## **United Kingdom Blood Transfusion Services (UKBTS)**

# Bone Marrow and Peripheral Blood Stem Cell Tissue Donor Selection Guidelines (TDSG-BM)

## Edition 203 - Published 01 June 2007 Release 26 - Published 01 August 2017

## Introduction

These guidelines form a constituent part of Chapter 22 (haemopoietic progenitor cells) of the <u>Guidelines for the Blood</u> 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:

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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:

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## **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**, preferably by e-mail to <u>caroline.smith@nhsbt.nhs.uk</u>

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

## **General Principles**

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

Donors are selected firstly to ensure that they do not come to harm from giving their donation and secondly to ensure that their donation is unlikely to harm any recipient. The ultimate responsibility for the selection of donors rests with the respective **National Medical Director**.

The immediate responsibility is with the **Qualified Healthcare Professional** who must ensure that the donor fulfils the respective selection guidelines. When it is not clear if an individual donor is acceptable, the donation should not be collected without discussion with a **Designated Medical Officer**. It is recognized that a particular donation of bone marrow or peripheral blood stem cells may be potentially uniquely life saving. It is important that when a **Designated Medical Officer** makes a concession outside of these guidelines, that this is discussed with the medical team of the recipient and the reasoning for the concession documented.

The prospective donor must be evaluated for their suitability to donate by a **Qualified Healthcare Professional** who has undergone appropriate training to use this document. They must verify their assessment by signing and dating the donation record.

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

It is the responsibility of the **Qualified Healthcare Professional** to ensure that the donor clearly understands the nature of the donation process. They must also understand the health questions and other information presented to them. The donor 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**.

Where there is separate guidance for **Bone Marrow** and for **Peripheral Blood Stem Cell** donors, this is made clear.

When there is a recognized risk to either the donor or the 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 donor must be dealt with by the use of several terms:

#### Must not donate

The donor **must** not donate 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 donor **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 donor 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 donor 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 donor.

#### **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-BM Edition 203, Release 02.

## Medication

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

In general, traces of drugs in stem cells are harmless to their recipients. However, donors treated with certain drugs are deferred for periods associated with the pharmacokinetic properties of the drug. Examples are some drugs used to treat acne, psoriasis and some prostate problems. All such drugs have their own entry in the **A-Z** section.

This section was last updated in TDSG-BM 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 stem cells, which, as a result, are 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 Tissues and Cellular Therapy Products, so they can be considered for incorporation into future revisions of these guidelines.

If late information is provided by the donor, 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 donors 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-BM Edition 203, Release 02.

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## **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-BM Edition 203, Release 02

## **Acetylcholinesterase Deficiency**

Obligatory Bone Marrow Donor:

Must not donate.

Discretionary PBSC Donor:

Accept.

Additional Information Bone marrow donation requires a general anaesthetic and acetylcholinesterase deficiency is an

anaesthetic risk.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Acitretin**

Neotigason

See Acne

**Psoriasis** 

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Acne

Obligatory Must not donate if:

a) Has ever taken Etretinate (Tigason).

b) Less than 24 months from the last dose of Acitretin (Neotigason).

c) Less than four weeks from 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-BM Edition 203, Release 17

## 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-BM Edition 203, Release 17

## **Addiction and Drug Abuse**

Obligatory Must not donate if:

a) Has ever injected, or has been injected with, drugs; even a long time ago or only once. This

includes bodybuilding drugs.

b) 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 donor'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-BM Edition 203, Release 02

#### Addison's Disease

Obligatory Bone Marrow Donor:

Must not donate.

Discretionary PBSC Donor:

If well on replacement treatment, accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **African Trypanosomiasis**

(Sleeping Sickness)

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Age

Obligatory Must not donate if:

a) Over sixty years of age.

b) Under seventeen years of age.

Additional Information The lower age limit takes account of national laws on age of consent. The upper age limit for

recruitment to the British Bone Marrow Registry is fifty years.

Reason for Change The upper age limit for acceptance has been raised from fifty-seven to sixty years.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **AIDS**

See HIV

Tissues Safety Entry

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Alcoholism**

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-BM 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.

Update Information

This entry was last updated in TDSG-BM Edition 203, Release 17

## **Allergy**

Obligatory Ensure:

a) Procedures will not expose the donor to something they are allergic to, e.g. iodine, latex,

lidocaine (previously known as lignocaine).

b) Inform Transplant Centre if:

Cells are from an individual with a known allergy.

See if Relevant

Asthma

Steroid Therapy

Update Information

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

## **Alternative Therapies**

See Complementary Therapy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Anaemia**

Obligatory **Inform Transplant Centre if:** 

Cells are from a donor that has an inherited disorder.

Discretionary

1. History of anaemia:

This must be assessed regarding its cause, current status and what treatment has been

received.

2. Iron deficiency:

a) If not under investigation or on treatment and the underlying cause is not a reason to

exclude, accept.

b) Medication to prevent, as opposed to treat, may be acceptable.

3. Other types:

a) Accept or exclude according to the guidelines.

b) 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).

Donating bone marrow will lower the haemoglobin concentration. People with a history of anaemia may not be able to make up this loss as easily as others.

Giving PBSC by apheresis results in a smaller loss of haemoglobin.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Anaesthetic**

**Obligatory** Bone Marrow Donor:

Must not donate if:

Previous severe reaction to general anaesthetic.

See if Relevant Accident

Dental Treatment

Surgery Transfusion

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Angina Pectoris**

Obligatory Must not donate.

See if Relevant Cardiovascular Disease

Additional Information A history of angina means that the donor has coronary artery disease. Removing blood from

the circulation may put the donor at risk of having a heart attack.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Animal Bite**

(Non-Human)

Obligatory 1. All donors:

Must not donate if:

a) Ever bitten by a non-human primate

b) Any wound is infected or not healed.

2. Bone marrow donors only:

Must not donate if:

Less than 12 months since bitten anywhere in the world by a bat or by any mammal outside of

the British Isles.

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 blood transfusion. 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.

Anyone who has been in unusual contact with a bat, such as handling a sick or injured bat, or woken to find that a bat has been with them while asleep, should be considered at risk of rabies. Bat bites are usually insignificant and easily overlooked. Merely being in a place where bats roost is not considered a risk.

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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-BM Edition 203, Release 02

## **Ankylosing Spondylitis**

Obligatory Must not donate if:

The cardiovascular system is involved.

Discretionary If mild and affecting the locomotor system only, accept.

See if Relevant Disabled Donor

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Additional Information Ankylosing spondylitis can affect the heart valves and the major artery of the body (aorta).

Removing blood from the circulation may put the donor at risk of having a heart problem.

See Autoimmune Disease

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

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Anthrax**

#### Infection

See Infection - Acute

#### **Exposure**

Discretionary Even if on prophylactic antibiotics, accept.

Additional Anthrax infection most commonly affects the skin through direct contact with infected Information material such as animal hides. If spores have been inhaled there is no evidence that

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 donors 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-BM Edition 203, Release 02

## **Anti Smoking Treatments**

Obligatory Must not donate if:

Experiencing symptoms related to treatment.

Discretionary If well, accept donors using nicotine replacement therapy (patches, sprays etc) or Bupropion

(Zyban, Amfebutamone).

See if Relevant Acupuncture

Additional Information Anti-smoking treatments can cause dizziness and nausea. Taking a donation from people who

are affected may make their problems worse.

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

## **Anticoagulant Therapy**

Obligatory Must not donate if:

a) Taking anticoagulant treatment.

b) Treatment was for cardiovascular disease.

c) Treatment was for axillary vein thrombosis.

d) Treatment was for repeated thrombophlebitis or thrombosis.

Discretionary If treatment has been completed more than seven days ago and a specific cause, not of itself a

reason for exclusion, has been identified for an isolated deep vein thrombosis or pulmonary

embolism, accept.

See if Relevant Cardiovascular Disease

Thrombosis

Additional Information Treatment with anticoagulants will make it more likely that a donor will bleed or bruise after

donation. The effect of treatment wears off over some days and after seven days, the blood clotting mechanisms should be back to normal.

If the donor has cardiovascular disease, removing blood from the circulation will put the donor at risk of having a heart problem.

Some causes of thrombosis make it more likely that blood clots will happen again. This could

be made worse by donating.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Anticonvulsant Therapy**

Obligatory Must not donate if:

Taken for epilepsy.

Discretionary If used for treating bipolar disorder or chronic pain syndromes and the underlying condition is

not a reason to exclude, accept.

See if Relevant Epilepsy

Mental Health Problems

Additional Information Faints following donation can lead to epileptiform convulsions due to a lack of oxygen reaching

the brain. This could lead to a true epileptic fit in a person with a recent history of epilepsy. It may also cause difficulties with the DVLA and/or employment in a person who has been free

from fits for some time.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Antifungals**

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Antihistamine Tablets**

Discretionary Accept.
See if Relevant Allergy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Anti-Obesity Drugs**

Discretionary Accept.
See if Relevant Weight

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Antivirals**

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Arrhythmias**

Obligatory 1. Must not donate if:

Symptomatic or requires treatment.

2. In other cases:

Refer to Designated Medical Officer.

See if Relevant Cardiovascular Disease

Additional Information Some heart irregularities may be made worse through blood loss or by a general anaesthetic. It

may be necessary to contact the specialist who has made the diagnosis.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Arthropod Borne Encephalitis**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Asthma**

Obligatory 1. Bone Marrow Donor:

Must not donate if:

Dependent on medication other than inhalers.

2. Bone Marrow & PBSC Donor:

Must not donate if:

a) Asthma is symptomatic.

b) Taking, or has completed, oral or parenteral steroids within the last seven days.

Discretionary If exercise induced, accept.

See if Relevant Infection - General

Steroid Therapy

Additional Information The risk associated with a general anaesthetic is increased in people with asthma.

Taking a donation from a person with symptomatic asthma will lower the amount of oxygen the

blood can carry and could make them worse.

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-BM Edition 203, Release 02

## **Autoimmune Disease**

Obligatory See

Is there an entry for the condition?

1. Must not donate if:

The donor has needed treatment to suppress the condition in the last 12 months.

2. Inform Transplant Centre if:

Cells are from a donor that has an autoimmune disorder.

See if Relevant G-CSF

If treated with immunoglobulin or plasma exchange or filtration:

**Transfusion** 

Additional Information

**PBSC Donors.** 

G-CSF may cause a flare of some autoimmune diseases. The risk should be assessed by the

**Designated Medical Officer** and discussed with the donor.

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 donor's immune system. This may make the donor more susceptible to certain types of infection and also will make some infections more difficult to

diagnose.

Autoimmune disease is caused by the body attacking itself. This is with antibodies that are in the fluid part of the blood (plasma), and with immune cells directly attacking target cells in the

part/s of the body affected.

Transfusion of antibodies, or transfer of immune cells, could lead to similar damage in the

people receiving them.

Reason for Change A note and link have been added about G-CSF flare of autoimmune disease.

Additional Information has been added to clarify treatment that may have been used to

suppress the condition.

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

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

## **Avodart**

Dutasteride

See Dutasteride (Avodart)

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Babesiosis**

Obligatory

Must not donate.

Update Information

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

## **Back Problems**

Obligatory

## 1. Bone Marrow Donor:

Must not donate if:

- a) Surgery within last five years.
- b) Disc problem/sciatica.
- c) Chronic pain requiring ongoing medical treatment.

## 2. PBSC Donor:

See:

Is there an entry for the underlying condition?

#### Must not donate if:

Not able to use the bleed facilities provided without risking their own safety or the safety of others (donors must not be bled in a wheelchair).

Discretionary

#### 1. Bone Marrow Donor:

If the pain is infrequent, related to exertion or strain, accept.

#### 2. PBSC Donor:

If the donor can tolerate the procedure, accept.

See if Relevant

Disabled Donor Neurosurgery Surgery

Additional Information

The operation to remove bone marrow could make any problem worse.

Reason for Change

An entry has been added for PBSC Donors.

An additional link has been added for 'Disabled Donor'.

Update Information

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

#### **BCG**

Obligatory Must not donate if:

a) The inoculation site has not yet healed.

b) Less than four weeks after inoculation.

Additional Information BCG is an immunization with live bacteria. By four weeks, the infection caused by the

inoculation should have been controlled. If the wound has not healed it is possible that there may still be infection present. We do not want to pass BCG, or other infections, on to people

receiving donated material.

Reason for Change Advice has been given from SACTTI that a period of four weeks is sufficient to ensure that

there would be no circulating virus or bacteria at time of donation for live immunizations other

than smallpox.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 09

## **BCG** Immunization

See BCG

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Beta Blockers**

Obligatory Must not donate if:

a) Used for the treatment of cardiovascular disease.

b) Used to control symptoms of thyroid disease.

Discretionary If used for non-cardiovascular disease or the donor has controlled hypertension, accept.

See if Relevant Anxiety Disorders

Blood Pressure - High

Migraine

Additional Information Beta blockers are often used to treat serious heart disease such as coronary artery disease

(angina and after a myocardial infarction) and arrhythmias (abnormal heart rhythm). They may also be used to control the symptoms associated with an overactive thyroid gland. Patients with

these disorders must not donate.

They are often used as treatment for hypertension (high blood pressure). There is evidence that shows that donors taking beta blockers do not have an increased incidence of adverse events

related to donation.

They are also used to treat many other conditions such as migraine, tremor, anxiety and

glaucoma. In most situations this should not prevent donation.

Reason for Change A link to 'Anxiety Disorders' has been added.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Bilharzia

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM 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-BM 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.

Discretionary Carrier state:

This does not necessarily prevent donation:

Refer to a Designated Medical Officer who will liaise with the haematologist that

investigated the donor.

See if Relevant Transfusion

Additional Information People who have received blood derived coagulation concentrates (these are made from the blood of many hundreds of individual donors) may have been put at risk of

infections that can be passed through donations.

If someone has had problems with bleeding or bruising taking blood or bone marrow

could be harmful.

Some people with the carrier state (trait) for some bleeding disorders may be at risk

of bleeding themselves.

## 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.

d) Diagnosed as affected (even mildly) by the disorder.

Discretionary

If six months 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.

Many bleeding disorders are inherited. Family members that are blood relations may be affected by the bleeding disorder so would be at risk of excessive bleeding or bruising. Most close blood relations would have been screened by a haematologist from whom additional information may be available.

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-BM Edition 203, Release 03

#### **Blind Donor**

See

Disabled Donor

Update Information

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

## **Blood Pressure - High**

#### Obligatory

#### Must not donate if:

- a) The cause of hypertension is under investigation.
- b) Anti-hypertensive medication has been altered in the last four weeks.
- c) Is having problems with feeling faint, fainting or giddiness.
- d) Has suffered from heart failure.
- e) Has renal impairment requiring dialysis, the use of erythropoietin or similar drugs, or is either under active investigation or continued follow up for their renal impairment.
- f) Has required surgery for a blocked or narrowed artery including any type of amputation.
- g) Has or has had gangrene.

Discretionary

- a) If the donor is being regularly assessed for high blood pressure but treatment has not been commenced, accept.
- b) If the donor is taking medication for raised blood pressure and neither the type nor the dose has been changed in the last four weeks and they are otherwise well, accept.
- c) If gangrene was not related to diabetes or peripheral vascular disease (e.g. it was due to hypothermia or meningococcal meningitis) and all wounds are fully healed, even if amputation was required, accept.

#### See if Relevant

Cardiovascular Disease

Central Nervous System Disease

Intermittent Claudication

Additional Information In the UK about one in twenty individuals has hypertension. Most people with hypertension are

in good health and are fit to donate blood.

It is however important that complications due to raised blood pressure are carefully assessed and, where necessary, donors are excluded from donating (e.g. those with heart failure or damage to their kidneys, or those experiencing hypotensive side effects from their medication.

Reason for Change The rationale for **not** accepting donors on medication, other than beta blockers or diuretics, for

the treatment of hypertension was reviewed by the Standing Advisory Committee for the Care and Selection of Donors in 2008. It was decided that available data did not support the deferral

of all individuals with controlled hypertension taking other medications.

Update Information This entry was last updated in

DSG-WB Edition 202 Release 11

## **Blood Pressure - Low**

Discretionary If the donor is in good health and does not have faints or dizzy spells, accept.

Additional Information Low blood pressure is not normally a problem. It is common in women and seems to be linked

with levels of the female sex hormone oestrogen.

Low blood pressure can be caused by serious heart disease. In such cases a donation would

not be taken.

Fainting can put a donor at risk of injury. Any donor who has problems with faints or dizzy spells

should not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Blood Transfusion**

See Transfusion

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Blood Volume Estimation**

Obligatory Must not donate:

If the estimated blood volume is less than 3.8 litres.

See if Relevant Weight

Additional Information It is recommended that no donor should lose more than 13% of their blood volume during any

donation procedure. This is to protect them from adverse effects such as fainting and becoming anaemic. There is a minimum donor weight at which a donation can be accepted. This is not always appropriate. Obesity also makes it desirable to use factors in addition to the donor's weight to estimate their blood volume. Fat contains far less blood as a proportion of its weight than muscle. In obese individuals the blood volume can be seriously overestimated from weight alone. Overestimating a donor's blood volume makes it more likely that they will have an

adverse incident.

Reason for Change This is a new entry to take account of increasing levels of obesity.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 17

## **Bone Graft**

See Surgery

Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Borrelioses**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Botulism Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Brain Surgery**

See Neurosurgery

Update Information This entry was last updated in

#### TDSG-BM Edition 203, Release 02

## **Brain Tumour**

See if Relevant Malignancy

Neurosurgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Breast Biopsy**

See Surgery

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

#### **Bronchitis**

#### **Acute**

See Infection - Acute

#### Chronic

Obligatory Must not donate if:

a) Repeated regular attacks of cough with sputum.

b) Dyspnoea at rest or on minimal exertion.

See if Relevant Infection - General

Steroid Therapy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Brucellosis**

**Undulant Fever** 

Obligatory M

Must not donate.

Update Information

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

#### Cancer

See

Malignancy

Update Information

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

#### Candida

See

Thrush - Oral Thrush - Vaginal

Update Information

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

#### **Cannabis**

See

Addiction and Drug Abuse

Update Information

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

### **Cardiac Surgery**

Obligatory

Must not donate.

Discretionary

If for congenital heart disease and has no residual disability, does not require antibiotic cover, and is not excluded because of their transfusion history:

Refer to a Designated Medical Officer.

See if Relevant

Cardiovascular Disease

Endocarditis
Surgery
Transfusion

Additional Information

Individuals who have had cardiac surgery, other than for congenital abnormality, are unlikely to be fit enough to safely have a large volume of blood removed. An individual who has had congenital abnormalities corrected can often lead a normal lifestyle and may be able to give blood safely. If the criteria under 'Discretionary' are met, the Designated Medical Officer can

make a documented decision based on the individual's medical history.

Update Information

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

### Cardiomyopathy

Obligatory

Must not donate.

Update Information

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

### Cardiovascular Disease

Obligatory 1. Must not donate if:

a) Has ischaemic heart disease.

b) Recurrent thrombophlebitis or thrombosis.

2. Bone Marrow Donor:

Discuss with the anaesthetist if the donor has any other form of cardiovascular disease.

Discretionary If asymptomatic mitral valve prolapse only, accept.

See if Relevant Angina Pectoris

Blood Pressure - High Cardiac Surgery Cardiomyopathy Endocarditis Myocarditis Thrombosis

Reason for Change Additional links have been added.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### Catarrh

#### **Acute**

See Infection - Acute

#### Chronic

Obligatory If on prescribed medication:

Refer to a Designated Medical Officer.

Discretionary If using a nasal decongestant only, accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-BM 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).

d) Stroke, transient ischaemic attack/s or cerebral embolus.

#### 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

Epilepsy 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.

A history of stroke, subarachnoid haemorrhage, transient ischaemic attack/s or cerebral embolus puts a potential donor at increased risk of a further vascular incident affecting their brain. As donation can result in a drop in blood pressure, there is the possibility that this could lead to further problems. Although the level of risk will vary from person to person, it is not acceptable to put an individual at increased risk, for what could be a severe adverse event, to any unnecessary further risk.

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-BM Edition 203, Release 17

#### 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-BM Edition 203, Release 02

### **Cervical Cone Biopsy**

See Cervical Carcinoma in Situ

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Cervical Dysplasia**

See Cervical Carcinoma in Situ

Update Information This entry was last updated in

#### TDSG-BM 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-BM Edition 203, Release 02

### **Chicken Pox**

### Herpes Zoster (Varicella Zoster)

See Infection - Acute

**Contact** 

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

### Cholecystitis

See Gall Bladder Disease

Update Information This entry wa

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

#### **Cholera Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Chondromalacia

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Christmas Disease**

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Chronic Fatigue Syndrome**

See Post Viral Fatigue Syndrome

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### Cirrhosis

Obligatory Must not donate.

See if Relevant Alcoholism

Autoimmune Disease

Malignancy

Reason for Change Additional links have been added.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Coagulation Factor Concentrates**

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Coeliac Disease**

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Colitis**

Obligatory Must not donate if history of:

a) Crohn's disease.

b) Ulcerative colitis.

Discretionary If more than two weeks since full recovery from an episode of infective colitis, accept.

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-BM 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-BM Edition 203, Release 02

### **Communication Difficulties**

Obligatory

#### 1. All donors 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 its suitability 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 donor 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 donor.
- 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. Potential donors with such difficulties are advised to seek advice from their local Blood Service before offering to donate stem cells to see if their needs can be met. **Every donor 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 donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor 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 donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor 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 donor, may accompany the donor 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 donor and the qualified health professional may compromise the confidentiality of the donor 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 potential donor 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 donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor

confidentiality, should be taken into account when deciding if an individual donor may be accepted.

To comply with both the HTA and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.

#### 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-BM Edition 203, Release 20

## **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 reuse 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 20

## **Cone Biopsy**

See Cervical Carcinoma in Situ

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

### **Contact with Infectious Disease**

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Contagious Pustular Dermatitis**

Orf

See Infection - Acute

Update Information This entry was last updated in

## **Contraceptive Implant**

Discretionary Accept.

See if Relevant Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Contraceptive Injection**

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Contraceptive Pill**

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Coronary Thrombosis**

Including Heart Attack

Myocardial Infarct

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Cortisone (Periarticular)

See Steroid Therapy

Update Information This entry was last updated in

### **Cortisone Tablets**

See Steroid Therapy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Creutzfeldt-Jakob Disease

See Prion Associated Diseases

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Crimean Fever**

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 19

### **Crohn's Disease**

See Inflammatory Bowel Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Cystitis**

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Cytomegalovirus

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Deaf Donor**

See Disabled Donor

Update Information This entry was last updated in

## **Deep Vein Thrombosis**

See Thrombosis

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM 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-BM Edition 203, Release 02

#### **Dermatitis**

Obligatory Must not donate if:

a) Venepuncture or harvest site is affected.

b) Using systemic therapy.

Discretionary If the area affected is small, the venepuncture or harvest site is unaffected and using topical

treatment only, accept.

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-BM Edition 203, Release 17

## Diabetes Insipidus

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Diabetes Mellitus**

Obligatory Must not donate if:

Requires medication.

Discretionary If controlled by diet alone, accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

### Digoxin

Obligatory Must not donate.

Update Information This entry was last updated in

## **Dilatation and Curettage**

See Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Diphtheria**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Diphtheria Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Diphtheria Tetanus Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Diphtheria Tetanus Pertussis Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Disabled Donor**

#### Obligatory 1. All donors 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 stem cells 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 donor 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 donor.

#### 3. PBSC Donor:

Must be able to use the bleed facilities provided without risking their own safety or the safety of others (donors must not be bled in a wheelchair).

#### 4. Bone Marrow donor:

Discuss with anaesthetist.

#### Discretionary

#### Donors with difficulty in reading:

Ensure by questioning the donor 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 disabled individuals. Potential donors with such difficulties are advised to seek advice from their local Service before offering to donate stem cells to see if their needs can be met. **Every donor 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 qualified health professional may assist a donor in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Service. To facilitate comprehension it is permissible to use alternative formats (e.g. audio, Braille, computer or alternative language) for the donor information leaflets, the health and medical history questionnaire and consent statements. The donor 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 donor and to assist in establishing effective communication between the donor and the qualified health professional. The third party **must not** however be present during any exchange of confidential information, unless they are **not** personally known to the donor 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 donor, may accompany the donor 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 donor and the qualified health professional may compromise the confidentiality of the donor 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 potential donor 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 donor and the blood supply at risk. There is also a requirement to communicate the results of any testing performed by the Blood Services that may be of relevance to the donor's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain donor confidentiality, should be taken into account when deciding if an individual donor may be accepted.

To comply with both the HTA and Health and Safety Regulations no donor can be accepted if it unnecessarily puts their own safety or the safety of others at risk.

Reason for Change

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

Update Information T

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

## **Disc Surgery**

See Back Problems

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

### **Diuretics**

conjunction with Beta Blockers, accept.

See if Relevant Blood Pressure - High

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Diverticulosis**

Discretionary Accept.

See if Relevant Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Drug Abuse**

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Drug Treatment**

Obligatory The taking of some drugs may make a donor 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 donor meets all other criteria.

See if Relevant Addiction and Drug Abuse

Nonsteroidal Anti-Inflammatory Drugs

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **DTP Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Duodenal Ulcer**

See Peptic Ulcer

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Dutasteride (Avodart)**

Obligatory If less than six months since completion of treatment:

Refer to a Designated Medical Officer.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Ear Piercing**

See Body Piercing

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Ebola Fever**

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

#### **Eczema**

See Dermatitis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Electrolysis**

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

### **Emphysema**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Encephalitis**

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Endocarditis**

Obligatory Must not donate if:

a) Active infection.

b) Has a heart defect and has been told to take antibiotics when having treatment (e.g. dental)

that may result in bacteraemia.

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

### **Endometriosis**

Discretionary Accept.

See if Relevant Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Epilepsy**

Obligatory Must not donate if:

a) Requiring treatment for epilepsy.

b) Has had an epileptic episode in the last three years.

Discretionary Previous epilepsy:

A person with a past history of epilepsy who for the past three years has neither required

anticonvulsant therapy, nor been subject to fits, may be considered as a donor.

See if Relevant Malignancy

Neurosurgery

Additional Information Faints following donation can lead to epileptiform convulsions due to a lack of oxygen reaching

the brain. This could lead to a true epileptic fit in a person with a recent history of epilepsy. It may also cause difficulties with the DVLA and/or employment in a person who has been free

from fits for some time.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

#### **Etretinate**

Tigason

Obligatory Must not donate if:

Has ever taken Etretinate (Tigason).

See if Relevant Acne

Psoriasis Psoriasis

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Eye Drops**

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-BM Edition 203, Release 02

#### Factor V Leiden

See Thrombosis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Faints**

Obligatory PBSC Donor:

Must not donate if:

History of either a severe syncopal attack or two consecutive faints following whole blood

donation.

Discretionary If the donor is accepted, careful observation is required.

Additional Information A previous history of being prone to faints increases the likelihood of an adverse reaction to

donation.

Update Information This entry was last updated in

## **Febrile Episodes**

See Pyrexia

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Fever**

See Pyrexia

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Fibroids - Removal

See Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Filariasis**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Finasteride (Proscar)

Obligatory If less than four weeks since completion of treatment:

Refer to a Designated Medical Officer.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Fits**

See Epilepsy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Food Allergy**

See Allergy

Update Information This entry was last updated in

### **Food Poisoning**

See Diarrhoea

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Foreign Travel**

See Travel

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Fungal Infection**

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Fungal Infection of Nails**

See Infection - Chronic

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **G6PD Deficiency**

Obligatory 1. Must not donate if:

Severe.

2. If accepted, must inform:

Anaesthetist.
Transplant Centre.

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-BM 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 If recovered or has asymptomatic gallstones, 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-BM Edition 203, Release 02

## Gastrectomy

See if Relevant Malignancy

Surgery

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **G-CSF**

Obligatory PBSC Donors:

The donor must be advised of the adverse events associated with this drug.

See if Relevant Autoimmune Disease

Sickle-cell Trait

Reason for Change To introduce an entry for G-CSF.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Genital Herpes Infection**

See Herpes - Genital

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Genital Warts**

Discretionary Accept.

See if Relevant Sexually Transmitted Disease
Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

### Gilbert's Disease

See Gilbert's Syndrome

Update Information This entry was last updated in

TDSG-BM 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 donor.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Glandular Fever

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Glaucoma

Obligatory Must not donate if:

Received transplant of sclera during glaucoma surgery.

Discretionary If treatment is complete, no scleral transplant was given, or if treated by eye drops only, accept.

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.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### Goitre

See Thyroid Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### Gonorrhoea

See Sexually Transmitted Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Gout

Discretionary Even if on treatment, accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Grand Mal**

See Epilepsy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Granuloma Inguinale**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### **Grave's Disease**

See Thyroid Disease

Update Information This entry was last updated in

### **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-BM 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 donor 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

Update Information This entry was last updated in

TDSG-BM 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

#### 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-BM Edition 203, Release 02

## Haemochromatosis

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Haemoglobin Disorders**

Obligatory 1. Must not donate if:

Has a sickle-cell or thalassaemia syndrome.

2. Inform Transplant Centre if:

Cells are from a donor that has an inherited disorder.

Discretionary Donors with traits for abnormal haemoglobin, 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-BM 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 To include an entry for haemolytic anaemia.

Update Information This entry was last updated in

## Haemophilia

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Haemophilus Influenzae Type B Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Haemorrhoids

Including Piles

Discretionary Accept.

See if Relevant Anaemia

Surgery

Update Information

This entry was last updated in

TDSG-BM Edition 203, Release 02

## Hand, Foot and Mouth Disease

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Hashimoto's Disease**

See Thyroid Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Hay Fever**

See Allergy

Update Information This entry was last updated in

## **Hazardous Activity**

Obligatory 1. PBSC Donor:

Must not donate if:

a) Required to undertake a hazardous activity the same working day.

b) Donors must be advised of the risks of delayed faints and told not to perform a hazardous

occupation or hobby on the same day.

Discretionary Hazardous occupation:

If going off duty, accept.

Additional Information If a donor has an adverse event after donating, some activities (occupations or hobbies) may

lead to harm to the donor or others.

Examples of hazardous activities include:

diving (all types), flying, parachuting, motor sport, climbing, etc.

Examples of hazardous occupations include:

air traffic controller, ambulance driver, climbing ladders or scaffolding, crane or heavy machine operator, diver, fire crew, flying, Large Goods Vehicle (LGV, HGV over 7.5 tonnes), bus or train

driver, miner working underground, etc.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Head Injury**

See Accident

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Headache

#### Occasional

Discretionary Accept.

See if Relevant Migraine

#### 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-BM Edition 203, Release 02

### **Heaf Test**

Obligatory Must not donate until:

Healing.

Update Information This entry was last updated in

#### **Health Care Worker**

### **History of Inoculation Injury**

See Inoculation Injury

#### No Inoculation History

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Heart Operation**

See Cardiac Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Henna Painting**

Discretionary Accept.

See if Relevant Body Piercing

Update Information This entry was last updated in

TDSG-BM 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-BM 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 Hepatitis A is spread by the faecal - oral route and by sewage-contaminated food 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

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 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

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 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

Information

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-BM Edition 203, Release 25

## **Hepatitis A Immunization**

See Hepatitis A - Post Immunization

Update Information This entry was last updated in

TDSG-BM 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 Only accept if all markers (i.e. HBsAg, HBV-DNA and HB core antibody) are negative

Information 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 Only accept if HB core antibody positive, HBsAg negative and HBV-DNA negative.

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Information

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.

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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 Only accept if

Information 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 If still sharing or less than six months since last sharing:

Information 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-BM Edition 203, Release 17

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

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 Sensitive assays for HBsAg may be positive following recent immunization. Full

Information 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 Tissues & Cells Directive.

> This entry was last updated in TDSG-BM Edition 203, Release 17

#### **Hepatitis C**

#### **Affected Individual**

Must not donate. Obligatory

Discretionary If the individual has been told that he/she is HCV antibody negative, then samples

should be taken to determine eligibility.

Tissues Safety Entry See if Relevant

Additional Hepatitis C is a serious viral infection that can lead to chronic liver disease, liver Information 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 donor'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 donor'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 <u>Tissues Safety Entry</u>

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**

Information

Discretionary Accept.

See if Relevant Sexual Partners of HCV Positive Individuals above.

Additional 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-BM Edition 203, Release 12 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-BM Edition 203, Release 02

# **Hepatitis of Unknown Origin**

#### **Affected Individuals**

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 If more than 12 months and less than 24 months from recovery:

Information 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-BM Edition 203, Release 17

# **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-BM Edition 203, Release 02

## **Hereditary Elliptocytosis**

Obligatory 1. Must not donate if:

Clinically significant haemolysis.

2. Inform Transplant Centre if:

Cells are from a donor with hereditary elliptocytosis.

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

TDSG-BM Edition 203, Release 02

## **Hereditary Spherocytosis**

Obligatory 1. Must not donate if:

Clinically significant haemolysis.

2. Inform Transplant Centre if:

Cells are from a donor with hereditary spherocytosis.

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 changed to be consistent with the guideline for 'Hereditary Elliptocytosis'.

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

**Herpes - Genital** 

Obligatory Must not donate if:

Fresh lesions.

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

TDSG-BM Edition 203, Release 02

**Herpes - Oral** 

Obligatory Must not donate if:

Fresh lesions.

Discretionary If lesions are healing, accept.

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

**Herpes Simplex** 

See if Relevant Herpes - Genital

Herpes - Oral

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

**Herpes Zoster** 

See if Relevant Infection - Acute

Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# Homeopathy

See Complementary Therapy

Update Information This entry was last updated in

TDSG-BM 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.

#### Male

Discretionary There is r

There is no specific restriction regarding donation for 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 anyone receiving their blood, tissues or cells. 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 deferral for men who have had sex with men should be removed for potential stem cell donors.

Reason for Change

To remove the restriction regarding donation for donors with a history of male-sexwith-male behaviour

### 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 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 stem cell 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.

c) If treatment for menopausal symptoms or osteoporosis prevention, 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-BM 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-BM Edition 203, Release 02

### **Human Bite**

See Inoculation Injury

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Human Pituitary Extract**

See Pituitary Extract - Human

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Huntington's Chorea**

See Huntington's Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Huntington's Disease**

Obligatory Must not donate if:

Symptomatic.

Discretionary Asymptomatic carriers, accept.

Update Information This entry was last updated in

# **Hydatid Disease**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Hydatidiform Mole**

See Pregnancy

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# Hypercholesterolaemia

Obligatory Must not donate if:

a) Has caused symptomatic disease.

b) Associated with cardiovascular disease.

Discretionary If has not led to symptomatic disease, even if on treatment, accept.

See if Relevant Cardiovascular Disease

Additional Information Hypercholesterolaemia occurs when the level of cholesterol in the blood is outside of the

reference range for the donor's age and sex. Usually this is managed by modifying the diet and often by the use of drugs. High levels of cholesterol are of themselves not a reason to defer a donor. If the hypercholesterolaemia has led to symptomatic disease, such as cardiovascular problems or transient visual or neurological problems the donor should not be accepted, even if

their cholesterol has returned to normal levels.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Hypertension**

See Blood Pressure - High

Update Information This entry was last updated in

# Hyperthyroidism

See Thyroid Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Hypnotics**

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Hypothyroidism

See Thyroid Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Hysterectomy

See Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Idiopathic Thrombocytopenic Purpura (ITP)**

See Immune Thrombocytopenia

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## IgA deficiency

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## lleostomy

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-BM Edition 203, Release 02

# Immune Thrombocytopenia

Obligatory Must not donate if:

a) Symptomatic.

b) Chronic.

c) Recovered, but less than six months from recovery.

This applies to both adult and childhood disease.

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.

The phrase, 'Recovered, but has ever had a recurrence' has been removed and 'five years from recovery' has been reduced to six months as both were considered unnecessarily restrictive.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

#### **Immunization - Live**

### No Exposure

Obligatory Must not donate if:

Less than eight weeks from administration.

Discretionary If more than four weeks from administration of a live immunization other than smallpox

immunization and the inoculation site has healed, accept.

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. By four weeks, any infection caused by the immunization should have been controlled and so should not be passed on through donated material. There are special rules for BCG and smallpox immunizations.

Reason for Change Advice has been given from SACTTI that a period of four weeks is sufficient to ensure that

there would be no circulating virus or bacteria at time of donation for live immunizations other

than smallpox.

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

This entry was last updated in TDSG-BM Edition 203, Release 09

#### 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

## **Immunodeficiency**

See Immunosuppression

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Immunoglobulin Therapy

Obligatory Must not donate if:

a ) Immunosuppressed.

b) Donors 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-BM Edition 203, Release 02

## **Immunosuppression**

Obligatory Must not donate if:

a ) Immunosuppressed.

b) Donors 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-BM 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) Infected.

b) Less than two weeks from recovery.

c) Less than seven days from completing systemic antibiotic, anti-fungal or antiviral treatment.

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 donor does not pose a risk of giving an infection to a recipient. Waiting two weeks from when the infection is better 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 transfusion but it is still necessary to wait until any such infection is obviously getting better before allowing anyone to donate.

Update Information

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

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

#### Infection - Chronic

Obligatory Must not donate.

Discretionary 1

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-BM Edition 203, Release 16

### 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-BM 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-BM 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-BM Edition 203, Release 02

## Infertility

Obligatory Must not donate if:

a) Under investigation.

b) Less than 12 weeks after completion of treatment with clomiphene (Clomid).

c) Less than 12 weeks after completion of treatment with tamoxifen.

d) Has ever been given human gonadotrophin of pituitary origin.

e) Has received donated eggs or embryos since 1980.

f) If donor knows that they have ever been treated with Metrodin HP<sup>®</sup>.

Discretionary Take care to exclude pregnancy.

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

See if Relevant 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.

The 12 week period is an additional safeguard to avoid taking a donation early in a pregnancy.

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

the spread of vCJD.

Metrodin HP<sup>®</sup> 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-BM Edition 203, Release 20

### **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-BM Edition 203, Release 02

### Inflammatory Eye Disease

See if Relevant Autoimmune Disease

Additional Information G-CSF may cause a flare up of inflammatory eye disease.

Reason for Change This is a new entry.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Influenza Immunization

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Injected Drugs of Misuse**

See Addiction and Drug Abuse

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 07

#### Inoculations

See <u>Immunization</u>

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Intermittent Claudication**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Irritable Bowel Syndrome**

Discretionary A

Accept.

Update Information

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

### Isotretinoin

Roaccutane

See Acne

Update Information

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

### **ITP**

See

Immune Thrombocytopenia

Update Information

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

# **Japanese Encephalitis Immunization**

See

Immunization - Non-Live

Update Information

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

### Kala-Azar

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 17

## **Kidney Donor**

See Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Kidney Recipient**

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Kidney Stones**

See if Relevant Infection - General

See Renal Colic

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Klinefelter's Syndrome

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Laminectomy

See Back Problems

Surgery

Reason for Change A link has been added for 'Back Problems'.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

### Lassa Fever

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 19

# Latex Allergy

See Allergy

Reason for Change To include a cross reference for 'Latex Allergy'.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Legionnaire's Disease

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Leishmaniasis

Including Kala-Azar

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Leptospirosis

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Lesbian

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Leukaemia

Obligatory Must not donate.

Update Information This entry was last updated in

### Listeriosis

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Lyme Disease

See

Infection - Acute

Update Information

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

## Lymphogranuloma Venereum

Obligatory

Must not donate.

Update Information

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

#### Malaria

#### Obligatory

#### Must not donate if:

- a) The donor has ever had malaria.
- b) The donor has had an undiagnosed fever (that could have been malaria) while abroad or within four months of leaving a malaria endemic area.
- c) The donor 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) Donors 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) Donors 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) Donors 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 donors:

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 donor 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 donor can be accepted without the need for malaria antibody testing.

If the donor does not comply with any of the above, 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.

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 donor 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 donate, 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 donor 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-BM Edition 203, Release 26

#### Malaria - Contact in UK

Discretionary

Accept.

Update Information

This entry was last updated in TDSG-BM 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 followup, 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-BM Edition 203, Release 17

# **Malignant Hypertension**

See Blood Pressure - High

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Malignant Melanoma**

See Malignancy

Update Information This entry was last updated in

TDSG-BM 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

## **Marburg Fever**

See Viral Haemorrhagic Fever

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 19

## **Marfan's Syndrome**

Obligatory Must not donate if:

Cardiac involvement.

Discretionary Otherwise accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Mastectomy**

See if Relevant Malignancy

See Surgery

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## **Measles Immunization**

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Measles Mumps Rubella (MMR) Immunization

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Measles Rubella Immunization**

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Medication (Drugs)**

See Drug Treatment

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Ménière's Disease

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# **Meningococcal Meningitis Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Menopause

Discretionary Accept.

See if Relevant Hormone Replacement Therapy

Update Information This entry was last updated in TDSG-BM 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-BM Edition 203, Release 17

# Migraine

Obligatory Must not donate if:

a) Attacks are frequent, severe, and require regular treatment.

b) On prophylaxis with clonidine.

Discretionary If on prophylaxis with beta-blockers or pizotifen (Sanomigran), accept.

See if Relevant Headache

Additional Information Migraine is caused by a disturbance in the normal blood flow to parts of the brain. In its more

severe forms it can be severely disabling. By not accepting people with the more severe forms of migraine we hope to prevent precipitating an attack through the process of donating blood. Any donor who has had severe migraine associated with giving blood on more than one

occasion should be advised not to continue as a donor.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Mitral Valve Prolapse

See Cardiovascular Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Molar Pregnancy

Hydatidiform Mole

See Pregnancy

Update Information This entry was last updated in

TDSG-BM 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 donor is not relevant to donation.

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

# **Mumps Immunization**

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Muscular Dystrophy**

Obligatory Bone Marrow Donor:

Must not donate.

Discretionary PBSC Donor:

Accept if able to tolerate the length of the procedure.

See if Relevant Disabled Donor

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Myalgic Encephalomyelitis

See Post Viral Fatigue Syndrome

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

## **Myasthenia Gravis**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Myelodysplastic Syndrome**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## Myocarditis

Obligatory Must not donate if:

Less than 12 months from recovery.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Myomectomy

See Surgery

Update Information

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

## Myxoedema

See

Thyroid Disease

Update Information

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

## **Narcolepsy**

Obligatory

Must not donate.

Update Information

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

# **Needle-Stick Injury**

See

**Inoculation Injury** 

Update Information

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

# Neotigason

Acitretin

See Acne

Psoriasis

Update Information

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

# Nephrectomy

See

Surgery

Update Information

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

# **Nephritis**

See

Kidney Disease

Update Information

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

### **Neurofibromatosis**

Obligatory 1. Must not donate if:

History of malignant change.

2. Bone Marrow Donor: Inform anaesthetist.

Additional Information

The anaesthetist should be informed because of the risk of pheochromocytoma.

Update Information

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

## **Neurological Conditions**

See Central Nervous System Disease

Update Information This entry was last updated in

TDSG-BM 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 donor 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-BM Edition 203, Release 02

## Night Sweats

Obligatory Must not donate if:

Unexplained.

Discretionary If due to the menopause, accept.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Obligatory Assess reason for treatment and see relevant entry.

Must not donate if:

Taken for a serious long-term illness including cardiovascular disease.

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

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **NSAID**

See Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **NSU**

See Non-Specific Urethritis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Obesity

See Weight

Update Information This entry was last updated in

TDSG-BM 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

# **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-BM Edition 203, Release 02

## **Operations**

See if Relevant Transfusion

See Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Orf

Contagious Pustular Dermatitis

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Organ Donor**

Discretionary Accept.

See if Relevant Transfusion

See Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Organ Recipient**

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Oseltamivir

See Tamiflu®

### **Osteoarthritis**

Discretionary Accept.

See if Relevant Disabled Donor

Nonsteroidal Anti-Inflammatory Drugs

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Osteomalacia

See if Relevant Disabled Donor

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

## Osteoporosis

Obligatory Bone Marrow Donor:

Must not donate.

Discretionary PBSC Donor:

If on treatment to prevent or treat, accept.

See if Relevant Disabled Donor

Steroid Therapy

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# Paget's Disease of Bone

Including Osteitis Deformans

See if Relevant Disabled Donor

Nonsteroidal Anti-Inflammatory Drugs

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-BM 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.

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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

# **Paratyphoid**

See if Relevant

See Chronic Infection

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

future changes to the guidelines simpler.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 17

## **Peptic Ulcer**

Gastric and Duodenal Ulcer and Erosions Including

Obligatory Must not donate if:

Associated with malignant change.

See if Relevant Surgery

Transfusion

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Pericarditis - Viral

See Infection - Acute

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

## **Periods**

Obligatory Must not donate if:

Period has been missed.

See if Relevant Pregnancy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Peritonitis**

See Infection - General

Surgery

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Peritonsillar Abscess**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Permanent Make-Up**

See Body Piercing

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Perthes' Disease**

Discretionary Accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Petit Mal**

See Epilepsy

Update Information This entry was last updated in

### **Phlebitis**

Obligatory Must not donate if:

a) More than one episode in 12 months.

b) Less than seven days off treatment.

Discretionary If recovered, accept.

See if Relevant Anticoagulant Therapy

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

### **Platelet Disorder**

Obligatory Must not donate if:

a) Causes excessive bleeding or bruising.

b) Has thromboctocytosis.

See if Relevant Haematological Disease

Immune Thrombocytopenia

Thrombocytosis

Additional Information Platelet counts in excess of 500 x 10<sup>9</sup> should be repeated. If found to be persistently raised the

donor 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

## **Pleurisy**

See if Relevant Infection - General

Malignancy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Pneumococcal Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Pneumonia**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Pneumothorax**

### **Spontaneous**

Obligatory Must not donate if:

a) Not recovered.

b) Associated with emphysema.

#### **Traumatic**

See Accident

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Polio Contact**

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Polio Injected Immunization**

See Immunization - Non-Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Polio Oral Immunization**

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Polycystic Kidney Disease**

Obligatory Bone Marrow Donor:

Request an anaesthetic assessment.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Polycythaemia**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM 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-BM 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

# **Post Viral Fatigue Syndrome**

Including Myalgic Encephalopathy (ME) and Chronic Fatigue Syndrome (CFS)

Obligatory Must not donate if:

Not resolved.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Pregnancy**

#### Obligatory Must not donate if:

a) Pregnant.

b) Less than one week has passed for every completed week of a recent pregnancy.

c) Resulted in a malignant (invasive) Hydatidiform mole.

d) Resulted in a non-malignant (non-invasive) Hydatidiform mole and treatment and follow up is

ongoing.

e) It is less than 7 days from the last dose of methotrexate.

See if Relevant Surgery

Transfusion

Additional Information Methotrexate is now increasingly used to medically treat ectopic pregnancy, to avoid surgery

and protect the fallopian tube. A week is needed for any residual methotrexate to clear the

system

Reason for Change The addition of information about methotrexate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 14

#### **Prion Associated Diseases**

Including Sporadic, Familial and Variant Creutzfeldt-Jakob Disease (CJD), Gerstmann-Sträussler-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 1980Recipients of any allogeneic human tissue.

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-BM Edition 203, Release 22

## **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-BM Edition 203, Release 02

### **Proscar**

See Finasteride (Proscar)

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Prostatectomy**

See Surgery

Update Information This entry was last updated in

### **Prostitutes**

Obligatory

Must not donate.

See if Relevant

Tissues Safety Entry

Update Information

This entry was last updated in TDSG-BM 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, the venepuncture/harvest site is unaffected 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-BM Edition 203, Release 14

# **Psychiatric Problems**

See Mental Health Problems

Update Information

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

# **Pulmonary Embolism**

See

**Thrombosis** 

Update Information

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

# **Pyelonephritis**

See

Infection - General

Update Information

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

# **Pyrexia**

### **Not Related to Travel in Malarious Areas**

Obligatory Must not donate if:

Less than two weeks from an episode of pyrexia.

donor is now recovered or recovering, accept.

See if Relevant Infection - General

Additional A Information th

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.

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

TDSG-BM Edition 203, Release 02

# **Pyruvate Kinase Deficiency**

Obligatory 1. Must not donate if:

Severe.

2. If accepted, must inform:

Anaesthetist. Transplant Centre.

Additional Information This is an autosomal recessive red cell enzyme deficiency that is variable in its severity.

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 'G6PD Deficiency'.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## Q Fever

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Quinsy

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

# Radionuclides

Obligatory 1. Radioactive iodine therapy:

Must not donate if:

a) For malignancy.

b) Administered in 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 donors must not be accepted unless at

least six months have passed.

Update Information This entry was last updated in

# Raynaud's Syndrome

Obligatory Must not donate if:

a) Part of a multisystem disorder.

b) On treatment with vasodilators.

Discretionary If this is an isolated condition and the donor is not taking vasodilators, accept.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# **Reiter's Syndrome**

Discretionary If fully recovered, accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Relapsing Fever

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Relenza®

Approved Name Zanamivir

Discretionary

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<sup>®</sup>, the donor 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: equal, headache, ruppy pose, diarrhead/yeniting)

more of the following symptoms: cough, headache, runny nose, diarrhoea/vomiting).

If the potential donor is 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-BM Edition 203, Release 05.

### **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-BM Edition 203, Release 02

### **Renal Disease**

See Kidney Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Respiratory Disease**

Obligatory Must not donate if:

Out of breath on minimal exertion.

See if Relevant Infection - General

Steroid Therapy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Resurfacing of Hip**

See Surgery

Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Retinitis Pigmentosa

Discretionary Accept.

See if Relevant Disabled Donor

Update Information This entry was last updated in

# **Rheumatic Fever**

Obligatory Must not donate if:

a) Has had more than one attack.

b) It is less than two years from any symptomatic disease.

c) Requires antibiotic cover for dental treatment.

Additional Information

Rheumatic fever can cause damage to the heart valves and this could make it unsafe to donate.

Update Information

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

# **Rheumatoid Arthritis**

Discretionary If mild and the only treatment is NSAIDs, accept.

See if Relevant Disabled Donor

Nonsteroidal Anti-Inflammatory Drugs (NSAID)

See Autoimmune Disease

Reason for Change This entry is now linked to 'Autoimmune Disease'.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Ringworm

Obligatory Must not donate if:

a) Affecting site of venepuncture or harvest.

b) On systemic treatment.

Discretionary If on local treatment only, accept.

See if Relevant Infection - General

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

#### **Risk Factors**

See Tissues Safety Entry

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Roaccutane

Isotretinoin

See Acne

Update Information This entry was last updated in

#### TDSG-BM Edition 203, Release 02

# **Rodent Ulcer**

See Basal Cell Carcinoma

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Rubella

### **Acute Infection**

See Infection - Acute

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Rubella Immunization**

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Salpingitis**

See if Relevant Sexually Transmitted Disease

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Sandfly Fever

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 17

# **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

### **Schistosomiasis**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Sclera Recipient**

See Ocular Tissue Recipient

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

#### **Self-Catheterization**

Obligatory Must not donate.

Additional Information Donors 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-BM Edition 203, Release 02

# **Semi-Permanent Make-Up**

See Body Piercing

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Sex Change

Discretionary Accept

Assessment of haemoglobin concentration should be according to the gender assigned

See if Relevant Tissues Safety Entry

Homosexual and Bisexual Individuals

Surgery

#### Additional Information

A careful and sympathetic consideration of sexual risk factors needs to be undertaken. There is no specific restriction regarding donation for 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.

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.

Assessment of haemoglobin concentration should be according to the gender assigned. The higher haemoglobin concentration of men, compared to women, is related to testosterone levels. As part of the gender reassignment process the sex hormone levels are changed so that a woman who becomes a man will receive testosterone. This will result in the haemoglobin concentration rising to the higher range seen in men. The opposite will be true if a man becomes a woman.

Reason for Change

To allow the donation without a deferral period from donors with a history of male-sex-with-male

behaviour.

For new links to be added.

Update Information

This entry was last updated in TDSG-BM 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

Is there is a specific entry for the disease with which there has been contact?

Must not donate if:

a) Donor required treatment and it is less than twelve months since completing that treatment.

b) Donor 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-BM Edition 203, Release 09

# **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-BM Edition 203, Release 02

## Sickle-Cell Disease

See Haemoglobin Disorders

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Sickle-Cell Trait

Obligatory 1. Bone Marrow Donor:

**Inform Transplant Centre if:** 

Cells are from a donor that has sickle-cell trait.

2. PBSC Donor:

Must not donate.

Additional Information PBSC donors with sickle-cell trait may be at risk of their red cells sickling if the WBC becomes

very raised following treatment with G-CSF.

Reason for Change PBSC donors with sickle-cell trait must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Skin Cancer**

See Malignancy

Update Information This entry was last updated in

## Skin Disease

Obligatory Must not donate if:

a) The condition is infected or infectious.

b) Malignant.

c) Affecting site of venepuncture or harvest.

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-BM Edition 203, Release 02

# Sleeping Sickness

(African Trypanosomiasis)

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Smallpox Immunization**

# **Immunized Individual**

Obligatory Must not donate if:

a) The inoculation site has not fully healed.

b) Any secondarily infected site has not fully healed.

c) Less than eight weeks from inoculation or from the appearance of any secondarily

infected site.

Additional Information Smallpox immunization is with live virus. By eight weeks, the infection caused by the inoculation should have been controlled. If the wound has not healed it is possible that there may still be infection present. We do not want to pass the virus, or other

infection, on to either donors or staff, or to people receiving stem cells.

### **Contacts**

Obligatory Must not donate if:

a) Any secondarily infected site has not yet healed.

b) Less than eight weeks after secondarily infected site appeared.

Discretionary If no new skin lesions, accept.

Additional Close contacts of vaccinees (household or direct bodily contact) may become secondarily infected from direct skin contact with an infected inoculation site or from the contact with the

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, other donors 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-BM Edition 203, Release 02

#### Snake Bite

Obligatory Must not donate until:

Recovered.

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# South American Trypanosomiasis Risk

#### Obligatory Must

#### Must not donate if:

- a) Born in South America or Central America (including Southern Mexico).
- b) 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) Has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.

Discretionary

- 1) 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.
- 2) If transfused before 1st January 1980 and a validated test for T. cruzi antibody is negative, accept.
- 3) If less than six months following the date of last exposure, discuss with a **Designated Medical Practitioner.**

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 amended.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 17

# **Spherocytosis**

See Hereditary Spherocytosis

Update Information This entry was last updated in

TDSG-BM 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.

See if Relevant Disabled Donor

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Spinal Surgery**

See if Relevant Neurosurgery

Surgery Transfusion

Update Information This entry was last updated in

TDSG-BM 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.

See if Relevant Immune Thrombocytopenia

Malignancy Surgery Transfusion

Update Information This entry was last updated in

# **Squamous Cell Carcinoma**

See Malignancy

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Steroid Therapy

### Obligatory 1. Must not donate if:

a) Regularly taking steroid tablets, injections or enemas, or applying creams over large areas.

b) The donor 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.

2. Bone Marrow Donor:

Inform anaesthetist if:

Course of steroids in last month.

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.

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.

Reason for Change To clarify when donors who have used steroid therapy may donate.

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

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

# **Stroke**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM 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

# 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. Malignancy:

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 donor may be accepted on a balance of risks following discussion with the Transplant Centre.

#### See if Relevant

Anaesthetic

Basal Cell Carcinoma Cervical Carcinoma in Situ Neurosurgery

Ocular Surgery

Tissue and Organ Recipients

Transfusion

Xenotransplantation

### Additional Information

Surgery may cause significant blood loss. It is important that donors waiting for an operation should not be put at risk of anaemia or poor iron stores by donating prior to planned surgery. Unless the type of surgery planned is unlikely to result in significant blood loss the donor should be deferred until after their planned surgery. This will minimize their own chance of needing a transfusion, which would of course prevent them from continuing as a donor. It is also important not to hinder the recovery of the donor. This requires waiting until they are fully recovered before they donate again.

Surgery may place the donor 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 donor 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-BM 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 & Cells Directive.

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

# **Syphilis Sexual Contact**

See Sexually Transmitted Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Systemic Lupus Erythematosus**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Tamiflu®**

Approved Name 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<sup>®</sup>, the donor 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 the potential donor is taking Tamiflu<sup>®</sup> 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:

### **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-BM Edition 203, Release 02

### **Tattoo**

See Body Piercing

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

# Thalassaemia Major

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Thalassaemia Trait

See Haemoglobin Disorders

Update Information This entry was last updated in

# **Therapeutic Venesection**

Obligatory Must not donate.

**Discretionary** 1. If for haemochromatosis, accept.

2. Bone marrow donation:

If for confirmed secondary polycythaemia, ask for anaesthetic opinion.

See if Relevant Haemochromatosis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Threadworms**

Discretionary Even if on treatment, accept.

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

### **Thrombosis**

Obligatory 1. Must not donate if:

a) Due to atherosclerosis (e.g. coronary thrombosis).

b) History of axillary vein thrombosis.

c) Recurrent thrombosis.

d) Less than seven days after completing anticoagulant therapy.

e) Has a thrombophilic trait and has had one or more episodes of thrombosis.

2. Bone Marrow Donor:

Inform anaesthetist of past history of thrombosis.

Discretionary a) If a specific cause for an isolated deep vein thrombos

a) If a specific cause for an isolated deep vein thrombosis or pulmonary embolism has been identified, not of itself a reason for exclusion, and anticoagulant therapy has been stopped for at

least seven days, accept.

b) Has a thrombophilic trait and has never had an episode of thrombosis, accept.

See if Relevant Anticoagulant Therapy

Malignancy

Additional Information Unexplained DVT is associated with an increased risk of atherosclerosis NEJM 348(15) 1435.

Update Information This entry was last updated in

TDSG-BM 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-BM 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-BM Edition 203, Release 02

# **Thyroid Disease**

Obligatory Must not donate if:

a) Under investigation.

b) Malignant.

c) Less than six months from treatment with radioactive iodine therapy.

d) Less than 24 months from stopping treatment with anti-thyroid tablets.

Discretionary If on stable maintenance treatment with thyroxine, accept.

See if Relevant Autoimmune disease

Beta Blockers Surgery

Reason for Change Links to 'Autoimmune Disease' and 'Beta Blockers' have been added.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Thyroxine

See Thyroid Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Tick-Borne Encephalitides

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Tick-Borne Encephalitis Immunization**

See Immunization - Non-Live

Update Information

This entry was last updated in TDSG-BM 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-BM 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 donor 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 donor, accept.
- b) If at anytime a non-stored autologous tissue or organ has been transplanted, accept.
- 2. Donor who has received an allogeneic tissue transplant since January 1st 1980 The full transplant/transfusion history must be recorded and 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-BM Edition 203, Release 02

### **Tissue Recipient**

See Tissue and Organ Recipients

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# **Toctino**

See Alitretinoin

Reason for Change New entry.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 17

# **Topical Medication**

Obligatory Must not donate if:

There is broken or infected skin at the site of venepuncture or harvest.

Discretionary If the condition being treated does not exclude, accept.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Toxoplasmosis**

Obligatory Must not donate if:

Less than six months from recovery.

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

### **Transfusion**

#### Including

Treatment with Blood Components, Products and Derivatives.

#### Obligatory

#### 1. Must not donate if:

#### At any time the donor 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.

# 2. Refer to a Designated Medical Officer if:

#### Since January 1st 1980:

- a) Anywhere in the world, the donor 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 babies have required intra-uterine transfusion.
- b) Had a plasma exchange performed.

#### Discretionary

- 1. a) If on medical inquiry it is unlikely that the donor 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 donor's own blood has been used, accept.

# 3. Donor transfused before 1st January 1980 in a country endemic for malaria or South American trypanosomiasis:

- a) If the donor 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. Donor transfused since January 1st 1980:

Discuss with the **Designated Medical Officer** who will decide if the donor may be accepted following a documented risk assessment. This must take into account the availability of alternative donors, the risks of vCJD transmission and the expected benefits of using a particular donor.

### See if Relevant

Bleeding Disorder

Immunoglobulin Therapy Immunosuppression

Malaria

**Prion Associated Diseases** 

South American Trypanosomiasis Risk Geographical Disease Risk Index

#### Additional Information

**Transfused donors** have previously contributed to the spread of some diseases. This happened with hepatitis C.

#### All transfused donors:

Transfusions in some countries may have put the donor at risk of malaria or South American trypanosomiasis. It is necessary to exclude these infections before accepting the donor.

### 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.

#### Donors 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.

In view of this, people 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-BM Edition 203, Release 02

### **Transient Ischaemic Attacks**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Trauma**

See Accident

Update Information This entry was last updated in

TDSG-BM 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-BM Edition 203, Release 02

# **Tropical Areas**

See Infection - Tropical

Geographical Disease Risk Index

Update Information This entry was last updated in

# **Tropical Diseases**

See Infection - Tropical

Update Information This entry was last updated in

TDSG-BM 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) It is less than six months from a donor's return from a Tropical Virus Risk endemic area and the donor has been diagnosed with chikungunya, dengue or zika virus infection whilst there or following their return to the UK.
- b) It is less than six months from a donor's return from a Tropical Virus Risk endemic area and the donor has either had a history of symptoms suggestive of chikungunya, dengue or zika virus infection whilst there or following their return to the UK.
- c) In other cases it is less than four weeks from a donor's return from a Tropical Virus Risk endemic area.

#### Discretionary

All donors may be accepted six months after their return from an affected area or resolution of symptoms. This may be reduced to four weeks, if they have had neither symptoms nor evidence of infection.

#### See if Relevant

Infection - General

Malaria

South American Trypanosomiasis The 'Geographical Disease Risk Index'

#### 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 since 2005 it has reached epidemic proportions in parts of India and islands in the Indian Ocean. 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 35°N and 35°S. 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

The main vector for chikungunya virus and dengue virus, Aedes aegypti (Aedes albopictus is another emerging vector), is found worldwide between latitudes 35°N and 35°S and Dengue is currently considered endemic in approximately 128 countries. There is no epidemiologically important animal reservoir. The main areas affected include the Caribbean, South and Central America, Mexico, Africa, the Pacific Islands, SE Asia, Indian sub-continent, Hawaii, Japan and Australia, where Dengue Fever has been reported.

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 or 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-BM Edition 203, Release 23.

# **Trypanosoma Cruzi Infection**

Obligatory Must not donate.

See if Relevant South American Trypanosomiasis Risk

Update Information This entry was last updated in

TDSG-BM 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 donor 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 people who may have active disease from donating

to prevent any possibility of transmitting the infection.

Update Information

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

# **Tumour Chemotherapy**

See

Malignancy

**Update Information** 

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

# **Turner's Syndrome**

Discretionary

Accept.

Update Information

This entry was last updated in TDSG-BM 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-BM Edition 203, Release 17

# **Typhoid Injected Immunization**

See

Immunization - Non-Live

Update Information

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

# **Typhoid Oral Immunization**

See

Immunization - Live

Update Information

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

# **Ulcerative Colitis**

See

Inflammatory Bowel Disease

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Urethritis (Non-Specific)**

See Non-Specific Urethritis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Urinary Tract Infection**

See Infection - General

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

## **Vaccination**

See Immunization

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Varicose Veins**

Discretionary Accept.

See if Relevant Phlebitis

Surgery Thrombosis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Vasculitis**

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### **Viral Disease**

See Infection - General

Update Information This entry was last updated in

# 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-BM Edition 203, Release 23.

### Vitamin Treatment

Obligatory Must not donate if:

On prescribed medication to treat a deficiency.

Discretionary If on oral self-medication or prescribed treatment to prevent deficiency, accept.

Additional Information People who are on treatment for a vitamin deficiency should not donate even if they pass the haemoglobin-screening test. Once treatment is completed they should be accepted or excluded

on the basis of the underlying condition that required treatment.

Vitamins are often prescribed to prevent deficiency. This might be for coeliac disease or for

people wanting to conceive. Providing any underlying condition is not a reason to exclude, the

donor should be accepted.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Vitiligo**

See Autoimmune Disease

Update Information This entry was last updated in

# Von Recklinghausen's Disease

See Neurofibromatosis

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

#### Von Willebrand's Disease

See Bleeding Disorder

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

### Warts

Discretionary Even

Even if on local treatment, accept.

Update Information

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

# Weight

#### Obligatory

# 1. Bone Marrow Donor: Must not donate if:

- a) Body Mass Index over 35.
- b) Under 50 kg (7 stone 12 lbs.).
- c) Obtain anaesthetic opinion if: Body Mass Index between 30 and 35.

### 2. PBSC Donor:

#### Must not donate if:

- a) Body Mass Index over 40.
- b) Under 50Kg (7 stone 12 lbs).
- c) The donor is so overweight that they have difficulty in getting onto or off the bleed bed.
- d) Venous access is very difficult.

## Discretionary

- a) Potential PBSC donors with a BMI between 35 and 40 should be carefully assessed for other risk factors for cardiovascular disease before they are accepted as suitable.
- b) Treatment with anti-obesity drugs, accept.

#### Additional Information

Blood service staff should not put their own health at risk by helping donors on and off the donation couch except in an emergency.

It is recommended that no donor should lose more than 13% of their blood volume during any donation procedure. This is to protect them from adverse effects such as fainting and becoming anaemic. There is a minimum donor weight at which a donation can be accepted. This is not always appropriate.

Obesity also makes it desirable to use more than a donor's weight to estimate their blood volume. Fat contains far less blood as a proportion of its weight

than muscle. In obese individuals the blood volume can be seriously overestimated from weight

alone. Overestimating a donor's blood volume makes it more likely that they will have an adverse incident.

Donors who are overweight or obese tend to have more moderate-severe pain with PBSC donation. BM harvest is technically a considerably more difficult procedure in overweight donors. There is much evidence to support the concept that the morbidly obese in general (i.e., with a BMI >35) have a higher risk of premature death, anesthetic complications and occult cardiovascular disease.

Reason for Change

The levels of BMI/weight at which a PBSC donor can be accepted have been changed to align with Anthony Nolan, DKMS, NMDP and Canadian current guidance and WMDA draft guidance.

Update Information

This entry was last updated in TDSG-BM Edition 203, Release 17

### **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-BM Edition 203, Release 22.

# **Whooping Cough**

### Infection

See Infection - Acute

Contact

See Infectious Diseases - Contact with

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Wilson's Disease

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Xenotransplantation**

Including Xenografts

Heterografts

Non-Human Organ Perfusion

### Recipient

Definition Any pro

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<sup>®</sup>, Bio-Oss<sup>®</sup>, Bio-Gide<sup>®</sup> and Surgibone<sup>®</sup>) 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 donor's blood supply. This does not include animal bites.

### Sexual Partners of Xenotransplant Recipients, Current and Former

Obligatory Must not donate.

Additional 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-BM Edition 203, Release 24

# **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-BM Edition 203, Release 12 Issue 01

### Yaws

Obligatory Must not donate.

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Yellow Fever**

See Infection - Acute

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# **Yellow Fever Immunization**

See Immunization - Live

Update Information This entry was last updated in

TDSG-BM Edition 203, Release 02

# Zanamivir

See Relenza®

# **Latest Updates**

This page lists all changes to TDSG-BM 203 after Release 02.

This pages constitutes Section 2 of Appendix 1 - Changes to the donor selection guidelines.

#### 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

Blood Pressure - High See Change Notification No. 1 - 2008

Appendix 4 removed See Change Notification No. 5 – 2008

This update also corrects an error where commas did not display in the A-Z topics content on the website.

### Changes introduced with Release 05

Tamiflu® (oseltamivir) See Change Notification No. 30 - 2009

Relenza® (zanamivir) See Change Notification No. 31 - 2009

#### Changes introduced with Release 06

Acupuncture See Change Notification No. 33 - 2009

Complementary Therapy See Change Notification No. 35 - 2009

#### Changes introduced with Release 07

Body Piercing See Change Notification No. 02 - 2010

Inoculation Injury See Change Notification No. 04 - 2010

Endoscopy See Change Notification No. 05 - 2010

#### Changes introduced with Release 08

West Nile Virus (WNV) See Change Notification No. 09 - 2010

#### Changes introduced with Release 09

Immunization - Live See Change Notification No. 06 - 2011

BCG See Change Notification No. 07 - 2011

Infertility See Change Notification No. 08 - 2011

Sexually Transmitted Disease See Change Notification No. 09 - 2011

#### Changes introduced with Release 10

West Nile Virus (WNV) See Change Notification No. 11 - 2011

#### Changes introduced with Release 11

Porphyria See Change Notification No. 20 - 2011

#### Changes introduced with Release 12

XMRV See Change Notification No. 25 - 2011

Hepatitis C See Change Notification No. 27 - 2011

#### **Changes introduced with Release 13**

West Nile Virus (WNV) See Change Notification No. 05 - 2012

#### **Changes introduced with Release 14**

Acne See Change Notification No. 15 - 2012

Pregnancy See Change Notification No. 16 - 2012

Psoriasis See Change Notification No. 17 - 2012

Toxoplasmosis See Change Notification No. 18 - 2012

### **Changes introduced with Release 15**

West Nile Virus (WNV) See Change Notification No. 01 - 2013

### **Changes introduced with Release 16**

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 17

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

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

Weight See Change Notification No. 16 - 2014

#### Changes introduced with Release 18

Change of Title See Change Notification No. 29 - 2014

Haematological Disease See Change Notification No. 30 - 2014

SARS See Change Notification No. 31 - 2014

Tissues Safety See Change Notification No. 32 - 2014

Homosexual and Bisexual Individuals See Change Notification No.34 - 2014

Sex Change See Change Notification No.38 - 2014

#### Changes introduced with Release 19

Viral Haemorrhagic Fever Risk See Change Notification No. 43 – 2014

#### **Changes Introduced with Release 20**

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 21**

Complementary Therapy See Change Notification No. 12 - 2015 Injectable Tanning Agents See Change Notification No.15 - 2015

#### **Changes Introduced with Release 22**

Appendix 2 Table of Immunizations
Tropical Viruses
West Nile Virus
Viral Haemorrhagic Fever

See Change Notification No. 04 - 2016
See Change Notification No. 08 - 2016
See Change Notification No. 09 - 2016
See Change Notification No. 11 - 2016

#### **Changes Introduced with Release 23**

Tropical Viruses See Change Notification No. 014 - 2016
Viral Haemorrhagic Fever See Change Notification No. 015 - 2016

### Changes Introduced with Release 24

Endoscopy Severe Excercise Intolerance Disease (SEID)

Xenotransplantation

See Change Notification No. 24 - 2016
See Change Notification No. 28 - 2016
See Change Notification No. 29 - 2016

### **Changes Introduced with Release 25**

Hepatitis A See Change Notification No.46 - 2016

# **Changes Introduced with Release 26**

Malaria See Change Notification No. 17 - 2017

Bone Marrow and Peripheral Blood Stem Cell Tissue Donor Selection Guidelines

# Appendix 1 - Changes to donor selection guidelines

#### Section 1

#### Changes introduced with TDSG-BM 203 Release 02 from TDSG-BM 202 Release 03

There have been changes made to the following entries:

Acupuncture

Age

Animal Bite

Ankylosing Spondylitis

Anti-Androgens

Antibiotic Therapy

**Antidepressant Therapy** 

Arthritis

Autoimmune Disease

**Back Problems** 

Beta Blockers

Bipolar Disorder

Bleeding Disorder

Blood Pressure - High

**Blood Volume Estimation** 

Cardiovascular Disease

Chikungunya Virus

Chlamydia

Cirrhosis

Colitis

Communication Difficulties

Depression

Dermatitis

**Disabled Donor** 

Disease of Unknown Aetiology

Elliptocytosis

Endocarditis

Endoscopy

Episcleritis

Eve Disease

Gall Bladder Disease

G-CSF

German Measles

Haemoglobin Disorders

Haemolytic Anaemia

Hepatitis B

Hepatitis B - Post Immunization

Hepatitis C

Hepatitis of Unknown Origin

Hereditary Elliptocytosis

Hereditary Spherocytosis

Hormone Replacement Therapy

Immune Thrombocytopenia

Immunoglobulin Therapy

Immunosuppression

Infection - Chronic

Inflammatory Eye Disease

Inoculation Injury

Jaundice

Laminectomy

Latex Allergy

Malaria

Mental Health Problems

Myeloproliferative Syndrome

Pituitary Extract - Human

Platelet Disorder

Polymyalgia Rheumatica

**Prion Associated Diseases** 

Psoriasis

Pyruvate Kinase Deficiency

Rheumatoid Arthritis

Scleritis Sexually Transmitted Disease Shingles Sickle-Cell Trait Skin Disease Steroid Therapy Subacute Bacterial Endocarditis Surgery Syphilis Temporal Arteritis Thrombocytosis Thyroid Disease Tigason Tissue and Organ Recipients Transfusion Weight West Nile Virus

### Section 2 Changes to TDSG-BM 203 after Release 02

See: Latest Updates

This appendix was last updated in TDSG-BM Edition 203, Release 02

# Appendix 2 - Withdrawal of Donations

#### General considerations.

Circumstances that should have excluded donation may only become known after stem cells have 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 stem cells. 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 donor at risk of infection with blood borne organisms (Tissues Safety Entry).
- b) Donors in the 'at risk' categories relating to possible transmission of Prion Associated Diseases e.g. CJD and vCJD.
- c) Donors with Malignancy (other than those for which there is a discretion in the A-Z)
- d) Autoimmune Disease.
- e) Allergy.
- f) Donors 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.
- g) Donors with diseases of unknown aetiology.

Action: Inform the Designated Medical Officer.

This appendix was last updated in TDSG-BM Edition 203, Release 02