or only once. This includes bodybuilding drugs. You may be able to give if a doctor prescribed the drugs, please ask.
f) A partner who has been, or you think may have been, sexually active in parts of the world where HIV/AIDS is very common. This includes most countries in Africa. There are exceptions, so please ask.

**4a. For donors of haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:**

There are no specific restrictions regarding donation after male-sex-with-male sexual contact, instead a documented individual risk/benefit donor assessment is required.

**4b. For donors of tissues/cells other than haematopoietic progenitor cells, pancreatic islet cells or hepatocytes:**

**You must not donate for at least 12 months after sex (even if you used a condom or other protective) with:**
a) (If you are a man): another man.
b) (If you are a woman): A man who has ever had oral or anal sex with another man, even if they used a condom or other protective.

*See if Relevant*

Addiction and Drug Abuse
Homosexual and Bisexual Individuals
Hepatitis of Viral Origin
HIV
HTLV
Infection - General

*Additional Information*

The guidance has been changed in line with recommendations from the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). The recommendations have been noted by the English Department of Health and the devolved authorities in Scotland, Wales and Northern Ireland.

*Reason for Change*

For haematopoietic progenitor cells, pancreatic islet cells or hepatocytes to place no specific restrictions regarding donation after male-sex-with-male sexual contact. Instead to ensure that a documented individual risk/benefit donor assessment is required to allow donation.

For other banked tissues/cells (eg amnion, bone, cornea ,heart valves, skin and tendon) to remove the current lifetime deferral and allow donation 12 months after last male-sex-with-male sexual contact.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Toctino

*See* Alitretinoin

*Reason for Change* New entry.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 16

## Toxoplasmosis

*Obligatory* **Must not donate if:**
a) Maternal recovery less than six months before this pregnancy.

b) Mother not shown to be IgM negative.

*Additional Information* This is a common parasitic infection, often spread by cat faeces or eating undercooked meat. It can be spread through transfusion. It may have serious consequences or even prove fatal for the recipient. Usually it does not cause symptoms, as the body's immune system easily overcomes the parasite. If the infection has caused symptoms that has lead to it being diagnosed, waiting six months from recovery will make it unlikely that it will be passed on by donation.

*Reason for Change* Entry has been simplified following a risk assessment by SACTTI.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 13

## Transfusion

*Including* Treatment with Blood Components, Products and Derivatives.

*Obligatory* **1. Must not donate if:**
**At any time the mother has:**
a) Received, or thinks they may have received, a transfusion of blood or blood components in a country endemic for malaria or South American trypanosomiasis.

b) Treated with blood derived coagulation factor concentrates. This includes prothrombin complex to reverse over-anticoagulation.

c) Intra-uterine transfusion has been required in this pregnancy.

**2. Refer to a Designated Medical Officer if:**
**Since January 1st 1980:**
a) Anywhere in the world, the mother has received, or thinks they may have received, a transfusion with red cells, platelets, fresh frozen plasma (FFP), cryoprecipitate, intravenous or subcutaneous human normal immunoglobulin. This includes mothers whose previous babies have required intra-uterine transfusion.

b) Had a plasma exchange performed.

*Discretionary* **1.** a) If on medical inquiry it is unlikely that the mother has been transfused, accept.

b) If treatment with human immunoglobulin has been limited to small quantities of specific

immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept.

**2. Autologous Transfusion in the United Kingdom:**
If **only** the mother's own blood has been used, accept.

**3. Mother transfused before 1st January 1980 in a country endemic for malaria or South American trypanosomiasis:**
a) If the mother received, or thinks they may have received, before 1st January 1980 a transfusion in a country endemic for malaria or South American trypanosomiasis check the Geographical Disease Risk Index. If transfused in an at risk country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, accept.

b) If the transfusion was not within a risk area for either malaria or South American trypanosomiasis, accept.

**4. Mother or foetus from an earlier pregnancy transfused since January 1st 1980:**
Discuss with the **Designated Medical Officer** who will decide if the donation may be accepted. The full transfusion history must be recorded and remain part of the documentation associated with the donation. The donation may only be issued after a documented risk assessment has been performed. This must take into account the availability of alternative donors, the risks of vCJD transmission and the expected benefits of using a particular donation.

*See if Relevant*

Bleeding Disorder
Immunoglobulin Therapy
Immunosuppression
Malaria
Prion Associated Diseases
South American Trypanosomiasis Risk
Geographical Disease Risk Index

*Additional Information*

**Transfused mothers** have previously contributed to the spread of some diseases. This happened with hepatitis C.

**All transfused mothers:**
Transfusions in some countries may have put the mother at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections before accepting the cord blood.

**Coagulation concentrates:**
People who have received blood derived coagulation concentrates (these are made from the blood of many donors) may have been put at risk of infections that can be passed through blood.

**Mothers transfused since 1980:**
In the autumn of 2003 a UK recipient of blood, taken from a healthy donor who later developed vCJD, died from vCJD. Since then there have been several cases of infection with the vCJD prion in recipients of blood from donors who have later developed vCJD. The risk of transplacental infection of a foetus with abnormal prion is not known but, even though it is thought to be small, can not be ignored.
In view of this, mothers transfused or possibly transfused since 1980 must have a documented risk assessment performed. This date is before BSE, which is believed to have caused vCJD, was prevalent. The assessment should be discussed with the physician of the intended recipient and should be shared with the recipient, or their next of kin as appropriate.

*Reason for Change*

To reflect guidance from the Committee on the Microbiological Safety of Blood Tissues and Organs. There is concern over a possible second wave of cases of vCJD from accepting donors who have been previously transfused.

*Update Information*

This entry was last updated in
TDSG-CB Edition 203, Release 02

## Trauma

*See*

Accident

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Travel

*See if Relevant*
Geographical Disease Risk Index
Malaria
South American Trypanosomiasis Risk
Infection - Tropical

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Tropical Areas

*See*
Infection - Tropical
Geographical Disease Risk Index

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Tropical Diseases

*See*
Infection - Tropical

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Tropical Viruses

*Definition* To include Dengue Virus, Dengue Fever and Chikungunya Virus, also known as CHIKV, Zika Virus and Zika Virus Fever..

**Tropical Virus endemic areas** are shown in the Geographical Disease Risk Index (GDRI) as a Tropical Virus Risk.

*Obligatory*
**Must not donate if:**
a) A mother has been diagnosed with chikungunya, dengue or zika virus infection whilst in an endemic area or following her return to the UK during this pregnancy.

b) A mother has either had a history of symptoms suggestive of chikungunya, dengue or zika virus infection whilst in an endemic area or following her return to the UK during this pregnancy.

c) In other cases it is less than four weeks from a mother's return from a Tropical Virus Risk endemic area.

*See if Relevant*
Geographical Disease Risk Index
Malaria
South American Trypanosomiasis Risk
Infection - Tropical

*Additional Information* Chikungunya is an alpha virus that can cause a wide spectrum of disease. This may range from no or minimal symptoms to death. Most commonly it causes arthritis (typically in the knee, ankle and small joints of the extremities), high fever, and a maculopapular rash.

It is geographically widespread but has reached epidemic proportions in parts of India and islands in the Indian Ocean since 2005. It is known to be spread by blood in symptomatic cases and on theoretical grounds could be spread by transfusion and transplantation of tissues and organs from people with pre-symptomatic or asymptomatic disease. A number of visitors returning from endemic areas to the UK have been diagnosed with this infection.

Dengue Virus is a flavivirus that typically gives rise to abrupt high fever with a range of accompanying symptoms. Dengue fever (DF) is the most common arthropod borne disease worldwide. Dengue is currently considered endemic in approximately 128 countries.

Overall, 15-90% of cases may have an asymptomatic course of infection, but clinical presentation varies with age group. However there is a risk of change in disease presentation and potential for increased incidence of more severe disease in older age groups due to co-circulation of different dengue types and emergence of new types in endemic areas patterns.

Zika virus is a flavivirus that is transmitted to humans through the bite of a carrier mosquito. Zika infection is a rapid acute infection that in the majority of cases is asymptomatic or has very mild general symptoms. A small number of cases may have more apparent symptoms but hospitalisation is rare. Zika infection may be mistaken for Chikungunya or Dengue infections as the virus often co-circulate.

The main vector for chikungunya virus, dengue virus and zika virus is Aedes aegypti (Aedes albopictus is another emerging vector), which is found worldwide between latitudes 35ºN and 35ºS. There is no epidemiologically important animal reservoir for Chikungunya, Dengue or Zika viruses. The main areas affected by all 3 viruses include the Caribbean, South and Central America, Mexico, Africa, the Pacific Islands, SE Asia, Indian sub-continent, Hawaii. Additionally Dengue fever has been reported in Japan and Australia.

As the problem can vary both in relation to geography and time of the year it is not possible to state areas from which donors need to be deferred and dates of disease activity. These are provided in the Geographical Disease Risk Index.

Position statements are available in the JPAC Document Library.

*Information* This entry is compliant with the Blood Safety and Quality Regulations 2005.

*Reason for Change* Information about Zika virus has been added

*Update Information* This entry was last updated in:
TDSG-CB Edition 203, Release 22.

## Trypanosoma Cruzi Infection

*Obligatory* **Must not donate.**

*See if Relevant* South American Trypanosomiasis Risk

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tuberculosis

### Affected Individual

*Obligatory* **Must not donate if:**
a) Infected.

b) Less than 24 months from confirmation of cure.

c) Under follow-up.

*See if Relevant* BCG
Heaf Test
Mantoux Test

### Contact

*Obligatory* **Must not donate until:**
Screened and cleared.

*Discretionary* If the mother has been informed that they do not need to be screened, accept.

*See if Relevant* BCG
Heaf Test
Mantoux Test

*Additional Information* Tuberculosis can be present in many tissues and be spread through the blood stream. It is sensible to exclude mothers who may have active disease from donating to prevent any possibility of transmitting the infection.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Tumour Chemotherapy

*See* Malignancy

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Turner's Syndrome

*Discretionary* Accept.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Typhoid

*See* Chronic Infection

*Reason for Change* To replace the entry for typhoid with a link to chronic infection. By using a link it will make future changes to the guidelines simpler.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 16

## Typhoid Injected Immunization

*See* Immunization - Non-Live

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Typhoid Oral Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Ulcerative Colitis

*See* Inflammatory Bowel Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Urethritis (Non-Specific)

*See* Non-Specific Urethritis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Urinary Tract Infection

*See* Infection - General

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Vaccination

*See* Immunization

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Vasculitis

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Viral Disease

*See* Infection - General

*Update Information* This entry was last updated in

TDSG-CB Edition 203, Release 02

## Viral Haemorrhagic Fever

### 1. Affected Individual

*Obligatory* **Must not donate**

### 2. Contact or traveller to endemic country

*Obligatory* **Must not donate if:**

Less than 6 months from last contact with an affected individual or travel to an endemic country.

*Discretionary* If more than 6 months from last contact, completion of investigations or return to the UK from endemic country, accept

*See if Relevant* The Geographical Disease Risk Index for countries with a current endemic Viral Haemorrhagic Fever risk

*Additional Information* These infections have very high death rates and there is evidence that the virus may persist for some time after recovery.

*Reason for Change* Guidance for travellers to endemic countries and contacts with these infections has been updated.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 22.

## Vitamin Treatment

*Discretionary* Accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Vitiligo

*See* Autoimmune Disease

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Von Recklinghausen's Disease

*See* Neurofibromatosis

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Von Willebrand's Disease

*See* Bleeding Disorder

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## Warts

*Discretionary* Even if on local treatment, accept.

*Update Information* This entry was last updated in TDSG-CB Edition 203, Release 02

## West Nile Virus

*Definition* **West Nile Virus (WNV) Endemic Areas:**
These are shown in the 'Geographical Disease Risk Index' (GDRI).

*Obligatory* **Must not donate if:**
a) It is less than six months from a donor's return from a WNV endemic area and the donor has been diagnosed with WNV whilst there or following their return.

b) It is less than six months from a donor's return from a WNV endemic area and the donor has either had a history of symptoms suggestive of WNV whilst there or within 28 days of their return.

c) In other cases it is less than four weeks from a donor's return from a WNV endemic area.

*Discretionary* 1) All donors may be accepted six months after their return from an affected area. This may be reduced to four weeks if they have had neither symptoms nor evidence of infection. For donors who have been back in the UK for less than four weeks, who have not been diagnosed with WNV infection and who have not had symptoms suggestive of WNV infection, if a validated NAT for WNV is to be undertaken on the donated component(s), accept.

2) Donors who have been back in the UK for less than six months, who have had symptoms suggestive of WNV infection while abroad or within 28 days of return, (but no firm diagnosis of WVN infection) if a validated NAT for WNV is to be undertaken on the donated component(s), accept.

*See if Relevant* The 'Geographical Disease Risk Index'

*Additional Information* West Nile Virus is a flavivirus, similar to Dengue, which causes a wide spectrum of infection. This may range from no or minimal symptoms to death. It is geographically widespread, including areas in Europe and other parts of the world not affected by Malaria, and it has reached epidemic proportions in North America in recent years. There it has caused illness and death post transfusion and post transplantation of tissues and organs. It is spread by mosquitoes and so is more prevalent at times of the year when mosquitoes are active.

As the problem can vary both in relation to geography and time of the year it is not possible to state areas from which donors need to be deferred and dates of disease activity. These are provided in the 'Geographical Disease Risk Index'.

A 'Position Statement on West Nile Virus (WNV)' is available in the 'Document Library' of 'www.transfusionguidelines.org'.

*Reason for Change* To increase the deferral of donors following infection with West Nile Virus or symptoms suggestive of West Nile Virus Infection to six months and to remove the requirement for a negative NAT test for these donors prior to donation.

*Update Information* This entry was last updated in:
TDSG-CB Edition 203, Release 21.

## Whooping Cough

### Infection

*See* Infection - Acute

### Contact

*See* Infectious Diseases - Contact with

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Wilson's Disease

*Discretionary* Accept.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Xenotransplantation

*Including* Xenografts
Heterografts
Non-Human Organ Perfusion

### Recipient

*Definition* Any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a non-human animal source, or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live, non-human animal cells, tissues, or organs. Xenotransplantation products include live cells, tissues and organs.

Biological products, drugs, or medical devices sourced from **nonliving cells**, tissues or organs from non-human animals, including but not limited to porcine insulin, porcine heart valves, and collagen matrices derived from acellular porcine, bovine or any other xenogeneic source (e.g. PelviSoft®, Bio-Oss®, Bio-Gide® and Surgibone®) are not considered xenotransplantation products.

*Obligatory* **Must not donate if:**
Material from a **living** non-human animal source has been directly or indirectly in contact with the mother's blood supply. This does not include animal bites.

### Sexual Partners of Xenotransplant Recipients, Current and Former

*Obligatory* **Must not donate.**

*Additional Information* Exposure to non-human animal material, particularly when the person exposed is immunosuppressed, may result in infections that would not normally affect humans being passed on.

*Reason for Change* Further guidance re Recipient definition

*Update Information* This advice is a requirement of the EU Tissue & Cells Directive.

This entry was last updated in
TDSG-CB Edition 203, Release 23

## XMRV

*Discretionary* Donors who have been tested positive for XMRV, accept.

*Additional Information* As there is no evidence that XMRV is implicated in human disease, a positive test is not a bar to donation.

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 11 Issue 01

## Yaws

*Obligatory* **Must not donate.**

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Yellow Fever

*See* Infection - Acute

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Yellow Fever Immunization

*See* Immunization - Live

*Update Information* This entry was last updated in
TDSG-CB Edition 203, Release 02

## Zanamivir

*See* Relenza®

## Latest Updates

This page lists all changes to TDSG-CB 203 after Release 02. This page constitutes **Section 2 of Appendix 1 - Changes to donor selection guidelines**.
The changes are listed with the most recent change at the bottom.

**Changes introduced with Release 03**
A change was made to the version control definitions and all Issue numbering information removed.
Bleeding Disorder See Change Notification No. 18 - 2007

**Changes introduced with Release 04**
Tamiflu® (oseltamivir) See Change Notification No. 30 - 2009
Relenza® (zanamivir) See Change Notification No. 31 - 2009

**Changes introduced with Release 05**
Acupuncture See Change Notification No. 33 - 2009
Complementary Therapy See Change Notification No. 35 - 2009

**Changes introduced with Release 06**
Body Piercing See Change Notification No. 02 - 2010
Endoscopy See Change Notification No. 03 - 2010
Inoculation Injury See Change Notification No. 04 - 2010

**Changes introduced with Release 07**
West Nile Virus (WNV) See Change Notification No. 09 - 2010

**Changes introduced with Release 08**
Infertility See Change Notification No. 08 - 2011
Sexually Transmitted Disease See Change Notification No. 09 - 2011

**Changes introduced with Release 09**
West Nile Virus See Change Notification No. 11 - 2011

**Changes introduced with Release 10**
Porphyria See Change Notification No. 20 - 2011

**Changes introduced with Release 11**
XMRV See Change Notification No. 25 - 2011
Hepatitis C See Change Notification No. 27 - 2011

**Changes introduced with Release 12**
West Nile Virus (WNV) See Change Notification No. 05 - 2012

**Changes introduced with Release 13**
Acne See Change Notification No. 15 - 2012
Psoriasis See Change Notification No. 17 - 2012
Toxoplasmosis See Change Notification No. 18 - 2012

**Changes introduced with Release 13 Issue 02**
Fertility treatment: entry replaced by link to infertility

**Changes introduced with Release 14**
West Nile Virus (WNV) See Change Notification No. 01 - 2013

**Changes introduced with Release 15**
Hepatitis B See Change Notification No. 08 - 2013
Hepatitis B Post Immunization See Change Notification No. 09 - 2013
Infection - Chronic See Change Notification No. 10 - 2013

**Changes introduced with Release 16**
Acupuncture See Change Notification No. 02 - 2014
Alitretinoin, Toctino, Acne and Dermatitis See Change Notification No. 03 - 2014
Body Piercing See Change Notification No. 04 - 2014
Central Nervous System Disease See Change Notification No. 05 - 2014
Hepatitis B - Post Immunization See Change Notification No. 06 - 2014
Hepatitis B See Change Notification No. 07 - 2014
Hepatitis of Unknown Origin See Change Notification No. 08 - 2014

Infection - Acute See Change Notification No. 09 - 2014
Kidney Disease See Change Notification No. 10 - 2014
Malignancy See Change Notification No. 11 - 2014
Mental Health Problems See Change Notification No. 12 - 2014
Sarcoidosis See Change Notification No. 13 - 2014
South American Trypanosomiasis Risk See Change Notification No. 14 - 2014
Paratyphoid and Typhoid See Change Notification No. 15 - 2014

**Changes intorduced with Release 17**
Haematological Disease See Change Notification No. 30 - 2014
SARS See Change Notification No.31 - 2014
Tissue Safety See Change Notification No.32 - 2014
Steroid Therapy See Change Notificiation No.33 - 2014
Homosexual and Bisexual Individuals See Change Notifcation No.35 - 2014

**Changes introducted with Release 18**
Viral Haemorrhagic Fever Risk See Change Notification No. 43 – 2014

**Changes Introduced with Release 19**
Communication Difficulties See Change Notification No.7 - 2015
Complementary Therapy See Change Noficiation No.8 - 2015
Infertility See Change Notification No.9 - 2015

**Changes Introduced with Release 20**
Complementary Therapy See Change Notification No. 12 - 2015
Injectable Tanning Agents See Change Notification No.15 - 2015

**Changes Introduced with Release 21**
Appendix 2 Table of Immunizations See Change Notification No. 04 - 2016
Tropical Viruses See Change Notification No. 07 - 2016
West Nile Virus See Change Notification No. 09 - 2016
Viral Haemorrhagic Fever See Change Notification No. 11 -2016

**Changes Introduced with Release 22**

Tropical Viruses See Change Notification No. 013 - 2016
Viral Haemorrhagic Fever See Change Notification No. 015 - 2016

**Changes Introduced with Release 23**

Endoscopy See Change Notificaiton No. 24 - 2016
Severe Excercise Intolerance Disease (SEID) See Change Notification No. 28 - 2016
Xenotransplantation See Change Notification No. 29 - 2016

**Changes Introduced with Release 24**

Hepatitis A See Change Notification No.46 - 2016

**Changes Introduced with Release 25**

Kidney Stones See Change Notification No.07 - 2017

**Changes Introduced with Release 26**

Malaria See Change Notification No.17 - 2017

# Appendix 1 - Changes to donor selection guidelines

**Section 1**
**Changes introduced with TDSG-CB 203 Release 02 from TDSG-CB 202 Release 03**

There have been changes made to the following entries:

Acupuncture
Animal Bite
Ankylosing Spondylitis
Anti-Androgens
Antibiotic Therapy
Antidepressant Therapy
Arthritis
Autoimmune Disease
Bipolar Disorder
Bleeding Disorder
Cardiomyopathy
Cardiovascular Disease
Chikungunya Virus
Chlamydia
Cirrhosis
Colitis
Communication Difficulties
Depression
Disabled Donor
Disease of Unknown Aetiology
Ehlers-Danlos Syndrome (Disease)
Elliptocytosis
Endocarditis
Endoscopy
Episcleritis
Eye Disease
Gall Bladder Disease
German Measles
Haemoglobin Disorders
Haemolytic Anaemia
Hepatitis B
Hepatitis B - Post Immunization
Hepatitis C
Hepatitis of Unknown Origin
Hereditary Elliptocytosis
Hormone Replacement Therapy
Immune Thrombocytopenia
Immunoglobulin Therapy
Immunosuppression
Infection - Acute
Infection - Chronic
Inflammatory Eye Disease
Inoculation Injury
Jaundice
Mental Health Problems
Myeloproliferative Syndrome
Pituitary Extract - Human
Platelet Disorder
Polymyalgia Rheumatica
Prion Associated Diseases
Psoriasis
Rheumatoid Arthritis
Scleritis
Sexually Transmitted Disease
Shingles
Skin Disease
Steroid Therapy
Subacute Bacterial Endocarditis
Surgery
Syphilis
Temporal Arteritis

Thrombocytosis
Thyroid Disease
Tigason
Tissue and Organ Recipients
Transfusion
West Nile Virus

**Section 2**
**Changes to TDSG-CB 203 after Release 02**

See: Latest Updates

This appendix was last updated in TDSG-CB Edition 203, Release 02

# Appendix 2 - Medical criteria for the withdrawal of donations following information received after donation

**General considerations.**

Circumstances that should have excluded donation may only become known after cord blood has been taken. For the purposes of these guidelines, these circumstances are categorised below, along with appropriate actions. The action to be taken will be determined by any **A-Z** entry relevant to the safety of the recipient. If there is no relevant entry, a consideration of recipient safety will underlie the action taken.

Procedures must be maintained by all Services to ensure prompt reporting of late donation information and, if necessary, withdrawal of donated cord blood. Concerns arising from hearsay reports should be addressed by procedures established to ascertain the credibility of any such concerns.

If donations have been used before a withdrawal could be initiated, the **Designated Medical Officer** must decide upon appropriate action. This will include, if there are likely to be severe consequences from having received the stem cell transplant, contacting the clinician caring for the recipient and discussing notification of the recipient.

**1. Late notification of donation test results.**

**This may occur because:**

a) The results of microbiological screening tests are brought into question.

b) Additional information becomes available, e.g. the results of further testing.

c) It is discovered that testing was not performed within the agreed procedures (e.g. as a result of audit or notification of defective reagents by the manufacturer).

d) A report is received from the recipient's medical attendants of a post-transplant infection thought to have been transmitted by the donation.

**Action:** Inform the **Designated Medical Officer**.

**2. Notification of circumstances that should have triggered deferral at the time of donor selection.**

a) Circumstances which place a mother at risk of infection with blood borne organisms (**Tissues Safety Entry**).

b) Mothers in the 'at risk' categories relating to possible transmission of **Prion Associated Diseases** e.g. CJD and vCJD.

c) Mothers with **Malignancy** (other than those for which there is a discretion in the **A-Z**)

d) **Autoimmune Disease**.

e) Mothers with certain **Infectious Diseases** at the time of donation or who were in contact with and still within the incubation period of an Infectious Disease at the time of donation.

f) Mothers with diseases of unknown aetiology.

**Action:** Inform the **Designated Medical Officer**.

This appendix was last updated in TDSG-CB Edition 203, Release 02