Issued by JPAC: 31 May 2022	**Implementation:** To be determined by each Service

Change Notification UK National Blood Services No. 38 - 2022

Immunosuppression

These changes apply to the Deceased Tissue Donor Selection Guidelines.

Please amend the following entry.

Obligatory	**Must not donate if:** a) Immunosuppressed. ~~b) Donors with recovered immunodeficiency:~~ ~~**Refer to a Designated Medical Officer.**~~
Discretionary	a) Donors who are on immunosuppressive therapy (if the underlying condition is not a contra-indication): If **ALL** the following criteria are met: • The quality of the tissue being donated is not affected • NAT testing is performed for HIV, HCV and HBV in addition to mandatory antibody tests and shown to be negative • The tissue being donated is not affected by severe local infection and there is no evidence of systemic infection. **(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.**

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	~~**Eyes:** For potential eye donors with a history of malignancy who are on chemotherapy, or autoimmune disease who are on immunosuppressive therapy, and provided that NAT testing is performed for HIV, HCV and HBV and shown to be negative, accept for corneas only.~~
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	~~A discretionary criteria has been added to allow the donation of cornea only.~~ 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.

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