**Guidance on Clinical Audit**

CLINICAL AUDIT VERSUS RESEARCH: WHAT IS THE DIFFERENCE?

“Research is concerned with discovering the right thing to do; audit with ensuring that it is done right” Smith R. Audit & Research. BMJ 1992; 305: 905-6

Clinical Audit must always be conducted within an ethical framework. This means ensuring patient and staff confidentiality and ensuring data is collected and stored appropriately in accordance with the following pieces of legislation and national guidance: [Caldicott Principles](https://www.gov.uk/government/publications/the-caldicott-principles) (2020); [Data Protection Act](https://www.gov.uk/data-protection) (2018); [NHS Confidentiality Code of Practice](https://www.gov.uk/government/publications/confidentiality-nhs-code-of-practice) (2003).

However, whilst clinical audit by definition does not involve anything being done to patients beyond their routine clinical management and therefore does not require formal ethics approval, it should still be conducted within an ethical framework. By registering a project as a clinical audit, the Trust is stating that the project fulfils the methodological criteria that allows for patient data to be accessed and analysed.

* **1. IS YOUR PROJECT REALLY A CLINICAL AUDIT PROJECT?**

Decisions about whether projects need ethics approval often hinge on whether they really are clinical audit, or whether they are actually research. Clinical audit asks the questions “are we following best practice?” and “what is happening to patients as a result?” Clinical audit projects never involve:

* + A new treatment or practice.
	+ The use of control groups or placebo treatments.
	+ Any disturbance to the patient beyond that required for routine clinical management.
	+ Allocating patients randomly to different treatment groups.
* **2. DOES YOUR PROJECT INCLUDE A PATIENT SURVEY?**

Patient surveys can be construed as doing something to patients ‘beyond normal clinical management’. It is therefore important to take advice on the design of patient surveys. Planned questions could touch upon potentially sensitive matters, giving rise to ethical concerns. Any patient surveys should be designed in such a manner as to cause minimum possible disruption to patients.

* **3. ARE YOU PLANNING TO PUBLISH?**

Clinical Audits are usually published because the topic and/or methodology may be of interest to a wider audience, for instance, demonstrating how an audit cycle was successfully followed after initially poor results against standards, by implementing changes and demonstrating an improvement in practice with a re-audit. Whilst clinical audit projects may be published without ethics approval increasingly, journal editors may refuse to publish articles if there are ethical concerns and ethics approval has not been granted. Please ensure that you find out if this will be a requirement by speaking with the journal/funder and contacting the BSMS Research Governance and Ethics Committee ahead of time. \***Ethics approval cannot be granted retrospectively by the committee\***

Sometimes healthcare professionals undertake what they mistakenly think is ‘clinical audit’, when what they are really doing is research. Research always requires ethics approval. Calling research by any other name does not remove this requirement.