

April 2007

DIFFERENTIATING AUDIT, SERVICE EVALUATION AND RESEARCH

A discussion document was drafted and distributed to the NRES ethics e-group.

10 replies were received and their comments considered before amending the document. Thanks to all who replied. We took account of their comments and reviewed the attached table with the Department of Health.

CONCLUSIONS and SUMMARY

The starting point is that it is not the remit of Research Ethics Committees to review all NHS activities that have ethical implications, but only those presented and managed as R&D.

However, the **taxonomy** (Is this work "Research", "Audit" or "Service Evaluation"?) was of less concern to the correspondents than the **consequences** for those involved in the project, particularly patients and other service users and carers. Many regarded the taxonomy as a surrogate marker for the level of risk in any project. Audit and Service Evaluation, however defined, were recognised to have no, or minimal risk, and there was broad agreement that such work need not come before a full committee meeting of an NHS REC, unless specifically requested.

This taxonomy serves a purpose. It **could** be replaced when there is an agreed methodology that classifies projects according to consequences. This would first have to be accepted by patients, clinicians, reviewers and regulators.

The table that was presented in the draft was broadly accepted, recognising that no watertight definitions could ever be provided. Judgement, on occasions, will be needed.

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A table for researchers and reviewers to use and for the “queries line” to refer to (modified from published literature)

RESEARCH	CLINICAL AUDIT	SERVICE EVALUATION
The attempt to derive generalisable new knowledge including studies that aim to generate hypotheses as well as studies that aim to test them.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted solely to define or judge current care.
Quantitative research – designed to test a hypothesis. Qualitative research – identifies/explores themes following established methodology.	Designed to answer the question: “Does this service reach a predetermined standard?”	Designed to answer the question: “What standard does this service achieve?”
Addresses clearly defined questions, aims and objectives.	Measures against a standard.	Measures current service without reference to a standard.
Quantitative research - may involve evaluating or comparing interventions, particularly new ones. Qualitative research – usually involves studying how interventions and relationships are experienced.	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)	Involves an intervention in use ONLY. (The choice of treatment is that of the clinician and patient according to guidance, professional standards and/or patient preference.)
Usually involves collecting data that are additional to those for routine care but may include data collected routinely. May involve treatments, samples or investigations additional to routine care.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.	Usually involves analysis of existing data but may include administration of simple interview or questionnaire.
Quantitative research - study design may involve allocating patients to intervention groups.	No allocation to intervention groups: the health care professional and patient have chosen intervention	No allocation to intervention groups: the health care professional and patient have chosen intervention

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RESEARCH	CLINICAL AUDIT	SERVICE EVALUATION
Qualitative research uses a clearly defined sampling framework underpinned by conceptual or theoretical justifications.	before clinical audit.	before service evaluation.
May involve randomisation	No randomisation	No randomisation
ALTHOUGH ANY OF THESE THREE MAY RAISE ETHICAL ISSUES, UNDER CURRENT GUIDANCE:-		
RESEARCH REQUIRES REC REVIEW	AUDIT DOES NOT REQUIRE REC REVIEW	SERVICE EVALUATION DOES NOT REQUIRE REC REVIEW