North West Anglia NHS Foundation Trust

# Policy for the use of Cytomegalovirus (CMV) negative blood products Version 6

| | | | |
|---|---|---|---|
| **Central Index Number:** | C0661 | | |
| **Document Owner:** (Name, job title and email) | Emily Rich, Lead Transfusion Practitioner, emily.rich3@nhs.net | | |
| **Division:** | Family and Integrated Support Services Division | | |
| **Directorate/CBU:** | FISS - Pathology | | |
| **Scope** (please select)**:** | ☑ Trust wide | ☐ Specific staff group: | |
| **Standards and Legislation and key related documents:** | NHS Blood and Transplant (2021) Cytomegalovirus (CMV) Negative Blood Components<br>Department of Health Advisory Committee on Safety of Blood Tissues and Organs (SaBTO) position statement on Cytomegalovirus tested Blood Components 2012 | | |
| **Specialty Meeting Approval:** | FISS - Hospital Transfusion Committee | **Date:** | 3 June 2025 |
| **CBU Meeting Approval:** | Select | **Date:** | Enter date |

| **Additional Approval** *(if required)*: | | | | |
|---|---|---|---|---|
| **PSC** - *Tick* ☐ | **D&TC** - *Tick* ☐ | **TIPCC** - *Tick* ☐ | **Safeguarding Committee** - *Tick* ☐ | **ELD** - *Tick* ☐ |
| Enter date | Enter date | Enter date | Enter date | Enter date |

| | | | |
|---|---|---|---|
| **First-Level Approval:** (Divisional Leadership Board) | FISS Divisional Leadership Board | **Date:** | 25 June 2025 |
| **Second Level Approval:** (*if required* – please consult sect. 6.4 of the Trust Wide Document Control Policy) | Quality Governance Oversight Committee | **Date:** | 10 July 2025 |
| **Review Date:** | 10 July 2028 | | |
| **Financial Implications:** | *Where a document has any financial implications on the Trust, the Local Counter Fraud Specialist (LCFS) has the authority to investigate and challenge this document with regard to current fraud and bribery legislation and to ensure appropriate counter fraud measures are in place. LCFS contact details are available on the Trust's Intranet.* | | |
| **Counter Fraud Approval:** | N/A | **Date:** | Enter date |
| **Equality and Diversity Impact:** (Policies only) | *The author has carried out an Equality and Freedom to Speak Up Impact Assessment (EqFSUIA) and, there are no negative impacts. The form is attached to this document.* | | |
| **Target Audience:** | Staff across all sites | | |
| **Trust Partnership Group Approval:** | N/A | **Date:** | Enter date |
| **Date archived:** | *For Corporate Governance Compliance Team use only*<br>Click or tap to enter a date. | | |

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

***UNCONTROLLED COPY WHEN PRINTED***

# AUTHOR'S CHECKLIST

| | |
|---|---|
| **Document Title:** | Policy for the use of Cytomegalovirus (CMV) negative blood products. Version 6 |
| **Central Index Number:** | C0661 |

**Must be completed when reviewing existing published documents only**

Before beginning the process of reviewing and updating an existing document, please take the below into consideration:

| **Considerations for all documents** | | **Y/N** | **Action** | |
|---|---|---|---|---|
| | | | "Yes" | "No" |
| 1. | Is the document still required? | Yes | Please see question 2. | Arrange document removal with Exec Director/Chair of DLB and forward to the relevant compliance team. |
| 2. | Has there been any change in guidance or national policy since the previous version? | No | Please see question 4. | Please see question 3. |
| 3. | **REVIEW DATE ROLL ON:** Where there has been no major[1] change to the document, can it be approved without having to go through all relevant committees (including those in chronological order)? | No | Exec Director/Chair of the DLB to approve new review date by email*. *(see version control summary/page 3)*<br><br>The following information must be sent to the relevant compliance team:<br><br>1. Evidence of review date approval (*email).<br>2. Author's Checklist page only.<br><br>Non-Clinical Compliance Team<br><br>Clinical Compliance Team | Please see question 4. |
| 4. | Can the document be approved at first-level only? (Please refer to section 6 of the Trust-wide Document Control Policy) | Yes | Proceed with review and **first-level only** approval processes. | Proceed with review and both first and second-level approval processes. |

[1] As defined in section 7.3 of the Trust-wide Document Control Policy

## VERSION CONTROL SUMMARY

| Version: | Page/Section of Document: | Description of change:<br><br>(List all amendments made to the document. "Review" or "Update" is not sufficient information.) | Date Exec Director/Chair of DLB approval given for change of review date only | Date approved: | Date published: |
|---|---|---|---|---|---|
| 1 | | Original document | | September 2010 | September 2010 |
| 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 in intrauterine transfusion and neonates (up to 28 days post expected date of delivery), and for transfusion during pregnancy. | | October 2011 | June 2012 |
| 3 | | Reviewed by Hospital Transfusion Team – no changes in practice | | February 2016 | February 2016 |
| 4 | | Reformatted into NWA template. Information on Granulocyte transfusion added. New version of factsheet added. No changes to practice. | | 17/05/19 | 28/05/19 |
| 5 | | Reviewed. New version of factsheet added. No changes to practice. | | 12/05/22 | 13/05/22 |
| 6 | | Reviewed. New version of factsheet added. No changes to practice. | | 10.07.2025 | 18.07.2025 |

## DOCUMENT CONTRIBUTORS

Please list the details of all who contributed to the development of this document.

| Name | Job Title | Version Contributed to |
|---|---|---|
| Kaye Bowen | Transfusion Practitioner | 1-5 |
| Emily Rich | Lead Transfusion Practitioner | 6 |
| | | |
| | | |
| | | |

# CONTENTS



**The latest version of this document is on the Document Library.**

**Any printed copies must be checked against the Document Library version to ensure that the latest version is being used.**

**Policy for the use of Cytomegalovirus (CMV) negative blood components C0661**

## 1. INTRODUCTION

1.1 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.

1.2 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 NHSBT 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 leukocyte depleted with effectively reduces CMV transmission.

## 2. OBJECTIVES/AIMS

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

## 3. DUTIES, ROLES and RESPONSIBILITIES

3.1 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.

### 3.2 Staff prescribing blood components

Must be aware of the indications for CMV negative blood components, and also ensure this indicated on Blood Products Prescription Form

### 3.3 Staff requesting blood components

Must ensure they request CMV negative components for patients who require them.

### 3.4 Biomedical scientists in the transfusion laboratory

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 comply with any request for CMV negative components.

### 3.5 Staff administering blood components

Must check that the unit issued by the transfusion laboratory meets and 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 with the transfusion.

### 3.6 Hospital Transfusion Team

Must regularly review the policy and make required amendments in line with current recommendations and practice.

### 3.7 Hospital Transfusion Committee

Review and approval of the policy

## 4. TRAINING and COMPETENCY

4.1 All staff involved in transfusion must ensure they have completed the relevant training and competency assessment. Please see the Policy for training and competency assessment of staff involved in transfusion C0175.

## 5. INDICATIONS FOR CMV NEGATIVE BLOOD PRODUCTS

5.1 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 allogenic bone marrow transplants) as these components cannot be leucodepleted. 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 ta above at-risk groups.

5.2 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.

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

5.4 **How to request CMV negative blood products**

The requirement for CMV negative blood products should be indicated when making the product request on ICE. If using a paper request form the requirement should be clearly indicated.

It is important to be clear about the reason for requiring 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 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 on the Special Requirements box on the Blood Products Prescription Form. This must be checked against the unit prior to administering the product.

# 6. ASSOCIATED DOCUMENTS AND REFERENCES

## 6.1 Associated documents

C0160 Blood Transfusion Policy

C0175 Policy for competency assessment of staff involved in transfusion

## 6.2 References


Department of Health Advisory Committee on Safety of Blood Tissues and Organs (SaBTO) (2012) Position statement on Cytomegalovirus tested Blood Components Available at: https://www.gov.uk/government/publications/sabto-report-of-the-cytomegalovirus-steering-group [Accessed 20/12/24]

New et al., (2016) Guideline on transfusion for fetuses, neonates and older children *British Journal of Haematology* Vol 175 No 5 https://doi.org/10.1111/bjh.14233

NHSBT (2021) Cytomegalovirus (CMV) Negative Blood Components Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/34222/cmv-factsheet-v5-310821.pdf [Accessed 20/12/24]

NHSBT Granulocyte working group (2021) Clinical guidelines for the use of granulocyte transfusion Available at: https://nhsbtdbe.blob.core.windows.net/umbraco-assets-corp/25196/clinical-guidelines-for-the-use-of-granulocyte-transfusions.pdf [Accessed 20/12/24]

## 7. MONITORING COMPLIANCE

| 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?** |
| | 5.4 | Staff administering the component check the component is of the correct specification before administration. | As part of the pre-transfusion bedside check. | Each transfusion | Staff performing the bedside check | Datix to be raised if non-conformance identified | On each occurrence |
| | 5.4 | 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. | Each request for blood components from a neonate | Transfusion Laboratory Biomedical Scientist | Datix to be raised if non-conformance identified | On each occurrence |
| | 5.4 | CMV negative red cells and platelets should be | Transfusion Laboratory will check that any requests received for blood | Each request for blood components | Transfusion Laboratory | Datix to be raised if non-conformance identified | On each occurrence |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | provided for pregnant women | components for pregnant women are for CMV negative components, and that CMV negative components are issued. | for pregnant women | Biomedical Scientist | | |

## APPENDIX A: NHSBT CMV NEGATIVE INFORMATION LEAFLET



NHS
Blood and Transplant


**Information for clinicians**

# Cytomegalovirus (CMV) Negative Blood Components

**Guidance on the indications for CMV IgG negative blood components.**

Version 5. Effective: 31/08/2021

**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. However, granulocyte components cannot be leucodepleted and therefore CMV negative granulocyte components are required for CMV negative patients.

## 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
- CMV negative patients requiring granulocyte transfusion.

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. 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

Griffiths P.D., et al. 1991.Congenital and maternal cytomegalovirus infections in a London population. Br.J.obstet.Gynaecol., 98, 135-140

Luck S. and Sharland M. (2009) Congenital cytomegalovirus: new progress in an old disease. Paediatrics and Child Health, 19, 178-184

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:**

By post to:

**Customer Services, NHS Blood and Transplant**

Part Academic Block – Level 2
John Radcliffe Hospital
Headley Way, Headington
Oxford OX3 9BQ

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 5. Effective: 31/08/2021

**Patient Blood** Management

## APPENDIX C: EQUALITY AND FREEDOM TO SPEAK UP IMPACT ASSESSMENT (EQFSUIA)

The Equality and Freedom to Speak Up Impact Assessment (EFSUIA) process is a key function to identify and mitigate inequality in policies and processes adopted by the organisation.

The Trust has introduced an automated system that is simple to use and utilises co-production where issues cannot be easily resolved.

All policies and processes agreed by formal committee must include an EqFSUIA form which is completed by the author or process lead, this enables a rapid identification of inequality. If no significant inequalities are identified in the **Stage 1** process, this is the end of the EqFSUIA process. If unsure about the likelihood and limitations please see example table Stage 1 – Equality and Freedom to Speak Up Matrix Key and Examples.

If moderate or greater inequalities (*highlighted in yellow, amber or red in the **Stage 2 Matrix Calculation Example table***) are identified the EqFSUIA will automatically calculate and initiate a Stage 2 advance impact assessment, creating a work programme to reduce the inequality to its minimum level.

- Stage 1 follow the link and answer the assessment questions
- You will receive an email showing the generated score in numbers
- If the individual scores are 1, 2 or 3 – place the generated numbers into the Stage 1 assessment and copy/paste into your document. No further action required
- If any individual generated score is 4 or 5 and above for a characteristic an advanced impact assessment will be initiated.
- Follow the Stage 2 Process Mapping
- Use the Stage 2 Action Plan to record how the inequalities will be implemented and the dates of completion.

In many cases, a discussion with the Equality, Diversity, Inclusion and Armed Forces team and/or the Freedom to Speak Up Guardian will provide an immediate solution, enabling the EqFSUIA to be resubmitted with no further action required.

**Contact:** Equality, Diversity, Inclusion and Armed Forces Team
Email: nwangliaft.edi@nhs.net

**Contact:** Freedom to Speak Up Guardian, Sally Mumford
Telephone 01733 678026 or 075171 32592
Email: sally.mumford1@nhs.net

In a few cases, where inequalities cannot be solved by revising the document, an Advanced EqFSUIA should be introduced.

The Equality Impact Assessment Stage 2 (*see Stage 2 Matrix Calculation Example table*) uses a matrix to identify the level of detriment the inequality will have upon the affected protected groups and guide the author to the level of action needed as a result. The process includes the forming of co-production groups to develop solutions to the inequality and a means by which unsolvable inequalities can be reviewed periodically if no solution becomes available.

# APPENDIX D: EQUALITY AND FREEDOM TO SPEAK UP 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;

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 check 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.edi@nhs.net**

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

# APPENDIX G: PHARMACY QUALITY ASSURANCE CHECKLIST

**Pharmacy Quality Assurance Checklist for all Medicine-Related Clinical Policies, Procedures and Guidelines**

**This form must be completed by the appropriate designated pharmacist for all policies, procedures and guidelines relating to medicines prior to being submitted to the Drugs and Therapeutics Committee.**

| **Title of Document:** | | | **Central Index Number:** |
|---|---|---|---|
| **1.** | **Document particulars:** | **Yes / No / N/A** | **Comments (as necessary)** |
| | Is the document written in clear, unambiguous language? | | |
| | Does the document also apply for Hinchingbrooke Hospital/ Peterborough City Hospital/ Stamford Hospital? | | |
| | If the answer to the above question is YES, has the relevant pharmacist at the cross site location been contacted for their input?<br>**(Please indicate name of person contacted in comments)** | | |
| **2.** | **Evidence Based** | | |
| | Are the product(s) on the Formulary? If non-formulary then please submit Formulary request/Business case. | | |
| | Have indications been clearly reviewed? | | |
| | Are the medicines, hospital supply only? | | |
| | Have doses of medication been clearly reviewed? | | |
| | Are definitions in the document clearly explained? | | |
| | Are roles and responsibilities in the document clearly explained? | | |
| | Are the products listed in the document licensed, unlicensed or off license? If unlicensed then please complete unlicensed form. | | |
| | Are there any Patient Safety Alerts/MHRA Alerts/NICE guidance associated with the document? | | |
| | Is there any specific ordering or storage requirements with the product(s) in the document? | | |
| | Are there any cost implications with the product(s) in the document? | | |
| | Is there any supporting evidence to support the document?<br>**(References should be checked and updated)** | | |
| | Are there measurable standards to support the monitoring of compliance?<br>**(Audit table applicable to policies only)** | | |
| **3.** | **Pharmacist Compliance Approval:** | | |
| | Name: | | |
| | Signature: | | |
| | Role: | | |
| | Date: | | |

**Please return completed form to the Pharmacy Medicines Governance Team.**

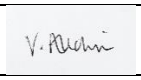
# APPENDIX H: QUALITY ASSURANCE CHECKLIST

***CORPORATE GOVERNANCE COMPLIANCE OFFICER'S USE ONLY***

| | | Y/N/ n/a | COMMENTS (to author for any amendments) |
|---|---|---|---|
| 1 | **Title of the document** | | |
| | Is the title clear and unambiguous | Y | |
| 2 | **Type of document (e.g. policy, guidance)** | | |
| | 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** | | |
| | Are all sections of the front cover completed correctly? | Y | |
| | Is the document in the correct Trust approved format? | Y | |
| | • Paragraphs numbered consecutively | Y | |
| | • Headers: only on front page to contain logo | Y | |
| | • Footers: on every page except front page | Y | |
| | Has the Author's Checklist been fully updated? | Y | |
| | Are the Version numbers correct in the title, summary and the footers? | Y | |
| | Has the Version Control Summary been fully updated with changes? | Y | |
| | Has the Document Contributors section been completed? | 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)** | N/A | |
| | 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? | N/A | |
| 5 | **Evidence Base** | | |
| | Is the type of evidence to support the document explicitly identified? | Y | |
| | Are associated documents referenced? | Y | |
| 6 | **Monitoring Compliance and Effectiveness (policies only)** | | |
| | Has section 'Compliance Monitoring' been completed? | Y | |
| 7 | **Equality and Diversity (policies only)** | | |
| | Is the Equality Impact Assessment completed? | Y | |
| 8 | **Approval Route** | | |
| | Has email approval been received for change of review date only? | N/A | |
| | Does the document identify which committee(s)/group(s) will approve it? | Y | |
| | Does the document meet the criteria for Second Level approval or Information Only? | Y | . |

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

***It is vitally important that documents are forwarded to the Corporate Governance Team after every amendment and approval meeting to ensure the most up-to-date version is held by the team at all times.***

| COMPLIANCE TEAM: | | |
|---|---|---|
| 1. | Date Comments returned to author by Compliance Lead | |
| 2. | Date of Compliance Team approval | 25.04.2025 |
| 3. | Name of Compliance Lead | Viv Allchin  |

**Please do not delete any of the below approval sections.**
**If certain sections are not applicable to the document's journey please enter 'N/A'**

| **SPECIALTY APPROVAL MEETING:** Hospital Transfusion Committee | | | |
|---|---|---|---|
| On approval, Chair to sign below and send the document and the minutes from the approval committee to the Corporate Governance Compliance Team. **To aid distribution all documentation should use electronic signatures and be sent electronically wherever possible.** | | | |
| **Chair's Name** | Dr Lynda Menadue | **Date** | 03/06/2025 |
| **Signature** |  | | |

| **CBU APPROVAL MEETING:** Enter name of **CBU** meeting | | | |
|---|---|---|---|
| On approval, Chair to sign below and send the document and the minutes from the approval committee to the Corporate Governance Compliance Team. **To aid distribution all documentation should use electronic signatures and be sent electronically wherever possible.** | | | |
| **Chair's Name** | | **Date** | Enter date |
| **Signature** | | | |

| **ADDITIONAL APPROVAL MEETINGS:** Complete all that apply | | | |
|---|---|---|---|
| On approval, Chair to sign below and send the document and the minutes from the approval committee to the Corporate Governance Compliance Team. **To aid distribution all documentation should use electronic signatures and be sent electronically wherever possible.** | | | |
| Select Meeting. | | Select Meeting. | |
| **Chair's Name** | | **Chair's Name** | |
| **Date** | Enter date | **Date** | Enter date |
| **Signature** | | **Signature** | |
| Select Meeting. | | Select Meeting. | |
| **Chair's Name** | | **Chair's Name** | |
| **Date** | Enter date | **Date** | Enter date |
| **Signature** | | **Signature** | |

| **FIRST-LEVEL APPROVAL:** FISS Divisional Leadership Board | | | |
|---|---|---|---|
| On approval, Chair to sign below and send the document and the minutes from the approval committee to the Corporate Governance Compliance Team. **To aid distribution all documentation should use electronic signatures and be sent electronically wherever possible.** | | | |
| **Chair's Name** | Dr. Tim Jones | **Date** | 25/06/2025 |
| **Signature** |  | | |
| Please confirm if document requires Second-Level **approval** or it is to be submitted for **information only**.<br>Please see section 6.4 of the Trust's Document Control Policy. | | ✓ **APPROVAL**<br>☐ **INFORMATION ONLY** | |

| **SECOND-LEVEL APPROVAL:** Quality Governance Oversight Committee | | | |
|---|---|---|---|
| On approval, Chair to sign below and send the document and the minutes from the approval committee to the Corporate Governance Compliance Team. **To aid distribution all documentation should use electronic signatures and be sent electronically wherever possible.** | | | |
| **Chair's Name** | Aber Eaqub | **Date** | 10/07/2025 |
| **Signature** |  | | |