

Other Ethical Considerations

Although clinical audit projects may not require ethical approval, the following must be considered:

The audit should do good and not cause harm.

Do not audit the work of others without their knowledge.

Minimise disturbance to patients/donors – discuss intrusive data collection methods (e.g. questionnaires, interviews) with senior audit staff.

Respect the wishes of patients/donors at all times. Provide written information and an opportunity to withdraw.

Ensure samples are representative and inclusive of the audit population

Pay due regard to explicit patient/donor wishes (e.g. do not contact donors with 'Do Not Contact' on their record).

All health professionals are responsible for their performance and should act on audit findings


Important Further Reading

For full guidance on ethics and confidentiality in clinical audit, consult:

- **Undertaking Clinical Audit Involving Third Party Organisations (MPD406)**
- **Ethics & Clinical Audit in NHSBT (POL133)**
- **Indicators for Best Practice in Clinical Audit (INF435)**
- **Sharing Protocol for Clinical Audit within NHSBT (FRM1272)**
- **NHS Code of Confidentiality – Department of Health:** <https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice>
- **Caldicott Principles:** <https://www.gov.uk/government/publications/caldicott-information-governance-review-department-of-health-response>
- **Data Protection Act:** <https://www.gov.uk/data-protection/the-data-protection-act>

Contact Us

For advice or support on any aspect of clinical audit at NHSBT, contact the Clinical Audit Team: clinical.audit@nhsbt.nhs.uk

 <https://nhsbloodandtransplant.sharepoint.com/sites/Clinical/SitePages/Clinical%20Audit.aspx>

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Clinical Audit Ethics and Confidentiality:

Conducting audits responsibly and ethically within NHSBT

This leaflet covers the ethics and confidentiality around clinical audit.






Clinical audit does not normally require formal ethical approval because it involves no changes to patient or donor care beyond routine management. However, it must still be conducted within an ethical framework that respects consent, confidentiality, and the responsible disclosure of results.

Ethics and Clinical Audit

Ensure the project is genuinely a clinical audit and not research.

Research projects involving patients or donors always require formal ethical approval.

Clinical audit should never involve:

-  Experiments on patients or donors
-  Comparing new and old treatments
-  Randomisation or control groups

If uncertain whether a project is research or audit, seek advice from the Clinical Audit Team. Calling a project 'audit' does not remove the requirement for ethical approval if it is actually research.

Confidentiality and Clinical Audit

All NHS staff have a personal and legal duty to keep patient and donor information confidential.

Key principles include:



The **Data Protection Act 2018** applies to all data relating to living individuals (paper and electronic).



Caldicott Principles set out best practice for handling confidential information.



All audit information should be anonymised to remove identifiers (name, NHS number, date of birth, etc.).



Personal information collected for clinical audit must not be used for other purposes.



The Project Lead is responsible for ensuring all team members understand and follow confidentiality rules.

Disclosure of Clinical Audit Results

Under the **Freedom of Information Act (2000)**, anyone can request copies of clinical audit reports.

SO....

- ✓ Ensure reports contain no identifiable information about patients/donors or clinicians.
- ✓ Obtain stakeholder approval before presenting audit results.
- ✓ Store, handle, and destroy information in line with NHSBT best practice policies.
- ✓ For collaborative audits involving external patient records, obtain permission from the relevant Hospital/NHS Trust Caldicott Guardian and follow the NHSBT Sharing Protocol.

Blood donors consent to the use of their records for clinical audit purposes when they sign the Donor Safety Check. Additional permissions are required for sharing information outside NHSBT.