

# **Tissue Donors (Deceased) Donor Selection Guidelines (TD-DSG)**

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## **Introduction**

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These guidelines form a constituent part of Chapter 20 (Tissue banking: selection of donors) of the Guidelines for the Blood Transfusion Services in the United Kingdom.

These criteria are reviewed regularly to ensure that the tissues obtained are of the highest quality and of sufficient quantity to meet the needs of recipients.

JPAC is responsible for this document and 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.

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

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These guidelines are under the continuing review of the Standing Advisory Committee for Tissues and Cellular Therapy Products (SACTCTP) and for Transfusion Transmitted Infection (SACTTI). 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).

**Ocular Guidelines.** The TDSG-DD contains information on the selection of donors of ocular tissue. There is continuing consultation with the Ocular Tissue Transplant Standards Group (OTTSG). This may lead to further changes in these guidelines, which will be notified through the website [www.transfusionguidelines.org.uk](http://www.transfusionguidelines.org.uk)

Questions and comments about the ocular guidelines should be addressed in the first instance to Professor John Armitage, e-mail [w.j.armitage@bristol.ac.uk](mailto:w.j.armitage@bristol.ac.uk) (who will ensure that they are referred to the Chair of the OTTSG).

### Change Notification.

A Change Notification Letter is used to communicate 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 [JPACOffice@nhsbt.nhs.uk](mailto:JPACOffice@nhsbt.nhs.uk)

## General Principles

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This document provides guidance for the selection of deceased donors of tissues. It must be read in conjunction with Chapter 20 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 to ensure that their tissue 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 fulfills the respective selection guidelines. When it is not clear from these guidelines if an individual donation is acceptable, no tissue should be used without discussion with a **Designated Medical Officer**.

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 **Tissue Safety Entry** in the **A-Z**.

It is the responsibility of the **Qualified Healthcare Professional** to ensure that relatives/partners clearly understand the nature of the donation process. Relatives/partners must also understand the health questions and other information presented to them. Relatives/partners are asked about confidential aspects of their relative's/partner's 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 different tissues this is made clear.

When there is a recognized risk to 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, relatives/partners **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's relatives/partner.

### 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-DD Edition 203, Release 02, Issue 01.

## Medication

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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 tissues 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-DD Edition 203, Release 02, Issue 01.

## Use of Alphabetical Listing (A-Z)

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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 tissue, which, as a result, is unsuitable for clinical use, **must** be clearly labelled as unfit for use.

Any new health risks identified by this process should be notified to the Standing Advisory Committee on 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 relatives/partner, or through any other source, that the donor was 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-DD Edition 203, Release 02, Issue 01.

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## Acanthamoeba (ocular infection)

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<i>Obligatory</i>	<b>Eyes:</b> <b>Must not donate if:</b> Past or active infection.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Accident

---

<i>Includes</i>	Trauma
<i>Obligatory</i>	If there is significant trauma, in particular penetrating trauma: <b>Refer to a Designated Medical Officer.</b> If the donor is accepted the rationale must be documented.
<i>Discretionary</i>	<b>Eyes.</b> If eyes uninvolved, accept.
<i>See if Relevant</i>	<u>Neurosurgery</u> <u>Tetanus Immunization</u> <u>Transfusion</u>
<i>Additional Information</i>	Blunt chest trauma can result in damage to cardiovascular tissue.  An open wound or other source of infection is a risk for tissues becoming contaminated.
<i>Reason for Change</i>	Additional links have been added.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Achondroplasia

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<i>Obligatory</i>	<b>Bone, structural:</b> <b>Must not donate.</b>
<i>Discretionary</i>	<b>Bone, non-structural:</b> Accept.
<i>Additional Information</i>	People with achondroplasia have abnormal structural bone. This may not be suitable for grafting.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Addiction and Drug Abuse

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<i>Obligatory</i>	<b>Must not donate if:</b> a) Has injected, or has been injected with drugs in the past 12 months.  b) Has injected, been injected with, or taken non-parenteral chemsex drugs in the past 3 months. Please see <u>Tissues Safety Entry</u> .
<i>Discretionary</i>	a) Accept if has not injected or been injected with other non-prescription drugs (other than drugs of addiction), such as bodybuilding drugs or injectable tanning agent within the past 3 months.  b) Accept if has not injected, or been injected with, drugs of addiction within the last 12 months.

c) If has not injected or been injected with drugs of addiction within the last 3 months – **refer to designated medical officer**. The donor may be accepted with individual risk assessment. See additional information section.

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

e) 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. The deferral periods specified above may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.

*Reason for Change* Obligatory section updated as a part of the implementation of recommendations from the FAIR III report, including addition of chemsex drugs.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 57

## African Trypanosomiasis

---

(Sleeping Sickness)

*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**  
Accept for corneas only.

*Additional Information* As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change* A 'Discretion' has been added for 'Eyes'.

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

## Age

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*Obligatory* **1. Bone, structural.**  
**Must not donate if:**  
a) Over 50 years of age.  
b) Under 17 years of age.

**2. Whole heart for tissue allografts.**  
**Must not donate if:**  
a) Over 70 years of age.  
b) A child of less than 32 weeks gestation (see **Children** below).

**3. Costal cartilage.**  
**Must not donate if:**  
a) Over 40 years of age.  
b) Under 10 years of age.

**4. Eyes.**  
If the donor is under three years old **Refer to Eye Bank** and, if applicable, observe the testing for **Children** below.

**5. Skin.**  
May be collected from a donor of any age but, if applicable, observe the testing for **Children**

below.

#### **6. Tendons.**

##### **Must not donate if:**

a) Over 60 years of age.

b) Under 17 years of age.

##### **Children:**

a) Under 18 months old.

If the mother would not be excluded by the Tissues Safety Entry and agrees to testing, and all her results are negative (for the infectious markers used for living tissue donors) and the markers of infection in the child are negative (as used for deceased donors), accept.

b) Breastfed in the preceding 12 months.

As in a) above, but only accept if the breast milk has been provided exclusively by the mother.

*See if Relevant*

Tissues Safety Entry

*Additional Information*

The biomechanical properties and cellularity of tissues vary with age.

Children, particularly those who are breastfed, may acquire infection risks from their mother or from the provider of breast milk if this has not been exclusively their mother.

*Reason for Change*

To state an upper age limit of 70 for whole heart donation for preparation of allografts.

*Update Information*

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

This entry was last updated in  
TDSG-DD Edition 203, Release 29

## **Alcoholism**

---

*Obligatory*

**Bone, structural.**

**Must not donate if:**

General nutrition is affected.

*See if Relevant*

Cirrhosis

*Additional Information*

If nutrition is poor the quality of bone is likely to be poor.

*See*

Addiction and Drug Abuse

*Update Information*

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

## **Allergy**

---

*Discretionary*

Accept.

*See if Relevant*

Steroid Therapy

*Update Information*

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

## **Anaemia**

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*Discretionary*

#### **1. History of anaemia:**

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

#### **2. Iron deficiency:**

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

exclude, accept.

### 3. Other types:

Accept or exclude according to the guidelines.

### 4. In other cases:

**Refer to a Designated Medical Officer.**

*See if Relevant*

Haemoglobin Disorders  
Malignancy

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

Transfusion

*Additional Information*

People with severe long-standing anaemia may have abnormal structural bone. This may not be suitable for grafting.

There are special rules for people who have received blood components or blood products.

*Reason for Change*

A link to 'Transfusion' has been added.

*Update Information*

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

## Animal Bite

---

(Non-human)

*Obligatory*

**Must not donate if:**

a) Ever bitten by a non-human primate.

b) Any wound is infected or not healed.

c) Less than 24 months since bitten anywhere in the world by a bat or by any other mammal outside of the British Isles.

*See if Relevant*

Human Bite  
Infection - General  
Rabies Immunization

*Additional Information*

Being bitten by a non-human primate should result in permanent deferral. Risks include simian T-lymphotropic virus, Herpes B, simian foamy virus and other as yet unknown viruses. Non-human primates include chimpanzees, gorillas, orangutans, gibbons, monkeys (old and new world), tarsiers, lemurs and lorises.

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.

*Reason for Change*

To extend the deferral period following being bitten by a bat or other mammal outside of the UK from 12 to 24 months, and to provide more information on the potential risks resulting from non-human primate bites. To provide a detailed definition of a non-human primate.

*Update Information*

This entry was last updated in  
TDSG-DD Edition 203, Release 41

## Ankylosing Spondylitis

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<i>Obligatory</i>	<p><b>1. Eyes.</b>  <b>Must not donate if:</b>  Active ocular inflammation.  See <a href="#">Eye Disease</a> entry for more information if the donor had recovered from inflammatory eye disease.</p> <p><b>2. Cardiovascular Tissue.</b>  <b>Must not donate if:</b>  The cardiovascular system is involved.</p>
<i>See if Relevant</i>	<a href="#">Autoimmune Disease</a> <a href="#">Eye Disease</a>
<i>Additional Information</i>	Ankylosing spondylitis can affect the eyes, heart valves and the major artery of the body (aorta).
<i>Reason for Change</i>	Obligatory section updated to refer to eye disease entry if ocular involvement, Link to eye disease entry added in "See if relevant" section.
<i>Update Information</i>	This entry was last updated in TD-DSG Edition 203 Release 60

## Anthrax

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### Exposure

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

### Immunization

<i>See</i>	<a href="#">Immunization - Non-Live</a>
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### Infection

<i>See</i>	<a href="#">Infection - Acute</a>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Antibiotic Therapy

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<i>Additional Information</i>	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 <b>Designated Medical Officer</b> .
<i>See</i>	<a href="#">Infection - General</a>
<i>Reason for Change</i>	Additional Information' has been added for clarity.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02



## Arthritis

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<i>See if Relevant</i>	<u>Ankylosing Spondylitis</u> <u>Autoimmune Disease</u> <u>Osteoarthritis</u> <u>Psoriasis</u> <u>Rheumatoid Arthritis</u>
<i>Reason for Change</i>	A link has been added for 'Autoimmune Disease'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Asthma

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<i>See if Relevant</i>	<u>Infection - General</u> <u>Steroid Therapy</u>
<i>Reason for Change</i>	The 'Obligatory' entry has been removed. This prevented many donors dying with asthma from being accepted as they would have been treated with steroids.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Autoimmune Disease

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<i>Obligatory</i>	<b>See:</b> Is there an entry for the condition?
	<b>Must not donate if:</b> The donor has needed treatment to suppress the condition in the last 12 months.
<i>Discretionary</i>	<b>Eyes:</b> If no ocular involvement, accept.
<i>See if Relevant</i>	<b>If treated with immunoglobulin or plasma exchange or filtration:</b> <u>Immunosuppression</u> <u>Transfusion</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	A link to Immunosuppression has been added.
<i>Update Information</i>	Part of this advice is a requirement of the EU Tissue & Cells Directive.  This entry was last updated in TDSG-DD Edition 203, Release 11

## Avascular Necrosis of the Femoral Head (Hip)

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<i>Obligatory</i>	<b>Must not donate:</b> Affected femoral heads.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Babesiosis

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	<b>Eyes:</b> Accept for corneas only.
<i>Additional Information</i>	As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.
<i>Reason for Change</i>	A 'Discretion' has been added for 'Eyes'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Basal Cell Carcinoma

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<i>Obligatory</i>	<p><b>1. Must not donate if:</b></p> <p>a) Still receiving treatment.</p> <p>b) Any wound has not healed.</p> <p><b>2. Eyes.</b> <b>Must not donate if:</b> From an eye with active Basal Cell Carcinoma (BCC) of the eyelid, unhealed wounds or corneal involvement e.g., exposure keratitis.</p> <p><b>3. Skin.</b> <b>Must not donate:</b> From the area affected by the lesion.</p>
<i>Discretionary</i>	<p><b>Eyes.</b></p> <p>Unhealed wounds not affecting the eye, if cornea is to be stored by organ culture, accept. See additional information.</p>
<i>See if Relevant</i>	<u>Malignancy</u> <u>Eye Disease</u>
<i>Additional Information</i>	<p>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.</p> <p>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 during storage.</p> <p>Exclusion of donors with unhealed wounds not affecting the eyes does not apply to corneas stored by organ culture as this gives an opportunity to detect infection, but does apply to corneas stored at 4°C.</p> <p>Donors with healed BCC of the eyelids can be accepted for eye donation, unless ocular tissue might be affected by the effects of treatment. Treatment records should be reviewed, esp. in relation to the effects of treatment e.g., radiotherapy, and eyes must undergo slit lamp examination in the eye bank.</p>
<i>Reason for Change</i>	To add guidance regarding donors with basal cell carcinoma of the eyelid.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 52

**BCG**

<i>Obligatory</i>	<b>Must not donate if:</b> a) The inoculation site has not yet healed.  b) Less than four weeks after inoculation.
<i>Additional Information</i>	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.
<i>Reason for Change</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 09

**Bleeding Disorder**

*Includes* Carriers

**Affected Individual**

<i>Obligatory</i>	<b>Must not donate if:</b> Treated with blood derived coagulation factor concentrates.
<i>See if Relevant</i>	<u>Transfusion</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	A link to 'Transfusion' has been added.

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

<i>Obligatory</i>	<b>Must not donate if:</b> 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) Less than 3 months after the date of an inoculation injury with either blood derived coagulation factor concentrates, or from blood contamination from an affected individual.
<i>Discretionary</i>	If 3 months or more from last sexual contact or inoculation injury, accept.
<i>See if Relevant</i>	<u>Inoculation Injury</u> <u>Transfusion</u>
<i>Additional Information</i>	<b>Blood derived coagulation concentrates:</b> These are made from the blood of many donors. They may put recipients at risk of infections that can be passed through blood. This risk may be shared by their sexual partners.  Waiting 3 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.
<i>Reason for Change</i>	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 29

## Blind Donor

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*Obligatory* **Eyes:**  
Determine the cause of blindness and discuss with a **Designated Medical Officer**

*Discretionary* **Other Tissues:**  
If no other contraindication, accept.

*Additional Information* Donors with corneal blindness must be deferred. Most donors with retinal and optic nerve blindness can be accepted.

*Reason for Change* To provide additional information regarding which types of blindness affect eye donation.

*Update Information* **Publication:** TDSG - LD Edition 203, Release 33

## Blood Pressure - High

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*Discretionary* Accept.

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

## Body Piercing

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*Includes* Derma-rolling, ear and body piercing, permanent and semi-permanent makeup, tattooing (including memorial tattoos), platelet rich plasma (PRP) facials and ritual self-flagellation.

*Obligatory* **Must not donate if:**  
Less than 3 months after last piercing.

*Discretionary* Piercings performed within the UK in a commercial setting: Accept

Piercings performed outside the UK or within the UK in an unlicensed non-commercial premises more than 3 months ago: Accept

Painting, stencilling or transfers applied to the skin without piercing: Accept

*Additional Information* Under all current legislation it is a criminal offence to trade without registration (licensing) or to be in breach of the relevant byelaws. Similar provisions are in place in Scotland in the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006. Some London boroughs also require a 'special treatment' license. It is expected that all premises will follow infection control processes including using single needles for treatments.

In the UK local authorities are responsible for regulating and monitoring businesses providing semi-permanent skin colouring procedures (micropigmentation, semi-permanent make-up and temporary tattooing). The focus of legislation covering local authorities in England, Wales and Northern Ireland (Local Government (Miscellaneous Provisions) Act 1982) is on minimising infection risks using compulsory registration of practitioners and premises and optional powers to make byelaws.

For piercings performed outside the UK or within the UK in an unlicensed, non-commercial establishment less than 3 months ago, the donor may only be accepted following documented individual risk assessment and discussion with the transplant centre if the risk of delaying transplant outweighs the risk of transmission of infections.

Piercing has passed infection from person to person. Waiting 3 months helps to ensure that the infections tested for by the Blood & Tissues Services will be picked up.

Platelet rich plasma (PRP) facials (also known as 'Vampire Facials') have been associated with HIV transmission.

Ritual self-flagellation is carried out by some religious groups. The practice includes beating or flogging oneself with sharp objects. It may be associated with exposure to blood from other participants, either directly or through contamination of shared equipment.

This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.

*Reason for Change* To add Derma-rolling, ear and body piercing, tattooing (including memorial tattoos), platelet rich plasma (PRP) facials and ritual self-flagellation to the entry and to add information regarding PRP facials and ritual self-flagellation.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 48.

## Breast Lump

*Obligatory* **Must not donate if:**  
 a) Malignant.  
 b) Not fully investigated and cleared of malignancy.

*Discretionary* **Eyes.**  
 If related to malignancy, see Malignancy.

*See if Relevant* Malignancy

*Reason for Change* The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 35

## Breastfeeding

*Obligatory* For infants that have been breastfed in the last 12 months:  
**See**  
Age

*Reason for Change* This is a new entry.

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

## Bronchitis

### Acute

*See* Infection - Acute

### Chronic

*See if Relevant* Infection - General  
Steroid Therapy

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

## Brucellosis

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Undulant Fever

*Obligatory* **Must not donate.**

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

## Cardiac Surgery

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*Obligatory* **Cardiovascular Tissue Donor:**  
Donors with a history of previous cardiac valve surgery:  
**Refer to a Designated Medical Officer.**

*See if Relevant* Endocarditis

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

## Cardiomyopathy

---

*Obligatory* **1. Eyes:**  
**Must not donate if:**  
a) Associated with extraocular muscle paresis, e.g. Kearns-Sayre Syndrome.  
b) Not recovered from infective causes.

**2. Other Tissues:**  
**Must not donate if:**  
a) Not recovered from infective causes.  
b) cardiomyopathy secondary to an infiltrative process e.g. amyloidosis, sarcoidosis.

*Reason for Change* The entry has been changed to make it clear that cardiomyopathy is not an absolute contraindication to donation of cardiovascular tissues.

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

## Cardiovascular Disease

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*Obligatory* **Cardiovascular Tissue Donor:**  
Donors with a history of cardiac valve abnormalities:  
**Refer to a Designated Medical Officer.**

*See if Relevant* Cardiac Surgery  
Cardiomyopathy  
Endocarditis  
Myocarditis

*Reason for Change* Additional links have been added.

An entry has been added for donors with a history of valve abnormalities.

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

## Catarrh

---

### Acute

*See* Infection - Acute

### Chronic

*See if Relevant* Infection - General

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

## Central Nervous System Disease

---

*Obligatory* **Must not donate if:**  
 a) Dementia.  
 b) History of CNS disease of unknown or suspected infective origin (e.g. multiple sclerosis (MS), optic neuritis, clinically isolated syndrome, transverse myelitis, Creutzfeldt-Jakob disease (CJD)).  
 c) Neurodegenerative conditions of unknown aetiology (e.g. Parkinson's disease).

*Discretionary*  
 a) Individuals who have had Bell's palsy more than four weeks ago and have discontinued any treatment for the condition for at least seven days, even if they have residual paralysis, accept.  
 b) If a definite diagnosis of transient global amnesia has been made, accept.  
 c) If the cause of the disease is not established, refer to designated medical officer

*See if Relevant* Neurosurgery  
Prion Associated Diseases  
Rabies

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

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

*Reason for Change* To clarify that CNS disease of unknown origin, and clinically isolated syndrome, are reasons for obligatory deferral and to permit individual risk assessment where appropriate.

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

This entry was last updated in  
TDSG-DD Edition 203, Release 31

## Cervical Dysplasia

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*Obligatory*

**Must not donate if:**

Diagnosed with invasive cervical carcinoma.

- Discretionary*
- a) If the donor had colposcopy treatment for abnormal cervical cells and has been discharged to routine screening, accept. It is not necessary to wait for a normal smear result before donating.
  - b) If only having regular review of smears, accept.
  - c) If undergoing investigation or treatment, refer to designated clinical support officer

**Eyes - Accept**

*Additional Information* Cervical screening includes testing for high risk Human Papilloma Virus (HR-HPV). Women who are positive for HR-HPV may be called for routine smear tests at more frequent intervals. They can donate provided they are not undergoing other tests or awaiting colposcopy investigation.

Women with abnormal cells on a smear test are triaged according to their risk of developing cervical carcinoma. Women at higher risk will be referred for investigation and treatment via colposcopy.

Abnormalities identified at colposcopy include cervical intra epithelial neoplasia (CIN, Grades 1-3) and cervical glandular intra epithelial neoplasia (CGIN). CIN-3 is also known as cervical carcinoma in situ. By definition, patients with CIN or CGIN do not have invasive cervical carcinoma, so can be accepted once treated, fully healed and discharged. There is no need to wait for the results of their next routine smear, usually at 6 months post treatment, unless the donor has been advised that follow up will be necessary at the colposcopy clinic.

*Reason for Change* Updated to clarify the scope of entry, when a donor can be accepted after treatment for cervical dysplasia and the significance of HR-HPV testing.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 48.

## Chagas' Disease

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South American Trypanosomiasis

*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**  
Accept for corneas only.

*See if Relevant* South American Trypanosomiasis Risk

*Additional Information* As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change* A 'Discretion' has been added for 'Eyes'.

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

## Chicken Pox

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**Contact**

See Infectious Diseases - Contact with

**Herpes Zoster (Varicella Zoster)**

See Infection - Acute

**Eyes:**



Herpes - Ocular

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

**Chondromalacia**

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*Discretionary* Accept.

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

**Cirrhosis**

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*Obligatory* **Must not donate if:**  
a) Complicated by hepatoma.  
b) Infectious or autoimmune cause.

*Discretionary* **1.** If secondary to alcohol or genetic cause, accept.  
**2. Bone Donation**  
check that the quality of bone is unaffected.

**3. Eyes:**  
If related to malignancy, see Malignancy.

*See if Relevant* Alcoholism  
Autoimmune Disease  
Malignancy

*Reason for Change* Additional links have been added.

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

**Clinical Trials**

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*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

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

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

**Coeliac Disease**

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*Discretionary* Accept.

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

**Colostomy**

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<i>Obligatory</i>	<b>Must not donate if:</b> For malignancy or inflammatory bowel disease.
<i>Discretionary</i>	<p>1. If the reason for the colostomy is not of itself a reason to exclude and the stoma is healthy, accept.</p> <p><b>2. Eyes:</b></p> <p>a) If related to inflammatory bowel disease and there is no evidence of ocular involvement, accept.</p> <p>b) If related to malignancy, see <u>Malignancy</u>.</p>
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' (malignancy) has changed.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Communication Difficulties

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<i>Obligatory</i>	<p><b>1. All persons giving consent must:</b></p> <p>a) Fully understand the donation process.</p> <p>b) Give their informed consent to the process and to the testing of the donor's blood for diseases that may affect the suitability of their tissues for use.</p> <p><b>2. Third party interpreters:</b></p> <p>If they are to be present at any part of the selection procedure where there is an exchange of confidential information between the persons giving consent and the qualified health professional, they must:</p> <p>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</p> <p>b) Not be personally known to the donor or to the persons giving consent.</p> <p>c) Fully understand their duty of confidentiality and the confidential nature of any information obtained from the donor.</p>
<i>Additional Information</i>	<p>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.</p> <p><b>Any persons giving consent must:</b></p> <p>a) Undergo a personal interview performed by a health professional.</p> <p>b) Provide informed consent to proceed with the donation process. This consent must be given in the presence of the qualified health professional responsible for obtaining the health history. The qualified health professional may be physically present or in communication with the person giving consent by telephone.</p> <p>A qualified health professional may assist in the completion of the health and medical history questionnaire and in understanding the consent statement and any other information provided by the Blood/Tissue Service. To facilitate comprehension it is permissible to use alternative formats (e.g. a language other than English, audio, computer, Braille) for the information leaflets, the health and medical history questionnaire and consent statements. The persons giving consent 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 qualified health professional.</p> <p><b>Use of third party interpreters.</b></p> <p>It is permissible for any third party to act as an enabler by helping to reassure the persons giving consent and to assist in establishing effective communication between them and the qualified health professional. The third party <b>must not</b> however be present during any exchange of confidential information, unless they are <b>not</b> personally known to the persons giving consent or to the donor and understand the need to accurately and truthfully communicate all the information, including personal and confidential information, provided</p>

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.

**Rationale.**

There is concern that the use of third parties during any exchange of confidential information between the persons giving consent and the qualified health professional may compromise the confidentiality of the process and the safety of any tissue donated. Interpreters are often part of a close community, or a family member, and this may inhibit or embarrass the persons giving consent in any confidential exchange of information. This may result in the non-disclosure of sensitive information that could affect the eligibility of the deceased person 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 any tissue donated 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 partner/family's health in a way that protects their confidentiality. The continuing availability of an independent interpreter, to maintain confidentiality, should be taken into account when deciding if an individual donor may be accepted.

<i>Reason for Change</i>	<ol style="list-style-type: none"> <li>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</li> <li>2. To clarify that interpreters and translators have a duty of confidentiality</li> <li>3. To clarify that consent for donation need not be signed by the person giving consent, it can be taken by telephone</li> </ol>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02, Issue 20

## Complementary Therapy

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<i>Obligatory</i>	<p><b>1. Must not donate if:</b> The condition for which treatment was given is not acceptable.</p> <p><b>2. Therapies involving penetration by needles or other invasive procedures:</b></p> <p><b>Must not donate if:</b> Less than 3 months from completing treatment</p>
<i>Discretionary</i>	<p>a) If oral or topical complementary medicines only and reason for which treatment was given is acceptable, accept</p> <p>b) For all other therapies involving penetration by needles or other invasive procedures:</p> <p><b>1. Performed within the NHS</b> If performed by a suitably qualified NHS healthcare professional on NHS premises, accept.</p> <p><b>2. Performed outside of the NHS</b></p> <p>2a) 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), General Pharmaceutical Council (GPhC), Pharmaceutical Society of Northern Ireland (PSNI), 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, Practitioner Psychologists, Physiotherapists, Prosthetists and Orthotists, Radiographers, Speech and Language Therapists), accept.</p> <p>2b) Treatments performed within commercial premises in the UK: Accept.</p> <p>2c) If performed within unlicensed, non-commercial premises in the UK, or for any treatment performed outside the UK more than 3 months ago: Accept.</p>

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

Commercial premises may be based in shops and clinics and also include operators running an acupuncture business from a residential premise such as their own homes. Under all current legislation it is a criminal offence to trade as an acupuncturist without registration (licensing) or to be in breach of the relevant byelaws. Similar provisions are in place in Scotland in the Civic Government (Scotland) Act 1982 (Licensing of Skin Piercing and Tattooing) Order 2006. Some London boroughs also require a 'special treatment' license. It is expected that all premises will follow infection control processes including using single needles for treatments.

In the UK local authorities are responsible for regulating and monitoring businesses providing tattooing, cosmetic piercings, semi-permanent skin colouring (micropigmentation, semi-permanent make-up and temporary tattooing), electrolysis and acupuncture. The focus of legislation covering local authorities in England, Wales and Northern Ireland (Local Government (Miscellaneous Provisions) Act 1982) is on minimising infection risks using compulsory registration of practitioners and premises and optional powers to make byelaws.

Healthcare professionals registered with statutory body may not need to register with the local authority as their statutory body is responsible for their regulation.

This guidance presumes that a validated NAT test for HIV, HBV and HCV 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 3 months means infections are more likely to be picked up by the tests used by Blood & Tissue Services

*Reason for Change* The regulatory organisations for Pharmacists in the UK have been added. The HCPC ceased to be the regulatory authority for Social Workers in England in 2019. The list of health and care professionals regulated by the HCPC has been amended.

*Update Information* This entry was last updated in TDSG-LD Edition 203, Release 47.

## Congo Fever

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*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-DD Edition 203, Release 02

## Contact Lenses

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*Obligatory* **Eyes:**  
**Must not donate if:**  
Underlying disease, e.g. keratoconus or infection.

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

## Contraceptive Implant

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*Discretionary* Accept.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

## Contraceptive Injection

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*Discretionary* Accept.

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

## Contraceptive Pill

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*Discretionary* Accept.

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

## Corneal Transplant

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*Obligatory* **Must not donate.**

*See if Relevant* Prion Associated Diseases

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

## Coronary Thrombosis

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*Includes* Heart Attack  
Myocardial Infarct

*Discretionary* Accept but may not be suitable for heart valves.

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

## Coronavirus Infection (COVID-19)

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*Includes* COVID-19 disease (due to infection with SARS-CoV-2 virus, previously known as Novel Coronavirus or 2019-nCoV).

### 1. Person with confirmed or suspected COVID-19

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

**Less than 7 days** since resolution of symptoms due to confirmed or suspected COVID-19.

*Discretionary* **Eyes** – Accept. See Additional Information.

**For all other tissues:**

- a) Confirmed symptomatic infection (COVID-19) – if **more than 7 days** have passed since resolution of symptoms, accept.
- b) Confirmed SARS-CoV-2 infection following diagnostic test without clinical symptoms - if **more than 7 days** have passed since most recent confirmed diagnostic test, accept.
- c) Suspected infection:
- If testing was not performed, and if **more than 7 days** after resolution of symptoms, see Infection - Acute entry.
  - If testing was performed, and COVID-19 has been ruled out as a clinical diagnosis, see Infection - Acute entry.
- d) For respiratory symptoms/failure not related to infection, or where COVID-19 was ruled out as a clinical diagnosis following testing, and if the underlying cause does not otherwise contradict donation, accept.

See Additional Information below.

<i>See if Relevant</i>	<u>Coronavirus Vaccination</u> <u>Infection - Acute</u> <u>Contact with Infectious Diseases</u>
<i>Additional Information</i>	<p>Common coronaviruses cause colds and respiratory tract infections but are not considered a risk for tissue transplant recipients. Since 2002 there have been outbreaks in humans of new strains of coronavirus, associated with severe pulmonary infections and mortality rates of 10-35% e.g. SARS and MERS.</p> <p>COVID-19 is an illness characterised by respiratory symptoms, including coughing and breathlessness, and fever. It is caused by infection with a newly identified Coronavirus, SARS-CoV-2. Its full pathogenesis remains unknown but individuals with certain underlying chronic conditions, the elderly and immunocompromised individuals are at risk of more severe disease.</p> <p>Some persons with SARS-CoV-2 infection may be asymptomatic. It is possible that they may have undergone testing for occupational health reasons (for example).</p> <p>Deceased tissue donors may have been subject to respiratory swab testing either on admission to hospital, or as organ donors. All organ donors are tested for SARS-CoV-2 on respiratory samples prior to donation. It is important to ascertain that, if the donor has been tested, the test was negative before proceeding with retrieval of tissues.</p> <p>There is no evidence at present that SARS-CoV-2 can be transmitted by tissue/ cell transplantation and therefore these measures are considered to be precautionary. Based on expert opinion COVID-19 infection is not a contraindication for eye donation, where the decontamination process includes a suitable virus inactivation step.</p>
<i>Reason for Change</i>	Delete outdated information in the definition section, and 'additional information' section. Reword 'obligatory' section and update 'discretionary' section.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 58

## Death from Unknown Causes

<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	If there is nothing to suggest that the retrieval of the tissues would be hazardous to staff and a post-mortem examination establishes that the cause/s of death would not exclude donation, accept.
<i>Reason for Change</i>	There has been a change to the wording of 'Discretionary' to better reflect the EU Tissue Directive.

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

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

## Deep Vein Thrombosis

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

*See if Relevant* Malignancy

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

## Dementia

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*Obligatory* **Must not donate.**

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

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

## Dermatitis

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*Obligatory* **Skin Donation**  
**Must not donate:**  
Areas of affected skin.

*Discretionary* **Other Tissues:**  
If no other contraindication, accept.

*See if Relevant* Infection - General  
Steroid Therapy

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

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

## Diabetes Insipidus

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

*See if Relevant* Neurosurgery

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

## Diabetes Mellitus

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*Obligatory* **Pancreatic Tissue:**  
**Must not donate.**

*Discretionary* **Other Tissues:**

Accept.

<i>See if Relevant</i>	<u>Infection - General</u>
<i>Reason for Change</i>	An entry has been added to indicate that pancreatic tissue should not be donated.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Diarrhoea

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<i>Includes</i>	D & V Entero-colitis Food Poisoning Gastric Flu Gastro-enteritis
<i>Obligatory</i>	<b>Must not donate if:</b> Associated with inflammatory bowel disease.
<i>Discretionary</i>	<b>Eyes:</b> a) If related to inflammatory bowel disease and there is no evidence of ocular involvement and the corneas are to be stored by organ culture, accept. b) If related to infection and the corneas are stored by organ culture, accept.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' has been amended.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Disabled Donor

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<i>Obligatory</i>	<b>Must not donate if:</b> Contractures will prevent retrieval.
<i>Discretionary</i>	If the underlying cause of the disability does not contra-indicate donation, accept.
<i>See if Relevant</i>	<u>Spina Bifida</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Disease of Unknown Aetiology

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<i>Obligatory</i>	<b>See:</b> Is there is a specific entry for the disease?  <b>Must not donate.</b>
<i>Discretionary</i>	If safety and quality of the donation is unlikely to be affected, discuss with Designated Clinical Support Officer. See 'additional information' section.
<i>Additional Information</i>	When the cause of an illness is not clear, there is an unknown risk to any recipient of donated material.  In certain circumstances, the aetiology could be multi-factorial, although it is not clearly established, there are no concerns relating to person to person transmission. In these cases, tissues could be accepted for clinical use, based on current available evidence. For example, the most frequent form of pulmonary fibrosis is idiopathic pulmonary fibrosis (IPF) where there is no identifiable underlying cause. Diagnostic criteria for IPF have evolved over the years, and IPF is currently defined as a disease characterized by the histopathologic pattern of interstitial pneumonia occurring in the absence of an identifiable cause of lung injury. IPF is believed to be a heterogeneous disorder caused by various interactions between genetic components and environmental exposures. Although an understanding of the pathogenesis of IPF is incomplete, recent advances delineating specific clinical and



pathologic features of IPF have led to better definition of the molecular pathways that are pathologically activated in the disease. On this basis, IPF is not an absolute contraindication for tissue donation.

*Reason for Change* To clarify that if the safety and quality of the tissues is not impacted, donation can be permitted.

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

This entry was last updated in  
TDSG-DD Edition 203, Release 48.

## Diverticulosis

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*Discretionary* Accept.

*See if Relevant* Infection - General

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

## Down's Syndrome

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*Includes* Mosaic Down's Syndrome

*Obligatory* **Eyes.**  
**Must not donate.**

*Discretionary* **Other Tissues:**  
If no other contraindication, accept.

*Additional Information* These syndromes are associated with corneal disease.

*Reason for Change* A 'Discretionary' entry has been added for other tissues.

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

## Drowning

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*Obligatory* **1. Cardiovascular Tissue:**  
**Must not donate:**  
If immersed for more than 12 hours.

**2. Eyes**  
**Refer to the Designated Medical Officer.**

**3. Skin.**  
**Must not donate.**

*Reason for Change* The entry for 'Eyes' has changed from 'Must not donate'.

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

## Drug Treatment

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*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.

<i>Discretionary</i>	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.
<i>See if Relevant</i>	<u>Addiction and Drug Abuse</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Dysplasia of the Hip

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Ehlers-Danlos Syndrome (Disease)

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<i>Obligatory</i>	<b>Must not donate.</b> All tissues with the exception of pancreatic islets
<i>Discretionary</i>	<b>Pancreatic Islets:</b> Accept
<i>Reason for Change</i>	Pancreatic islets have been added to the list of tissues that may be donated.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 26

## Electrolysis

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Emphysema

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Encephalitis

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<i>Discretionary</i>	<b>Eyes.</b> If caused by bacterial infection and the corneas are to be stored by organ culture, accept.
<i>See</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Endocarditis

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<i>Obligatory</i>	<p><b>1. Must not donate if:</b> Active infection.</p> <p><b>2. Cardiovascular tissue:</b> <b>History of infection:</b> <b>Must not donate.</b></p>
<i>Discretionary</i>	<p>1. If infection resolved, for non-cardiovascular tissue, accept.</p> <p><b>2. Eyes.</b> If the cause is bacterial and the corneas are to be stored by organ culture, accept.</p>
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Reason for Change</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Endometriosis

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Epilepsy

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<i>Obligatory</i>	<p><b>Must not donate if:</b></p> <p>a) Recent onset and not fully investigated.</p> <p>b) Secondary to malignancy or degenerative neurological disease.</p>
<i>Discretionary</i>	<p><b>Eyes:</b> If related to malignancy, see <u>Malignancy</u>.</p>
<i>See if Relevant</i>	<u>Malignancy</u> <u>Neurosurgery</u>
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' (malignancy) has changed.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Eye Disease

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<i>Obligatory</i>	<p><b>1. Must not donate if:</b></p> <p>a) Ocular tissue transplanted</p> <p>b) Malignancy</p> <p><b>2. Eyes</b></p> <p>a) Active ocular inflammation or infection</p> <p>b) Congenital or acquired ocular disorders or previous ocular surgery that may preclude a successful graft outcome. This includes iridocorneal syndrome and keratoconus</p>
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c) History of malignant tumours of the anterior segment, or retinoblastoma, ocular metastasis or ocular melanoma

d) Past history of ocular Herpes or interstitial keratitis in either eye

*Discretionary*

**1. Eyes**

a) Past ocular trauma - discuss with medical eye bank advisor.

b) If a donor has fully recovered from:

- an isolated past episode of inflammatory eye disease (e.g. uveitis or episcleritis), and the condition is not associated in the donor with other general contraindications to donation, accept.
- no more than 3 past episodes of inflammatory eye disease: refer to DSCO for individual risk assessment.

c) If a donor has fully recovered from an isolated past episode of scleritis, accept for cornea donation only.

d) If a donor is known to have a choroidal naevus which has been diagnosed and followed up in an eye clinic, and no concerns over alternative diagnoses, particularly malignancy, have been raised, refer to DCSO.

e) Punctate epithelial erosions: if there is no known visible abnormality, accept. (See 'Additional Information' section regarding cornea assessment at retrieval and at the eye bank.)

**2. Other Tissues:**

If no other contraindication, accept.

*See if Relevant*

Autoimmune Disease  
Basal Cell Carcinoma  
Central Nervous System Disease  
Glaucoma  
Herpes – Ocular  
Immunosuppression  
Infection - General  
Laser Treatment  
Malignancy  
Ocular Surgery  
Ocular Tissue Recipient  
Steroid Therapy  
Tissue and Cell Allograft Recipients

*Additional Information*

For donors with a past history of inflammatory, infectious or traumatic ocular conditions, relevant clinical records, especially ophthalmology records, should be reviewed.

Choroidal naevi are common, benign melanocytic lesions of the posterior uvea. It is important to confirm that they have been diagnosed and monitored in an eye clinic.

Punctate epithelial erosions develop commonly due to a diminished lid reflex, especially in ventilated patients. Corneas must be deferred from clinical use if they are visibly abnormal. Corneas can be accepted for endothelial keratoplasty (EK) if they pass assessment at retrieval and in the eye bank.

*Reason for Change*

'Discretionary' and 'Additional Information' sections updated regarding inflammatory eye disease, choroidal naevus and punctate epithelial erosions.

*Update Information*

This entry was last updated in TD-DSG Edition 203 Release 60

## Eye Drops

*Obligatory*

**Determine what they are being used to treat.  
See:**

	Is there any relevant entry.
<i>See if Relevant</i>	<u>Autoimmune Disease</u> <u>Glaucoma</u> <u>Infection - General</u> <u>Steroid Therapy</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Factor V Leiden

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Fibromyalgia

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<i>Also Known As</i>	Fibromyositis or fibrositis.
<i>Obligatory</i>	Must not donate tendons
<i>Discretionary</i>	All other tissues, accept
<i>See if Relevant</i>	<u>Disabled Donor</u> <u>Nonsteroidal Anti-Inflammatory Drugs</u> <u>Steroid Therapy</u>
<i>Additional Information</i>	Fibromyalgia is a common problem affecting soft tissues (muscles, tendons and ligaments) rather than bones or joints. It is often linked to sleep disorders.
<i>Reason for Change</i>	This is a new entry.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 25

## Filariasis

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## G6PD Deficiency

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Gall Bladder Disease

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<i>Discretionary</i>	If recovered or had asymptomatic gallstones, accept.
<i>See if Relevant</i>	

Infection - General  
Malignancy

<i>Reason for Change</i>	A link has been added for 'Malignancy'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Genital Warts

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<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Sexually Transmitted Disease</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Giardiasis

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<i>Discretionary</i>	Accept.
<i>Additional Information</i>	This is a local intestinal infection that does not affect donation.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Gilbert's Syndrome

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<i>Discretionary</i>	Accept.
<i>Additional Information</i>	Gilbert's syndrome is an inherited defect in bilirubin metabolism. It is harmless but can cause jaundice in the donor.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Glasses

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<i>Discretionary</i>	<b>Eyes:</b> Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Glaucoma

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<i>Obligatory</i>	<b>Must not donate if:</b> Received transplant of sclera during glaucoma surgery.
<i>See if Relevant</i>	<u>Ocular Tissue Recipient</u> <u>Tissue and Cell Allograft Recipients</u>
<i>Additional Information</i>	If surgery was performed after 1997 and the sclera was supplied through UK Transplant, this information will be stored on the National Transplant Database.
<i>Reason for Change</i>	A link has been added to 'Ocular Tissue Recipient'.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

## Gout

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*Discretionary* Even if on treatment, accept.  
*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 02

## Granuloma Inguinale

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*Obligatory* **Must not donate.**  
*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 02

## Growth Hormone

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*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-DD Edition 203, Release 02

## Guillain-Barré Syndrome

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*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  
*Reason for Change* There is now a requirement to 'Refer to a Designated Medical Officer'.  
A link has been added to 'Transfusion'.  
*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 02

## Haematological Disease

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*Obligatory* **Must not donate if:**  
a) Malignant.  
b) Clonal disorder such as primary polycythaemia (rubra vera) or essential  
thrombocythaemia.

<i>Discretionary</i>	a) If polycythaemia or thrombocytosis is secondary to a non-malignant/clonal condition, accept.  b) Monoclonal gammopathy of unknown significance (MGUS) – see 'Malignancy' entry.
<i>See if Relevant</i>	<u>Anaemia</u> <u>Haemoglobin Disorders</u> <u>Immune Thrombocytopenia</u> <u>Malignancy</u> <u>Therapeutic Venesection</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	Monoclonal gammopathy of unknown significance (MGUS) moved to the 'Discretionary' section, and a reference to the 'Malignancy' entry added.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 46

## Haematuria

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<i>Obligatory</i>	<b>Must not donate if:</b> a) Uncontrolled infection.  b) Due to malignancy.
<i>Discretionary</i>	<b>Eyes.</b> a) If caused by bacterial infection and the corneas are to be stored by organ culture, accept.  b) If related to malignancy, see <u>Malignancy</u> .
<i>See if Relevant</i>	<u>Kidney Disease</u>
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' (malignancy) has changed.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Haemochromatosis

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<i>Obligatory</i>	<b>1. Cardiovascular Tissue:</b> <b>Must not donate if:</b> Cardiac involvement.  <b>2. Pancreas:</b> <b>Must not donate if:</b> Diabetic.
<i>Discretionary</i>	Other tissues, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Haemoglobin Disorders

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<i>Obligatory</i>	<b>Must not donate if:</b> Has a sickle-cell or thalassaemia syndrome.
<i>Discretionary</i>	<b>1. Eyes:</b> Even if has a sickle-cell or thalassaemia syndrome, accept.



**2. All tissues:**

Donors with traits for abnormal haemoglobin, accept.

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

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

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

**Haemolytic Anaemia**

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

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

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

Additional links have been added.

To include an entry for 'Haemolytic Anaemia'.

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

**Haemorrhoids**

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*Includes* Piles

*Discretionary* Accept.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

**Headache**

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**Occasional**

*Discretionary* Accept.

**Regular**

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

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

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

## Heaf Test

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

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

## Health Care Worker

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### History of Inoculation Injury

See Inoculation Injury

### No Inoculation History

*Discretionary* Accept.

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

## Henna Painting

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*Discretionary* Accept.

*See if Relevant* Body Piercing

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

## Hepatitis

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*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-DD Edition 203, Release 02

## Hepatitis A

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### 1. Affected Individual

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 6 months from recovery
<i>Discretionary</i>	If less than 6 months from infection, but fully recovered, documented HAV RNA negative and anti HAV IgG positive after recovery, accept.
<i>See if Relevant</i>	<u>Travel</u>
<i>Additional Information</i>	Hepatitis A is spread by the faecal - oral route and by sewage-contaminated food and water. It can also be spread sexually. There is no long term infection with the virus but there are many reports of transmission by transfusion. Infection may be symptom free but can be serious and occasionally fatal. The Blood Services do not test for this infection.
<i>Reason for Change</i>	To clarify the wording of the discretionary entry

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

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 6 months from recovery of current sexual partner, or from last sexual contact if a former sexual partner.
<i>Discretionary</i>	If shown to be immune, accept.
<i>Additional Information</i>	There is a risk of transmitting the infection through sexual activity. Infection may be symptom free but can be serious and occasionally fatal. The 6 month exclusion allows any infection to run its natural course and for any risk of passing the infection on through donation to have passed.
<i>Reason for Change</i>	To permit acceptance of donors who are shown to be immune.

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

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 6 months from recovery of the last affected person in the home, or from the last contact if no longer sharing.
<i>Discretionary</i>	If shown to be immune, accept.
<i>Additional Information</i>	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.
<i>Reason for Change</i>	To permit acceptance of donors who are shown to be immune.

## 4. Immunization

<i>Obligatory</i>	<b>Known Exposure:</b> <b>Must not donate if:</b> Less than six months after vaccine or intramuscular immunoglobulin was given.
<i>Discretionary</i>	<b>No known Exposure:</b> Accept.
<i>See if Relevant</i>	<u>Hepatitis B - Post Immunization</u> <u>Travel</u>

*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.

If less than 6 months from immunisation following known exposure, the donor may be accepted following individual risk assessment if the risk of delaying transplant outweighs the risk of transmission of hepatitis A.

*Reason for Change* The deferral period for immunization post known exposure has been reviewed following guidance from Public Health England.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 34

## Hepatitis B

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### 1. Person with current hepatitis B infection

*Obligatory* **Must not donate.**

*Additional Information* Hepatitis B is a serious viral infection that can lead to chronic liver disease and liver cancer (hepatoma).

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

Cases are often linked to place of birth, or mother's place of birth. The condition is very common in many parts of the world and vertical spread from mother to baby is often a major route of transmission. Hepatitis B may also be acquired by injecting drug use, sexual transmission and more rarely tattoos and piercings

### 2. Person with previous diagnosed (recovered) hepatitis B infection

*Obligatory* **Must not donate:**  
if less than 12 months since diagnosis

*Discretionary* If more than 12 months since diagnosis of HBV infection, and if they have successfully cleared the infection, accept.

Refer to the designated medical officer if advice on interpretation of test results is required.

*See if Relevant* Tissue Safety Entry

*Additional Information* Leaving 12 months from diagnosis before testing allows sufficient time for a donor to clear any acute infection or develop markers of a chronic infection which will be detected on screening.

If less than 12 months from diagnosis the donor may be accepted if the risk of delaying transplant outweighs the risk of transmission of hepatitis B subject to documented individual risk assessment.

Anti-HBc is required as a mandatory test under the EU Cell and Tissue Directive for cell and tissue donations, and is therefore a regulatory requirement. If the donor is HBsAg negative and HBV DNA negative anti-HBs testing is not required. Anti-HBc must be carried out to comply with regulation and there is no requirement for anti-HBs levels. However some international stem cell registries require anti-HBs status to determine donor suitability.

### 3. Current or Former Sexual Partner of an infected individual

*Obligatory* Obtain history (including time since last sexual contact, and the dates that HBV immunisation given).

**Must not donate if:**

Less than 3 months from last sexual contact

*Discretionary* If more than 3 months since last sexual contact, accept.

If less than 3 months since last sexual contact, and the donor is shown to be naturally immune, accept.

*Additional Information*

A donor with a period of less than 3 months since the last sexual contact with an infected individual may be accepted following individual risk assessment if risk of delaying transplant outweighs the risk of transmission of hepatitis B. A shortened time between last sexual contact and testing increases the risk of not detecting a recently acquired infection on screening.

The current partner of an individual with hepatitis B infection should have been offered immunisation. If the relationship started after the diagnosis of hepatitis B, immunisation may not have been carried out.

*Reason for Change*

This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July (2017).

### 4. Current or former sexual partner of person who had recovered from hepatitis B infection at the time of last sexual contact

*Obligatory* Obtain history (including time since last contact, date that the partner was diagnosed with HBV infection and the date that HBV immunisation of the donor commenced).

**Must not donate if:**

Less than 3 months from last sexual contact with the a partner who has been diagnosed with HBV infection **less than** 12 months ago

*Discretionary*

a) If **more than** 3 months since last sexual contact, regardless of when the partner was diagnosed with the HBV infection, accept  
or  
b) If partner was diagnosed with HBV infection **more than** 12 months ago and has cleared the infection at the time of last sexual contact, accept.

*Additional Information*

A donor who had sexual contact less than 3 months ago with a partner who had been diagnosed with the HBV infection less than 12 months ago at the time of sexual contact, may be accepted following individual risk assessment if risk of delaying transplant outweighs the risk of transmission of hepatitis B.

The current partner of an individual with hepatitis B infection should have been offered immunisation. If the relationship started after the diagnosis of hepatitis B, immunisation may not have been carried out.

*Reason for Change*

This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

### 5. Person Sharing a Home with a person with hepatitis B infection

*Obligatory* Obtain history to determine if they are still sharing a home, and if not, the time since sharing ceased

**Must not donate:**

If less than 3 months since sharing ceased.

*Discretionary*

If more than 3 months since sharing ceased, accept.

If less than 3 months since sharing ceased, and the donor is shown to be naturally immune, accept

*See if Relevant* 6. Hepatitis B Immunization, below.

*Additional Information* A person sharing a home with a person infected with hepatitis B within the past 3 months may be accepted following individual risk assessment if the risk of delaying transplant outweighs the risk of transmission of hepatitis B.

*Reason for Change* This entry has been modified in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

## 6. Hepatitis B Immunization

*Obligatory* **a) If Immunised Following Known Exposure:**

**Must not donate**

**b) If Immunised With No Known Exposure:**

**Must not donate if:**

Less than 7 days after the last immunization was given.

*Discretionary* **a) If Immunised Following Known Exposure:**  
If more than 3 months from immunization, accept

**b) If Immunised With No Known Exposure:**

If more than 7 days after the last immunization was given, accept.

*See if Relevant* Hepatitis A - 4. Immunization

*Additional Information* Immunization post exposure may be with specific anti-HB immunoglobulin as well as with HBsAg. Generally immunoglobulin would only be given after a known exposure to hepatitis B.

There is no requirement to monitor the anti-HBs level.

May be combined with hepatitis A immunization.

Sensitive assays for HBsAg may be positive following recent immunization. This is why a 7 day deferral is required.

*Reason for Change* The immunisation section has been incorporated into the main Hepatitis B entry.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 29

## Hepatitis C

### 1. Affected Individual

*Obligatory* **Must not donate.**

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

*See if Relevant* Tissues Safety Entry

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

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

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

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

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

## 2. Current or Former Sexual Partners of HCV Positive Individuals

*Obligatory* **Must not donate if**  
Less than 3 months from the last sexual contact

*Discretionary* a) If less than 3 months from the last sexual contact and the donor/donor family reports that their current or former HCV positive partner has been successfully treated for hepatitis C infection and has been free of therapy for at least 6 months prior to the last sexual contact and continues in sustained remission, accept.

b) If more than 3 months since last sexual contact, accept.

*See if Relevant* Tissues Safety Entry

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

Individuals who remain HCV RNA negative six months after completing treatment are likely to have been 'cured', with a risk of relapse of less than 1%

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

*Reason for Change* To include guidance for persons with treated and successfully cleared past Hepatitis C infection.

## 3. Person currently or formerly Sharing Home with an affected individual

*Discretionary* Accept.

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

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

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 34

## Hepatitis E

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### Infection

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 6 months from recovery.
<i>Discretionary</i>	If less than 6 months from recovery and HEV RNA negative and anti HEV IgG positive, accept.
<i>See if Relevant</i>	<u>Travel</u>
<i>Additional Information</i>	Hepatitis E is an infectious hepatitis that is usually spread through contaminated food or water. Infection may be associated with travel to countries with poor hygiene/sewage conditions but increasingly, cases of hepatitis E are being identified in the UK usually due to consumption of undercooked contaminated meat. Hepatitis E can affect non-human animals and has been found in pigs in the UK. There have been reports of transmission by transfusion and transplant. Infection in healthy individuals is often symptom free but in people with underlying problems in their immune systems it can be serious and occasionally fatal. The Blood Services currently test for this infection.
<i>Reason for Change</i>	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. The deferral for household and sexual contacts has been removed.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 31

## Hepatitis of Unknown Origin

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### Affected Individuals

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 24 months from recovery.
<i>Discretionary</i>	a) If more than 12 months, but less than 24 months from recovery, obtain history and blood samples and refer to a <b>Designated Medical Officer</b> .  b) If more than 24 months from recovery, accept.
<i>Additional Information</i>	If more than 12 months and less than 24 months from recovery: c) If negative for all markers of hepatitis B, accept. d) If HB core antibody is positive and HBsAg is negative, HBV-DNA is negative and anti-HBs has been documented at more than 100 iu/l at some time, accept.

### Person Sharing Home

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 12 months from recovery of the last affected person in the home.
<i>See if Relevant</i>	Sexual Partner of Affected Individuals above.
<i>Additional Information</i>	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.

## Sexual Partner of Affected Individuals

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

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

## Hereditary Elliptocytosis

*Discretionary* Accept.

*Reason for Change* This entry replaces the previous entry for 'Elliptocytosis'.

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

## Hereditary Spherocytosis

*Discretionary* Accept.

*Update Information* This entry was last updated in  
TDSG-DD 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

*Additional Information* There is no need to defer donors who have a sexual partner with Herpes if the donor themselves is asymptomatic.

*Reason for Change* Addition of 'Additional Information' section, to include clarification regarding sexual partners.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 57

## Herpes - Ocular

*Includes* Simplex & Zoster Infection

*Obligatory* **Eyes:**  
**Must not donate if:**  
Past or active infection in either eye.

*Discretionary* **Other Tissues:**  
If no active infection or other contraindication, accept.

<i>Additional Information</i>	Ocular herpes can lead to serious complications in the tissue recipient, e.g. primary graft failure, and this risk must be minimized as far as possible.
<i>Reason for Change</i>	To clarify that even if only one eye is affected, donation of both eyes is contraindicated.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 33

## Herpes - Oral

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<i>Obligatory</i>	<b>Must not donate if:</b> Fresh lesions.
<i>Discretionary</i>	If lesions are healing, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Herpes Simplex

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<i>See if Relevant</i>	<u>Herpes - Genital</u> <u>Herpes - Oral</u>
<i>Update Information</i>	<b>Eyes:</b> <u>Herpes - Ocular</u> This entry was last updated in TDSG-DD Edition 203, Release 02

## Herpes Zoster

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<i>See if Relevant</i>	<u>Infection - Acute</u> <u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	<b>Eyes:</b> <u>Herpes - Ocular</u> This entry was last updated in TDSG-DD Edition 203, Release 02

## Hip Dysplasia

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## HIV

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*Includes*     AIDS

### Current or Former Sexual Partners of Confirmed Case

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 3 months from last sexual contact.
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<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	<p>HIV infection can be spread through sexual activity, including oral and anal sex. Despite regular sexual contact transmission of infection may not happen. It may however not be transmitted for a long time into a relationship. This could be because the infection becomes more active in the infected partner, the uninfected partner acquires another infection or injury to a mucous membrane, or there is a change in the use of, or failure of, barrier contraceptives (condoms etc.). In the early stages of infection the testing used by the Blood Services may not detect the virus allowing it to be passed on by transfusion or transplantation.</p> <p>Waiting 3 months from the last sexual contact will ensure that any infection is picked up by the tests used by the Blood Services. This guidance presumes that a validated NAT test for HIV is negative, if this test is stopped for any reason the guidance will change.</p>
<i>Reason for Change</i>	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017. The current and former sexual partner entries have been combined. Additional information section added

## Infection

<i>Obligatory</i>	<b>Must not donate.</b>
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>

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

<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	Current or Former Sexual Partner of Affected Individual above.
<i>Additional Information</i>	HIV is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood or sexual route. For these reasons household contacts do not need to be deferred.
<i>Reason for Change</i>	This is an additional entry.
<i>Update Information</i>	<p>This advice is a requirement of the EU Tissue &amp; Cells Directive.</p> <p>This entry was last updated in TDSG-DD Edition 203, Release 29</p>

## Hormone Replacement Therapy

<i>Obligatory</i>	<p><b>Must not donate if:</b></p> <p>a) Used for malignancy.</p> <p>b) A recipient of human gonadotrophin of pituitary origin.</p> <p>c) A recipient of human pituitary growth hormone.</p>
<i>Discretionary</i>	<p><b>1. All tissues</b> a) If treated with gonadotrophins that were exclusively non-pituitary derived, accept.</p> <p>b) If treated with growth hormone that was exclusively recombinant, accept.</p> <p>c) If treatment for menopausal symptoms or osteoporosis prevention, accept.</p> <p><b>2. Eyes:</b> If related to malignancy, see <u>Malignancy</u>.</p>
<i>See if Relevant</i>	<u>Prion Associated Diseases</u>

Thyroid Disease

<i>Reason for Change</i>	The 'Discretionary' entry has been re-worded for clarity and the 'Discretionary' entry for 'Eyes' (malignancy) has changed.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

**HTLV**

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**Current and Former Sexual Partners of Confirmed Case**

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 3 months from last sexual contact
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	There is no defined infectious window period for HTLV. The risk of missing recent infection with individual sample testing is low after 3 months.
<i>Reason for Change</i>	This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

**Infection**

<i>Obligatory</i>	<b>Must not donate.</b>
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>

**Person Currently or Formerly Sharing a Home with an Affected Individual**

<i>Discretionary</i>	Accept
<i>See if Relevant</i>	Current or Former Sexual Partner of Affected Individual above.
<i>Additional Information</i>	HTLV is neither contagious nor spread by the faecal-oral route. It is usually only spread through a direct blood to blood or sexual route. For these reasons household contacts do not need to be deferred.
<i>Reason for Change</i>	This is an additional entry.
<i>Update Information</i>	This advice is a requirement of the EU Tissue & Cells Directive.  This entry was last updated in TDSG-DD Edition 203, Release 29

**Huntington's Disease**

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<i>Obligatory</i>	If the diagnosis is uncertain: <b>Refer to a Designated Medical Officer.</b>
<i>Discretionary</i>	If diagnosis can be confirmed, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Hydatid Disease

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Hydrocephalus

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<i>Obligatory</i>	<b>Must not donate if:</b> Has an indwelling shunt and there is evidence of shunt infection.
<i>Discretionary</i>	<b>Eyes:</b> Shunt infection - if the corneas are to be stored by organ culture, accept.
<i>See if Relevant</i>	<u>Neurosurgery</u> <u>Spina Bifida</u>
<i>Additional Information</i>	Donated tissue is cultured to exclude occult bacterial and fungal infection. However it should not be collected from bacteraemic subjects.
<i>Reason for Change</i>	A 'Discretion' has been added for 'Eyes'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Hypnotics

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Ileostomy

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<i>Obligatory</i>	<b>Must not donate if:</b> a) For malignancy  b) Inflammatory bowel disease.
<i>Discretionary</i>	<b>1. All tissues:</b> If the reason for the ileostomy is not of itself a reason to exclude and the stoma is healthy, accept.  <b>2. Eyes:</b> a) If related to malignancy, see <u>Malignancy</u> .  b) If related to inflammatory bowel disease and there is no evidence of ocular involvement, accept.
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' (malignancy) has changed.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Immune Thrombocytopenia

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<i>Obligatory</i>	<b>Must not donate if:</b> Associated with malignancy
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<i>Discretionary</i>	If underlying cause of thrombocytopenia is not a contraindication, accept. Refer to relevant DSG entry. Refer to designated clinical support officer if further advice required.
<i>See if Relevant</i>	<p><b>If treated with immunoglobulin:</b>  <u>Immunoglobulin Therapy</u>  <u>Transfusion</u>  <u>Malignancy</u></p> <p><b>If treated with plasma exchange:</b>  <u>Transfusion</u></p> <p><b>If treated with immunosuppressive therapy:</b>  <u>Immunosuppression</u></p> <p><b>If treated with splenectomy:</b>  <u>Splenectomy</u>  <u>Transfusion</u></p>
<i>Additional Information</i>	Immune thrombocytopenia can be associated with malignancies, especially haematological malignancies such as chronic lymphocytic leukaemia.
<i>Reason for Change</i>	To add link to 'Splenectomy' in the 'See if Relevant' section.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 59

## Immunisation

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### Non-exposed

*See* [Immunisation - Live](#)  
[Immunisation - Non-Live](#)

If you do not know if an immunisation is live or not, see the specific entry for the type of immunisation or:

**Refer to a Designated Medical Officer.**

### Post Exposure

*Obligatory*

- 1. BCG:**  
**See**  
BCG
- 2. Hepatitis A:**  
**See**  
Hepatitis A
- 3. Hepatitis B:**  
**See**  
Hepatitis B
- 4. Rabies:**  
**See**  
Rabies
- 5. Smallpox:**  
**See**  
Smallpox Immunisation
- 6. Tetanus:**  
**See**  
Tetanus Immunisation

<i>Reason for Change</i>	Update the 'Hepatitis A' part of the 'Post-exposure' section to refer directly to the 'Hepatitis A' entry.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 41

## Immunisation - Live

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### No Exposure

<i>Obligatory</i>	<b>Must not donate if:</b> Less than eight weeks from administration.
<i>Discretionary</i>	If more than four weeks from administration of a live immunisation other than smallpox immunisation and the inoculation site has healed, accept.
<i>See if Relevant</i>	<u>BCG</u> <u>Smallpox Immunisation</u>
<i>Additional Information</i>	Live immunisations 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 immunisation should have been controlled and so should not be passed on through donated material. There are special rules for BCG and smallpox immunisations.
<i>Reason for Change</i>	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 immunisations other than smallpox.
<i>Update Information</i>	This advice is a requirement of the EU Tissue & Cells Directive.  This entry was last updated in TDSG-DD Edition 203, Release 09

## Immunisation - Non-Live

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### No Exposure

<i>Excludes</i>	Post-exposure. See: <u>Immunisation</u> - Post Exposure
<i>Obligatory</i>	1. Hepatitis B <b>Must not donate if:</b> Less than seven days after administration
<i>Discretionary</i>	Other non-live immunisations, accept.
<i>Additional Information</i>	Sensitive assays for HBsAg may be positive following recent immunisation. Full screening for Hepatitis B may be required.  Note, hepatitis A immunisation may be combined with hepatitis B immunisation.  'Non-Live' immunisations do not use material that can cause infection. This means there is no risk to people receiving donated material from a recently immunised non-exposed donor.
<i>Reason for Change</i>	To remove Coronavirus Vaccination from obligatory section, and additional information section updated.
<i>Update Information</i>	This entry was last updated in TD-DSG Edition 203 Release 60

## Immunoglobulin Therapy

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<i>Obligatory</i>	<p><b>Must not donate if:</b></p> <p>a ) Immunosuppressed.</p> <p>b) Donors with recovered immunodeficiency: <b>Refer to a Designated Clinical Support Officer.</b></p>
<i>Discretionary</i>	<p>a) If the intravenous or subcutaneous human immunoglobulin was given before 1980, accept.</p> <p>b) Routine ante- and post- natal use of anti-D immunoglobulin, accept.</p> <p>c) If single dose prophylactic immunoglobulin has been given, accept.</p> <p>d) If treated with intravenous immunoglobulins after 1st January 1999: if underlying condition is not a contraindication, accept. Refer to designated clinical support officer if further advice required.</p>
<i>See if Relevant</i>	<p><u>Hepatitis A</u> <u>Hepatitis B</u> <u>Rabies</u> <u>Tetanus Immunization</u></p>
<i>Additional Information</i>	<p>Immunoglobulin used before 1980 is unlikely to be affected by vCJD.</p> <p>Single dose immunoglobulin is unlikely to pose a significant risk for transmitting vCJD.</p> <p>Since 1999, intravenous immunoglobulins prepared from UK donors have no longer been used, as a risk reduction measure for vCJD transmission.</p>
<i>See</i>	<p><b><u>If treated with intravenous or subcutaneous human immunoglobulin: Transfusion</u></b></p>
<i>Reason for Change</i>	<p>To permit donation from donors who have received intravenous immunoglobulin after 1st January 1999, if the reason for treatment is not a contraindication.</p>
<i>Update Information</i>	<p>This entry was last updated in TDSG-DD Edition 203, Release 45</p>

## Immunosuppression

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<i>Obligatory</i>	<p><b>Must not donate if:</b></p> <p>a ) Immunosuppressed.</p>
<i>Discretionary</i>	<p>a) Donors who are on immunosuppressive therapy (if the underlying condition is not a contra-indication):</p> <p>If <b>ALL</b> the following criteria are met:</p> <ul style="list-style-type: none"> <li>• The quality of the tissue being donated is not affected</li> <li>• NAT testing is performed for HIV, HCV and HBV in addition to mandatory antibody tests and shown to be negative</li> <li>• The tissue being donated is not affected by severe local infection and there is no evidence of systemic infection.</li> </ul>



**(OR) For corneas only:** In cases of bacterial infection (where there is no active ocular infection) and the corneas are to be stored by organ culture.

Donor may be accepted subject to a documented risk assessment (refer to the Additional Information section).

b) Donors with recovered immunodeficiency:

**Refer to a Designated Medical Officer.**

*See if Relevant*

Autoimmune Disease  
Immunoglobulin Therapy  
Steroid Therapy  
Infection – acute  
Infection - chronic

*Additional Information*

The Human Tissue (Quality and Safety for Human Application) Regulations, 2007, as amended, specifies a range of allogeneic donor deferral criteria. These are set out in Annex A of the HTA 'Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment'. Regulatory requirements for donor testing are set out in Annex B of the Guide and specify the requirement for serological testing irrespective of NAT testing.

Annex A, part 1.1.8 states: 'Indications that test results of donor blood samples will be invalid due to...treatment with immunosuppressive agents.'  
Whilst antibody detection relies on the host response, antigen and molecular assays directly detect components of the infectious agent. Assays which directly detect the virus are not affected adversely by immunosuppression and are appropriate to use to support decision making in this situation. This is permitted under the SaBTO Guidance on the microbiological safety of human organs, tissues and cells used in transplantation (2020).

The regulatory requirement, as set out in the HTA Guide is as follows: Para 85: 'Donors must be excluded from donation if any of the criteria in Annex A apply unless donation is justified on the basis of a documented risk assessment approved by the Designated Individual (DI)'. To comply with the regulatory requirement Tissue Establishments (TEs) must ensure that they have a current documented risk assessment that covers all the tissues in question before authorising a donation for clinical use on the basis of the discretionary criteria set out above.

Donors on immunosuppression may be prone to an increased risk of infection and symptoms may be masked by immunosuppressive medication. All available information must be carefully assessed as part of donor evaluation and expert opinion sought where required.

*Reason for Change*

To allow acceptance of tissues where the safety and quality is not compromised by immunosuppression. Additional Information section updated to include information particularly regarding regulation.

*Update Information*

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

This entry was last updated in  
TDSG-DD Edition 203, Release 51.

## Infection - Acute

*Obligatory*

**See:**

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

**Must not donate if:**

Less than two weeks from recovery from a systemic infection.

*Discretionary*

**1. All tissues:**

If the clinician caring for the potential donor thinks that therapy given for a localised infection has successfully cleared it, accept.

Common acute local viral respiratory tract infections including colds, sore throats, and

seasonal influenza, accept. See additional information.

Cold sores and genital herpes, accept.

## 2. Eyes.

If caused by bacterial infection and the corneas are to be stored by organ culture, accept.

### See if Relevant

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

### Additional Information

Three distinct types of influenza infection need to be considered separately: seasonal influenza, pandemic influenza and avian influenza. This guidance applies only to seasonal influenza; avian and pandemic influenza are out with the scope of this guidance. Donors with these diagnoses should not be accepted. Any outbreaks of avian or pandemic influenza will be communicated via public health alert guidance for professionals.

Seasonal influenza in the UK normally extends over a period of approximately 16 weeks during the winter months. Due to the spectrum of disease presentation, only the minority of infected individuals are tested for respiratory viruses and during the annual epidemics, most cases are diagnosed clinically. Systemic infection with viraemia is not a feature of seasonal influenza.

Potential donors who have been cared for on an ITU may have a local chest infection as a result of ventilation - these patients are acceptable as donors.

Donors who have bacterial pneumonia are acceptable as eye donors. Other tissues may be accepted if the infection has been successfully treated, or with individual risk assessment to exclude severe or systemic sepsis. The same applies to a donor with seasonal influenza who had developed secondary bacterial infection.

Donors who have had a positive screening test for MRSA (carriers) are acceptable, whereas donors with active MRSA infection at the time of death are not acceptable.

There is no evidence that cold sores, genital herpes and common viral respiratory infections such as seasonal influenza, colds and sore throats can be passed on by processed tissue grafts.

### Unusual bacterial/fungal/protozoal infections

Specialist microbiological advice should be sought when considering using cells and tissues from donors who have had unusual infections in the past, including those acquired outside of Western Europe. This should include infections common in immuno-compromised patients, or infections which lie dormant or may be difficult to eradicate.

A risk assessment should be performed to ensure that retrieval staff are not put at risk from the infection.

### Reason for Change

Updated guidance regarding donors who are recovering from seasonal influenza.

### Update Information

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

This entry was last updated in  
 TDSG-DD Edition 203, Release 41

## Infection - Chronic

*Obligatory*     **Must not donate.**

<i>Discretionary</i>	<p><b>1. Acne:</b> Most donors with acne can be accepted.</p> <p><b>2. Chronic fungal infections:</b> a) If on local therapy for superficial infections only, accept.</p> <p>b) If on systemic anti-fungal treatment only for treatment of a localised, non-systemic fungal infection, and there are no complications, accept.</p> <p>c) If otherwise more than seven days from completing systemic antifungal therapy, accept.</p> <p>d) If undiagnosed or untreated local infection, refer to designated clinical support officer.</p> <p><b>3. Typhoid and Paratyphoid</b> If more than seven days from completion of antibiotic course and last symptoms, accept.</p> <p><b>4. Eyes.</b> If caused by bacterial infection and the corneas are to be stored by organ culture, accept.</p>
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*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 transmitted by tissue or cell transplantation.

#### **Unusual bacterial/fungal/protozoal infections**

Specialist microbiological advice should be sought when considering using cells and tissues from donors who have had unusual infections in the past, including those acquired outside of Western Europe. This should include infections common in immuno-compromised patients, or infections which lie dormant or may be difficult to eradicate.

#### **Local fungal infections, e.g. nail infection or athlete's foot**

Systemic oral antifungal treatment may be prescribed to treat localised fungal nail infections or athlete's foot which are difficult to eradicate. Despite the systemic treatment, due to the fact that the infection is localised to the nails/digits the risk to donated tissue/cells is considered to be remote.

*Reason for Change*      To add guidance for acceptance of donors on oral antifungal treatment for localised nail infections or athlete's foot.

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

This entry was last updated in  
TDSG-DD Edition 203, Release 42.

## **Infection - General**

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<i>Obligatory</i>	<b>See:</b> Is there a specific entry for the disease?
<i>See if Relevant</i>	Decide if the infection is of short duration with no long lasting carrier stage, e.g. flu: <u>Infection - Acute</u>  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 <u>Infection - Chronic</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Infection - Tropical

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<i>Obligatory</i>	<b>Must not donate if:</b> Filariasis or Leishmaniasis
<i>Discretionary</i>	<b>Eyes:</b> If Leishmaniasis, accept for corneas only.
<i>See if Relevant</i>	<u>Congo Fever</u> <u>Crimean Fever</u> <u>Ebola Fever</u> <u>Lassa Fever</u> <u>Marburg Fever</u> <u>Malaria</u> <u>South American Trypanosomiasis Risk</u> <b>Other infections, see:</b> <u>Infection - General</u>
<i>Additional Information</i>	As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.
<i>Reason for Change</i>	A 'Discretion' has been added for 'Eyes'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Infectious Diseases - Contact with

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<i>Obligatory</i>	<b>See:</b> Is there a specific entry for the disease with which there has been contact?
	<b>Must not donate if:</b>
	a) Within the incubation period for the condition or, if this is not known, less than four weeks from last contact.
	b) <b>Skin only</b> – Contact with skin conditions that may be transmissible by the donated material, (such as scabies, ringworm, tinea)
<i>Discretionary</i>	a) If the infection is known to lead to permanent immunity (e.g. chickenpox, measles, mumps, rubella, whooping cough) and there is a definite history of past infection with the disease with which contact has occurred, accept.
	b) Contact with common upper respiratory tract infections (e.g. colds, sore throats, influenza, SARS CoV-2), accept.
	c) Contact with norovirus and other causes of diarrhoea and vomiting, provided the donor is symptom free, accept.
	d) <b>All tissues except skin</b> - Contact with skin conditions which are not transmissible by donated material (e.g. scabies, ringworm, tinea) if no signs of infection, accept.
	e) <b>Skin only</b> - Contact with skin conditions which may be transmissible by donated material (e.g. scabies, ringworm, tinea). If the donated tissue is to be sterilised prior to transplant, accept.
	f) Individuals who have been prescribed prophylactic antibiotics after contact with meningitis, anthrax or chlamydia, provided they are symptom free, accept.

*See if Relevant* Coronavirus Infection  
Hepatitis  
Hepatitis A  
Hepatitis B  
Hepatitis C  
Hepatitis E  
HIV  
HTLV  
Meningitis  
Monkeypox  
Sexually Transmitted Disease  
Smallpox Immunization  
Syphilis  
Tuberculosis

*Additional Information* Many infectious diseases can be passed on through donated material, even before a potential donor develops any symptoms of the infection. This may lead to serious infection in the person receiving a donation.

Many diseases are not infectious and so are not normally a risk.

Contacts with meningitis or anthrax are often prescribed prophylactic antibiotics. These should prevent the disease from developing, so provided the potential donor is well, they may be accepted.

If in doubt, contact a '**Designated Clinical Support Officer**'.

*Reason for Change* To add 'discretionary' and 'additional information' sections and to update the 'obligatory' and 'see if relevant' sections.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 53

## Infertility

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

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

*Discretionary* 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 **no evidence** 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 update the 'additional information' section with a statement that there is no evidence that transplantation of eggs or embryos might lead to spread of vCJD.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 48.

## Inflammatory Bowel Disease

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*Includes* Crohn's Disease  
Ulcerative Colitis

*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**

If no ocular involvement and if the corneas are to be stored by organ culture, accept.

**Other Tissues:**

If mild, with no evidence of infection, tissues can be accepted subject to individual assessment. Refer to Designated Clinical Support Officer for advice if necessary.

*See if Relevant* Infection – General  
Malignancy  
Radiation Therapy

*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.

*Reason for Change* 'See if Relevant' section has been added.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 46

## Inherited Diseases

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*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-DD Edition 203, Release 02

## Inoculation Injury

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*Includes* Human Bite

*Definition* A non-consented injury or assault in which an individual is exposed to potentially infective material that could be transferred through donation. The causes may range from a sharps injury to bites, punches and abrasions or sexual assault where mucous membranes have been contaminated with human blood or other body fluids. It also applies to any inoculation injury with abnormal prions from any species.

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

a) The incident involved any material containing abnormal prions.

b) Less than 3 months after the date of an inoculation injury, or contamination of mucosa or non-intact skin with blood or body fluids.

c) Under ongoing investigations following exposure - **refer to DSCO.**

*See if Relevant* Animal Bite  
Hepatitis

HIV  
HTLV  
Prion Associated Diseases  
Tissues Safety Entry  
Xenotransplantation

<i>Additional Information</i>	Human blood or body fluids may be contaminated with infective material such that the infection may then be passed on by donated material. Waiting three months (if validated tests for infectious markers that include HBV, HCV HIV NAT are negative) helps to ensure that any infection is not passed on.  Donors who are under investigation may be accepted subject to individual risk assessment.
<i>Reason for Change</i>	The 'Definitions' section was updated as part of the implementation of recommendations from the FAIR III report. Additional 'see if relevant' links added. 'Additional information' section updated.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 57

## Irritable Bowel Syndrome

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Jaundice

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<i>Obligatory</i>	<b>Must not donate if:</b> 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 <b>Hepatitis of Unknown Origin</b> .
<i>Discretionary</i>	a) If the cause of jaundice was non-viral (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.
<i>See if Relevant</i>	<u>Gall Bladder Disease</u> <u>Gilbert's Syndrome</u> <u>Hepatitis A</u> <u>Hepatitis B</u> <u>Hepatitis C</u> <u>Hepatitis E</u> <u>Hepatitis of Unknown Origin</u>
<i>Additional Information</i>	Many things can cause jaundice. The concern is with infectious causes that might be passed on by donation.
<i>Reason for Change</i>	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.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Kala-Azar

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	<b>Eyes:</b>

	Accept for corneas only.
<i>Additional Information</i>	As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Kidney Disease

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### Acute Nephritis

<i>Obligatory</i>	<b>Must not donate if:</b> Less than 12 months since recovery.
<i>Discretionary</i>	<b>1. All tissues:</b> 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 <b>Designated Medical Officer</b> .  <b>2. Eyes:</b> If not immunosuppressed, accept.
<i>Additional Information</i>	If the donor 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.
<i>Reason for Change</i>	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

<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	<b>Eyes:</b> If not immunosuppressed, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 17

## Klinefelter's Syndrome

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Laser Treatment

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<i>Obligatory</i>	<b>1. All tissues:</b> <b>Must not donate if:</b> For malignancy.
<i>Discretionary</i>	<b>1. Tissues other than Eyes:</b> a) If for Basal Cell Carcinoma, treatment is completed and fully recovered, accept.  b) If for Cervical Carcinoma in Situ, see <u>Cervical Dysplasia</u> entry.



- c) If for cosmetic purposes, accept when healed.
- d) If laser refractive surgery to the cornea, accept when healed.

**2. Eyes:**

- a) if donor has had laser-refractive surgery to the cornea – accept when healed (see 'Additional Information' section)
- b) If laser surgery to other structures of the eye (retina, iris, trabecular meshwork or ciliary body), accept.
- c) If related to malignancy, see Malignancy.

*See if Relevant* Basal Cell Carcinoma  
Cervical Dysplasia  
Ocular Surgery

*Additional Information* Laser refractive surgery affects the anterior part of the cornea. Corneal tissue from donors with healed laser refractive surgery can be used for Descemet Membrane Endothelial Keratoplasty (DMEK). The tissue establishment might apply additional criteria for donors with a history of laser-refractive surgery, especially a minimum age for use of corneal tissue for DMEK.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 48.

## Leishmaniasis

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*Includes* Kala-azar

*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**  
Accept for corneas only.

*Additional Information* As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change* A 'Discretion' has been added for 'Eyes'.

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

## Leukaemia

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*Obligatory* **Must not donate.**

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

## Malaria

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*Definition* **Resident** – A donor who has ever been present in a malaria risk area, (or areas), for a continuous period of 6 months or more (at any point in their lifetime)

**Visitor** – A donor who has visited or travelled through a malaria risk area, (or areas), within the past 12 months,

**Unexplained febrile illness** – A donor who had undiagnosed fever (that could have been malaria) while present in, or within four months of leaving, a malaria risk area.

**Previous diagnosis of malaria** – A donor who previously had a confirmed diagnosis of malaria, at any point in their lifetime.

**Malaria risk area** – Risk area for country as defined by the GDRI

**MAT:** Malarial Antibody Test

**NAT:** Nucleic Acid Test (for malaria)

*Obligatory* **Must not donate (if no testing is available):**  
Applies to all groups as defined above

*Discretionary* **1a) Previous Malaria:** If **more than 4 months** have passed since anti-malaria therapy has been completed and symptoms caused by malaria have resolved, obtain a blood sample for MAT and NAT test. See information below in this section.

**1b) Unexplained Febrile illness:**

If **less than 4 months** from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. See information below in this section.

If **more than 4 months** from the date of recovery of symptoms of unexplained febrile illness that could have been malaria: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.

**1c) Resident:**

If **less than 4 months** since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. See information below in this section.

If **more than 4 months** since date last present in a malaria risk area: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.

**1d) Visitor:**

If **less than 4 months** since return: Obtain a blood sample for MAT and NAT. See information below in this section.

If **more than 4 and less than 12 months** since return: Obtain a blood sample for MAT and NAT. If MAT negative, NAT is not required to release tissues. See information below in this section.

If **more than 12 months** since return: testing not required, accept

**NB.** Please consider *T. cruzi* or a tropical virus risk if the area is also identified as a risk area for these infections

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The results of MAT and NAT tests must be reviewed as a part of donor medical clearance to determine the suitability of tissues for clinical use. If the exposure event is more than four months prior to donation, and MAT is negative, NAT is not required. If the exposure event is less than four months prior to donation, NAT must be done and shown to be negative, irrespective of MAT results. For donors with a history of malaria where treatment was completed and symptoms have resolved at least four months prior to donation, if MAT is negative, NAT is not required. In case of positive MAT results with a confirmed negative NAT test, a risk assessment can be performed for accepting tissues for clinical release after seeking expert opinion.

**2. If tissue will be sterilized by irradiation post-donation:**

Accept – MAT and NAT testing not required.

**3. Eyes**

Accept for corneas only – MAT and NAT testing not required.

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

*Additional Information* Symptoms and signs of possible malaria include: fever, flu-like illness, (including shaking chills, headache, muscle aches, and tiredness), anaemia, jaundice, nausea, vomiting, diarrhoea and cough.

SaBTO Guidance confirms that irradiation of the tissue can be allowed as an alternative to malaria antibody testing.

As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

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* This guidance was updated based on advice from the SACTTI parasitology sub-group.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 54

## Malaria - Contact in UK

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*Discretionary* Accept.

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

## Malignancy

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*Obligatory*

**1. Eyes:**  
**Must not donate if:**  
 a) Haematological malignancy.  
 b) Malignant tumour of anterior segment.  
 c) Ocular melanoma.  
 d) Ocular metastasis.  
 e) Retinoblastoma.  
 f) Malignant melanoma with known metastatic disease.

**2. Other tissues:**  
**Must not donate.**

*Discretionary*

**1. Eyes:**  
 If not excluded under 'Obligatory', accept for corneas only.

**2. Other tissues:**

**a)** If this was a basal cell carcinoma (rodent ulcer) and treatment is completed and all wounds are healed, accept. If any systemic medical treatment was required refer to designated clinical support officer

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

**c)** Monoclonal gammopathy of uncertain significance (MGUS) with IgG paraproteins at <15 g/l and normal serum free light chain ratio: if diagnosed more than 12 months ago, accept. For other MGUS: refer to designated clinical support officer for individual risk assessment. See additional information section for other MGUS and smouldering myeloma.

**d)** If the potential donor has been cured of a carcinoma in situ (CIS) and discharged from follow-up, accept. Donors who have been returned to routine screening following treatment for cervical CIS can be accepted.

Examples of CIS include cervical or vulval CIS, ductal CIS of the breast (DCIS), and Bowen's disease.

If the potential donor has had a diagnosis of melanoma in situ (including Lentigo Maligna), refer to Designated Clinical Support Officer to confirm they have not had an invasive

melanoma (eg 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), or on routine follow up, accept.

f) Primary tumours of the central nervous system with a low risk of distant metastasis are acceptable for all tissues except for sclera: See additional information section for information.

*See if Relevant* Basal Cell Carcinoma  
Cervical Carcinoma in Situ  
Immunosuppression  
Transfusion  
Haematological Disease

*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.

Basal cell carcinoma (rodent ulcer) does not spread through the blood, therefore people who have had successful treatment may donate.

The term carcinoma in situ (CIS) refers to a group of abnormal cells which have not invaded deeper tissue or spread to another part of the body. Donors who have been cured and discharged from follow up may donate. For cervical CIS, donors can be accepted if treatment is complete and any follow up smear, if performed, 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. However donors with a haematological clonal pre-malignant condition e.g. smouldering myeloma should not be accepted for tissue donation. Monoclonal gammopathy of uncertain significance (MGUS) with IgG paraproteins (rather than IgA or IgM) at <15 g/l and normal serum free light chain ratio has a 1% risk of progression to multiple myeloma over 25 years.

MGUS must be distinguished from smouldering myeloma, which is diagnosed when paraprotein levels are above 30 g/l and bone marrow plasma cells are >10% total nucleated cells. Donors with smouldering myeloma must not be accepted for tissue donation

Melanoma in situ which has been cured by excision is not associated with a risk of metastasis. Patients with a confirmed diagnosis of melanoma in situ (i.e. Breslow thickness of 0 and no regression) do not require ongoing follow up beyond the initial post-operative appointment.

Lentigo Maligna is a form of melanoma in situ found on the head and neck. It should be distinguished from Lentigo Maligna Melanoma which is a true malignant melanoma.

Primary CNS Tumours:

(a) Refer to the Appendix 5 for WHO classification of tumours of the CNS (shown in the Guide to the Quality and Safety of Tissues and Cells for Human Application). Grade I and II tumours have low potential for metastasis and Grade III & IV are aggressive tumours. High grade CNS tumours need careful evaluation and those that are not spread outside CNS can be accepted except for sclera donation.

(b) Refer to SaBTO document "Transplantation of organs from deceased donors with cancer or a history of cancer" for generic advice: <https://www.gov.uk/government/publications/transplantation-of-organs-from-donors-with-a-history-of-cancer>,

**Eyes** - only corneas are accepted under discretionary (1) above as these are avascular and therefore are not likely to be involved in distant metastasis. The vascular parts of the eye are excluded. The predominant mode of progression of primary tumours of the CNS is by

invasion and infiltration. Due to the anatomical proximity of the CNS and orbit, these donors should be deferred from sclera donation.

*Reason for Change* Advice has been added for basal cell carcinoma treated systemically.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

## Malignant Hypertension

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*Discretionary* Accept.

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

## Mantoux Test

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

*See if Relevant* Tuberculosis

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

## Marfan's Syndrome

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*Obligatory* **Must not donate.**  
a) Bone structural  
  
b) Eyes  
  
c) Cardiovascular Tissue  
  
d) Tendons

*Discretionary* **Bone non-structural, Skin and Pancreatic Islets:**  
Accept

*Reason for Change* Pancreatic islets have been added to the list of tissues that may be donated.

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

## Measles

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### Affected Individual

See Infection - Acute

### Contact

See Infectious Diseases - Contact with

*Update Information*

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

## Meningitis

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### Affected Individual

<i>Discretionary</i>	<b>Eyes:</b> If caused by bacterial infection and the corneas are to be stored by organ culture, accept.
<i>See</i>	<u>Infection - Acute</u>

### Contact

<i>Discretionary</i>	Even if on prophylactic antibiotics, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Menopause

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<i>Discretionary</i>	Accept.
<i>See if Relevant</i>	<u>Hormone Replacement Therapy</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Mental Health Problems

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<i>Obligatory</i>	If the donor has had a new mental health problem within the last 12 months, or their condition has deteriorated in the last 12 months: <b>Refer to a Designated Medical Officer.</b>
<i>Discretionary</i>	If the donor has known mental health problems and has been stable in the last 12 months, whether on medication or not, accept.
<i>See if Relevant</i>	<u>Central Nervous System Disease</u> <u>Rabies</u>
<i>Additional Information</i>	Many people have mental health problems that can be controlled with regular medication. There is no reason why they cannot donate whether on medication or not provided a firm diagnosis has been made and their condition has not deteriorated in the last 12 months. It is important to exclude other central nervous system disease including prion disease and rabies, which could present as new or deteriorating mental health problems.
<i>Reason for Change</i>	The entry has been changed to allow donors with known mental health conditions at the time of death to be accepted.  'Additional information' has been added
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 17

## Mitral Valve Prolapse

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Mpox (Monkeypox)

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### 1. Affected Individuals

*Obligatory* **Must not donate**

*Discretionary* If the donor had recovered from confirmed or suspected Mpox infection and

- It is at least 28 days since the diagnosis of Mpox was made, and
- It is at least 14 days since recovery, and
- It is at least 14 days since all skin lesions had healed, and
- It is more than seven days since completing any antiviral or antibiotic therapy, and
- The donor was had been discharged from all follow up (including public health surveillance)

accept.

### 2. Contact with an individual with Mpox

*Includes* Individuals who have been identified by public health teams as a close contact of an individual with Mpox.

*Obligatory* **Must not donate**

*Discretionary* If it is more than 21 days since last contact, and

- the donor had no symptoms of Mpox and
- the donor had completed any isolation period, and
- the donor had been discharged from all follow-up (including surveillance by public health), and
- the donor fulfils the criteria in section 3 below regarding vaccination if applicable,

accept.

See additional information below for donors who received vaccination.

### 3. Immunisation for contact or risk

*Excludes* Individuals who have received vaccination because they work in a health care setting – see section 4 below

*Obligatory* **Must not donate**

*Discretionary* the donor fulfils the criteria in section 2 above, and:

- it is more than four weeks since the most recent dose of a non- live or attenuated smallpox vaccination e.g. Imvanex, and:
- the course of vaccination (if more than one dose) is complete,

accept.

### 4. Immunisation – No known contact

*Includes* Individuals who have received vaccination because they work in a health care setting.

<i>Discretionary</i>	An individual who had received routine vaccination with Imvanex or another third-generation smallpox vaccination in an occupational setting, can be accepted provided that they were not deemed to be at risk due to an exposure episode.
<i>See if Relevant</i>	<u>Immunisation</u>
<i>Additional Information</i>	<p>Mpox was previously known as Monkeypox. In November 2022, WHO recommended Mpox as the new name for Monkeypox disease. Mpox is endemic in some African countries. During 2022 a multi-country outbreak was identified with cases in the UK, Europe, North America and other regions.</p> <p>The incubation period of Mpox is up to 21 days. The initial symptom are fever, myalgia, fatigue and headache. These symptoms are followed by a rash starting from the site of the primary infection, this rash develops into vesicles and pustules followed by scabs. Infectivity may start during initial symptoms and lasts until the rash clears and all scabs have dropped off.</p> <p>Staff should be alert for donors who report rashes and illnesses consistent with Mpox, regardless of sexual behaviour, travel history or other risk factors.</p> <p>Mpox does not spread easily between people. Human-to-human transmission occurs through contact with:</p> <ul style="list-style-type: none"> <li>• infectious material from skin lesions</li> <li>• respiratory droplets in prolonged face-to-face contact</li> <li>• virus-contaminated objects such as bedding or clothing</li> </ul> <p>During the 2022 multi-country outbreak, the predominance of cases among men who have sex with men and the distribution of the Mpox skin rash at presentation, suggests Mpox transmission is associated with direct contact during sex.</p> <p>Contacts may have received vaccination, to reduce the risk of serious illness. Usually vaccination will be with Imvanex or other third generation vaccine against smallpox. Contacts are eligible to donate once they satisfy the requirements of Sections 2 and 3 above.</p> <p>Health care workers may also have received vaccination to protect against Mpox in the event of possible exposure to monkeypox during their work. They will be working in accordance with Infection Prevention and Control policies and with suitable Personal Protective Equipment, which if not breached means they are eligible to donate. Other recipients of vaccination for Mpox must be assessed according to section 3 above.</p> <p>Imvanex is a live attenuated non-replicating third generation Smallpox vaccination. For donor selection purposes this can be assessed as a non-live vaccine but primarily donors must be assessed according to their individual risk of exposure to Mpox. The deferral of some donors for four weeks from the date of a non-live vaccination allows symptoms of Mpox from prior exposure to become evident (incubation period up to 21 days) and encompasses the time for maximum efficacy of the immunisation (up to four weeks). Donors should be deferred until completion of a course of vaccination.</p>
<i>Reason for Change</i>	<p>The title and contents have been updated with the new name as recommended by WHO. Inclusion of sections for donors who had received vaccination either because they could have been a close contact, had risk of exposure, or had received vaccination because they were health care workers.</p> <p>Additional Information applicable for the whole entry contained within one section.</p>
<i>Update Information</i>	<p>This entry was last updated in TDSG-DD Edition 203, Release 54</p>

## **MRSA**

Methicillin Resistant Staphylococcus Aureus

*See if Relevant*     Infection - General



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

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

## Multiple Sclerosis

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*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-DD Edition 203, Release 02

## Mumps

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### Affected Individual

See Infection - Acute

### Contact

See Infectious Diseases - Contact with

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

## Muscular Dystrophy

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*Obligatory* **1. All tissues other than eyes:  
Must not donate if:**  
1. Has severe contractures.

**2. Cardiovascular Tissue:  
Must not donate.**

**3. Structural Bone:  
Must not donate if:**  
Osteoporotic.

*Discretionary* **Eyes.**  
Accept.

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

## Myasthenia Gravis

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*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**  
Accept.

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

## Myelodysplastic Syndrome

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Myeloproliferative Syndrome

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Reason for Change</i>	This entry has been added to clarify the eligibility of donors with this condition.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Myocarditis

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<i>Obligatory</i>	<p><b>1. Cardiovascular Tissue:</b> <b>Must not donate.</b></p> <p><b>2. Other Tissues:</b> <b>Must not donate if:</b> not recovered.</p>
<i>Discretionary</i>	<p><b>Eyes.</b> If caused by bacterial infection and the corneas are to be stored by organ culture, accept.</p>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Ménière's Disease

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Necrotising Soft Tissue Infections

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	<p>Eyes: If no orbital or periorbital necrotising soft tissue infection and corneas stored in organ culture – refer to DCSO.</p> <p>All tissues: If donor has been treated and fully recovered – accept.</p>
<i>Additional Information</i>	<p>Necrotising soft tissue infections (NSTIs) include necrotising forms of fasciitis, myositis and cellulitis. It is a life-threatening bacterial infection that causes necrosis of subcutaneous tissue, fascia, or muscle, typically after some superficial wound infection. It is fortunately very rare.</p> <p>Donors who had NSTIs at the time of death are excluded from tissue donation as a precaution as the effect of endotoxins on the quality and safety of tissues is not known. There are reports of orbital or periorbital NSTIs, but not bulbar involvement. Cornea donation is excluded from deceased donors with ocular/periocular NSTIs, as a precaution, though the transmission of the causative bacteria is minimal/low risk when using organ culture.</p>

Donors can be accepted if the infection was resolved at the time of death.

*Reason for Change* Title of entry changed. Expanded to include Discretionary and Additional Information sections.

*Update Information* This entry was last updated in TD-DSG Edition 203 Release 61

## Neurofibromatosis

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

*Discretionary* **Eyes:**  
If related to malignancy, see Malignancy.

*Reason for Change* The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

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

## Neurosurgery

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*Obligatory* **Must not donate.**

*Discretionary* **1. All Tissues:**  
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 (donors with non-metastizing primary tumours of the central nervous system may be accepted), the donor may be accepted by a **Designated Medical Officer**.

**2. Eyes:**  
If related to malignancy, see Malignancy.

*See if Relevant* Malignancy  
Prion Associated Diseases

*Reason for Change* The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

*Update Information* This is a requirement of the EU Tissue & Cells Directive.  
This entry was last updated  
Edition 203, Release 35

## Night Sweats

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

*Discretionary* If due to the menopause, accept.

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

## Non-Specific Urethritis

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### Acute

See [Infection - Acute](#)

### Chronic

*Obligatory* **Must not donate.**

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

## Nonsteroidal Anti-Inflammatory Drugs (NSAID)

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

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

## Ocular Surgery

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*Obligatory* **Eyes:**  
**Must not donate.**

**Other Tissues:**  
**Must not donate if ever received ocular tissue allograft transplant.**

*Discretionary* **1. Eyes:**

- a. If the procedure is unlikely to prejudice quality and outcome of graft, accept.
- b. If cataract surgery only, accept
- c. If laser-refractive surgery to the cornea, accept when healed
- d. If laser-refractive surgery to any other ocular structure (retina, iris trabecular meshwork or ciliary body) accept.
- e. If both cataract surgery and any type of laser-refractive surgery, discuss with designated clinical support officer.

See additional information section

**2. Other Tissues**  
If no other contraindication, accept.

*See if Relevant* [Eye Disease](#)  
[Glaucoma](#)  
[Laser Treatment](#)  
[Malignancy](#)  
[Ocular Tissue Recipient](#)  
[Tissue and Cell Allograft Recipients](#)

*Additional Information* Laser-refractive surgery to the cornea renders corneal tissue unsuitable for standard corneal transplant procedures. Corneal tissue from donors with healed laser refractive surgery can be used for Descemet Membrane Endothelial Keratoplasty (DMEK).

A Tissue Establishment might apply additional donor selection criteria for donors with a history of ocular surgery, such as a minimum age for donors with a history of laser-refractive surgery and a maximum age for donors with a history of cataract surgery.

The combination of cataract and laser-refractive surgery in a donor eye renders corneal tissue unsuitable for standard corneal transplant procedures.

Recipients of ocular tissue allografts must not donate; e.g. donors who have received cornea transplant or a sclera graft during glaucoma surgery must not donate

*Reason for Change* Additional detail on discretionary criteria for ocular tissue donors with a history of ocular surgery has been added, together with additional information.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 34

## Ocular Tissue Recipient

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*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-DD Edition 203, Release 02

## Organ Donor

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*Discretionary* Accept.

*See if Relevant* Transfusion

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 35

## Organ Recipient

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*Obligatory* **Must not donate**

*Reason for Change* This is a new entry

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 56

## Osteoarthritis

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*Discretionary* Accept.

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

## Osteogenesis Imperfecta

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*Obligatory* **Must not donate**

*Discretionary*

**Skin**

Accept for split skin allografts only; not suitable for the preparation of acellular dermal allografts

<i>Additional Information</i>	Osteogenesis Imperfecta is a congenital disorder that results in defective connective tissue due to defects in the genes relating to production of Collagen I or other connective tissue proteins. Pathology includes bones that fracture easily, loose joints, poor muscle tone and thin, discoloured sclera.
<i>Reason for Change</i>	This is a new entry
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 25

**Osteomalacia**

<i>Obligatory</i>	<b>Bone donation: Must not donate.</b>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

**Osteomyelitis**

<i>Obligatory</i>	<p><b>1. Must not donate if:</b></p> <p>a) Less than two years from completing treatment and cure.</p> <p>b) Has chronic sinus.</p> <p><b>2. Exclude:</b> Previously affected bone.</p>
<i>Discretionary</i>	<p>1. If two years from completing treatment and cure, unaffected bone may be accepted.</p> <p><b>2. Eyes:</b> If the corneas are to be stored by organ culture, accept.</p>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' has been amended.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

**Osteoporosis**

<i>Obligatory</i>	<b>Structural bone: Must not donate if:</b> Donor has, or is at risk of, osteoporosis.
<i>Discretionary</i>	May be acceptable for donation of non-weight bearing bone.
<i>See if Relevant</i>	<u>Steroid Therapy</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

**Ovarian Cyst**

*Obligatory*

**Must not donate if:**  
Malignant.

*Discretionary* **Eyes:**  
If related to malignancy, see Malignancy.

*See if Relevant* Malignancy

*Reason for Change* The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

## Paget's Disease of Bone

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*Includes* Osteitis Deformans

*Obligatory* **Bone:**  
**Must not donate.**

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

## Pain Killers

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*Obligatory* Assess the reason for treatment, see any relevant entry and, if necessary:  
**Refer to a Designated Medical Officer.**

*See if Relevant* Arthritis  
Malignancy

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

## Peptic Ulcer

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*Includes* Gastric and Duodenal Ulcer and Erosions

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

*Discretionary* **Eyes.**  
If related to malignancy, see Malignancy.

*See if Relevant* Transfusion

*Reason for Change* The 'Discretionary' entry for 'Eyes' (malignancy) has changed.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 02, Issue 35

## Perthes' Disease

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*Discretionary* Accept.

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

## Pituitary Extract - Human

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<i>Includes</i>	Adrenocorticotrophic Hormone, Follicle Stimulating Hormone, Gonadotrophin, Growth Hormone, Luteinising Hormone, Thyroid Stimulating Hormone.
<i>Obligatory</i>	<b>Must not donate if:</b> Has ever received injection(s) of Human Pituitary Extract.
<i>See if Relevant</i>	<u>Growth Hormone</u> <u>Prion Associated Diseases</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	Additional Information' has been added for clarity.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Plasma Dilution

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<i>Obligatory</i>	<b>Must not donate if:</b> A pre-transfusion sample is not available and plasma dilution from intra-venous infusions is estimated to be more than 50% following significant blood loss. This can be calculated from the algorithm in Appendix 4.
<i>See</i>	<u>Appendix 4 - Calculation of Plasma Dilution.</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02, Issue 02

## Platelet Disorder

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<i>Obligatory</i>	<b>See:</b> Is there an entry for the condition?
<i>Discretionary</i>	If not covered by a specific entry, accept.
<i>See if Relevant</i>	<u>Haematological Disease</u> <u>Immune Thrombocytopenia</u> <u>Thrombocytosis</u>
<i>Reason for Change</i>	Some minor alterations have been made to improve clarity.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02, Issue 02

## Pleurisy

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<i>See if Relevant</i>	<u>Infection - General</u> <u>Malignancy</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02



## Pneumothorax

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### Spontaneous

*Discretionary*    Accept.

### Traumatic

See    Accident

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

## Poisoning

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*Obligatory*    **Must not donate if:**  
There is evidence that the individual (donor/or mother of cord blood donor) has ingested, or been otherwise exposed to toxic substances that could be transmitted in donated material in dosages that could endanger the health of recipients.

*Discretionary*    If the individual is being monitored following exposure and the levels of the agent in question are within safe limits, accept.

*See if Relevant*    Addiction and Drug Abuse

*Additional Information*    Advice may be sought from the National Poisons Information Service if required.

*Reason for Change*    This is a new entry. This is a requirement of the Human Tissue Authority Guide to Quality and Safety Assurance for Human Tissues and Cells for Patient Treatment

*Update Information*    This entry was last updated in  
TDSG-DD Edition 203, Release 30

## Polycythaemia

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*Obligatory*    **Must not donate.**

*Discretionary*    If confirmed as secondary polycythaemia, accept.

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

## Porphyria

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*Obligatory*    **Must not donate if:**  
Suffers from porphyria.

*Discretionary*    If the potential donor suffers from Acute Intermittent Porphyria (AIP), Varigate Porphyria (VP), Hereditary Coproporphyrinuria (HCP), Erythropoietic Protoporphyrinuria (EPP) or Congenital Erythropoietic Porphyria (CEP), accept for all tissues except skin.

*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.

	Porphyrias may be associated with skin lesions.
<i>Reason for Change</i>	This is a new guideline.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 11

## Post Viral Fatigue Syndrome

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<i>Obligatory</i>	<b>Must not donate if:</b> Not resolved.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Pre- and Post Exposure Prophylaxis for HIV

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<i>Obligatory</i>	<p><b>Must not donate if:</b> Donor has taken Pre-Exposure Prophylaxis (PrEP) or Post-Exposure Prophylaxis (PEP) in the previous three months.</p> <p>Assess any donor using PrEP or PEP for tissue safety risks relating to sexual activity.</p>
<i>Discretionary</i>	If it is over three months since use of PrEP or PEP and there is no other tissue safety risk, accept
<i>See if Relevant</i>	<p><u>Tissues Safety Entry</u> <u>HIV</u> <u>Human Bite</u> <u>Inoculation Injury</u></p>
<i>Additional Information</i>	<p>The use of Pre-Exposure Prophylaxis (PrEP), e.g. Truvada<sup>®</sup>, to prevent HIV is increasing. Individuals taking PrEP are unlikely to be eligible to donate due to criteria within the tissue safety entry. However, PrEP is also available via private prescription and/or online pharmacies and may be used by individuals who would not otherwise be deferred.</p> <p>Use of PrEP may interfere with testing for HIV by delaying seroconversion or giving unclear results in a positive donor. For this reason, it is important that donors who have taken PrEP in the previous three months are not accepted to donate, even if they do not have another tissue safety risk.</p> <p>Post-Exposure Prophylaxis (PEP) has a similar mechanism of action to PrEP and may also interfere with testing results. In the UK PEP is prescribed to people who have been exposed to someone who may have HIV. This includes through sexual activity or exposure through a needle stick injury. Donors who have received PEP will usually be ineligible to donate for the same reason they were given PEP.</p> <p>If the underlying reason for taking PrEP or PEP warrants a longer deferral period, this should be applied.</p> <p>This guidance will be updated as more information about the use and effects of PrEP/PEP becomes available.</p>
<i>Reason for Change</i>	This entry was revised to support the implementation of recommendations from the FAIR III report.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 57

## Pregnancy

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<i>Obligatory</i>	<p><b>Must not donate if:</b></p> <p>a) Resulted in a malignant (invasive) Hydatidiform mole.</p> <p>b) Resulted in a non-malignant (non-invasive) Hydatidiform mole and treatment and follow up is ongoing.</p> <p>c) It is less than 7 days from the last dose of methotrexate.</p>
<i>Discretionary</i>	<p><b>Eyes:</b> If resulted in malignancy, see <u>Malignancy</u>.</p>
<i>See if Relevant</i>	<u>Malignancy</u>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	The addition of information about methotrexate.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Prion Associated Diseases

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<i>Includes</i>	Sporadic, Familial and Variant Creutzfeldt-Jakob Disease (CJD), Gerstmann-Sträussler-Scheinker Disease and Fatal Familial Insomnia
<i>Obligatory</i>	<p><b>Must not donate if:</b></p> <p>1. Diagnosed with any form of CJD, or other human prion disease.</p> <p>2. Identified at increased risk of developing a prion associated disorder. This includes:</p> <p>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).</p> <p>b) Individuals who have potentially been put at increased risk from surgery, transfusion or transplant of tissues or organs.</p> <p>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.</p> <p>d) Recipients of dura mater grafts.</p> <p>e) Recipients of corneal, scleral or other ocular tissue grafts.</p> <p>f) Recipients of human pituitary derived extracts.</p> <p>g) <b>Since January 1st 1980:</b> Recipients of any allogeneic human tissue.</p>
<i>Discretionary</i>	If the donor has had two or more blood relatives develop a prion-associated disease and, following genetic counselling, they have been informed that they are not at risk, accept. This requires confirmation by a <b>Designated Medical Officer</b> .
<i>See if Relevant</i>	<u>Pituitary Extract - Human Tissue and Cell Allograft Recipients Transfusion</u>
<i>Additional Information</i>	See the <u>Position Statement on Creutzfeldt-Jakob Disease</u> available in the JPAC Document Library.
<i>Reason for Change</i>	

The entry has been modified to comply with advice from the MSBTO committee of the DH.

Appropriate links have been added.

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

This entry was last updated in  
TDSG-DD Edition 203, Release 23

## Prisons

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*Obligatory* **Must not donate if:**  
Has been held in prison during the preceding twelve months.

*Discretionary* a) If just held in a police cell for a period not exceeding 96 hours, accept.  
b) If held in prison for more than 96 hours but released more than three months ago, refer to designated medical officer.

*See if Relevant* Addiction drug abuse

*Additional Information* A deceased person cannot be questioned about 'at risk behaviour' that has occurred in prison. Risk behaviour is unlikely to have occurred while held in police custody under police powers of arrest.

The 12 month deferral period specified above may be reduced to 3 months by doing individual risk assessment. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.

*Reason for Change* Relevant entries have been updated.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 57

## Progressive Multifocal Leukoencephalopathy

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*Obligatory* **Must not donate.**

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

## Psoriasis

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*Obligatory* **Must not donate if:**  
a) Generalized or severe.  
b) There is secondary infection.  
c) Immunosuppressed

*Discretionary* a) If the quality of the tissue being donated is not affected, accept  
b) If mild and only using topical treatment, accept.  
c) If the donor is on immunosuppressive medication, see Immunosuppression entry.

*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.  
Donations may be accepted if the safety and quality of the tissues is not affected.

*See* [Autoimmune Disease  
Immunosuppression](#)

*Reason for Change* Treatment with Etrretinate/Neotigason is no longer a reason for deferral. To clarify that if there is no involvement of the tissue to be donated, donation may proceed. Link to 'immunosuppression' entry added.

*Update Information* This entry was last updated in TDSG-DD Edition 203, Release 48.

## Pulmonary Embolism

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*Discretionary* Accept.

*See if Relevant* [Malignancy](#)

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

## Pyelonephritis

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*Discretionary* **Eyes:**  
If the corneas are to be stored by organ culture, accept.

*See* [Infection - General](#)

*Reason for Change* The 'Discretionary' entry for 'Eyes' has changed to include a reference to organ culture.

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

## Pyrexia

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### Not Related to Travel in Malarious Areas

*Obligatory* If less than two weeks from an undiagnosed episode of pyrexia:  
**Refer to a Designated Medical Officer.**

*See if Relevant* [Infection - General](#)

### Related to Travel in Malarious Areas

*See* [Malaria](#)

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

## Pyruvate Kinase Deficiency

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*Discretionary* Accept.

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

## Q Fever

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Quinsy

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<i>Discretionary</i>	<b>Eyes:</b> If the corneas are to be stored by organ culture, accept.
<i>See</i>	<u>Infection - Acute</u>
<i>Reason for Change</i>	The 'Discretionary' entry for 'Eyes' has changed to include a reference to organ culture.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Rabies

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### Immunization - Non-exposed

<i>Discretionary</i>	If non-exposed, accept.
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### Immunization - Post Exposure

<i>Obligatory</i>	<b>Must not donate until:</b> At least 24 months post exposure and fully cleared by treating physician.
<i>Reason for Change</i>	To extend the deferral period post exposure to 24 months.

### Infection

<i>Obligatory</i>	<b>Must not donate.</b>
<i>See if Relevant</i>	<u>Animal Bite</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 41

## Radiation Therapy

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<i>Obligatory</i>	<b>Must not donate if:</b> a) For malignancy other than basal cell carcinoma.  b) For other treatments: <b>Refer to a Designated Medical Officer.</b>  c) Tissue to be collected has been irradiated.
<i>Discretionary</i>	<b>a) Eyes:</b> If related to malignancy and the eyes were not included in the field of irradiation, see <u>Malignancy</u> .  b) If fully recovered and is acceptable according to immunosuppression advice, accept.

c) If for basal cell carcinoma or ductal carcinoma in situ of the breast, all treatment has been completed, the donor has been discharged from follow up and is eligible under the Malignancy Guideline, accept.

*See if Relevant* Basal Cell Carcinoma  
Immunosuppression  
Malignancy

*Additional Information* Radiation therapy is sometimes used for non-malignant conditions, particularly for some skin conditions. It is often used as a substitute for other treatments that work by suppressing the immune system such as high dose steroids and cytotoxic drugs. More information is likely to be required before a decision can be made as to if an individual can donate. This why a referral to a 'Designated Medical Officer' is required.

*Reason for Change* Additional discretionary acceptance for basal cell carcinomas and ductal carcinoma in situ of the breast. A link had been added to autoimmune disease, and additional information has been added.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 29

## Radionuclides

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*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.**

*Discretionary* **Eyes:**  
If related to malignancy, see Malignancy.

*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.

*Reason for Change* A 'Discretion' has been added for 'Eyes'.

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

## Raynaud's Syndrome

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*Obligatory* **Must not donate if:**  
Part of a multisystem disorder.

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

## Recipients of Normal Human Immunoglobulin

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*See if Relevant* Hepatitis A  
Immunosuppression  
Immunoglobulin Therapy

*See* Transfusion

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

## Renal Colic

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<i>See if Relevant</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Respiratory Disease

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<i>See if Relevant</i>	<u>Infection - General</u> <u>Steroid Therapy</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Retinitis Pigmentosa

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Reyes Syndrome

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<i>Obligatory</i>	<b>Eyes:</b> <b>Must not donate.</b>
<i>Discretionary</i>	<b>Eyes:</b> If more than three months after recovery, accept
	<b>Other Tissues:</b> If no other contraindication, accept.
<i>See if Relevant</i>	<u>Infection - Acute</u>
<i>Reason for Change</i>	To add a discretionary acceptance for eyes
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 33

## Rheumatic Fever

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<i>Obligatory</i>	<b>1. Cardiovascular Tissue:</b> <b>Must not donate.</b>
	<b>2. Other Tissues:</b> <b>Must not donate if:</b> Active infection.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02



## Rheumatoid Arthritis

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<i>Discretionary</i>	1. If mild and the only treatment is NSAIDs, accept.
	<b>2. Eyes:</b> Accept if no ocular involvement.
<i>See</i>	<u>Autoimmune Disease</u>
<i>Reason for Change</i>	The entry has been changed for consistency from 'Must not donate' to 'See Autoimmune Disease'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Ringworm

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<i>Obligatory</i>	<b>Must not donate if:</b> On systemic treatment.
<i>Discretionary</i>	If on local treatment only, accept.
<i>See if Relevant</i>	<u>Infection - General</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Rubella

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### Acute Infection.

<i>See</i>	<u>Infection - Acute</u>
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### Congenital

<i>Obligatory</i>	<b>Eyes:</b> Must not donate.
<i>Discretionary</i>	<b>Other Tissues:</b> If no other contraindication, accept.
<i>See</i>	<u>Infection - Acute</u>
<i>Reason for Change</i>	A 'Discretionary' entry has been added for other tissues.

### Contact

<i>See</i>	<u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Sarcoidosis

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### Acute

<i>Obligatory</i>	<b>Must not donate if:</b> a) Not recovered.
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b) Less than five years from both finishing all treatment and full recovery.

*Discretionary* 1. If more than five years since finishing all treatment and full recovery, accept  
**2. Eyes:**  
 If no ocular involvement, 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.**

*Discretionary* **Eyes:**  
 If no ocular involvement, accept.

*Additional Information* Chronic sarcoidosis can cause a range of problems, particularly with the lungs but also with the heart. 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-DD Edition 203, Release 17

## Sex Worker

*Obligatory* **Must not donate.**

*Discretionary* If 3 months or more has elapsed since the donor last received money or drugs for sex, accept

*See if Relevant* Addiction and Drug Abuse  
Hepatitis of Viral Origin  
HIV  
HTLV  
Infection - General

*Additional Information* In this context sex is defined as vaginal, oral or anal sex with or without a condom /protective. This guidance presumes that a validated NAT test for HIV, HBV and HCV is negative, if this test is stopped for any reason the guidance will change.  
 If received injectable drugs of addiction for sex, see 'Addiction and Drug Abuse' entry as a 12 month deferral may apply.

*Reason for Change* This entry was updated in line with the recommendations of the SaBTO Donor Selection Criteria Review Report published on 23rd July 2017.

*Update Information* This entry was last updated in  
 TDSG-DD Edition 203, Release 57

## Sexually Transmitted Disease

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### Infected Individual

<i>Obligatory</i>	<p><b>See:</b> Is there is a specific entry for the disease?</p> <p><b>Must not donate</b></p>
<i>Discretionary</i>	<p>If fully treated, at least three months from completion of treatment, accept. Additionally, for gonorrhoea, evidence of a test of cure after treatment is required. This may be a verbal confirmation, provided by the person answering the relevant Medical and Social History questions about the donor or someone with access to records of the donor's treatment.</p>
<i>See if Relevant</i>	<p><u>Tissues Safety Entry</u> <u>Chlamydia</u> <u>Genital Warts</u> <u>Herpes - Genital</u> <u>Syphilis</u></p>

### Sexual Partner

<i>Obligatory</i>	<p><b>See:</b> Is there is a specific entry for the disease with which there has been contact?</p> <p><b>Must not donate if:</b></p> <p>a) Donor required treatment and it is less than three months since completing that treatment.</p> <p>b) Donor did not require treatment and it is less than three months from the last sexual contact with the infected partner.</p>
<i>Discretionary</i>	<p>a) Donor did not require treatment and it is more than three months since the infected partner has completed treatment, accept.</p> <p>b) Donor required treatment: if fully treated, and if it is at least three months from completion of treatment, accept. Additionally, for gonorrhoea, evidence of a test of cure after treatment is required. This may be a verbal confirmation, provided by the person answering the relevant Medical and Social History questions about the donor or someone with access to records of the donor's treatment.</p> <p>c) If the donor's sexual partner has been diagnosed with chlamydia (except lymphogranuloma venereum, see (b) above), genital warts or genital herpes and the donor is asymptomatic and not undergoing treatment or investigation, accept.</p>
<i>See if Relevant</i>	<p><u>Tissues Safety Entry</u> <u>Chlamydia</u> <u>Genital Warts</u> <u>Herpes - Genital</u> <u>Syphilis</u></p>
<i>Additional Information</i>	<p>Guidelines (NICE, BASHH) recommend that current sexual partners of lymphogranuloma venereum (LGV) probable or confirmed individuals should receive testing and empiric treatment with a chlamydial regimen. They can be accepted 3 months after completion of treatment.</p>
<i>Reason for Change</i>	<p>Discretionary guidance updated to clarify verbal confirmation is not provided by the donor themselves.</p>
<i>Update Information</i>	<p>This entry was last updated in TD-DSG Edition 203 Release 60, Issue 03</p>

## Shingles

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### Affected Individual

<i>See if Relevant</i>	<u>Herpes - Ocular</u>
<i>See</i>	<u>Herpes Zoster</u>
<i>Reason for Change</i>	The links have been changed for clarity.

### Contact

<i>See</i>	<u>Infectious Diseases - Contact with</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Sickle-Cell Trait

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Sideroblastic Anaemia

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<i>Obligatory</i>	<b>Must not donate</b>
<i>See if Relevant</i>	<u>Myelodysplastic Syndrome</u>
<i>Reason for Change</i>	'Must not donate' has been extended to all tissues.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Skin Disease

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<i>Obligatory</i>	<p><b>1. Must not donate if:</b></p> <p>a) The condition is infected or infectious.</p> <p>b) Malignant.</p> <p><b>2. Skin Donor:</b></p> <p><b>Must not donate:</b></p> <p>a) If the skin disease is part of a generalized condition.</p> <p>b) Affected skin.</p>
<i>Discretionary</i>	<p><b>1. Eyes:</b></p> <p>a) If related to malignancy, see <u>Malignancy</u>.</p> <p>b) If any infection is bacterial and the corneas are to be stored by organ culture, accept.</p> <p><b>2. Skin:</b></p> <p>If malignancy was a Basal Cell Carcinoma and treatment is completed, accept unaffected skin only.</p> <p><b>3. Other Tissues:</b></p> <p>If malignancy was a Basal Cell Carcinoma and treatment is completed, accept.</p>

*See if Relevant*     Dermatitis  
Infection - General  
Malignancy  
Psoriasis

*Reason for Change*     Discretions have been added for 'Eyes' and 'Skin'.  
  
' Malignancy' has been added to 'Obligatory' and additional links have been included.

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

## Sleeping Sickness

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(African Trypanosomiasis)

*Obligatory*     **Must not donate.**

*Discretionary*     **Eyes:**  
Accept for corneas only.

*Additional Information*     As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change*     A 'Discretion' has been added for 'Eyes'.

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

## Smallpox Immunization

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### Contacts

*Obligatory*     **Must not donate if:**  
**1. All Tissues:**  
a) Any secondarily infected site has not yet healed.  
  
b) Less than eight weeks after secondarily infected site appeared.

**2. Skin Only:**  
Less than two weeks after the last lesion healed on the infected contact.

*Discretionary*     **All Tissues Except Skin:**  
If no new skin lesions, accept.

*Additional Information*     Close contacts of vaccinees (household or direct bodily contact) may become secondarily infected from direct skin contact with an infected inoculation site or from virus on clothing, bedding, dressings etc. If infection occurs, a new skin rash, blister or sore appears at the site of contact, which could be anywhere on the body. The rash represents a secondary vaccination site and presents exactly the same potential risk to patients and staff as that of a person who has been intentionally immunized.

### Immunized Individual

*Obligatory*     **Must not donate if:**  
**1. All Tissues:**  
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.

**2. Skin Only:**  
Less than two weeks after the last lesion healed.

*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 staff, or to people receiving tissues.

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

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

## South American Trypanosomiasis

*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**  
Accept for corneas only.

*See if Relevant* South American Trypanosomiasis Risk

*Additional Information* As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change* The 'Discretionary' entry for 'Eyes' has been amended.

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

## South American Trypanosomiasis Risk

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

1) Born in South America or Central America (including Mexico).

2) Mother was born in South America or Central America (including Mexico).

3) Has had a transfusion in South America or Central America (including Mexico).

4) Has lived and/or worked in rural subsistence farming communities in these countries for a continuous period of four weeks or more.

*Discretionary* 1) If at least four months from the date of last exposure, including transfusion abroad, and a validated *T. cruzi* antibody test is negative, accept.

2) **Eyes:**  
Accept for corneas only (testing not required). For other ocular tissues, as (1) above.

*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 four 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 Mexico) is not considered of high enough risk to merit exclusion.

As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change* To reduce deferral period following last date of exposure from six to four months, and align this entry with the 'Transfusion' entry. To also align this entry with the Geographical Disease Risk Index and change the reference to "Southern Mexico" to "Mexico".

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 42.

## Spherocytosis

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<i>See</i>	<u>Hereditary Spherocytosis</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Spina Bifida

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<i>Obligatory</i>	<b>Must not donate if:</b> a) Has an indwelling shunt and there is evidence of shunt infection.  b) Has an infected pressure sore.
<i>Discretionary</i>	<b>Eyes:</b> Shunt infection or infected pressure sore - if the corneas are to be stored by organ culture, accept.
<i>Additional Information</i>	Donated bone is cultured to exclude occult bacterial and fungal infection. However it should not be collected from bacteraemic subjects.
<i>Reason for Change</i>	A 'Discretion' has been added for 'Eyes'.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Spinal Surgery

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<i>See if Relevant</i>	<u>Neurosurgery</u> <u>Transfusion</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02, Issue 35

## Splenectomy

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<i>Obligatory</i>	<b>Must not donate if:</b> a) For malignancy.  b) For a myeloproliferative disorder.
<i>Discretionary</i>	<b>1. All Tissues:</b> a) If for trauma, or if underlying reason for splenectomy is not a contraindication to donation, even if on prophylactic antibiotics, accept.  <b>2. Eyes:</b> If related to malignancy, see <u>Malignancy</u> .
<i>See if Relevant</i>	<u>Haematological Disease</u> <u>Haemolytic Anaemia</u> <u>Immune Thrombocytopenia</u> <u>Malignancy</u> <u>Transfusion</u>
<i>Reason for Change</i>	To update 'obligatory' and 'discretionary' sections and add 'see if relevant' links.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 59

## Steroid Therapy

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<i>Obligatory</i>	<p><b>Discuss with a Designated Medical Officer if:</b> Has been regularly taking steroid tablets, injections or enemas, or applying creams over large areas.</p> <p>For information on other situations where steroid therapy may be acceptable, refer to entry for immunosuppression.</p>
<i>Discretionary</i>	<p>1. a) If occasional use of creams over small areas of skin for minor skin complaints, accept.</p> <p>b) If using steroid inhalers for prophylaxis, accept.</p> <p>c) Cornea only: If corneas are stored in organ culture and in the absence of other contraindications, accept. See additional information section</p>
<i>See if Relevant</i>	<p><u>Autoimmune Disease</u> <u>Eye Disease</u> <u>Immunosuppression</u> <u>Infection – acute</u> <u>Infection – chronic</u> <u>Skin Disease</u> <u>Tissue and Cell Allograft Recipients</u></p>
<i>Additional Information</i>	<p>Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation. For further information refer to 'Immunosuppression' entry.</p> <p>The underlying condition requiring steroid treatment should always be taken into consideration.</p> <p>Eye donors receiving steroid treatment e.g. steroid eye drops, should be evaluated on a case by case basis, taking into consideration the indication for treatment as well as any possible side effects. Relevant clinical records, especially ophthalmology records, should be reviewed.</p>
<i>Reason for Change</i>	<p>Links to the Infection – acute, Infection – chronic and Eye Disease entries have been added. Discretionary section amended regarding cornea donation.</p>
<i>Update Information</i>	<p>Part of this advice is a requirement of the EU Tissue &amp; Cells Directive.</p> <p>This entry was last updated in TDSG-DD Edition 203, Release 52</p>

## Stroke

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Syphilis

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### 1. Affected Individual

*Obligatory*



**Must not donate.**

<i>Discretionary</i>	If fully treated in the past and confirmatory tests exclude recent infection, discuss with a <b>Designated Medical Officer</b> .
<i>Additional Information</i>	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.

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

<i>Obligatory</i>	<b>Must not donate if:</b> a) The potential donor was diagnosed with syphilis (see 'Affected Individual' section above). b) It is less than three months since last sexual contact with an infected partner.
<i>Discretionary</i>	a) If it is more than three months from the last sexual contact with an infected partner, accept. b) If it is more than three months since an infected partner has completed treatment, accept.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Reason for Change</i>	The deferral period after sexual contact with an infected person has been reduced to three months.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 57

**Systemic Lupus Erythematosus**

<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	If the tissues to be donated are not affected by the condition, subject to individual risk assessment, accept.  Discuss with Designated Clinical Support Officer for advice if required.
<i>See if Relevant</i>	<u>Immunosuppression</u>
<i>Reason for Change</i>	To permit discretionary acceptance of unaffected tissues subject to individual risk assessment.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 42.

**Tamoxifen**

<i>Obligatory</i>	See <u>Malignancy</u> entry.
<i>Discretionary</i>	If taken for non-malignant conditions, accept.
<i>Reason for Change</i>	To clarify that use of Tamoxifen for non-malignant conditions is not a contraindication to donation.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 42.

## Tetanus Immunization

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<i>Obligatory</i>	<b>Must not donate if:</b> Less than four weeks from exposure.
<i>Discretionary</i>	If non-exposed, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Thalassaemia Major

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	<b>Eyes:</b> Accept.
<i>See if Relevant</i>	<u>Transfusion</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Thalassaemia Trait

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Therapeutic Venesection

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	If for haemochromatosis or confirmed secondary polycythaemia, accept.
<i>See if Relevant</i>	<u>Haemochromatosis</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Threadworms

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<i>Discretionary</i>	Even if on treatment, accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Thrombocytosis

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<i>Obligatory</i>	<b>Must not donate if:</b> Due to a myeloproliferative disorder.
<i>Additional Information</i>	People with unexplained persistently raised platelet counts should not be accepted.
<i>Reason for Change</i>	This entry has been added to clarify the eligibility of donors with this condition.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Thrombosis

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<i>Discretionary</i>	If the underlying cause does not exclude, accept.
<i>See if Relevant</i>	<u>Malignancy</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Thrush - Oral

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<i>Obligatory</i>	<b>Must not donate if:</b> a) Unexplained.  b) Related to immunodeficiency.
<i>See if Relevant</i>	<u>Infection: Chronic</u>
<i>Reason for Change</i>	This entry has been revised to link discretionary acceptance to the current 'Infection: Chronic' entry.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 46

## Thrush - Vaginal

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<i>Obligatory</i>	<b>Must not donate if:</b> a) Related to immunodeficiency.
<i>Discretionary</i>	<u>Infection: Chronic</u>
<i>Reason for Change</i>	This entry has been revised to link discretionary acceptance to the current 'Infection: Chronic' entry.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 46

## Thyroid Disease

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<i>Obligatory</i>	<b>Must not donate if:</b> a) Under investigation.  b) Malignant.  c) Less than six months from treatment with radioactive iodine therapy.
<i>Discretionary</i>	<b>Eyes:</b> a) If related to malignancy, see <u>Malignancy</u> .  b) If associated with Thyroid Eye Disease (Grave's Disease): accept if no history of corneal involvement.
<i>See if Relevant</i>	<u>Autoimmune disease</u>
<i>Reason for Change</i>	To add an additional discretion for 'Eyes'.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 35

## Tissue and Cell Allograft Recipients

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*Excludes* Xenograft recipients, recipients of biological grafts of non-human origin and bio-prosthetic grafts and organ recipients.

*Obligatory* All donors:  
**Must not donate if:**  
a) Dura mater transplanted at any time.  
  
b) Ocular tissue transplanted at any time.  
  
c) Any other allogeneic human tissue or cell transplanted since 1st January 1980.

*Discretionary* a) If an autologous tissue, or cells, has been transplanted at any time, and there is no other reason to exclude the donor, accept.  
  
b) If an allogeneic tissue (except dura mater or ocular tissue) or cell transplant was performed before 1st January 1980, and there is no other reason to exclude the donor, accept.  
  
c) For donations of heart valves, skin, ocular tissue and pancreatic islets only: If an allogeneic tissue (except dura mater or ocular tissue), or cells, has been transplanted at any time, and there is no other reason to exclude the donor, accept.

*See if Relevant* Immunosuppression  
Ocular Tissue Recipient  
Organ Recipient  
Prion Associated Diseases  
Transfusion  
Xenotransplantation

*Additional Information* The transfer of tissues or cells between individuals and species has led to the spread of infection. The above guidelines are intended to minimise these risks.

People who have received a tissue or cell transplant since 1980 are excluded from donation of any tissues except for heart valves, ocular tissue, pancreatic islets and skin as a precautionary measure against the risk of transmission of vCJD in the same way as recipients of transfusion are.

Dura mater and ocular tissue allografts have been implicated in iatrogenic CJD. Iatrogenic CJD refers to the transmission of prions via inadvertent medical exposure. Recipients of dura mater and ocular tissue recipients are excluded.

Dura mater use stopped in the UK by 1993. The situation in other countries varied so specific dates cannot be given.

Tissue allograft recipients do not require immunosuppression. If the recipient was on immunosuppression for any other reason, see Immunosuppression entry.

*Reason for Change* This is a new entry.

*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 56

## Tissue and Organ Recipients

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<i>Obligatory</i>	<p><b>All donors:</b> <b>Must not donate if:</b></p> <p><b>1. At any time:</b></p> <p>a) Has needed immunosuppression.</p> <p>b) Dura mater transplanted.</p> <p>c) Ocular tissue transplanted.</p> <p>d) Xenotransplant performed.</p> <p><b>2. Since January 1st 1980:</b> Any allogeneic human tissue or organ transplanted.</p>
<i>Discretionary</i>	<p>a) If an allogeneic tissue or cell transplant was performed before January 1st 1980 and there is no other reason to exclude the donor, accept.</p> <p>b) If at anytime an autologous tissue tissue, or cells, has been transplanted, accept.</p> <p>c) For donations of heart valves, skin, ocular tissue and pancreatic islets: If at anytime a allogeneic tissue,or cells, has been transplanted, accept</p>
<i>See if Relevant</i>	<p><u>Immunosuppression</u> <u>Ocular Tissue Recipient</u> <u>Prion Associated Diseases</u> <u>Xenotransplantation</u></p>
<i>Additional Information</i>	<p>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.</p> <p>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 has been a very small number of 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, will be excluded from donation except for donation of heart valves, ocular tissue, pancreatic islets and skin. These tissues provide considerable benefits to patients.</p>
<i>See</i>	<u>Transfusion</u>
<i>Reason for Change</i>	To update discretionary entry to accept skin, heart valve, ocular tissue and pancreatic islets from those who might have received allogeneic tissue transplant.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 35

## Tissues Safety Entry

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<i>Definition</i>	<p><b>Individual risk</b> is based on the donor's sexual behaviour, including new partners and the number of partners in the 3 months prior to donation.</p> <p><b>Partner risk</b> is based on sexual contact with a partner who may, at a population level, be at higher risk of acquiring infection, as described in this entry.</p> <p><b>Sexual contact</b> is defined as oral, vaginal or anal sex.</p> <p><b>Anal sex</b> is defined as penile-anal intercourse only. It does not apply to oro-anal sex or the use of sex toys.</p> <p><b>Chemsex</b> is sex while using stimulant drugs taken for the specific purpose of enhancing sexual experience and reducing inhibitions. Chemsex does not refer to sex after using alcohol or recreational drugs for other purposes, nor the use of drugs such as Viagra or Cialis to treat erectile dysfunction.</p>
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*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

**3. You must not donate for at least 12 months:**

After stopping habitual use of injected drugs of addiction.

**4. You must not donate for at least three months if:**

- a) You have taken Pre-Exposure Prophylaxis (PrEP) / Truvada for prevention of HIV
- b) You have taken or been prescribed Post-Exposure Prophylaxis (PEP) for prevention of HIV.

If the underlying reason for taking PrEP or PEP warrants a longer deferral period, this should be applied.

**5. You must not donate for at least 3 months if:**

- a) You have received money or drugs for sex
- b) You have injected, or been injected with, non-prescription drugs, even only once. This includes, for example, bodybuilding drugs or injectable tanning agents. You may be able to donate if a doctor prescribed the drugs. Please ask.
- c) You have injected, been injected with, or used non-parenteral Chemsex drugs.

**6. Individual risk criteria (FAIR):**

**You must not donate for at least 3 months if:**

- a) You have taken part in chemsex activity, including the use of stimulant drugs. This risk applies for all sexual contact.
- b) You have been diagnosed with gonorrhoea. You must wait for at least three months after you have successfully completed treatment and been discharged from further follow up.
- c) You have had more than one sexual partner in the last 3 months AND you have had anal sex with any of these partners.
- d) You have had anal sex with a new sexual partner. For the purpose of donor selection, a new partner is someone that you have not had sex with before or a previous partner with whom you have restarted a sexual relationship in the last 3 months.

If you are in a sexual relationship with one partner only, you can donate once it is three months from the date of first sexual contact, even if you are having anal sex.

**7. You must not donate for at least 3 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 received money or drugs for sex
- e) A partner who has injected, or been injected with non-prescription drugs. This includes, for example, bodybuilding drugs or injected tanning agents. You may be able to give if a doctor prescribed the drugs, please ask.

*See if Relevant*

Addiction and Drug Abuse

Hepatitis B

Hepatitis C

Hepatitis of Viral Origin

HIV

HTLV

Infection - General

Pre- or Post-Exposure Prophylaxis for HIV

Sexually Transmitted Disease

Syphilis

*Additional Information*

The FAIR (For the Assessment of Individualised Risk) report (2020) recommended changes to blood donor selection policy to allow a more individualised risk-based approach. This approach was approved by ministers in devolved administrations and has now been implemented by the UK Transfusion Services.

The FAIR III working group recommended that a similar approach could be applied to tissue and cell donors in principle, acknowledging that the current donor selection policies already permit an individual risk assessment approach for life saving tissues and cells.

FAIR identified several factors associated with a higher risk of blood borne infections. These include the recent diagnosis of a bacterial sexually transmitted disease and the following sexual behaviours:

- new or multiple sexual partners
- anal sex
- participation in chemsex activity

Drugs used for chemsex include methamphetamine, mephedrone and GHB/GBL, but other drugs may be used (e.g. ketamine, poppers, cocaine). Chemsex is a high risk activity because it usually involves multiple sexual partners, sometimes for extended periods of time. The drugs involved also reduce inhibition leading to riskier sexual activity.

The drugs used in both Pre- and Post-Exposure Prophylaxis for HIV (PrEP and PEP) may interfere with the routine HIV screening tests carried out on all tissue and cell donors. For this reason, donors who have taken PrEP or PEP should not donate for three months, even if they are otherwise eligible under individual risk criteria.

The deferral periods specified above may be reduced by doing individual risk assessment if the risk of acquiring an infectious disease may be outweighed by the risk of delaying a lifesaving transplantation.

<i>Reason for Change</i>	The entry was revised to include individual risk assessment of recent sexual behaviour for all donors. The deferral for donors whose sexual partners have been sexually active in Sub-Saharan Africa has been removed. This supports implementation of recommendations from the FAIR III Report.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 57

## Toxoplasmosis

<i>Obligatory</i>	<b>Must not donate if:</b> Confirmed current active infection at the time of donation.
<i>See if Relevant</i>	<u>Infection - Acute</u>
<i>Additional Information</i>	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.  Testing of tissue donors is not required. Toxoplasma IgG results from organ donors, if available, do not require further investigation.
<i>Reason for Change</i>	To clarify that toxoplasma IgG results from organ donors, if available do not require further investigation
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 30

## Transfusion

<i>Includes</i>	Treatment with Blood Components, Products and Derivatives.
<i>Obligatory</i>	<b>1. Must not donate if:</b> 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. See 'Discretionary' section below for exceptions.

b) Has received regular treatment with blood derived coagulation factor concentrates.

**2. 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) or cryoprecipitate. This includes mothers whose babies have required intra-uterine transfusion.

b) Had a plasma exchange performed.

**3. Before January 1st 1999:**

a) Treated with prothrombin complex to reverse over-anticoagulation.

b) Received intravenous or subcutaneous human normal immunoglobulin.

*Discretionary*

1. a) If on medical inquiry it is unlikely that the donor has been transfused, accept.

b) Received, or thinks they may have received, a transfusion of blood or blood components before 1st Jan 1980, accept – See 4 below if transfused abroad.

c) If treatment with human immunoglobulin has been limited to small quantities of specific immunoglobulin as prophylaxis (e.g. rhesus, tetanus, hepatitis, immunoglobulin etc.), accept.

d) If the only transfusion has been within the last week of life, accept.

e) Treated with prothrombin complex (PCC) to reverse over-anticoagulation after 1st January 1999, accept.

f) If treated with intravenous immunoglobulins after 1st January 1999: if underlying condition is not a contraindication, accept. Refer to designated clinical support officer if further advice required.

**2. Autologous Transfusion:**

If only the donor's own blood has been used, accept.

**3. Heart valve, ocular tissue, skin and pancreatic islet donors only:**

Provided the donor's total transfusion exposure is limited to less than 80 units of blood or blood components, accept. – See 4 below if transfused abroad.

**4. Donor transfused in a country endemic for malaria or South American trypanosomiasis:**

a) Check the Geographical Disease Risk Index. If transfused in an at risk endemic country and a validated malarial antibody test and/or (as appropriate) a validated test for T.cruzi antibody is negative, accept.

b) If tissue will be sterilized by irradiation post-donation: Accept (testing not required)

c) For Eyes only, if the risk was for Malaria or South American trypanosomiasis, accept for corneas only (testing not required).

*See if Relevant*

Bleeding Disorder  
Immunoglobulin Therapy  
Immunosuppression  
Malaria  
Prion Associated Diseases  
South American Trypanosomiasis Risk  
Geographical Disease Risk Index  
Appendix 3 - Calculation of Plasma Dilution.

*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 (with the exception of Malaria and South American trypanosomiasis for cornea donors only, or for tissues that are terminally sterilised) before accepting the donor.

**Coagulation concentrates:**

People who have received blood derived coagulation concentrates (these are made from the blood of many donors) regularly 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 has been a very small number of 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 (except in the last week of life) should not normally be accepted. Because of shortages in supply, this does not currently apply to the donation of heart valves, ocular tissue, pancreatic islets and skin. Any history of transfusion after 1980 must be recorded and remain part of the documentation associated with the donation.

Plasma exchange results in the patient having been exposed to multiple donors. In view of the increased vCJD risk, donations may not be taken from individuals who have had a plasma exchange performed since 1980.

Commonly used PCCs, such as Beriplex or Octaplex, currently used in the UK, are prepared from non-UK donors. They are administered as one-off doses to reverse anticoagulation or peri-operative prophylaxis. Since 1999, coagulation factors prepared from UK donors have no longer been used as a risk reduction measure for vCJD transmission.

<i>Reason for Change</i>	To permit donation from donors who have received intravenous immunoglobulin after 1st January 1999, if the reason for treatment is not a contraindication.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 45

## Transgender Individuals

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<i>Definition</i>	<b>Cisgender (cis)</b> describes someone whose gender identity is the same as the sex they were assigned at birth.  <b>Transgender (trans)</b> describes someone whose gender is not the same as, or does not sit comfortably with, the sex they were assigned at birth.
<i>Obligatory</i>	Assessment of the donor suitability should be according to the gender assigned at the time of donation.
<i>Discretionary</i>	Obtain history and refer to designated medical officer if necessary.
<i>See if Relevant</i>	<u>Tissues Safety Entry</u>
<i>Additional Information</i>	Consideration should be given to the medications used during gender re-assignment. An individual risk assessment is required with regard to potential effects on the donor, donated material and any potential risk to the recipient.
<i>Reason for Change</i>	This entry was revised to support the implementation of the FAIR III report; the additional information section has been revised to reflect the circumstances of tissue and cell donations.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 57

## Travel

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<i>See if Relevant</i>	<u>Geographical Disease Risk Index</u> <u>Malaria</u> <u>South American Trypanosomiasis Risk</u> <u>Infection - Tropical</u>
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Trisomy 21 (Down's Syndrome)

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<i>Includes</i>	Mosaic Down's Syndrome
<i>Obligatory</i>	<b>Eyes: Must not donate.</b>
<i>Discretionary</i>	<b>Other Tissues:</b> If no other contraindication, accept.
<i>Reason for Change</i>	A 'Discretionary' entry has been added for other tissues.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Trisomy E (Trisomy 18)

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<i>Obligatory</i>	<b>Eyes: Must not donate.</b>
<i>Discretionary</i>	<b>Other Tissues:</b> If no other contraindication, accept.
<i>Reason for Change</i>	A 'Discretionary' entry has been added for other tissues.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Tropical Viruses

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<i>Includes</i>	Chikungunya Virus, also known as CHIKV Dengue Virus, also known as Dengue Fever Yellow Fever, also known as YF Zika Virus, also known as ZIKV, and Zika Virus Fever
<i>Definition</i>	<b>Tropical Virus Endemic Areas:</b> are shown in the 'Geographical Disease Risk Index' (GDRI) as a Tropical Virus Risk.
<i>Obligatory</i>	<b>Must not donate if:</b> 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, Yellow Fever 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, Yellow Fever 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.
<i>Discretionary</i>	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 no clinical evidence of infection.
<i>See if Relevant</i>	<u>Infection - General</u> <u>Malaria</u> <u>South American Trypanosomiasis</u> <u>The 'Geographical Disease Risk Index'</u>
<i>Additional Information</i>	Chikungunya, Dengue, Yellow Fever and Zika virus are spread by the day-flying mosquito species <i>Aedes aegypti</i> and <i>Aedes albopictus</i> . As these mosquitos are typically found in tropical and subtropical regions, the main geographical areas affected by tropical virus infection are the Caribbean, South and Central America, Mexico, Africa, the Pacific Islands, Southeast Asia, Indian sub-continent, Hawaii and northern parts of Australia. The range of <i>Aedes albopictus</i> is also increasing into more temperate zones leading to outbreaks of tropical virus disease in new areas. There have been outbreaks of Dengue and Chikungunya in parts of Europe.

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.

Chikungunya virus is found in countries in Asia, Africa, Central and South America, and in the islands of the Caribbean. There is no evidence of person-to-person transmission except through blood transfer. Transfusion-transmission from an asymptomatic individual has not been documented. Nevertheless, restrictions after travel to a Chikungunya virus risk area were introduced to reduce any risk of transmission through blood or tissue donation.

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 insect-borne disease worldwide. Dengue is currently considered endemic in approximately 140 countries. Transfusion-transmission has been reported.

Overall, up to 75% of cases are asymptomatic or mild. If symptoms occur, they can range from non-specific acute febrile illness to severe disease including dengue haemorrhagic fever and dengue shock syndrome. Mild cases may be misdiagnosed as other febrile illnesses.

Yellow Fever Virus is a flavivirus which is found in Africa, South America, Central America and parts of the Caribbean. Symptoms of Yellow Fever include high temperature, headache, nausea and vomiting, muscle pains and backache. One in four individuals may suffer from jaundice and bleeding from the gastrointestinal tract and other sites.

Zika Virus is a flavivirus which was known to occur in Africa and parts of Southeast Asia. More recently, Zika Virus has been associated with epidemic outbreaks in the Pacific region and in the Americas. As well as mosquito-borne infection, Zika Virus can be spread through sexual transmission. Infection is usually asymptomatic or presents as a mild self-limiting febrile illness. More severe disease and hospitalisation are rare but infection during pregnancy carries a high risk of congenital abnormalities in the baby. Zika Virus infection may be mistaken for Chikungunya or Dengue infections as these viruses often co-circulate.

Position statements are available in the JPAC Document Library.

*Reason for Change* Discretionary guidance has been revised.

*Update Information* This entry was last updated in:  
TD-DSG Edition 203 Release 60

## Trypanosoma Cruzi Infection

*Obligatory* **Must not donate.**

*Discretionary* **Eyes:**  
Accept for corneas only.

*See if Relevant* South American Trypanosomiasis Risk

*Additional Information* As corneas are avascular there is not considered to be a risk of transmitting protozoal infections.

*Reason for Change* The 'Discretionary' entry for 'Eyes' has been amended.

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

## Tuberculosis

### Affected Individual

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

- b) Under follow-up.
- c) Ever had clinically active tuberculosis.
- d) Diagnosed with latent tuberculosis within past two years.

<i>Discretionary</i>	<p>a) If donor with a history of tuberculosis that has been successfully treated, with treatment being completed at least 24 months previously, been discharged from follow up, and has remained well and asymptomatic – refer to DCSO for individual risk assessment.</p> <p>b) Donors with a diagnosis of latent tuberculosis currently not undergoing investigation, or more than seven days after completion of treatment: refer to DCSO for individual risk assessment.</p> <p>c) See Additional Information.</p>
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*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.

Individuals with latent tuberculosis do not have symptoms of active infection. Treatment is usually recommended for individuals aged under 65. Antibiotics used to treat tuberculosis can cause liver damage in older adults, and hence treatment may not be offered. If latent tuberculosis is thought to be drug resistant, or if the individual is taking immunosuppressive medication for any reason, they may be regularly monitored to check the infection does not become active.

DCSOs should consider all the TB risk factors in combination, and along with any clinical signs, symptoms, or radiological evidence of TB, treatment during review of donor eligibility, along with the processing methodology applied.

Donors with past treated tuberculosis can be accepted if tissues are to be terminally sterilised or processed in a manner validated to remove viable donor cells. However, this does not apply to any bone that has been the site of previous infection.

*Reason for Change*     Obligatory section updated to include past active TB and latent TB. Discretionary section updated to require that donors with a past history of treated TB be referred to DCSO for individual risk assessment. Additional points added to Discretionary section and Additional Information section updated.

*Update Information*     This entry was last updated in  
TD-DSG Edition 203 Release 61

## Turner's Syndrome

*Discretionary*     Accept.

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

## Vasculitis

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<i>Obligatory</i>	<b>Must not donate.</b>
<i>Discretionary</i>	Eyes: If no known ocular involvement, accept.
<i>See if Relevant</i>	<u>Autoimmune disease</u> <u>Immunosuppression</u> <u>Steroid Therapy</u> <u>Immunoglobulin Therapy</u>
<i>Reason for Change</i>	To allow discretionary acceptance of cornea donors
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 33

## Viral Haemorrhagic Fever

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<i>Includes</i>	<u>Crimean-Congo Fever</u> <u>Ebola Virus Disease</u> <u>Lassa Fever</u> <u>Marburg Fever</u>
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### 1. Affected Individual

<i>Obligatory</i>	<b>Must not donate if:</b> a) Has ever been infected
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### 2. Contact or traveller to endemic country

<i>Obligatory</i>	<b>Must not donate if:</b> a) Was present in an area during an active outbreak b) Under investigation for viral haemorrhagic fever c) Has been in contact with an individual who was present in an area during an active outbreak d) Was in contact with an individual infected with, or was under investigation for viral haemorrhagic fever e) less than six months after return to UK from an endemic area when there was no active outbreak.
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Under exceptional circumstances, the donor may be accepted subject to individual risk assessment. **Refer to designated medical officer.** See additional information section.

<i>Discretionary</i>	<b>Accept if:</b> a) If more than 6 months after return to UK from an endemic area when there was no active outbreak at the time of visit b) If the individual, or the contact person, under investigation had viral haemorrhagic fever infection excluded as diagnosis.
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### 3. Sexual Partner of Affected Individual

<i>Obligatory</i>	<b>Must not donate:</b> If the donor has had sex with an individual who had been diagnosed with a Viral Haemorrhagic Fever at any time before their last sexual contact.
<i>See if Relevant</i>	<u>The Geographical Disease Risk Index</u> for countries with a current endemic Viral Haemorrhagic Fever risk.
<i>Additional Information</i>	<p>These infections have very high death rates and there is evidence that the virus may persist for some time after recovery. The 2014-16 outbreak of Ebola in West Africa had increased understanding about the persistence of the virus in affected individuals and the number of asymptomatic individuals who may be able to transmit the virus to others.</p> <p>There is no routine screening test for EBOV currently available. There is an option to test donors serologically for the presence of anti-EBOV (antibodies) two months after the exposure event if a test becomes available. A reactive test would result in permanent deferral, a negative test would allow donation to proceed. Designated medical officers may seek expert advice where necessary, under exceptional circumstances.</p> <p>There is evidence of persistent virus in individuals who recover from several forms of Viral Haemorrhagic Fever. For this reason, it is necessary to defer the sexual partners of these individuals.</p>
<i>Reason for Change</i>	A permanent deferral has been introduced for donors who have had sex with an individual who has been diagnosed with a Viral Haemorrhagic Fever, and definition of Viral Haemorrhagic Fever provided.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 41

### Vitamin Treatment

<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

### Warts

<i>Discretionary</i>	Even if on local treatment, accept.
<i>Additional Information</i>	<p>Warts (including verruca) are caused by infection with the human papilloma virus (HPV) of which there are over 100 different types. They may occur on the skin and mucous membranes. The virus is spread by skin to skin contact and it can be very infectious. Genital warts are possibly the commonest sexually transmitted disease, but they do not necessarily indicate high risk sexually activity, so no specific deferral is required.</p> <p>Molluscum contagiosum is also caused by a virus and can be managed in the same way as warts.</p>
<i>Reason for Change</i>	'Additional Information' section added following FAIR III report.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 57

### West Nile Virus

<i>Definition</i>	<b>West Nile Virus (WNV) Endemic Areas:</b> These are shown in the 'Geographical Disease Risk Index' (GDRI).
<i>Obligatory</i>	<b>Must not donate if:</b> 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.
<i>Discretionary</i>	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 WNV infection) if a validated NAT for WNV is to be undertaken on the donated component (s), accept.
<i>See if Relevant</i>	<u>The 'Geographical Disease Risk Index'</u>
<i>Additional Information</i>	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 <u>'Geographical Disease Risk Index'</u> .  A ' <u>Position Statement on West Nile Virus (WNV)</u> ' is available in the 'Document Library' of ' <a href="http://www.transfusionguidelines.org">www.transfusionguidelines.org</a> '.
<i>Reason for Change</i>	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.
<i>Update Information</i>	This entry was last updated in: TDSG-DD Edition 203, Release 23.

## Whooping Cough

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### Contact

See Infectious Diseases - Contact with

### Infection

See Infection - Acute

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

## Wilson's Disease

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<i>Discretionary</i>	Accept.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 02

## Xenotransplantation

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<i>Includes</i>	Xenografts Heterografts Non-Human Organ Perfusion
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### Recipient

<i>Definition</i>	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.
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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.

<i>Obligatory</i>	<b>Must not donate if:</b> Material from a <b>living</b> non-human animal source has been directly or indirectly in contact with the donor's blood supply. This does not include animal bites.
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### Sexual Partners of Xenotransplant Recipients, Current and Former

<i>Obligatory</i>	<b>Must not donate.</b>
<i>Additional Information</i>	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.
<i>Reason for Change</i>	Further guidance re Recipient definition
<i>Update Information</i>	This advice is a requirement of the EU Tissue & Cells Directive.  This entry was last updated in TDSG-DD Edition 203, Release 25

## XMRV

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<i>Discretionary</i>	Donors who have been tested positive for XMRV, accept.
<i>Additional Information</i>	As there is no evidence that XMRV is implicated in human disease, a positive test is not a bar to donation.
<i>Reason for Change</i>	This is a new entry.
<i>Update Information</i>	This entry was last updated in TDSG-DD Edition 203, Release 12 Issue 01

## Yaws

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<i>Obligatory</i>	<b>Must not donate.</b>
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*Update Information* This entry was last updated in  
TDSG-DD Edition 203, Release 02

## Updates

Specification of Current Version		
Publication	TD-DSG	
Edition	203	
Release	61	
Issue	01	13 August 2024

### All changes to TD-DSG Edition 203 after Release 01

Release	Date	Change Notifications	
		Title	CN No.
61	13 August 2024	Tuberculosis	<u>33 - 2024</u>
		Necrotising Fasciitis	<u>32 - 2024</u>
60	18 April 2024	Issue 03	
		Sexually Transmitted Disease	<u>23 - 2024</u>
		Issue 02	
		Tropical Viruses	<u>13 - 2024</u>
		Ankylosing Spondylitis and Eye Disease	<u>12 - 2024</u>
		Coronavirus Vaccination	<u>10 - 2024</u>
		Issue 01	
		<i>Issue 01 was superseded by Issue 02 prior to publication.</i>	
59	29 January 2024	Splenectomy & ITP	<u>38 - 2023</u>
58	15 November 2023	Coronavirus Infection (COVID-19)	<u>33 - 2023</u>
57	15 November 2023	Changes arising from the FAIR III report	<u>17 - 2023</u>
56	04 July 2023	Tuberculosis	<u>25 - 2023</u>
		Tissue and Cell Allograft Recipients	<u>14 - 2023</u>
55	09 May 2023	Tropical Viruses	<u>12 - 2023</u>
54	12 April 2023	Malaria	<u>21 - 2023</u>
		Mpox (Monkeypox)	<u>13 - 2023</u>
53	13 December 2022	Infectious Disease - Contact With	<u>52 - 2022</u>
		Coronavirus Infection (COVID-19)	<u>51 - 2022</u>
52	12 September 2022	Table of Immunisations	<u>55 - 2022</u>
		Steroid Therapy	<u>54 - 2022</u>
		Basal Cell Carcinoma	<u>53 - 2022</u>
51	31 May 2022	Monkeypox	<u>41 - 2022</u>
		Immunosuppression	<u>38 - 2022</u>
50	26 April 2022	Yellow Fever	<u>21 - 2022</u>
49	07 April 2022	Coronavirus Infection	<u>30 - 2022</u>
48	16 March 2022	Diseases of Unknown Aetiology	<u>17 - 2022</u>
		Cervical Dysplasia	<u>16 - 2022</u>
		Body Piercing	<u>15 - 2022</u>
		Psoriasis	<u>14 - 2022</u>
		Infertility	<u>13 - 2022</u>
47	22 February 2022	Complementary Therapy	<u>04 - 2022</u>
46	04 August 2021	Thrush - Oral & Vaginal	<u>30 - 2021</u>
		Inflammatory Eye Disease	<u>28 - 2021</u>
		Infertility	<u>27 - 2021</u>
		Immunisation	<u>26 - 2021</u>

		Haematological Disease	<u>24 - 2021</u>
		Coronavirus Vaccination	<u>23 - 2021</u>
		Coronavirus Infection	<u>22 - 2021</u>
		Colitis, Proctitis and Gastrointestinal Disease	<u>20 - 2021</u>
		Acne and Teratogenic Medications	<u>19 - 2021</u>
45	11 May 2021	Transfusion	<u>14 - 2021</u>
		Immunoglobulin Therapy	<u>13 - 2021</u>
		Immune Thrombocytopenia	<u>12 - 2021</u>
44	21 January 2021	COVID-19 Vaccination	<u>05 - 2021</u>
43	16 December 2020	COVID-19 Vaccination	<u>74 - 2020</u>
42	07 October 2020	Sexually Transmitted Disease	<u>61 - 2020</u>
		Systemic Lupus Erythematosus	<u>46 - 2020</u>
		South American Trypanosomiasis Risk	<u>44 - 2020</u>
		Infection - Chronic	<u>43 - 2020</u>
		Tamoxifen	<u>42 - 2020</u>
41	15 July 2020	Tamiflu® and Relenza®	<u>40 - 2020</u>
		Infection - Acute	<u>39 - 2020</u>
		Viral Haemorrhagic Fever	<u>38 - 2020</u>
		Rabies	<u>37 - 2020</u>
		Animal Bite	<u>36 - 2020</u>
40	24 June 2020	Coronavirus Infection	<u>33 - 2020</u>
39	23 March 2020	Coronavirus Infection	<u>16 - 2020</u>
38	24 February 2020	Coronavirus Infection	<u>10 - 2020</u>
37	17 February 2020	Coronavirus Infection	<u>08 - 2020</u>
36	24 January 2020	Coronavirus Infection	<u>05 - 2020</u>
35	12 November 2019	Surgery	<u>16 - 2019</u>
34	30 September 2019	Ocular Surgery	<u>32 - 2019</u>
		Laser Treatment	<u>31 - 2019</u>
		Sexually Transmitted Disease	<u>23 - 2019</u>
		Malignancy	<u>21 - 2019</u>
		Inflammatory Bowel Disease	<u>20 - 2019</u>
		Hepatitis C	<u>19 - 2019</u>
		Eye Disease	<u>18 - 2019</u>
		Complementary Therapy	<u>17 - 2019</u>
		Viral Haemorrhagic Fever	<u>15 - 2019</u>
		Tissue Safety Entry	<u>14 - 2019</u>
		Pre- and Post-Exposure Prophylaxis for HIV	<u>13 - 2019</u>
Hepatitis A	<u>12 - 2019</u>		
33	26 September 2018	Vasculitis	<u>33 - 2018</u>
		Transgender Individual	<u>32 - 2018</u>
		Thyroid Disease	<u>31 - 2018</u>
		Reyes Syndrome	<u>30 - 2018</u>
		Laser Treatment	<u>29 - 2018</u>
		Infection - Chronic	<u>28 - 2018</u>
		Infection - Acute	<u>27 - 2018</u>
		Herpes - Ocular	<u>25 - 2018</u>
		Eye Disease	<u>24 - 2018</u>
Blind Donor	<u>23 - 2018</u>		
32	26 July 2018	Haemodilution algorithm	<u>07 - 2018</u>

<b>31</b>	24 April 2018	Viral Haemorrhagic Fever	<u>15 - 2018</u>
		Transfusion	<u>14 - 2018</u>
		Tissue and Organ Recipients	<u>13 - 2018</u>
		Prisons	<u>12 - 2018</u>
		Hepatitis E	<u>10 - 2018</u>
		Hepatitis A	<u>09 - 2018</u>
		Central Nervous System Disease	<u>04 - 2018</u>
<b>30</b>	17 January 2018	Toxoplasmosis	<u>02 - 2018</u>
		Poisoning	<u>01 - 2018</u>
<b>29</b>	27 November 2017	Bleeding Disorder	<u>50 - 2017</u>
		Syphilis	<u>48 - 2017</u>
		Sex Worker	<u>46 - 2017</u>
		Inoculation Injury	<u>43 - 2017</u>
		HTLV	<u>42 - 2017</u>
		Homosexual and Bisexual Individuals	<u>40 - 2017</u>
		HIV	<u>38 - 2017</u>
		Hepatitis C	<u>36 - 2017</u>
		Hepatitis B	<u>34 - 2017</u>
		Complementary Therapy	<u>32 - 2017</u>
		Body Piercing	<u>30 - 2017</u>
		Addiction and Drug Abuse	<u>28 - 2017</u>
		Tissue Safety Entry	<u>27 - 2017</u>
		Tissue and Organ Recipients	<u>23 - 2017</u>
Radiation Therapy	<u>22 - 2017</u>		
Age	<u>21 - 2017</u>		
<b>28</b>	01 August 2017	Malaria	<u>17 - 2017</u>
<b>27</b>	24 February 2017	Malignancy	<u>05 - 2017</u>
<b>26</b>	10 October 2016	Transfusion	<u>48 - 2016</u>
		Marfan's Syndrome	<u>47 - 2016</u>
		Hepatitis A	<u>46 - 2016</u>
		Ehlers Danlos Syndrome	<u>45 - 2016</u>
		Cardiomyopathy	<u>44 - 2016</u>
<b>25</b>	13 July 2016	Xenotransplantation	<u>29 - 2016</u>
		Severe Exercise Intolerance Syndrome (SEID)	<u>28 - 2016</u>
		Osteogenesis Imperfecta	<u>27 - 2016</u>
		Necrotising Fasciitis	<u>26 - 2016</u>
		Fibromyalgia	<u>25 - 2016</u>
		Endoscopy	<u>24 - 2016</u>
<b>24</b>	02 February 2016	Viral Haemorrhagic Fever	<u>15 - 2016</u>
		Tropical Viruses	<u>14 - 2016</u>
<b>23</b>	18 January 2016	Viral Haemorrhagic Fever	<u>11 - 2016</u>
		West Nile Virus	<u>09 - 2016</u>
		Tropical Viruses	<u>08 - 2016</u>
		Table of Immunisations	<u>04 - 2016</u>
<b>22</b>	08 July 2015	Age	<u>16 - 2015</u>
<b>21</b>	23 June 2015	Injectable Tanning Agents	<u>15 - 2015</u>
		Complementary Therapy	<u>12 - 2015</u>
<b>20</b>	17 March 2015	Infertility	<u>09 - 2015</u>
		Complementary Therapy	<u>08 - 2015</u>

		Communication Difficulties	<u>07 - 2015</u>
<b>19</b>	20 October 2014	Viral Haemorrhagic Fever Risk	<u>43 - 2014</u>
<b>18</b>	11 August 2014	Sex Change	<u>39 - 2014</u>
		Homosexual and Bisexual Individuals	<u>36 - 2014</u>
		Tissues Safety Entry	<u>32 - 2014</u>
		SARS	<u>31 - 2014</u>
		Haematological Disease	<u>30 - 2014</u>
<b>17</b>	31 March 2013	Paratyphoid and Typhoid	<u>15 - 2013</u>
		South American Trypanosomiasis Risk	<u>14 - 2013</u>
		Sarcoidosis	<u>13 - 2013</u>
		Mental Health Problems	<u>12 - 2013</u>
		Malignancy	<u>11 - 2013</u>
		Kidney Disease	<u>10 - 2013</u>
		Hepatitis of Unknown Origin	<u>08 - 2013</u>
		Central Nervous System Disease	<u>05 - 2013</u>
		Aliretinoin, Toctino, Acne and Dermatitis	<u>03 - 2013</u>
		Acupuncture	<u>02 - 2013</u>
		<b>16</b>	09 July 2013
Hepatitis B - Post Immunisation	<u>09 - 2013</u>		
Hepatitis B	<u>08 - 2013</u>		
<b>15</b>	04 June 2013	West Nile Virus	<u>01 - 2013</u>
<b>14</b>	29 June 2012	Toxoplasmosis	<u>18 - 2012</u>
		Psoriasis	<u>17 - 2012</u>
		Pregnancy	<u>16 - 2012</u>
		Acne	<u>15 - 2012</u>
<b>13</b>	28 March 2012	West Nile Virus	<u>05 - 2012</u>
<b>12</b>	24 January 2012	Hepatitis C	<u>27 - 2011</u>
		XMRV	<u>25 - 2011</u>
<b>11</b>	06 December 2011	Immunosuppression	<u>21 - 2011</u>
		Porphyria	<u>20 - 2011</u>
<b>10</b>	08 August 2011	West Nile Virus	<u>11 - 2011</u>
<b>09</b>	21 June 2011	Sexually Transmitted Disease	<u>09 - 2011</u>
		Infertility	<u>08 - 2011</u>
		BCG	<u>07 - 2011</u>
		Immunisation - Live	<u>06 - 2011</u>
<b>08</b>	01 September 2010	West Nile Virus	<u>09 - 2010</u>
<b>07</b>	03 March 2010	Inoculation Injury	<u>04 - 2010</u>
		Body Piercing	<u>02 - 2010</u>
<b>06</b>	24 December 2009	Complementary Therapy	<u>35 - 2009</u>
		Acupuncture	<u>33 - 2009</u>
<b>05</b>	04 December 2009	Relenza <sup>®</sup> (Zanamivir)	<u>29 - 2009</u>
		Tamiflu <sup>®</sup> (Oseltamivir)	<u>28 - 2009</u>
<b>04</b>	21 May 2009	Age	<u>08 - 2009</u>
<b>03</b>	02 January 2008	<i>A change was made to the version control definitions and all Issue numbering information removed.</i>	
<b>02</b>	01 November 2007	Public release – for changes see <u>Appendix 1 - Changes to the Guidelines</u>	
<b>01</b>	01 June 2007	Consultation release – not for implementation	

## Appendix 1 - Changes to Donor Selection Guidelines

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### Section 1

#### Changes introduced with TDSG-DD 203 Release 02 from TDSG-DD 202 Release 04

There have been changes made to the following entries:

Accident  
 Acne  
 Acne Rosacea  
 Acupuncture  
 African Trypanosomiasis  
 Age  
 Anaemia  
 Animal Bite  
 Ankylosing Spondylitis  
 Anti-Androgens  
 Antibiotic Therapy  
 Arthritis  
 Asthma  
 Autoimmune Disease  
 Babesiosis  
 Bipolar Disorder  
 Bleeding Disorder  
 Blind Donor  
 Body Piercing  
 Breast Lump  
 Breastfeeding  
 Cardiomyopathy  
 Cardiovascular Disease  
 Central Nervous System Disease  
 Chagas' Disease  
 Chikungunya Virus  
 Chlamydia  
 Cirrhosis  
 Clinical Trials  
 Colitis  
 Colostomy  
 Communication Difficulties  
 Death from Unknown Causes  
 Diabetes Mellitus  
 Diarrhoea  
 Disease of Unknown Aetiology  
 Down's Syndrome  
 Drowning  
 Dutasteride (Avodart)  
 Ehlers-Danlos Syndrome (Disease)  
 Elliptocytosis  
 Endocarditis  
 Endoscopy  
 Epilepsy  
 Episcleritis  
 Etreinate  
 Eye Disease  
 Finasteride (Proscar)  
 Gall Bladder Disease  
 Gastrointestinal Disease  
 German Measles  
 Glaucoma  
 Guillain-Barré Syndrome  
 Haematuria  
 Haemoglobin Disorders  
 Haemolytic Anaemia  
 Hepatitis B  
 Hepatitis B - Post Immunization  
 Hepatitis C  
 Hepatitis of Unknown Origin  
 Hereditary Elliptocytosis  
 Herpes – Ocular  
 Hormone Replacement Therapy  
 Hydrocephalus  
 Ileostomy  
 Immune Thrombocytopenia

Immunoglobulin Therapy  
 Immunosuppression  
 Infection – Chronic  
 Infection - Tropical  
 Inflammatory Bowel Disease  
 Inflammatory Eye Disease  
 Inoculation Injury  
 Jaundice  
 Kala-Azar  
 Laser Treatment  
 Leishmaniasis  
 Malaria  
 Malignancy  
 Marfan's Syndrome  
 Mental Health Problems  
 Myeloproliferative Syndrome  
 Neurofibromatosis  
 Neurosurgery  
 Ocular Surgery  
 Osteomyelitis  
 Ovarian Cyst  
 Peptic Ulcer  
 Pituitary Extract – Human  
 Platelet Disorder  
 Polymyalgia Rheumatica  
 Pregnancy  
 Prion Associated Diseases  
 Prisons  
 Proctitis  
 Psoriasis  
 Pyelonephritis  
 Quinsy  
 Radiation Therapy  
 Radionuclides  
 Reyes Syndrome  
 Rheumatoid Arthritis  
 Rubella  
 Scleritis  
 Sexually Transmitted Disease  
 Shingles  
 Sideroblastic Anaemia  
 Skin Disease  
 Sleeping Sickness  
 South American Trypanosomiasis  
 South American Trypanosomiasis Risk  
 Spina Bifida  
 Splenectomy  
 Steroid Therapy  
 Subacute Bacterial Endocarditis  
 Surgery  
 Syphilis  
 Tamoxifen  
 Temporal Arteritis  
 Thyroid Disease  
 Tigason  
 Tissue and Organ Recipients  
 TransfusionThrombocytosis  
 Trisomy 21 (Down's Syndrome)  
 Trisomy E (Trisomy 18)  
 Trypanosoma Cruzi Infection  
 West Nile Virus

**Section 2**  
**Changes to TDSG-DD 203 after Release 02**

See: [Latest Updates](#)

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

## Appendix 2 - Medical criteria for the withdrawal of donations following information received after donation

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### General considerations.

Circumstances that should have excluded donation may only become known after tissue has been taken. For the purposes of these guidelines, these circumstances are categorized 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 tissue. 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 tissue transplant, contacting the clinician caring for the recipient and discussing notification of the recipient. In certain circumstances, a look-back procedure may need to be initiated.

### 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-DD Edition 203, Release 02, Issue 01



## Appendix 3 - Calculation of Blood and Plasma Dilution

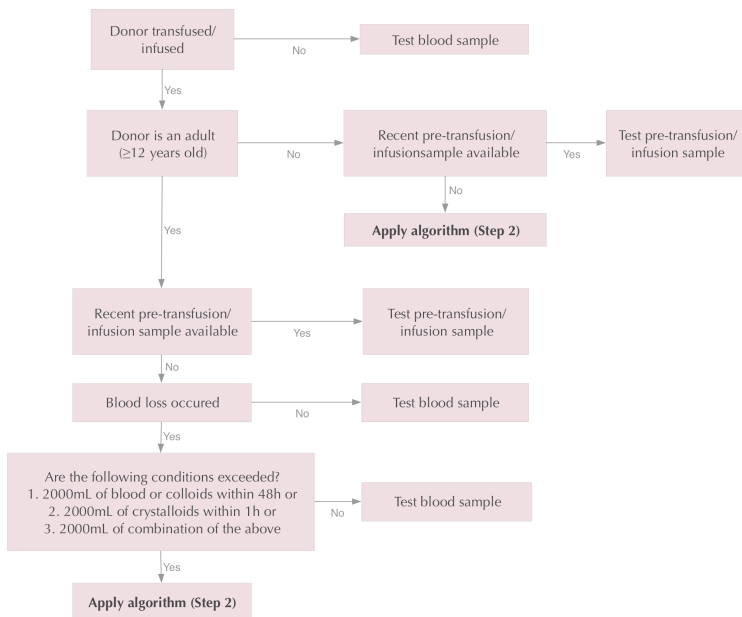
### Haemodilution algorithm

#### Appendix 3 – Calculation of Blood & Plasma Dilution

Please find attached an algorithm for determining the suitability of post-transfusion/infusion samples for mandatory screening for transmissible infections.

### Determining the Suitability of Post-transfusion/Infusion Samples for Mandatory Screening for Transmissible Infections

#### Determining sample suitability - Step 1



#### Determining sample suitability - Step 2

Donor ID: \_\_\_\_\_ Date & Time blood sample taken: \_\_\_\_\_

#### STEP 2A

Calculate plasma volume Donor weight (kg) \_\_\_\_\_  $\frac{\quad}{0.025}$  \_\_\_\_\_ mL

Calculate blood volume Donor weight (kg) \_\_\_\_\_  $\frac{\quad}{0.015}$  \_\_\_\_\_ mL

A) Record total volume of blood transfused in the **48 h** prior to death or sample collection (whichever comes first)

\_\_\_\_\_ mL of RBC transfused/48 h Sum A: \_\_\_\_\_ mL

\_\_\_\_\_ mL of whole blood transfused/48 h

\_\_\_\_\_ mL of reconstituted blood/48 h

B) Record total volume of colloid infused in the **48 h** prior to death or sample collection (whichever comes first)

\_\_\_\_\_ mL plasma/48 h Sum B: \_\_\_\_\_ mL

\_\_\_\_\_ mL platelets/48 h

\_\_\_\_\_ mL albumin/48 h

\_\_\_\_\_ mL HES or other colloids/48 h

C) Record total volume of crystalloid infused in the **1 h** prior to death or sample collection (whichever comes first)

\_\_\_\_\_ mL Sum C: \_\_\_\_\_ mL

**Step 2B**

Calculated Plasma Volume	_____mL	Sum B + Sum C	_____mL
Calculated Blood Volume	_____mL	Sum A + Sum B + Sum C	_____mL
Calculate plasma dilution	Is Sum B + Sum C > plasma volume?		No Yes
Calculate blood dilution	Is Sum A + Sum B + Sum C > blood volume?		No Yes

If the answers to **both** questions are 'No', the post-transfusion/infusion sample is acceptable

If the answer to **either** of the questions is 'Yes' use a pre-transfusion/infusion sample. If a suitable sample is not available, seek expert advice and inform transplant centre, testing laboratory, tissue bank as necessary.

RBC = red blood cells; HES = hydroxyethyl starch

Based on the algorithm developed by the Food and Drug Administration, USA

[www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf](http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/ucm091345.pdf) (Appendices 2&3)

This appendix was last updated in TDSG-DD Edition 203, Release 32, Issue 01

## Appendix 4 - Table of Immunisations

Diseases protected against	Comments and example trade names of adult preparations	
Anthrax	Rarely given available only through Public Health England.	<u>Non-Live</u>
Cholera	Oral vaccine. Dukoral <sup>®</sup>	<u>Non-Live</u>
COVID-19 (SARS-CoV-2)	All COVID-19 vaccines licenced in the UK are Non-Live. These include: <ul style="list-style-type: none"> <li>• Pfizer BioNTech (tozinameran/Comirnaty<sup>®</sup>)</li> <li>• AstraZeneca (Vaxzevira<sup>®</sup>)</li> <li>• Moderna (Spikevax<sup>®</sup>)</li> <li>• Janssen Ad26.COVS-2-S</li> <li>• Novavax (Nuvaxovid<sup>®</sup>)</li> <li>• COVID-19 Vaccine Valneva</li> </ul>	<u>Non-Live</u>
HiB	Haemophilus influenza, Menitorex <sup>®</sup>	<u>Non-Live</u>
Hepatitis A	May be combined with typhoid or hepatitis B. Hepatitis A only: Vaqta <sup>®</sup> , Avaxim <sup>®</sup> , Havrix <sup>®</sup> Combined with typhoid: Viatim <sup>®</sup> Combined with Hepatitis B, Ambirix <sup>®</sup> , Twinrix <sup>®</sup> ,	<u>Non-Live</u>
Hepatitis B	May be combined with hepatitis A if unexposed and more than 7 days from last immunization, accept. See: Hepatitis B – Immunisation Engerix <sup>®</sup> , Fendrix <sup>®</sup> , HBvaxPRO <sup>®</sup> , Ambirix <sup>®</sup> , Twinrix <sup>®</sup>	<u>Non-Live</u>
HPV	Cervarix <sup>®</sup> , Gardasil <sup>®</sup>	<u>Non-Live</u>
Influenza-intra-nasal	<b>Live vaccine given by intra-nasal spray, age 2-18</b> <b>Fluenz Tetra<sup>®</sup></b>	<u>Live</u>
Influenza, injected	annual flu jab, given by injection Several preparations, updated annually.	<u>Non-Live</u>
Japanese Encephalitis	Travel. Ixiaro <sup>®</sup>	<u>Non-Live</u>
<b>Measles, Mumps, Rubella</b>	<b>MMR vaccines. M-M-RvaxPro<sup>®</sup>, Priorix<sup>®</sup></b>	<u>Live</u>
Meningitis	Meningococcal group C: NeisVac-C <sup>®</sup> , Menjugate Kit <sup>®</sup> Meningococcal group B: Bexsero <sup>®</sup> , Trumenba <sup>®</sup> MenACWY Quadrivalent vaccine: Menveo <sup>®</sup> , Nimenrix <sup>®</sup> , MenQuadfi <sup>®</sup> Combined with H. influenzae type b (Hib): Menitorix	<u>Non-Live</u>
Monkeypox	During the 2022 Monkeypox outbreaks, contacts of Monkeypox cases may receive Imvanex, a live attenuated non-replicating Smallpox vaccine. For donor selection purposes this should be assessed as a non-live vaccine. See DSG entry for Monkeypox	
Pertussis	Usually pregnant women, Boostrix-IPV <sup>®</sup> , Repavax <sup>®</sup>	<u>Non-Live</u>
Pneumococcal disease	Given to people with specific risks for example, people who have had a splenectomy or over 65s Pneumovax23 <sup>®</sup>	<u>Non-Live</u>
Polio, injected	Would usually be given Diphtheria, Tetanus and Polio (injection). Boostrix-IPV <sup>®</sup> , Revaxis <sup>®</sup> , Repevax <sup>®</sup>	<u>Non-Live</u>
<b>Polio, oral</b>	<b>Not in routine use in UK. May be used abroad</b>	<u>Live</u>

Rabies	Given to non-exposed individuals if occupation or activity has an exposure risk, or for some travellers to endemic areas: Rabipur <sup>®</sup> , Verorab <sup>®</sup>	<u>Non-Live</u>
<b>Shingles</b>	<b>There are two vaccines available to prevent shingles: Zostavax<sup>®</sup> and Shingrix<sup>®</sup>. (See below). Ensure the correct guidance is applied depending on the vaccine given. If vaccine name not certain, treat as a Live vaccine</b>	<u>Live</u>
	Zostavax <sup>®</sup> for shingles prevention	<u>Live</u>
	Shingrix <sup>®</sup> for shingles prevention	<u>Non-Live</u>
<b>Smallpox</b>	<b>Note this live vaccine requires an 8 week deferral If given, see DSG entry for Smallpox Immunization. See Monkeypox (above)</b>	<u>Live</u>
Tetanus	Would usually be given Diphtheria, Tetanus and Polio. Revaxis <sup>®</sup>	<u>Non-Live</u>
Tick-borne encephalitis	Tico-vac <sup>®</sup>	<u>Non-Live</u>
<b>Tuberculosis</b>	<b>BCG vaccine</b>	<u>Live</u>
Typhoid - injected	Typhim Vi <sup>®</sup> Combined with hepatitis A: Viatim <sup>®</sup>	<u>Non-Live</u>
<b>Typhoid - Oral</b>	<b>Given in capsule form</b> <b>Vivotif<sup>®</sup></b>	<u>Live</u>
<b>Varicella (chickenpox)</b>	<b>Usually given to healthcare workers. Varilrix<sup>®</sup>, Varivax<sup>®</sup></b>	<u>Live</u>
<b>Yellow Fever</b>	<b>Stamari<sup>®</sup></b>	<u>Live</u>

## Appendix 5 - Grading of selected central nervous system tumours (WHO 2016 classification)

<b>Diffuse astrocytic and oligodendroglial tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Diffuse astrocytoma, IDH-mutant		•		
Anaplastic astrocytoma, IDH-mutant			•	
Glioblastoma, IDH-wildtype				•
Glioblastoma, IDH-mutant				•
Diffuse midline glioma, H3K27M-mutant				•
Oligodendroglioma, IDH-mutant and 1p/19q-codeleted		•		
Anaplastic oligodendroglioma, IDH-mutant and 1p/19q-codeleted			•	

<b>Other astrocytic tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Pilocytic astrocytoma	•			
Subependymal giant cell astrocytoma	•			
Pleomorphic xanthoastrocytoma		•		
Anaplastic pleomorphic xanthoastrocytoma			•	

<b>Ependymal tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Subependymoma	•			
Myxopapillary ependymoma	•			
Ependymoma		•		
Ependymoma, RELA fusion-positive		•	•	
Anaplastic ependymoma			•	

<b>Other gliomas</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Angiocentric glioma	•			
Chordoid glioma of third ventricle		•		

<b>Choroid plexus tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Choroid plexus papilloma	•			
Atypical choroid plexus papilloma		•		
Choroid plexus carcinoma			•	

<b>Tumours of the pineal region</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Pineocytoma	•			
Pineal parenchymal tumour of intermediate differentiation		•	•	
Pineoblastoma				•
Papillary tumour of the pineal region		•	•	

<b>Meningiomas</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Meningioma	•			
Atypical meningioma		•		
Anaplastic (malignant) meningioma			•	

<b>Embryonal tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Medulloblastoma (all subtypes)				•
Embryonal tumour with multi-layered rosettes, C19MC-altered				•
Medulloepithelioma				•
CNS embryonal tumour, NOS				•
Atypical teratoid/rhabdoid tumour				•
CNS embryonal tumour with rhabdoid features				•

<b>Neuronal and mixed neuronal-gliial tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Dysembryoplastic neuroepithelial tumour	•			
Gangliocytoma	•			
Ganglioglioma	•			
Anaplastic ganglioglioma			•	
Dysplastic gangliocytoma of cerebellum (Lhermitte–Duclos)	•			
Desmoplastic infantile astrocytoma and ganglioglioma	•			
Papillary glioneuronal tumour	•			
Rosette-forming glioneuronal tumour	•			
Central neurocytoma		•		
Extraventricular neurocytoma		•		
Cerebellar liponeurocytoma		•		

<b>Tumours of the cranial and paraspinal nerves</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Schwannoma	•			

Neurofibroma	•			
Perineurioma	•			
Malignant peripheral nerve sheath tumour (MPNST)		•	•	•

<b>Mesenchymal, non-meningothelial tumours</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Solitary fibrous tumour/haemangiopericytoma	•	•	•	
Haemangioblastoma	•			

<b>Tumours of the sellar region</b>	<b>I</b>	<b>II</b>	<b>III</b>	<b>IV</b>
Craniopharyngioma	•			
Granular cell tumour	•			
Pituicytoma	•			
Spindle cell oncocytoma	•			

Source: adapted from: Louis DN, Ohgaki H, Wiestler OD et al. (2016) World Health Organization histological classification of tumours of the central nervous system. Geneva: WHO Press/Lyon: International Agency for Research on Cancer.