

Change Notification for the UK Blood Transfusion Services

Date of Issue: 02 May 2024

Implementation: to be determined by each Service

No. 07 – 2024

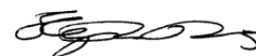
Immunosuppression

This notification includes the following changes:

	BM-DSG Bone Marrow & Peripheral Blood Stem Cell	CB-DSG Cord Blood	GDRI Geographical Disease Risk Index	TD-DSG Tissue - Deceased Donors	TL-DSG Tissue - Live Donors	WB-DSG Whole Blood & Components	Red Book Guidelines for the BTS in the UK
1. Autoimmune Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
2. Immunodeficiency	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
3. Monoclonal antibody therapy and other Biological Modalities	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
4. Skin Disease	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
5. Dermatitis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
6. Psoriasis	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
7. Osteopenia	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
8. Steroid Therapy	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
9. Asthma	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
10. Clinical Trials	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>
11. Changes to the A-Z index	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input type="radio"/>	<input checked="" type="radio"/>	<input type="radio"/>



Dr Angus Wells
Chair of Standing Advisory Committee on Care & Selection of Donors (SACCSD)



Dr Stephen Thomas
Professional Director of JPAC

Changes are indicated using the key below. This formatting will not appear in the final entry.

original text	«inserted text»	deleted text
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1. Changes apply to the **Whole Blood & Components DSG**

Autoimmune Disease

(revised entry)

<i>Obligatory</i>	<p>Must not donate if:</p> <p>a) The donor has needed treatment to suppress the condition in the last 12 months.</p> <p>b) The cardiovascular system is involved.</p> <p>«c) The donor has ongoing lung disease or renal impairment due to their condition.»</p>
<i>Discretionary</i>	<p>«a) If the donor:</p> <ul style="list-style-type: none"> • has been established on a stable maintenance treatment for an Autoimmune Disease with only one of the following drugs: Methotrexate, Sulfasalazine, Hydroxychloroquine or Azathioprine, and • the dose of the drug has not increased in the previous 6 months, and • the donor is well, <p>accept.</p> <p>b) If there is any uncertainty about the diagnosis or the nature of treatment, refer to a DCSO.»</p> <p>If donor is being treated with Methotrexate, Sulfasalazine or Hydroxychloroquine as maintenance treatment for Arthritis or to treat alopecia and has no associated cardiovascular disease, accept.</p>
«See	Is there a specific A-Z index entry for the condition you are assessing?»
<i>See if Relevant</i>	<p><u>Cardiovascular Disease</u></p> <p><u>Disabled Donor</u></p> <p><u>Drug Index - preparations which may affect platelet function</u></p> <p><u>Inflammatory Bowel Disease</u></p> <p>«<u>Liver Disease</u></p> <p><u>Monoclonal antibody therapy and other Biological Modalities</u>»</p> <p><u>Nonsteroidal Anti-inflammatory Drugs</u></p> <p>«<u>Skin Disease</u></p> <p><u>Steroid Therapy</u>»</p> <p><u>Thrombosis and Thrombophilia</u></p> <p><u>Trying to Conceive</u></p> <p>If treated with transfusion, immunoglobulin, plasma exchange or filtration:</p> <p><u>Transfusion</u></p>
<i>Additional Information</i>	<p>«Conventional systemic Disease Modifying Antirheumatic drugs (csDMARDs) are viewed as disease-modifying drugs. They include Methotrexate, Sulfasalazine, Hydroxychloroquine and Azathioprine. Sulfasalazine and Hydroxychloroquine have limited effect on the immune system. If used for maintenance treatment, Methotrexate and Azathioprine</p>

	<p>are usually given at lower doses which do not cause a significant degree of immunosuppression.</p> <p>If the donor is taking higher dose Methotrexate or Azathioprine, they should not be accepted. If there is uncertainty about the dose refer to the DCSSO for assessment. Further information on these drugs and immunosuppression can be found in 'The Green Book: Immunisation against Infectious Disease' (available at: www.gov.uk).»</p> <p>Treatment to suppress the condition may be with monoclonal antibodies (e.g. Adalimumab (Humira), Etanercept (Enbrel), Infliximab (Remicade), Rituximab (Mab Thera) etc), steroids, immunosuppressive drugs, antimetabolites, as well as other therapies such as PUVA (psoralen plus ultraviolet A). 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.</p> <p>Nonsteroidal anti-inflammatory drugs and Methotrexate, Sulfasalazine and Hydroxychloroquine, are treatments which do not «suppress» affect the donor's immune system in this way. If Methotrexate, Sulfasalazine and Hydroxychloroquine are used as maintenance treatment for Arthritis and donor fits the rest of the criteria they may be accepted.</p> <p>Physical therapies such as physiotherapy and hydrotherapy are not considered treatments to suppress the condition.</p> <p>Autoimmune disease can cause problems such as infertility and thrombosis (antiphospholipid or Hughes' syndrome).</p> <p>Some autoimmune conditions can permanently damage the cardiovascular system. If this is known to have happened, the person should not donate as they are more likely to have a serious adverse event.</p>
<p><i>Information</i></p>	<p>Part of this entry is a requirement of the Blood Safety and Quality Regulations 2005.</p>
<p><i>Reason for Change</i></p>	<p>«The acceptance criteria for donors taking csDMARDS has been clarified and extended. The See if Relevant section has been expanded.»</p> <p>The addition of monoclonal antibodies to the list of agents that may affect a donor's immune system.</p>

2. Changes apply to the **Whole Blood & Components DSG**

«Immunodeficiency» **Immunosuppression**

(revised entry)

<i>Includes</i>	«Immunosuppression» Immunodeficiency
<i>Obligatory</i>	<p>1. Must not donate if:</p> <p>«a) Diagnosed with a congenital or acquired condition causing immunodeficiency with increased susceptibility to infection. b)» Immunosuppressed «due to drug treatment».</p> <p>2. Donors with recovered immunosuppression: Refer to a 'Designated Clinical Support Officer'.</p>
<i>«Discretionary</i>	<p>1. Donors taking immunosuppressive or immunomodulatory therapy to treat autoimmune disease Refer to the Autoimmune Disease entry.</p> <p>2. Donors with recovered immunosuppression If the underlying cause does not preclude donation, refer to the DCSO.</p> <p>3. IgA deficiency If not experiencing frequent infections, accept.»</p>
<i>See if Relevant</i>	<p>Autoimmune Disease Immunoglobulin Therapy «Monoclonal antibody therapy and other Biological Modalities» Steroid Therapy</p>
<i>Additional Information</i>	<p>«Immunodeficiency» Immunosuppression can mask the body's normal response to some infectious and inflammatory conditions. This could result in diseases that may be transmitted by donation from being missed by the Blood Services. If a donor reports recovery from «immunodeficiency» Immunosuppression or, if the underlying cause was unclear, refer to a 'Designated Clinical Support Officer'.</p> <p>«IgA deficiency is relatively common. Most people with this condition are healthy but some individuals may experience frequent infections, especially of the ears, sinuses, gut and lungs. Some blood services may screen donors for IgA deficiency to provide a supply of IgA-deficient blood components.»</p>
<i>Reason for Change</i>	<p>«Entry reworded, with addition of a discretionary section to improve clarity and provide guidance for donors with IgA deficiency. New links added.»</p> <p>New links and 'Additional Information' have been added.</p>

3. Changes apply to the **Whole Blood & Components DSG**

«**Monoclonal antibody therapy and other Biological Modalities**»

(new entry)

<i>«Includes</i>	Systemic treatment with monoclonal antibody (MAb) treatments
<i>Obligatory</i>	Must not donate
<i>Discretionary</i>	a) If an individual monoclonal antibody treatment is listed in the entry for the underlying condition, apply guidance as per that entry. b) If the underlying condition does not preclude donation, and it is more than 6 months from last treatment, accept.
<i>See</i>	Is there is a specific A-Z index entry for the treatment and/or condition you are concerned about?
<i>See if Relevant</i>	Autoimmune Disease Clinical Trials Eye Disease Hypercholesterolemia Osteopenia
<i>Additional Information</i>	Current scientific literature does not provide conclusive evidence to reject concerns that individuals on these treatments are more prone to infection. Until further clarity is provided in the literature, donors on these medications are withdrawn, unless otherwise stated.
<i>Reason for Change</i>	This is a new entry.»

4. Changes apply to the **Whole Blood & Components DSG**

Skin Disease

(revised entry)

<i>Obligatory</i>	<p>Must not donate if:</p> <ul style="list-style-type: none"> a) The donor has a condition that is infected or infectious e.g. Scabies. b) History of malignancy. c) The venepuncture site is affected. d) Required application of steroid, tacrolimus (Protopic®) or pimecrolimus (Elidel®) creams over large areas for periods of more than three weeks in the last six months. e) Ever been treated with Etreinate (Tigason®). f) Less than 36 months from the last dose of acitretin (Neotigason®). g) Less than four weeks from the last does of isotretinoin (Roaccutane®) or Alitretinoin (Toctino®). h) Has any current open skin wounds or infection.
<i>Discretionary</i>	<ul style="list-style-type: none"> a) If occasional use of steroid, tacrolimus (Protopic®) or pimecrolimus (Elidel®) or other creams over small areas of skin and none of the above apply, accept. b) If chronic superficial fungal infection (e.g. ringworm, athlete's foot, chronic fungal nail infection or tinea) on local therapy only or has been in contact with an infected individual, accept. c) If in contact with scabies but not obviously infected, accept. d) If malignancy was a basal cell carcinoma (rodent ulcer) and treatment is completed and all wounds healed, accept. <p>For donors with Lichen Sclerosus requiring treatment other than topical steroid therapy only, excluding Etreinate (Tigason®):</p> <ul style="list-style-type: none"> e) If more than 24 months from completing treatment, have no areas of open wound or infection, have no history of associated malignancy and symptoms are controlled with or without intermittent use of topical steroid therapy only, accept.
<i>«See</i>	<p><i>Is there is a specific A-Z index entry for the treatment and/or condition you are concerned about?»</i></p>
<i>See if Relevant</i>	<ul style="list-style-type: none"> <u>Acne</u> <u>Anaemia</u> <u>Autoimmune disease</u> <u>Dermatitis</u> <u>Hepatitis C – 1. Affected Individual</u> <u>Herpes Simplex</u> <u>Immunosuppression</u> <u>Infection - General</u> <u>Malignancy</u> <u>Psoriasis</u> <u>Steroid Therapy</u> <u>Surgery</u>

	<p><u>Thrush</u></p> <p><u>Thyroid disease</u></p> <p><u>Wounds, Mouth and Skin Ulcers</u></p>
<i>Additional Information</i>	<p>A donor who has been in contact with scabies but has no symptoms (e.g. itching) does not pose a risk to other donors or staff.</p> <p>Damaged skin can increase the risk of infection contaminating a donation. For this reason a venepuncture should not be performed through an area of affected skin.</p> <p>Many malignancies spread through the blood stream. It is therefore considered safer not to accept donations of blood from people who have been diagnosed with malignancy. Treated basal cell carcinoma is an exception to this as it is not spread through the blood stream.</p> <p>Initial treatment of Lichen Sclerosus is through specialist care with potent steroid therapies. This and other possible therapies used such as psoralenultraviolet A (PUVA) or methotrexate can cause immunosuppression. This may mask infective conditions which would prevent donation.</p> <p>Treatment can also be with «methotrexate and» retinoids such as Etretinate (Tigason®) or acitretin (Neotigason®). If taken systemically these can cause birth defects for babies exposed to them before birth. It is important to allow time for the drug to be cleared from the blood of a donor. Some drugs take longer to be cleared than others. Lichen Sclerosus itself is not an infection and is not contagious.</p> <p>Under normal circumstances the use of topical treatment with steroid, tacrolimus and pimecrolimus will not result in blood levels which cause suppression of the «adrenal system or» immune response. «Side effects are» Immunosuppression is more likely if there is a skin barrier defect or high doses are used over large areas for extended periods. A large area of skin is defined as >9% (Wallace Rule of Nines). 1% is equal to the area of the closed digits and palm of the donor's hand.</p> <p>The cause of lichen planus is unknown but some cases have been associated with hepatitis C. It can take many months for the symptoms to resolve. Less than one in 50 adults is affected and it is slightly more common in women. It is not infectious or hereditary. Rarely can it become malignant.</p>
<i>Reason for Change</i>	<p>«The additional information section has been updated to ensure consistency with other DSG references to immunosuppression.»</p> <p>The deferral period after acitretin therapy has increased from 24 to 36 months.</p>

5. Changes apply to the **Whole Blood & Components DSG**

Dermatitis

(revised entry)

<i>Includes</i>	Eczema
<i>Obligatory</i>	<p>Must not donate if:</p> <p>a) The venepuncture site is affected.</p> <p>b) Large areas of skin are affected.</p> <p>c) Taking steroid tablets, injections, or applying steroid, tacrolimus (Protopic®) or pimecrolimus (Elidel®) creams over large areas.</p> <p>d) The donor has needed long term (six months or more) steroid treatment within the last 12 months.</p> <p>e) Within 12 months of using systemic therapies affecting immune function.</p> <p>«e)» f) The affected areas are infected.</p> <p>«f)» g) Less than four weeks from the last dose of Alitretinoin (Toctino®).</p>
<i>Discretionary</i>	<p>«a)» If the area affected is small, the venepuncture site (where the needle is put in) is not affected and using topical treatment only, accept.</p> <p>« b) If the donor:</p> <ul style="list-style-type: none"> • has been established on oral treatment for their skin disease with only one of the following drugs: Methotrexate, Sulfasalazine, Hydroxychloroquine or Azathioprine, and • the dose of the drug has not increased in the previous 6 months, and • their skin disease is controlled by medication, and • The venepuncture site is not affected, and • the donor is well, <p>accept.</p> <p>c) If there is any uncertainty about the diagnosis or the nature of treatment, refer to a DCSO.»</p>
<i>See if Relevant</i>	<p><u>Allergy</u></p> <p><u>Autoimmune Disease</u></p> <p><u>Infection – General</u></p> <p><u>«Monoclonal antibody therapy and other Biological Modalities»</u></p> <p><u>Steroid Therapy</u></p>
<i>Additional Information</i>	<p>« Dermatitis refers to a group of skin conditions characterised by epidermal change.» Eczema (also known as contact dermatitis) is a skin reaction due to sensitivity to substances that come into contact with the skin. It may involve both allergic and non-allergic processes. Because of damage to the skin, local infection is a common problem. For this reason the «venepuncture site» place where the needle goes in must not be affected.</p> <p>Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent</p>

	<p>donation. Long term steroid therapy may also cause temporary adrenal dysfunction. A waiting period of 12 months from the last dose allows time for the adrenal glands to recover.</p> <p>Some of the treatments used to treat eczema can affect the immune system (e.g. azathioprine (Imuran®), ciclosporin, hydroxycarbamide (hydroxyurea, Hydrea®), mycophenolate (CellCept®)) and so can mask signs of infection. This is why systemic treatments (taken by mouth or injection and so affecting the whole body) requires a 12 month deferral period from the time the treatment stops. Under normal circumstances the use of topical treatment with steroid, tacrolimus (Protopic®) or pimecrolimus (Elide®) will not result in blood levels which cause systemic suppression of the immune response. Systemic suppression is more likely if there is a skin barrier defect or high doses are used over large areas for extended periods. A large area of skin is defined as >9% (Wallace Rule of Nines). 1% is equal to the area of the closed digits and palm of the donor's hand.</p>
<p><i>Reason for Change</i></p>	<p>«A discretion to accept donors on oral medication has been added and the text has been updated to ensure consistency with other DSG references to immunosuppression.»</p> <p>To improve clarity and include information on Alitretinoin (Toctino®).</p>

6. Changes apply to the **Whole Blood & Components DSG**

Psoriasis

(revised entry)

<i>«Includes</i>	Psoriatic Arthritis
<i>Obligatory</i>	<p>Must not donate if:</p> <p>a) Has ever taken etretinate (Tigason®).</p> <p>b) Less than 36 months from the last dose of acitretin (Neotigason®).</p> <p>c) Less than «6» 12 months from the last dose of any treatment that may affect the immune system.</p> <p>d) Generalised or severe.</p> <p>e) There is secondary infection.</p>
<i>Discretionary</i>	<p>«a)» If mild, the venepuncture site is unaffected and only using topical treatment, accept.</p> <p>«b) If the donor:</p> <ul style="list-style-type: none"> • has been established on oral treatment for their disease with only one of the following drugs: Methotrexate, Sulfasalazine, Hydroxychloroquine or Azathioprine, and • their disease is controlled by medication, and • the venepuncture site is not affected, and • the donor is well, <p>accept.</p> <p>c) If the donor:</p> <ul style="list-style-type: none"> • is receiving PUVA or UVA therapy for their skin disease, and • their disease is controlled, and • the venepuncture site is not affected, and • the donor is well, <p>accept.»</p>
<i>See</i>	<p>Autoimmune Disease</p> <p>«Steroid Therapy»</p>
<i>Additional Information</i>	<p>Psoriasis is primarily a skin condition caused by an autoimmune process. Sometimes the disease is treated with powerful drugs and/or ultraviolet radiation to suppress the underlying autoimmune process. This may be with treatment with PUVA, methotrexate, ciclosporin, hydroxycarbamide etc. and this may alter the body's defence mechanisms to infection. In such cases donations should not be taken for at least 12 months after such treatment has finished.</p> <p>Etretinate (Tigason®) and acitretin (Neotigason®) can cause birth defects in babies exposed to them while inside the womb. It is important to allow time for the drug to be cleared from the blood of a donor. It takes longer to clear some drugs than others.</p>

<i>Reason for Change</i>	<p>«A discretion to accept donors on oral medication has been added and the text has been updated to ensure consistency with other DSG references to immunosuppression.»</p> <p>The deferral period after acitretin therapy has increased from 24 to 36 months.</p>
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7. Changes apply to the **Whole Blood & Components DSG**

Osteopenia

(revised entry)

<i>Obligatory</i>	Must not donate if: The donor is being treated with systemic monoclonal antibody therapy e.g. Denosumab (Prolia®). «See Monoclonal antibody therapy and other Biological Modalities. »
<i>Discretionary</i>	If the cause is not of itself a reason to defer, even if on treatment to prevent or treat (other than Denosumab), accept.
<i>See if Relevant</i>	Autoimmune Disease Disabled Donor Malignancy « Monoclonal antibody therapy and other Biological Modalities » Steroid Therapy Vitamins and Other Nutritional Supplements
<i>Additional Information</i>	Osteopenia occurs when there is decreased mineralization (mainly lack of calcium) of bone. It can occur for many reasons so it is important to ensure that it is not associated with a condition that would require a potential donor to be deferred.
<i>Reason for Change</i>	« The See if Relevant section has been updated. » The addition of the obligatory deferral for donors with osteoporosis treated with systemic monoclonal antibody therapy and the addition of a link to Autoimmune Disease.

8. Changes apply to the **Whole Blood & Components DSG**

Steroid Therapy

(revised entry)

<p><i>Obligatory</i></p>	<p>Must not donate if:</p> <p>a) Taking steroid tablets, injections, or enemas, or applying creams over large areas for periods of more than three weeks in the last six months.</p> <p>b) The donor has needed treatment to suppress an autoimmune condition in the last 12 months.</p> <p>«b)» e) Less than seven days after completing a course of oral or injected steroids for asthma, other disorders associated with allergy or a musculoskeletal condition.</p> <p>«c)» d) A donor has needed long term (six months or more) treatment within the last 12 months.</p>
<p><i>Discretionary</i></p>	<p>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) If using steroid eye drops, nasal spray or ear drops for control of allergic symptoms, accept.</p> <p>d) If more than seven days from completing a course of intramuscular, periarticular or intra-articular injected steroids for a musculoskeletal condition, accept unless the musculoskeletal condition itself would lead to deferral.</p>
<p><i>See if Relevant</i></p>	<p><u>Adrenal Failure</u></p> <p><u>Allergy</u></p> <p><u>Asthma</u></p> <p><u>Autoimmune Disease</u></p> <p><u>Hormone Replacement Therapy</u></p> <p><u>Skin Disease</u></p> <p><u>Tissue and Organ Recipients</u></p>
<p><i>Additional Information</i></p>	<p>«A large area of skin is defined as >9% (Wallace Rule of Nines). 1% is equal to the area of the closed digits and palm of the donor's hand.»</p> <p>Steroid therapy in high doses causes immunosuppression. This may mask infective and inflammatory conditions that would otherwise prevent donation.</p> <p>Some individuals have to take replacement steroid hormones because they do not produce enough themselves. The dose of these must be increased during times of stress. It is considered that taking blood from people who need replacement therapy may put them at unnecessary risk.</p> <p>Long term steroid therapy may cause temporary adrenal dysfunction. Waiting 12 months from the last dose allows time for the adrenal glands to recover.</p>
<p><i>Reason for Change</i></p>	<p>«The text has been updated to ensure consistency with other DSG references to immunosuppression. The see if relevant section has been revised.»</p> <p>A discretion has been added to clarify advice for donors having injected steroid treatment.</p>

9. Changes apply to the **Whole Blood & Components DSG**

Asthma

(revised entry)

<i>Obligatory</i>	<p>Must not donate if:</p> <p>a) Asthma is symptomatic.</p> <p>b) Taking, or has completed, a course of oral or injected steroids lasting more than 3 weeks within the last six months.</p> <p>c) The donor has needed long term (six months or more) treatment with oral or injected steroids within the last 12 months.</p> <p>d) The donor has taken a short course (less than three weeks) of oral or injected steroids in the last seven days.</p> <p>«e) The donor has been treated with monoclonal antibodies, or other biological modalities, in the last six months.»</p>
<i>Discretionary</i>	If b), c) or d) above do not apply and the potential donor is asymptomatic at the time of donation, even if taking regular preventive treatment, including inhaled steroids, accept.
<i>See if Relevant</i>	<p><u>Infection – General</u></p> <p>«Monoclonal antibody therapy and other Biological Modalities»</p> <p><u>Steroid Therapy</u></p>
<i>Additional Information</i>	<p>Taking blood from a person with symptomatic asthma will lower the amount of oxygen the blood can carry and could make their symptoms worse.</p> <p>Steroid therapy can hide the signs and symptoms of infection. Blood from an infected donor can be dangerous to the person receiving it.</p>
<i>Reason for Change</i>	<p>«Guidance has been added for donors treated with monoclonal antibodies and other biological modalities.»</p> <p>To bring the guidance on steroid therapy for asthma in line with that with steroid therapy for other conditions.</p>

10. Changes apply to the **Whole Blood & Components DSG**

Clinical Trials

(revised entry)

1.-Clinical Trials:- General													
<i>Obligatory</i>	Must not donate if: Participating in a clinical trial. This includes the use of drugs of any kind (oral, injected, transcutaneous, etc.) and applies to healthy individuals participating as volunteers - for example in 'phase 1' clinical trials.												
<i>Discretionary</i>	a) If a ' Designated Clinical Support Officer ' has examined and agreed the trial protocol, accept. b) If the trial does not involve the use of drugs (e.g. hypnotherapy, physiotherapy) and any underlying condition would not be a reason to defer, accept.												
2.- COVID-19 Clinical Trials													
<i>Discretionary</i>	<p><i>For donors who have been enrolled in Covid-19 treatment trials, if:</i></p> <ul style="list-style-type: none"> • the donor is fully recovered from Covid-19 for 28 days or more, and • the treatment which the donor received (or was randomised to) in the trial does not prevent donation, and • the donor meets all other criteria in the Donor Selection Guidelines, accept. <p><i>The table shows individual treatments used in Covid-19 clinical trials and their consequences for whole blood or component donation. Donors must be assessed on the basis of their recovery from Covid-19 as well as the information below. If in doubt, refer to a DCSO.</i></p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th>Treatment Received</th> <th>Consequence for donation</th> </tr> </thead> <tbody> <tr> <td>Short course of steroids e.g. dexamethasone</td> <td>Can donate, provided at least 7 days from last date of treatment</td> </tr> <tr> <td>Antivirals e.g. lopinavir, remdesivir, ritonavir</td> <td>Can donate, provided at least 7 days from last date of treatment</td> </tr> <tr> <td>Convalescent plasma</td> <td>Permanent Deferral (see Transfusion entry)</td> </tr> <tr> <td>Anti-SARS-CoV-2 monoclonal antibodies e.g. AZD7442, bamlanivimab, Regeneron</td> <td>Defer for 12 months from last day of treatment</td> </tr> <tr> <td>Monoclonal antibodies that affect the immune system e.g. infliximab, MEDI3506, ravulizumab, arilumab, tocilizumab</td> <td>Defer for 12 months from last day of treatment</td> </tr> </tbody> </table>	Treatment Received	Consequence for donation	Short course of steroids e.g. dexamethasone	Can donate, provided at least 7 days from last date of treatment	Antivirals e.g. lopinavir, remdesivir, ritonavir	Can donate, provided at least 7 days from last date of treatment	Convalescent plasma	Permanent Deferral (see Transfusion entry)	Anti-SARS-CoV-2 monoclonal antibodies e.g. AZD7442, bamlanivimab, Regeneron	Defer for 12 months from last day of treatment	Monoclonal antibodies that affect the immune system e.g. infliximab, MEDI3506, ravulizumab, arilumab, tocilizumab	Defer for 12 months from last day of treatment
Treatment Received	Consequence for donation												
Short course of steroids e.g. dexamethasone	Can donate, provided at least 7 days from last date of treatment												
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Convalescent plasma	Permanent Deferral (see Transfusion entry)												
Anti-SARS-CoV-2 monoclonal antibodies e.g. AZD7442, bamlanivimab, Regeneron	Defer for 12 months from last day of treatment												
Monoclonal antibodies that affect the immune system e.g. infliximab, MEDI3506, ravulizumab, arilumab, tocilizumab	Defer for 12 months from last day of treatment												

	<p><i>Immunosuppressive or immunomodulatory therapy e.g. acalabrutinib, anakinra, baricitinib, bemcentinib, interferon-β1a, interferon-β1b, recombinant IL-7 (CYT107), zilucoplan</i></p>	<p><i>Defer for 12 months from last day of treatment</i></p>
See if Relevant	<p><u>Complementary Therapy</u> <u>Transfusion</u> <u>Coronavirus Infection</u> <u>Steroid Therapy</u> <u>Infection – Acute</u> <u>«Monoclonal antibody therapy and other Biological Modalities»</u></p>	
Additional Information	<p>It is important for the Blood Services to know that anything being given to a donor as part of a clinical trial will not affect either the safety of the donor or of any potential recipient. If medical staff are given the contact details of the person responsible for the trial any safety issues can be checked.</p> <p>Some patients with Covid-19 have been enrolled in clinical trials. Many of these trials involve the use of drugs which interact with the immune system. Specific drugs listed in the table above include interferons and other cytokines, monoclonal antibodies (which have generic drug names ending in 'mab') and tyrosine kinase inhibitors (which have generic drug names ending in 'inib'). Because of potential effects on the immune system, donors receiving these types of drug are deferred for a year.</p> <p>Steroid therapy for treatment of covid-19 is usually a short course of 10 days or less. As donors are deferred for 28 days post recovery from covid-19, they will have already passed the 7 day deferral period for short term systemic steroids.</p> <p>When a particular drug treatment is being assessed, trial participants <u>«may be»</u> are randomly allocated to receive the treatment or a placebo drug. Participants should know which treatment is under investigation in their trial (or trial arm) but will not know whether they have had the treatment or not. They should be assessed for donation on the basis that they might have done.</p> <p>Some donors may not recall which treatment was under investigation in their trial (or trial arm). In this case, the donor should be asked to find out and contact us again when they have the information available.</p>	
Reason for Change	<p><u>«Removal of specific details regarding COVID-19 trials. The See if Relevant section has been revised.»</u></p> <p>Removal of the discretion allowing recipients of Covid-19 convalescent plasma to donate convalescent plasma after recovery.</p>	

11. Changes apply to the **Whole Blood & Components DSG**

Changes to the A-Z index

The following index entries will be **created**:

Biological Modalities and Therapies » Monoclonal antibody therapy and other Biological Modalities

IgA deficiency » Immunodeficiency

Immunoglobulin A deficiency » Immunodeficiency

Monoclonal Antibody Therapy » Monoclonal antibody therapy and other Biological Modalities

Seronegative Arthritis » Autoimmune Disease

The following index entries will be **amended**:

Arthritis – due to Psoriasis » [Psoriasis](#) ~~Autoimmune Disease~~

Discoid Lupus Erythematosus » [Skin Disease](#) ~~Autoimmune Disease~~

Immunosuppression » [Immunodeficiency](#)

Pemphigoid » [Skin Disease](#) ~~Autoimmune Disease~~

Pemphigus » [Skin Disease](#) ~~Autoimmune Disease~~

PUVA » [Psoriasis](#) ~~Autoimmune Disease~~

The following index entry will be **removed**:

Immunodeficiency » Immunosuppression