

Issued by JPAC: 12 November 2020

Implementation: To be determined by each Service

Change Notification UK National Blood Services No. 65 - 2020

Clinical Trials

This change applies to the Whole Blood and Components Donor Selection Guidelines

Please make the following changes to the entry:

1. Clinical Trials: General

- Obligatory* **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.
- Discretionary* 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

- Discretionary* For donors who have been enrolled in Covid-19 treatment trials, if:
- 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.

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 DCSSO.

\Continued

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	Can donate convalescent plasma only, provided at least 2 months from date of convalescent plasma transfusion
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, sarilumab, tocilizumab	Defer for 12 months from last day of treatment
Immunosuppressive or immunomodulatory therapy e.g. acalabrutinib, anakinra, baricitinib, bemcentinib, interferon-β1a, interferon β1b, recombinant IL-7 (CYT107), zilucoplan	Defer for 12 months from last day of treatment

See if Relevant

Complementary Therapy
Transfusion
Coronavirus Infection
Steroid Therapy
Infection - Acute

Additional Information

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.

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.

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.

\Continued

When a particular drug treatment is being assessed, trial participants 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.

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.

Reason for change

~~An additional entry has been added under 'Discretionary' and 'Additional Information' has been added.~~
Addition of specific information for Covid-19 clinical trials

SmacLennan

Dr Sheila MacLennan
Professional Director - Joint UKBTS Professional Advisory Committee
☎ Direct Dial : (0113) 820 8638 ✉ sheila.maclennan@nhsbt.nhs.uk