NHS
Blood and Transplant

Board Clinical Governance Committee

Terms of Reference

1. Purpose

The Clinical Governance Committee is established by the Board of NHSBT as a joint non-executive/executive committee of the Board with powers and responsibilities delegated to it within the NHSBT Standing Orders, Schedule of Delegations and these Terms of Reference.

The Clinical Governance Committee's purpose is to provide assurance to the Board that ~~the~~ NHSBT has a robust framework for the management of all critical clinical systems and processes and in delivering patient/donor safety. This is a framework through which NHSBT is accountable for continuously improving the quality of services and safe-guarding high standards of care by creating an environment in which excellence in clinical care will flourish and innovation is supported. It includes systems for, but not limited to:

- Clinical Incident and complaints management and reporting information
- Clinical quality improvement
- Clinical Audit
- Maintaining clinical competence
- Compliance with the CQC essential standards of quality and safety
- Clinical effectiveness, including Research and Development
- Medical and Nursing revalidations
- ~~Education, training and staff management~~
- Patient and public involvement.

The Clinical Governance Committee (CGC or the Committee) sets the tone and direction for patient/donor safety, clinical effectiveness, patient outcomes and patient/donor experience. It supports the operating directorates in the development, implementation and monitoring of a robust framework for clinical governance, meeting donors' and patients' needs.

The purpose of the Committee shall be delivered through the performance of the duties set out in section 5.

2. Composition

2.1. Membership

The Non-Executive Committee members will be appointed by the Board and in normal circumstances will have clinical experience. The Executive membership will be reviewed in conjunction with the terms of reference or at any time at the discretion of the Committee Chair.

The Committee shall consist of not less than four voting members, who in normal circumstances will all have clinical experience. The number of Executive Director appointments as voting members shall not exceed the number of Non-Executive Director voting member appointments, to ensure sufficient independence.

Voting Members of the Committee:

- Clinical NED (Chair)
- Clinical NED
- Chief Nursing Officer (*Nominee for Care Quality Commission*)
- Chief Medical Officer/Director of Clinical Services

Executive Director voting members may arrange for a deputy to attend in their place if unavailable for a meeting, however the deputy shall not have voting rights, and must hold sufficient knowledge to contribute to the meeting effectively. When appointing deputies care should be taken to ensure that meetings remain quorate.

Non-Voting Members of the Committee

- Director of Quality and Governance (*Legal Responsible Person to Medicines and Healthcare products Regulatory Agency and Designated Individual for the Human Tissue Authority*)
- Director of Blood Supply
- Director of Organ and Tissue Donation and Transplantation (OTDT)
- ~~Director of Plasma~~

Regular Attendees of the Committee:

- Corporate Clinical Governance Lead / Deputy
- Chief Scientific Officer
- Assistant Director of Quality and Regulatory Compliance
- Operational Directorate Clinical Leadership Team (represented by Chief Nurse and/or Medical Director)
- Clinical Risk Lead
- Patient and Donor Safety Partners
- Company Secretary, or deputy

The following regular attendees will receive access to all meeting papers and determine whether their attendance is appropriate on a meeting-by-meeting basis:

- Consultant in Epidemiology and Health Protection
- Deputy Chief Information Officer/Chief Information Security Officer

- ~~Medical Director (MD) for each operating directorate~~
- ~~Clinical Director Microbiology and Public Health~~
- ~~Chief Nurse for each operating directorate~~
- ~~Head of Patient and Donor Safety~~
- ~~Data Security, Privacy, and Records Management Representative~~
- ~~Clinical Audit Manager~~
- ~~A representative from the People Directorate~~

~~Other attendees and observers~~

- ~~IAdditional individuals will be invited as and when required to present reports~~
- ~~Two places will be available at each meeting for shadowing/observing.~~

The Board may appoint Associate Non-Executive Directors or independent members of the Committee to fill any identified skills and experience or diversity gaps~~, however they shall not hold voting rights~~.

2.2. Committee Chair

The Committee will be chaired by the appropriate Clinical NED or a nominated NED as deputy.

2.3. Lead Executive

The Lead Executive (and Accountable Executive Director) for the Committee is the Chief Nursing Officer.

2.4. Attendees

Only members of the Committee have a right to attend Committee meetings, however, subject to the approval of the Committee Chair, the meetings shall be open to attendance by the Board Chair, NEDs or Executive Directors.

Representatives ~~of relevant~~ from Directorates may be invited by the Committee Chair, or any Committee member~~,~~ via the Company Secretary, to ~~present to, or attend to contribute at Committee meetings, either on a regular basis, or at specific times depending upon the subject matter of meetings. or~~ be in attendance for the whole meeting or specific agenda items as dictated by the subject matter. This may include, but is not limited to:

- Clinical Director, Microbiology and Public Health
- Head of Patient and Donor Safety
- Head of Data Security, Privacy and Records Management & DPO
- Clinical Audit Manager
- People Directorate representative
- Regulatory Affairs Manager

Parties external to NHSBT may also be invited by the Committee Chair to attend all, or part of a meeting, e.g. professional advisors/service providers, partners, regulators, etc.

The Committee Chair may ask any person in attendance who is not a member of the Committee to withdraw from a meeting to facilitate open and frank discussion of a particular matter.

~~Regular attendees are set out in section 2.1. Other attendees should attend only for the matter they are presenting, or that are relevant to them, as agreed by the Chair.~~

2.5. Secretary

The Corporate Governance Team overseen by the Company Secretary will provide administrative secretariat support. Duties of the secretariat will include:

- Agreement of agenda with Chair, Lead Executive and Corporate Clinical Governance Lead
- Collation and distribution of papers for meetings
- Drafting of minutes for agreement by Chair and Lead Executive
- With the Corporate Clinical Governance Lead, advising the Committee on pertinent areas and briefing the Chair as appropriate.

Scientific and clinical support to the Secretariat is provided by the Chief Nursing Officer.

3. Meeting Arrangements

3.1. Format

Meetings may be held in person, by telephone, video conferencing or in hybrid format.

3.2. Frequency

The Committee shall meet as frequently as it may determine to be necessary to complete its key tasks, with a minimum of four ~~4~~ meetings a year. ~~, and not more than 6 meetings a year~~.

Outside of the formal meeting programme, the Committee Chair will maintain a dialogue with key individuals and third parties, including the Board Chair, the Chief Executive, Executive Leads for relevant directorates and the Company Secretary.

3.3. Quorum and Decision Making

The quorum for meetings shall be three~~3~~ voting members plus the Director of Quality and Governance (or their ~~a~~ deputy ~~of the Director of Quality~~), the Director of Blood Supply (or their operational deputy) and the Director of OTDT (or their operational deputy). ~~At least 2 operational Executive Directorshall also be in present for a meeting to be quorate~~.

A duly convened meeting of the Committee at which a quorum is present shall be competent to exercise all or any of the authorities, powers and discretions vested in or exercisable by the Committee. A meeting that is inquorate may proceed, however no decisions may be made, and the minutes should reflect this.

Decisions and recommendations will be reached by consensus. The CGC should aim to reach a unanimous decision, but if this is not possible, a majority vote will be sufficient. The Chair will have a casting vote if there is a tie.

If all members agree, urgent matters arising, or decisions required, between formal meetings can be dealt with by e-mail, telephone or videoconference, with the outcomes of such exchanges formally recorded in the minutes of the next full meeting.

3.4. Notice of Meetings

Meetings of the committee shall be called by the secretary of the committee at the request of the Committee Chair or any of its members.

Unless otherwise agreed, notice of each meeting confirming the venue, time and date together with an agenda shall be circulated c. one month prior to the meeting. Papers shall in normal circumstances be circulated to each member of the Committee and any other person required to attend, no later than seven days before the date of the meeting. All papers submitted should be submitted in the format of the approved Board template.

3.5. Minutes

The Secretary shall minute the proceedings and decisions of all meetings of the Committee, including recording the names of members present and those in attendance.

Draft minutes will in normal circumstances be sent to the Executive Lead for the Committee within five working days of the meeting. The Executive Lead will review the draft within five working days, and a final draft will be sent to the Committee Chair within ten working days of the meeting. The draft minutes will be submitted for formal agreement at the next meeting.

The Committee will ensure the minutes are made available to the next private Board meeting. In exceptional circumstances, where meeting content is highly confidential and/or sensitive and not appropriate for full minutes, the Chair and Lead Executive shall decide how to record and report this to the Board.

4. Declarations of Interest

All members and attendees of the Committee must declare any relevant actual, or potential, conflicts of interest at the commencement of any meeting. This includes financial interests, non-financial professional interests, non-financial personal interests and indirect interests. (See Conflicts of Interest Policy (BLP 1) for guidance. The Company Secretary can provide advice and guidance on reporting declarations of interests.)

Members and attendees will be invited to declare any interests they might have in any issue arising at the meeting which might conflict with the business of the Committee.

The Chair of the Committee will determine if there is a conflict of interest such that the member and/or attendee will be required not to participate in a discussion. No member shall participate in decision making in relation to any matter for which they have an interest.

5. Delegated Authority, Duties and Responsibilities

5.1. Delegated Authority

The Committee has specific delegated authority from the Board in relation to the following:

5.1.1 CARE sub-groups
5.1.2 Clinical Governance Policies and Procedures
5.1.3 Clinical Performance
5.1.4 Clinical Complaints and Incidents
5.1.5 Patient Safety and Incident Reporting
5.1.6 Clinical Risk Management
5.1.7 Clinical Claims Process
5.1.8 Views of Patient, Donors, Service Users and Carers
5.1.9 National Guidance
5.1.10 Central Alerting System
5.1.11 Compliance with Care Quality Commission
5.1.12 Information Governance Committee/Caldicott Principles
5.1.13 Safeguarding
5.1.14 Management Quality Review process
5.1.15 Clinical Governance Decision Making
5.1.16 Clinical Audits

5.1.17 Clinical Training
5.1.18 Clinical Excellence and Innovation

These matters may be considered by the Committee directly or through assurance from the Clinical Quality and Safety Governance Group.

5.2. Duties and Responsibilities

The Committee shall perform the following duties in order to achieve its purpose either directly or through the Clinical Quality and Safety Governance Group:

5.2.1 Through the Clinical Quality and Safety Governance Group, Support and oversee the work of the operating directorates' CARE (Clinical, Audit, Risk and Effectiveness) groups and monitor their effectiveness and performance in achieving clinical effectiveness, including approval of the Terms of Reference and membership of Directorate CARE sub-groups.

5.2.2 Develop overarching clinical governance policies and procedures and ensure reviews are in line with their set review dates.

5.2.3 Ensure effective mechanisms are in place to review and monitor the effectiveness and quality of clinical care and services across NHSBT, including ensuring actions are taken to address issues of poor clinical performance.

5.2.4 Ensure that lessons are identified for improvement and ensure these are implemented in relevant areas.

5.2.5 Encourage a continuous improvement culture and gain assurance that systems are in place to deliver it.

5.2.6 Provide assurance to the Board that clinical complaints and incidents are managed in accordance with NHSBT procedures. This ensures that there is a robust process for serious incidents and near miss reporting, investigation and organisational learning through ensuring trends are identified, learning is shared and appropriate actions are taken.

5.2.7 Conduct a serious incident deep dive annually, in order to assure processes.

5.2.8 Gain assurance that clinical risks are managed as set out in the NHSBT Risk Management policies.

5.2.9 Have oversight of all corporate and business unit level risks with a clinical risk impact, review and challenge the actions and controls for those risks, ensure appropriate escalation of any areas of concern to the Board and highlight areas of good practice and shared learning.

5.2.10 Provide scrutiny and seek assurance from the management of the clinical claims process.

5.2.11 Promote positive complaints handling, advocacy and feedback including learning from adverse events

5.2.12 Ensure that the views of patient, donors, service users and carers are systematically and effectively engaged in clinical governance activities.

5.2.13 Ensure that systems are in place for review of external national guidance (e.g., NICE) and for ensuring compliance with relevant recommendations made.

5.2.14 Monitor alerts received via the Central Alerting System and review any actions taken in response to any relevant alerts.

5.2.15 Monitor compliance with all relevant Care Quality Commission (CQC) outcomes and the organisation's overall preparedness for CQC inspection.

5.2.16 Have oversight of and approve any significant changes to Organ Allocation policies

5.2.17 Receive reports seeking clinical advice and/or audit-related findings related to patient records, the Caldicott principles and Information Governance (IG) standards from the Information Governance Committee.

5.2.18 Review reports relating to children and adult safeguarding and gain assurance that effective management and process are in place.

5.2.19 Link into the Management Quality Review (MQR) process and have oversight of the MQR quarterly and annual reports.

5.2.20 Review and approve research proposals that relate to more than one operating directorate for which the relevant operating directorate CARE group (with expert input from the Scientific Advisory Group) have been unable to reach a decision.

5.2.21 Disseminate learning from research findings reported to relevant groups.

~~5.2.21~~5.2.22 Review examples of clinical services excellence and innovation across CQC domains, ensuring care is safe, effective, caring, responsive and well-led.

~~5.2.22~~5.2.23 Ensure that clinical governance decision making is informed by evidence-based information and research contributions from the Scientific Advisory Committee (SAC) overseeing the NHSBT Research and Development programme and partnerships.

~~5.2.23~~5.2.24 Through the Clinical Quality and Safety Governance Group, seek assurance from the Directorate CARE groups that practice is evidence-based and supported by a robust process of clinical audit.

~~5.2.24~~5.2.25 Oversee and prioritise the clinical audit work plan and ensure that the schedule is aligned with internal audits and that it triangulates themes from risks, incidents, complaints, clinical claims and patient/donor feedback.

~~5.2.25~~5.2.26 Review summaries of clinical audit findings and gain assurance that the recommendations and their implementation by operational directorate CARE groups will focus on identifying any concerns or

significant issues and/or where no improvements have been made since the last audit; and gain assurance that the action plan in response to the audit is implemented without undue delay, especially where limited assurance is given.

~~5.2.26~~5.2.27 Ensuring that an appropriate process of revalidations is in place for medical and nursing staff~~Ensure that best clinical practice is provided by appropriately trained and skilled professionals with the competencies required for service delivery including ensuring that an appropriate process of revalidations is in place and operating effectively for medical, nursing and scientific and professional posts~~.

~~5.2.27~~5.2.28 Monitor the education and development system for the clinical workforce that supports performance improvement within their scope of practice.

~~5.2.28~~5.2.29 Ensure adequate resources are allocated to support the provision of safe and responsive care and services.

~~5.2.29~~5.2.30 Provide the Board with regular clinical effectiveness updates and exception reports.

~~5.2.30~~5.2.31 Provide the Board with an annual report of work undertaken, providing positive assurance that clinical governance mechanisms are in place and effective and highlighting key concerns; meeting the terms of reference for the committee and supporting the annual Governance Statement. This annual report should cover key findings from the programme of audits and the proposed plan for the subsequent year. This report should also be shared with the ARG Committee for information.

~~5.2.31~~5.2.32 To note safety policies affecting NHSBT and undertake a review of the internal safety policy decision making ~~and~~ framework (i.e., through Therapeutic Product Safety Group (TPSG). To agree a~~A~~ny changes to the organ allocation policies in OTDT~~, the policies that should come to CGC for oversight~~.

~~5.2.32~~5.2.33 Support and oversee the work of the Clinical Quality and Safety Governance Group and monitor its effectiveness and performance in achieving clinical effectiveness, including approval of the Terms of Reference and receiving an annual report of work undertaken~~and membership of Group~~.

~~5.2.33~~5.2.34 The Committee will consider any other relevant matters where requested to do so by the Board, e.g. delivery of Infected Blood Inquiry recommendations.

6. Risk and Assurance

The Committee will monitor the organisation's progress in managing clinical risks and principle and contributory risks relevant to its remit. At least annually they will undertake a deep dive into such risks and assess progress in relation to the mitigation of the risks.

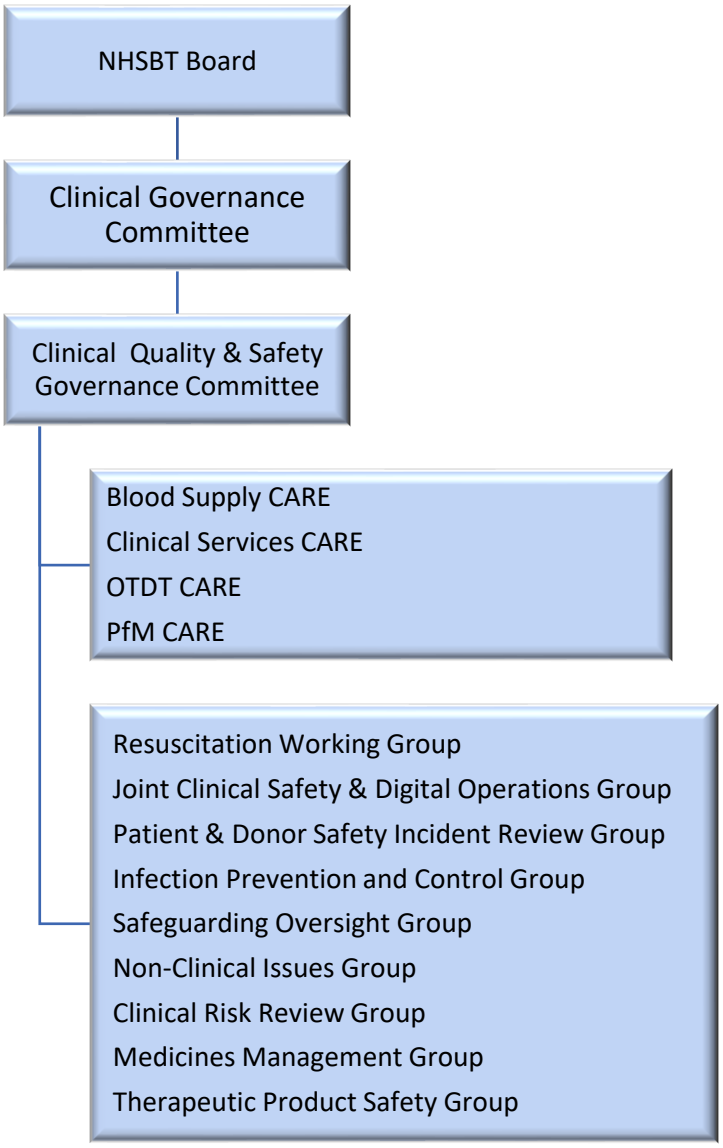
As at the date of approval of these Terms of Reference, the risks monitored by the Committee include:
P-01 Donor and Patient Safety ~~Harm to a donor or patient~~
P-06 Clinical Outcomes and Health Inequalities ~~Failure to monitor clinical outcomes~~

The Committee will also approve, or recommend to the Board for approval, Board Level Policies and will receive assurance reports in relation to compliance with regulatory and statutory duties related to matters delegated to it.

The Committee will receive internal audit reports in relation to areas under its remit, and will monitor progress in completing management actions related thereto.

7. Reporting Responsibilities

7.1. Reporting Structure



The CGC is a Committee of the NHSBT Board and therefore obtains its authority from the NHSBT Board and reports on its activities to the NHSBT Board and will escalate any major concerns in a timely manner.

The CGC has the Clinical Quality & Safety Governance Group (CQSGG) reporting directly to it, the CQSGG has the groups shown above reporting to it.

Clinical Governance reporting periods are aligned to ensure structured flow of information to the Board~~. For example, the January Clinical Governance meeting would have a reporting period of October-November and be reflected at the December Directorate CARE Groups. Exception reporting is included for patient and donor incidents investigations or other urgent clinical governance issues.~~

~~The Directorate CARE reports submitted to the CQSGG should cover specific areas corresponding to the reporting period. The structure of these reports should be aligned, and the Board template applied.~~
~~As a guide the Directorate reports should include, where applicable:~~

- ~~Status - public or confidential~~
- ~~Executive Summary - Key details of the report~~
- ~~Action Requested~~
- ~~Clinical Risks~~
- ~~Clinical Incidents or Events~~
- ~~Patient and Donor Safety Incidents Investigations (PSII) – An overview of PSII plus a separate report for any open PSII~~
- ~~Clinical Complaints or Commendations~~
- ~~Research Requests/ Approvals (by exception)~~
- ~~Inspections and Relevant Findings~~
- ~~Applicable New Policies, Alerts and Guidelines~~
- ~~Relevant Clinical Audits~~
- ~~Clinical Claims.~~

~~The Chair of the Therapeutic Products Safety Group (TPSG) should provide an update report to each CQSGG meeting, with a focus on key decisions taken. TPSG meetings will be scheduled prior to the CQSGG meeting which in turn will be scheduled prior to the Clinical Governance Committee in order that the CQSGG can report significant matters and escalate as required to the Clinical Governance Committee and the terms of reference reflect reporting into the Committee.~~

~~Safeguarding Incidents will be reported by exception via the Safeguarding Oversight Group via the CQSGG.~~

The Committee will either ~~re~~receive the following annual reports or an overview of them ~~view these annual reports either directly or~~ via the CQSGG, highlighting areas of risk or non-compliance:

a) Clinical audit
b) Safeguarding,
c) TPSG (to include review of safety framework),
d) Clinical claims,
e) Director of Infection Prevention and Control (DIPC)
f) Patient and Donor Safety Incident Investigations
g) PSIRF Implementation Plan
h) SHOT (Serious Hazards of Transfusion haemovigilance) summary,

i) Joint NHSBT/ UK Health Security Agency (UKHSA) epidemiology summary
j) ODT biovigilance report
k) Scientific Advisory Committee (SAC) report
l) Education, training, competencies and appraisals.
m) Medical Appraisal and Revalidation
n) Management Quality Review (MQR)
o) Regulatory Radar
p) Information Governance (inc Toolkit submission Report)
q) Non-Clinical Issue report
r) Nursing Revalidations Annual Report
s) Scientific and Professional Revalidations Annual Report

7.2. Post Meeting Reporting

The Chair of the CGC will formally report to the Board, in private session, on its proceeding after each meeting. The Chair of the Committee will draw to the attention of the Board any issues that require disclosure to the full Board or require Executive action. The Committee shall make whatever recommendations to the Board it deems appropriate on any area within its remit where action or improvement is needed.

The Chair of the Committee will also provide a report on its activities, after each meeting, for the Board to publish within its papers for its next public meeting.

~~To ensure the flow of papers up to the Board is efficient and effective, the schedule of meetings is Directorate CARE groups and other committees as highlighted in section 7.1 to the CQSGG, the CQSGG to the Clinical Governance Committee, the Clinical Governance Committee to the Board.~~

7.3. Annual Reporting

In line with the annual reporting year, the Committee Chair will provide an Annual Report to the Board on how it has discharged its responsibilities, including:

- The Committee membership, the frequency of meetings and levels of attendance of members,
- Business conducted by the Committee during the year of the report,
- Risks monitored by the Committee,
- Internal Audit activity in the year related to remit of the Committee,
- Gaps in assurance identified, if any,
- Confirmation of review of Terms of Reference and any recommendations,
- Confirmation of review of effectiveness and summary of findings/actions agreed,
- A statement of whether the Committee is satisfied that it has discharged its responsibilities.

The Committee shall also compile a short report on its activities to be included in NHSBT's Annual Report to describe the work of the Committee.

8. Authority

The Committee is authorised by the Board to investigate any activity within its terms of reference.

The Committee is authorised to create sub-groups or working groups as are necessary to fulfil its responsibilities within its terms of reference. The Committee may not delegate executive powers (unless expressly authorised by the Board) and remains accountable for the work of any such group.

The Committee has the authority to request and review reports and assurances from management in order to undertake its duties and achieve its overall purpose.

The Committee is authorised by the Board to:

- obtain, at NHSBT's expense, reasonable external legal or other independent professional advice on any matter within its terms of reference (subject to budgets agreed by the Board), and liaising through the Company Secretary, in relation to whether such advice can be provided internally, or the best procurement of such advice.

- seek any information it requires, and/or to secure the attendance of non-members (internal and external to NHSBT) with relevant experience and expertise if it considers this necessary in order to perform its duties.

9. Terms of Reference and Effectiveness Reviews

9.1. Terms of Reference

The Committee will review its Terms of Reference on an annual basis, or earlier if required, and make such recommendations to the Board as are required to take into account changes to laws or regulations together with organisational changes be they strategic, structural, technological or operational.

9.2. Committee Effectiveness

A work programme which reflects the Committee's accountabilities, responsibilities and risks arising from the clinical risk register will be maintained and monitored, and reviewed annually, or earlier if required.
The Committee will, on an annual basis, review its work programme, performance and evaluate any support or development needs, and review its effectiveness, to include a gap analysis of its work during the year compared to the duties set out within the Terms of Reference, and consideration of the following:

- Membership, independence and objectivity
- Skills and experience
- Roles and responsibilities
- Communication and reporting
- Continual improvement.

and recommend any changes to the Board. The results of the effectiveness review and delegations review will be reported to the Board.

10. Other Matters

10.1 External and Internal Audit Access to Committee

Appropriate external and internal auditors, as agreed by the Board, shall have the right of direct access to the Committee for the purposes of auditing its work and effectiveness.

10.2. Resources

The Committee will have access to sufficient resources to carry out its duties, including access to the Company Secretary and the Corporate Governance Team, for assistance as required.

10.3. Training and Development

Members of the Committee shall be provided with appropriate and timely training, both in the form of an induction programme for new members and on an ongoing basis for all members. Training needs shall be identified through the annual skills and capability assessment, the Director appraisal process and through discussion with the Committee Chair.

Version Control and RACI view

Version	Approved by and basis of changes	Approved Date	Effective Date	Date of Next Review
3.0	Committee and Board Reformatting to provide a consistent format for all Board Committees. Addition of clauses to meet best practice. Clarity on members and voting rights and quorum. Addition of intended Clinical Quality and Safety Governance Group.	30/07/2024	30/07/2024	Within a year
4.0	Committee and Board Updates to quorum and attendees. Specific reference inserted to IBI. Revalidation delegation amended. BAF references updated. Reference to administration streamlined.	(insert July Board date when approved)		

(R) Responsible	Chief Nursing Officer / Company Secretary
(A) Accountable	Chair of Clinical Governance Committee / Chief Nursing Officer
(C) Consultees	Chief Nurse Clinical Services/Corporate Clinical Governance Lead and Head of Clinical Governance – Clinical Services
(I) Informed	Directors / Clinical Governance Teams/Groups - Terms of Reference available on website