The following operational definitions Research, Clinical Audit, Service Evaluation and Service Improvement activity have been agreed between the Trust's Clinical Governance Manager, Research & Development Manager and Head of Innovation (September 2007).

	Research	Clinical Audit	Service Evaluation	Service Improvement
Definition	Aims to derive new knowledge which is potentially generalisable or transferable. Asks the question – "what is best practice?"	Aims to improve the quality of local patient care and clinical outcomes through peer-led review of practice against evidence-based standards and the implementation of change where subsequently indicated. Asks the questions – "are we following best practice?" and "what is happening to patients as a result?"	Aims to judge a service's effectiveness or efficiency through systematic assessment of its aims, objectives, activities, outputs, outcomes and costs. In different contexts, may also be referred to as "activity analysis", "benchmarking", "organisational audit", "non-clinical audit", etc. Asks questions like – "has this service been a success?" May also be used to compare the effectiveness or efficiency of a new practice/service (where supported by evidence) with an existing one - however this would be for the purposes of local comparison, i.e. not with a view to derive generalisable or transferable results (which would be research). Whilst benchmarking may be used to compare services, the evaluation will not involve measurement against agreed standards (which would be clinical audit)	Aims to improve patient care through continuous improvement of clinical outcomes and patient experience through group-led activity which focuses explicitly on quality and safety as routes to improving services, whilst also delivering essential productivity and efficiency gains. In different contexts may also be referred to as "service development". Asks questions like – "how can we make this service safer, more efficient, better for patients?"
Initiated by	Usually initiated by researchers.	Initiated by national bodies (e.g. Healthcare Commission, Royal Colleges, NICE, etc), commissioners (PCTs) or service providers (including local healthcare staff and managers)	Usually initiated by service managers/leads.	Initiated in numerous ways: • as a corporate priority to support the delivery of the Trust's objectives • as part of a national initiative (e.g. DH, NHS Institute for Innovation & Improvement) • by individuals and/or teams in a department or speciality area • by service managers and/or clinical lead

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Methodology & Design	Addresses clearly defined questions / hypotheses using systematic and rigorous processes. Designed so that it can be replicated and so that its results can be generalised to other similar groups.	Addresses clearly defined audit questions using robust methodology – usually asking whether a specific clinical standard has been met. Results are specific and local to a particular team or service although the audit tool may be used by more than one team/service	Addresses specific questions about the service concerned. Results are specific and local to a particular team or service although the evaluation tool may be used by more than one team/service.	The approach includes: • Awareness and engagement of individuals/teams so that there is agreement that improvement is necessary/possible • Analysis of the current process/pathway highlighting areas that cause unnecessary waits and delays for patients and are wasteful of staff time • Understanding the bottlenecks, existing demand on the process and current capacity to deliver, as well as the variation that exists within the process • Designing the desired future process/pathway and agreeing the steps needed • Developing a project implementation plan that gets us to the future state • Ensuring the changes are sustained and that there is continuous improvement.
Coverage	Research projects may be service-specific, trust-wide, regional or national.	Clinical audit projects may be service-specific, trust-wide, regional or national.	Service Evaluation projects may be service-specific, or trust or community-wide.	Service improvement projects can be patient pathway specific, service/specialty specific, trust-wide, health and social care economy wide, regional or national
New treatments	May involve a completely new treatment or practice	Will never involve a completely new treatment or practice.	Will never involve a completely new treatment practice (but see Definition box above).	Will never involve a completely new treatment or practice.
Controls & Placebos	May involve use of control groups or placebo treatment for purposes of comparison	Will never involve use of control groups or placebo treatment	Will never involve use of control groups or placebo treatment	Will never involve use of control groups or placebo treatments

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Patient involvement	May involve allocating service users randomly to different treatment groups.	May involve input from patients at a number of levels, e.g. • Patients may be asked to participate in surveys which help to determine whether standards have been met • Patients may be involved in the design of individual audit projects or indeed whole programmes of activity (e.g. as members of steering groups) Never involves allocating patients randomly to different treatment groups.	May involve input from patients at a number of levels, e.g. • Patients may be asked to participate in surveys which help to determine the effectiveness or efficiency of a service • Patients may be involved in the design of individual projects or indeed whole programmes of improvement activity (e.g. as members of steering groups) Never involves allocating service users randomly to different treatment groups.	May involve input from patients at a number of levels: • Patients may be asked to participate in surveys which help to determine the effectiveness or efficiency of a service • Systematic use of tools such as discovery interviews, patient diaries etc. and on-going feedback mechanism through patient involvement in redesign and service user groups • Patients may be involved in the design of individual projects to ensure the needs of different groups are met (equality and diversity issues). Never involves allocating service users randomly to different treatment groups.
Governance arrangements	Must comply with Research Governance	Must be registered with Clinical Audit Team (and therefore implicitly have been approved by the relevant Clinical Audit Convenor). Use of patient survey methodologies as part of clinical audits is also subject to approval by the Trust's Questionnaire Interview & Survey Group (QIS).	UBHT does not have a department of Service Evaluation; nor does it have known expertise in this field (September 2007). If Service Evaluation activity is undertaken via the Clinical Audit Team or the Research & Development Department, it will be subject to the scrutiny and advice of those teams, however it should be noted that neither team currently has expertise in the field of Service Evaluation. A proposal has been agreed to create a 'projects' database which will attempt to capture non-clinical audit and non-research activity in one place. This should enable Divisions to monitor project activity via their local governance arrangements, and for the Trust to capture additional evidence in support of compliance with Core Healthcare Standard C5d. Use of patient survey methodologies as part of service evaluations is also subject to approval by the Trust's Questionnaire Interview & Survey Group (QIS).	Delivery of the improvement programme is overseen by the Innovation Board and objectives relating to improving performance are monitored at the Trust Operational Group. Use of patient survey methodologies as part of service improvement activity is also subject to approval by the Trust's Questionnaire Interview & Survey Group (QIS).

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Ethical Approval required?	Research ethics committee (REC) approval required	Should be scrutinised for ethical implications but REC approval not needed	Should be scrutinised for ethical implications but REC approval not needed	Should be scrutinised for ethical implications but REC approval not needed
End product	Generates evidence to refute, support or develop a hypothesis. May lead to development of new services or new practices.	Generates evidence to demonstrate level of compliance with agreed standards. This may lead to changes in practice.	Generates evidence of effectiveness of a service which may lead to service redesign and reconfiguration.	• Generates evidence of improvements by comparing new service performance against the baseline position at the start of the project. • Generates ideas for continuous improvement • Demonstrates skills transfer, in terms of individuals and teams understanding and applying the methodology
One-off or ongoing?	Will often be a one-off study.	May be one-off, however approximately 25% of Trust audit activity involves re-audit (seeking to confirm improvements in practice). Some National Audits involve continuous data collection.	Usually a one-off study, but may be repeated to compare changes over time	On-going. The approach promotes sustaining the improvements made and identifying new opportunities for improvement to develop a culture of continuous improvement