North West Anglia NHS Foundation Trust

Policy for the use of Cytomegalovirus (CMV) negative blood products Version 5

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Document Owner: (Name, job title and email)	Hospital Transfusion Team nwangliaft.transfusion@nhs.net		
Division:	Family and Integrated Support Services Division		
Directorate/CBU:	FISS - Pathology - Transfusion		
Scope:	Trust-wide	All NWAFT staff involved in blood transfusion	
Standards and Legislation and key related documents:	NHS Blood and Transplant (2020). Cytomegalovirus (CMV) Negative Blood Components- Information for clinicians. Version 3. Department of Health Advisory Committee on Safety of Blood Tissues and Organs (SaBTO) position statement on Cytomegalovirus tested Blood Components. 2012.		
First-Level Approval: (Specialty)	FISS - Hospital Transfusion Committee	**Date:**	4 May 2022
First-Level Approval: (CBU)	Select	**Date:**	Enter date
First-Level Approval: (Divisional Leadership Board)	Select	**Date:**	Enter date

First-Level Approval: NMAG		**First-Level Approval:** D&TC		**First-Level Approval:** TIPCC		**First-Level Approval:** Safeguarding Committee	
Tick ☐	Enter date	*Tick* ☐	Enter date	*Tick* ☐	Enter date	*Tick* ☐	Enter date

Review Date:	12 May 2025		
Second-Level Approval: (if required)	Quality Governance Operational Committee	**Date:**	5 May 2021
Financial Implications:	None		
Counter Fraud Approval:	N/A	**Date:**	Enter date
Equality and Diversity Impact: **(Policies only)**	The author has carried out an Equality Impact Assessment (EIA) and, there are no negative impacts. The form is attached to this document.		
Target Audience:	Staff across all sites		
Staff Side Approval:	N/A	**Date:**	Enter date

CAUTION: REFER TO THE DOCUMENT LIBRARY FOR THE MOST RECENT VERSION OF THIS DOCUMENT

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VERSION CONTROL SUMMARY

Version:	Page or section:	Description of change:	Date approved:	Date published:
2010 Version 1		Original Document	September 2010	September 2010
2012 Version 2		New advice from the Advisory committee on the Safety of Blood Tissues and Organs (SaBTO) regarding the use of CMV negative components- now only indicated for intrauterine transfusion and neonates (up to 28 days post expected date of delivery), and for transfusion during pregnancy.	October 2011	June 2012
2015 Version 3		Reviewed by Hospital Transfusion Team- no changes in practice.	February 2016	February 2016
2019 Version 4		Reformatted into NWA template. Information on Granulocyte transfusion added. New version of factsheet added. No changes to practice.	17/5/2019	28/5/2019
2022 Version 5		Reviewed. New version of factsheet added. No changes to practice.	12/5/2022	13/5/2022

Summary of key points in this document:

- This policy applies to all staff with responsibility for prescribing and administering blood and blood components.
- This policy gives guidance on when and how to request CMV negative blood products.

CONTENTS

Policy for the use of Cytomegalovirus (CMV) negative blood products

1. INTRODUCTION

Cytomegalovirus (CMV) is a member of the herpes virus group, which includes herpes simplex and varicella zoster. These share the ability to remain dormant within the body for long periods. Primary infection is usually asymptomatic but may cause a flu or glandular fever like illness, leading to a lifelong infection. In the majority of individuals there will be no adverse effects from infection. More severe disease may occur in certain groups, such as foetuses, neonates and patients of any age who are immunocompromised. In susceptible groups CMV disease can have significant impact, it may lead to neurodevelopment abnormalities in babies and can be fatal in some immunocompromised patients.

Infection frequently occurs in childhood and in the UK it is estimated that 50-60% of adults are CMV positive. As CMV is very common, most adults will have been infected earlier in life and will have developed an immune response to the virus in the form of immunoglobulin (Ig) G i.e. they will be CMV IgG positive.

CMV is most commonly transmissible by person-to-person contact through exposure to bodily fluids (e.g. a mother can infect her newborn baby via breastfeeding). In the context of blood transfusion, CMV is transmissible in certain blood components, with the greatest risk being through white cells contained within the products e.g. in units of red cells and platelets.

CMV negative blood components are those that are collected from donors who have been tested and found negative for CMV IgG antibodies. A proportion of donations are screened by the Blood Services for CMV IgG antibodies to provide a ‘CMV negative’ inventory for red cells and platelets, which are provided to hospitals on request. Fresh frozen plasma (FFP) and cryoprecipitate contain very few cells, they are therefore extremely unlikely to transmit CMV and thus CMV seronegative issues of these products are not manufactured.

In addition to providing CMV negative blood components for some patient groups, all blood products apart from granulocytes are routinely leucocyte depleted which effectively reduces CMV transmission.

2. PURPOSE

The purpose of this policy is to ensure that CMV negative components are requested for and transfused to patients who require them.

3. SCOPE

This document applies to all members of staff involved in transfusion, and all patients who are prescribed red cells and/or platelet transfusion.

4. DUTIES AND RESPONSIBILITIES

It is the responsibility of the prescriber to ensure that the indication for CMV negative components is noted on the prescription chart and the laboratory request form.

It is the responsibility of the member of staff administering the component to check the component is of the correct specification before administration.

Role	Responsibility
Any member Staff requesting Blood components	Must ensure they are aware of which patients may require CMV negative components, and that the request form (whether paper or electronic) clearly states that CMV products are required if applicable
Biomedical Scientists working in Transfusion	Must ensure that any units requested for neonates and pregnant women include the information that CMV negative units are required. Must ensure that units issued must comply with any request for CMV negative components
Staff prescribing blood components	Must be aware of the indications for CMV negative blood components, and also ensure this is indicated on the dedicated Blood Component Prescription Chart
Staff administering blood components	Must check that the unit issued by the transfusion laboratory meets any requirement for CMV negative units on the prescription chart. If the chart has not been completed correctly, or the requirements are not clear, they must check with the prescriber and ask them to amend the chart before proceeding the transfusion.
Transfusion Practitioners	Regular review of the policy, and making amendments if required. Reviewing new evidence for changes in practice, amending policy, and communicating these changes to the wider clinical teams. Ensuring that the approved document is sent to the compliance leads with evidence of minutes from the approval committee Ensure that the correct version has been uploaded to Document Library. Ensure that information on the document is communicated to staff. Ensure the implementation of the policy is assured as specified in the compliance monitoring table.
Hospital Transfusion Committee	Responsible for review and approval of the policy.

5. DEFINITIONS

Definition of Terms

A.1 Cytomegalovirus (CMV) - Cytomegalovirus is a common herpes virus that causes asymptomatic infection or a mild glandular fever-like illness in most healthy individuals. Despite an antibody response (seroconversion), the virus persists in blood monocytes and 50–60% of adults in the UK, are lifelong carriers of the virus. It can be transmitted by transfusion of cellular blood components although this may be difficult to distinguish from reactivation of previous infection. CMV can cause severe, sometimes fatal, infection in foetuses, neonates and immunocompromised adults.

A.2 Leucodepletion - All blood donations are filtered to remove white blood cells (pre-storage leucodepletion) to leave $<1\times10^6$ leucocytes in the pack. This was introduced in 1998 as a vCJD risk-reduction measure but also reduces the incidence of febrile transfusion reactions and alloimmunisation to white cell (including HLA) antigens.

A.3 SaBTO - the Advisory Committee for the Safety of Blood Tissues and Organs. SaBTO advises UK ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation.

A.4 SOP - Standard Operational Procedure. This is a set of detailed step by step actions that describes how tasks or activities should be carried out to achieve the highest standards possible and to ensure efficiency, consistency and safety.

A.5 DATIX - Electronic adverse event and near miss reporting form.

A.6 SHOT - Serious Hazards of Transfusion UK-wide haemovigilance reporting system for adverse transfusion events and ‘near misses’.

A.7 SABRE - Serious Adverse Blood Reactions and Events. This system allows reporters to electronically submit reports of serious adverse events or serious adverse reactions directly to the Medicines and Healthcare Products Regulatory Agency (MHRA).

6. INDICATIONS FOR USE OF CMV NEGATIVE BLOOD PRODUCTS

CMV negative red cells and platelets should be provided for intrauterine transfusions and neonates (up to 28 days after expected date of delivery).

CMV negative red cells and platelets should be provided, where possible, for pregnant women. In an emergency, such as major haemorrhage, standard leucocyte depleted components should be given to avoid delay.

CMV negative granulocytes should ideally be provided for recipients who are at risk of CMV disease (infants, pregnant women, CMV negative recipients of CMV negative allogeneic bone marrow transplants) as these components cannot be leucocyte depleted. The risk of failure to supply and morbidity/mortality from bacterial or fungal infection would need to be balanced against a risk of subsequent CMV disease. Discussion between an NHSBT consultant and the consultant looking after the patient would be required if there were

inadequate supplies to support the issue of CMV negative components to a patient in the above at risk groups.

Standard pre-storage leucodepleted components are suitable for all other transfusion recipients, including haemopoietic stem cell transplant patients, organ transplant patients and immune deficient patients, including those with HIV.

For shared care patients (for example children under shared care with Great Ormond Street Hospital), the Transfusion Laboratory will honour the request from the referring hospital for CMV negative products.

7. HOW TO REQUEST CMV NEGATIVE BLOOD PRODUCTS

If using the ICE requesting system, the requirement for CMV negative blood products should be indicated by clicking the yes button at the 'special requirement' option screen. If using paper requests, the need for CMV negative components must be clearly indicated. The Transfusion Laboratory must also be informed by telephone of the requirement for CMV negative blood products.

Once the requirement for CMV negative blood products has been communicated to the Transfusion Laboratory, all further blood products issued will be CMV negative until the Transfusion Laboratory is informed otherwise, or until it is evident that the patient is no longer pregnant.

The requirement for CMV negative blood products must be noted in the Special Requirement box on the dedicated Blood and Blood Products Prescription and Transfusion Record.

8. MONITORING OF COMPLIANCE

The Transfusion Laboratory will maintain responsibility for ensuring CMV negative products are issued when requested appropriately.

Compliance with the policy will be monitored each time a component is issued, as described in Appendix D. A DATIX will be raised if any non-conformances are identified. If CMV unscreened products are transfused in error to a patient who requires CMV negative components, a report must be made to the Serious Hazards of Transfusion (SHOT) Haemovigilance reporting scheme, as 'Incorrect Blood Component Transfused – Special Requirements Not Met'

9. REFERENCES

Department of Health Advisory Committee on Safety of Blood Tissues and Organs (SaBTO) position statement on Cytomegalovirus tested Blood Components. 2012. Available http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_132965 [Accessed 04 February 2022]

Morton, S, Stanworth, S *et al* (2021) Clinical Guidelines for the Use of Granulocyte Transfusion – Information Document INF276/5 Available: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/25196/clinical-guidelines-for-the-use-of-granulocyte-transfusions.pdf [Accessed 07 February 2022]

New, H. V. *et al* and the British Committee for Standards in Haematology (2016), Guidelines on transfusion for fetuses, neonates and older children. *British Journal of Haematology,* 175: 784–828.
NHS Blood and Transplant (2020). Cytomegalovirus (CMV) Negative Blood Components- Information for clinicians. Version 3. Available: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/20881/cmv-factsheet-v3.pdf [Accessed 07 February 2022]

Norfolk D., (Ed) (2013) Handbook of Transfusion Medicine.5th Edition, TSO

APPENDIX A COMPLIANCE MONITORING TABLE

Document Section		Control	Checks to be carried out to confirm compliance with the policy	How often the check will be carried out	Responsible for carrying out the check	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting
Page	**Section**	**WHAT?**	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
4.2		Staff administering the component check the component is of the correct specification before administration.	As part of pre transfusion bedside check	Each transfusion	Staff performing the bedside check	DATIX to be raised if non-conformance identified	On each occurrence
5.1		CMV negative red cells and platelets should be provided for neonates (up to 28 days after expected date of delivery).	Transfusion Laboratory will check that any requests received for blood components for neonates are for CMV negative components, and that CMV negative components are issued	At each request of blood components for neonates	Transfusion Laboratory Biomedical Scientist	DATIX to be raised if non-conformance identified	On each occurrence
5.2		CMV negative red cells and platelets should be provided for pregnant women	Transfusion Laboratory will check that any requests received for blood components for pregnant women are for CMV negative components, and that CMV negative components are issued	At each request of blood components for pregnant women	Transfusion Laboratory Biomedical Scientist	DATIX to be raised if non-conformance identified	On each occurrence

APPENDIX B: NHS BLOOD AND TRANSPLANT FACTSHEET

NHS
Blood and Transplant

Information for clinicians

Cytomegalovirus (CMV) Negative Blood Components

Guidance on the indications for CMV IgG negative blood components.

Version 3. Effective: 3/12/2020

Patient Blood Management

What is CMV?

CMV is a type of herpes virus. Primary infection is usually asymptomatic but may cause a flu or glandular fever-like illness, leading to a lifelong infection in all age groups. The virus can reactivate from its latent state and it is commonly shed asymptomatically in various bodily secretions, such as nasopharyngeal secretions and urine. More severe disease may occur in individuals with impaired immunity such as fetuses, neonates and patients, of any age, who have been immuno-suppressed by disease or treatment.

How are people exposed to CMV?

Infection frequently occurs in childhood and, in the UK, it is estimated that 50-60% of adults are CMV positive. As CMV is very common, most adults will have been infected earlier in life and will have developed an immune response to the virus in the form of immunoglobulin (IgG) i.e. they will be CMV IgG positive.

A person can become infected with CMV in several ways, most commonly via person-to-person contact, through exposure to body fluids. A mother can infect her unborn baby in utero or her newborn baby via breastfeeding. Most disease in immuno-compromised patients occurs through these routes or from reactivation of a previous CMV infection.

CMV is less commonly transmitted by receiving donated blood or organs from a donor who is carrying CMV, or who has acute CMV infection but is CMV IgG negative i.e. they have not yet formed an immune response but have the virus circulating in their blood. Transmission of CMV present in blood components can give rise to primary infection in CMV negative patients or reinfection in previously infected patients.

Why is CMV important?

CMV can cause a potentially life-threatening infection in patients who cannot form an effective immune response, particularly following haemopoietic stem cell transplant and in the perinatal period.

There are certain groups at particular risk of severe disease:

- **Fetuses and neonates:** CMV is the most common congenital infection in the developed world, affecting 1-2% of infants worldwide (Luck and Sharland, 2009) and 0.3-0.4% in the UK (Griffiths et al, 1991). CMV is estimated to cause up to 12% of all sensorineural hearing loss (Peckham et al, 1987) and 10% of cerebral palsy. Primary infection is more likely to cause symptomatic congenital CMV and may increase the risk of spontaneous abortion, stillbirth and fetal hydrops. Ophthalmic complications including chorioretinitis, cataract and blindness occur in 10-20% of congenital cases presenting in the neonatal period. Mortality from symptomatic neonatal CMV infection is 10-30%, but much higher if the baby is premature.
- **Immuno-compromised patients:** Immuno-compromised patients who have not been infected with CMV (CMV negative) are also at risk from transfusion-transmitted CMV infection, person-to-person contact, and stem cell or solid organ transplants. The Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) undertook a literature review and risk assessment and concluded that leucodepletion (i.e. the blood component is filtered to reduce white cells) is as effective as CMV IgG negative blood components. These patients should therefore receive leucodepleted blood; CMV IgG negative donations are not required. This approach has also been adopted in other developed countries.

Who needs to receive CMV IgG negative blood components?

In March 2012, SaBTO released a position statement containing the following indications for the provision of CMV IgG negative blood components:

- Intra-uterine transfusions
- Neonates up to 28 days post expected date of delivery
- Pregnancy:
  - Elective transfusions during pregnancy (not during labour or delivery)
  - If in an emergency situation it is not possible to provide CMV negative blood components, leucodepleted components may be used.

Organ transplant patients do not require CMV IgG negative blood components. CMV IgG negative red cells and platelets may be replaced with leucodepleted blood components for adults and children post haemopoietic stem cell transplantation for all patient groups, including negative donors and recipients. However, individual transplant centres should have a policy of CMV monitoring by PCR for haemopoietic stem cell transplants and some groups of transplant patients. This practice allows early detection of any possible CMV infection (whether transfusion-transmitted, acquired or reactivated).

What is a CMV negative blood component?

CMV negative blood components are those collected from donors who have been tested and found negative for CMV IgG antibodies. A proportion of donations are screened by the blood services for CMV IgG antibodies to provide a 'CMV negative' inventory for red cells and platelets, which are provided to hospitals on request.

Depending on age group, 25-40% of UK blood donors are CMV IgG antibody positive (this is a smaller number than that stated above for 'adults', as the prevalence of CMV IgG positivity increases with age and donor populations are younger than screened adult populations).

How is the risk of CMV transmission through blood components reduced?

The virus can be transmitted through white cells contained in blood components e.g. units of red cells and platelets. In the UK, blood components (except white cell components) are leucodepleted to reduce the transmission risk of variant Creutzfeldt Jakob Disease (vCJD). However, it cannot be guaranteed that the risk of transmitting CMV is eliminated (Vamvakas, 2005), in the same way that CMV IgG testing is not a guarantee.

Frozen components, including fresh frozen plasma (FFP) and cryoprecipitate, have not been shown to transmit CMV so the CMV status is not shown on the label of these components.

Granulocyte components should be provided as CMV negative for all CMV negative patients as these components cannot be leucodepleted. A medical decision may be made to transfuse units which are not CMV tested, or which are known to be CMV IgG positive, into a CMV negative patient if the urgency to treat a non-responsive bacterial or fungal infection outweighs the risks of potentially developing CMV infection at a later stage. For further information contact your transfusion practitioner, consultant haematologist or transfusion laboratory.

References:

New, H. V. et al and the British Committee for Standards in Haematology. 2016. Guidelines on transfusion for fetuses, neonates and older children. Br J Haematol, 175: 784–828. Available at: https://b-s-h.org.uk/guidelines/guidelines/transfusion-for-fetuses-neonates-and-older-children/

Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO). 2012. Cytomegalovirus Tested Blood Components Position Statement. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/215125/dh_133086.pdf

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Norfolk D., (Ed). 2013. Handbook of Transfusion Medicine. 5th Edition, TSO. Available at: https://www.transfusionguidelines.org/transfusion-handbook

Peckham C. S., et al. 1987. Congenital cytomegalovirus infection: a cause of sensorineural hearing loss. Arch.Dis.Child., 62, 1233-1237

Vamvakas E.C. 2005. Is white blood cell reduction equivalent to antibody screening in preventing transmission of cytomegalovirus by transfusion? A review of the literature and meta-analysis. Transfus.Med.Rev., 19, 181-199

Contact us

We would welcome your feedback and comments on this factsheet. You can contact us:

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Or by email to: **nhsbt.customerservice@nhsbt.nhs.uk**

NHS Blood and Transplant (NHSBT) saves and improves lives by providing a safe, reliable and efficient supply of blood and associated services to the NHS in England. We are the organ donor organisation for the UK and are responsible for matching and allocating donated organs. We rely on thousands of members of the public who voluntarily donate their blood, organs, tissues and stem cells.

For more information visit **nhsbt.nhs.uk**
Email **enquiries@nhsbt.nhs.uk**

Version 3. Effective: 3/12/2020

Patient Blood Management

APPENDIX C: EQUALITY IMPACT ASSESSMENT STAGE 1

Indicate in the table below what kind of impact this policy will have upon the protected groups or how it is likely to influence the Trust's ability to comply with the Public Sector Equality Duty, which is to;

a) Eliminate discrimination, victimisation, harassment or other unlawful conduct that is prohibited under the Equality Act 2010 and/or;
b) Advance equality of opportunity between people who share a characteristic and those who do not and/or;
c) Foster good relations between people who share a relevant protected characteristic and those who do not.

Consider this in the context of the whole policy being updated. The easiest means of approaching this is to consider the following questions;

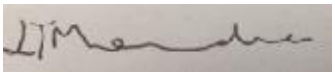
- **Would the adaptation meet my needs or ensure I had equal opportunities if I had any of the protected characteristics?**
- **Is there anything about the policy that would have a detrimental impact on me if I had one of the protected characteristics?**
- **Does it affect our ability to comply with the Public Sector Equality Duty?**

Please select the appropriate boxes relating to the impact of the policy or adaption:

Age	○ Positive	◉ None	○ Negative	○ Unknown
Disability	○ Positive	◉ None	○ Negative	○ Unknown
Gender Reassignment	○ Positive	◉ None	○ Negative	○ Unknown
Marriage/Civil Partnership	○ Positive	◉ None	○ Negative	○ Unknown
Pregnancy and Maternity	○ Positive	◉ None	○ Negative	○ Unknown
Race	○ Positive	◉ None	○ Negative	○ Unknown
Religion or Belief	○ Positive	◉ None	○ Negative	○ Unknown
Sex (Gender)	○ Positive	◉ None	○ Negative	○ Unknown
Sexual Orientation	○ Positive	◉ None	○ Negative	○ Unknown

If any boxes are checked as Negative, please escalate to a stage 2 assessment by emailing nwangliaft.qualitygovernance@nhs.net or nwangliaft.corporategovernance@nhs.net

If any boxes are checked as Unknown, please contact nwangliaft.edi@nhs.net

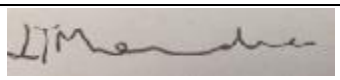
Agreement by	**Signature**	**Date**
Approving Panel Chair Stage 1 (if required)		4/5/2022
Equality, Diversity and Inclusion Lead (if required)		
Approving Panel Chair Stage 2 (if required)		

APPENDIX D: QUALITY ASSURANCE CHECKLIST

		Y/N/ n/a	COMMENTS (to author for any amendments)
1	**Title of the document Policy for the use of Cytomegalovirus (CMV) negative blood products(C0661)**		
	Is the title clear and unambiguous	Y	
2	**Type of document (e.g. policy, guidance)**	**Policy**	
	Is it clear whether the document is a policy, guideline, procedure?	Y	
3	**Introduction**		
	Are reasons for the development of the document clearly stated?	Y	
4	**Content**		
	Is the standard model template used?	Y	
	Is the document in the correct format?	Y	
	• Paragraphs numbered consecutively	Y	
	• Headers: only on front page to contain logo	Y	
	• Footers: on every page except front page	Y	
	Are the Version Control numbers correct in the panel and the footer	Y	
	Is the introduction of the document clear?	Y	
	Are the objectives/aims clearly stated?	Y	
	Are the duties, roles and responsibilities clearly explained? **(policies only)**	Y	
	Are the definitions of terms clearly explained?	Y	
	Have recommendations from Counter Fraud/Internal Audit been included? **(policies only)**		
	Does this document concern the handling, moving or storage of personal identifiable or commercially sensitive information? If yes, has a Summary Privacy Impact Assessment been completed?		
5	**Evidence Base**		
	Is the type of evidence to support the document explicitly identified?		
	Are associated documents referenced?		
6	**Approval Route**		
	Does the document identify which committee/group will approve it?	Y	
7	**Review Date**		
	Is the review date identified?		
8	**Equality and Diversity (policies only)**		
	Is a completed Equality Impact Assessment attached?		
9	**Monitoring Compliance and Effectiveness (policies only)**		
	Has section 'Compliance Monitoring' been completed?	Y	

If answers to any of the above questions is 'no', then this document is not ready for approval, it needs further review.

COMPLIANCE TEAM:		
1.	Date Comments returned to author by Compliance Lead	16/12/2021
2.	Date of Compliance Team approval	16/12/2021
3.	Name of Compliance Lead	Stanley Balachander, Policies and Compliance Officer

FIRST-LEVEL APPROVAL: Hospital Transfusion Committee			
If the committee/group is happy to approve this document would the chair please sign below and send the document and the minutes from the approval committee to the author. To aid distribution all documentation should be sent electronically wherever possible.			
Name	**Dr Lynda Menadue**	**Date**	04/05/2022
Signature			
SECOND-LEVEL APPROVAL COMMITTEE: Quality Governance Operational Committee			
If the committee/group is happy to approve this document would the chair please sign below and send the document and the minutes from the approval committee to the author. To aid distribution all documentation should be sent electronically wherever possible.			
Name	Kanchan Rege	**Date**	12/05/2022
Signature