This table describes the key characteristics of research, service evaluation, audit and health surveillance projects in order to assist with deciding how a project should be managed. Each of these project types has their own separate governance requirements which you will need to arrange before starting the work. A programme of work may involve more than one project type, but each individual project within the programme should sit clearly under one column. If you find that your planned project spans more than one column, it is likely that its scope and purpose is not defined clearly enough. Consider making revisions to the project design to ensure that it clearly sets out what you want to achieve, and the methodology you will use.

	RESEARCH*	SERVICE EVALUATION / IMPROVEMENT / DEVELOPMENT	CLINICAL/ NON-FINANCIAL AUDIT	HEALTH SURVEILLANCE
PURPOSE	A key feature of research is that it is intentionally planned and designed using documented methodology which will allow results to be extrapolated or applied from the study sample to a larger population. This extrapolation / application is what the terms 'generalisable' and 'transferable' refer to. In the case of quantitative research, statistical methods are used to achieve results that are 'generalisable' from a sample to the sampled population. In the case of qualitative research, the context and findings are described and defined so that the conclusions can be applied or transferred to other settings.	Designed and conducted solely to define or judge current care or service, or to deliver and measure improvements in quality of the current service.	Designed and conducted to produce information to inform delivery of best care.	Designed and conducted to assess priorities, evaluate interventions, and detect and manage threats to health and adverse health status (including incidents, risk factors, hazards, outbreaks and epidemics, may also address health inequalities).
QUESTION/ HYPOTHESIS	Aims to generate a new hypothesis or test a hypothesis. The approach to this may be quantitative, qualitative or both.	Service evaluation is designed to answer the question: "What standard does this service achieve?" This is normally addressed by asking those in receipt of the service. Service development or improvement seeks to find out what improvement can be achieved within that service only.	Designed to answer the question: "Does this service reach a predetermined, recognised or pre- established standard?"	Designed to answer the questions: "Is there a need to start, continue or stop defined public health interventions", or "Is there need for further investigations", or "What is the cause of this outbreak (often of a disease) or incident and how do we manage it?"
AIM	Has clearly defined aims and objectives. The project seeks to answer a specific research question or questions.	Measures current service without reference to a standard. (In the case of service improvement / development the current service may be compared to the previous service).	Measures against a standard.	Measures against historical (or geographical) comparators and/or defined levels (triggers) for action. Systematic, quantitative or qualitative methods may be used.
INTERVENTIONS	May involve evaluating or comparing interventions, particularly new ones. Not all research involves interventions.	Service evaluation involves an intervention or service already in use only. Service improvement or development involves a new intervention or service, or one that is new to that context. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/ service user preference.	Involves an intervention or service already in use only. The choice of treatment, care or services is that of the care professional and patient/service user according to guidance, professional standards and/or patient/service user preference.	Intervention (if relevant) in use only. Any choice of intervention, treatment, care or services is based on best public health evidence or professional consensus, but may also be used to assess the need for an intervention when none is being taken currently.

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DATA	Usually involves collecting data that are additional to those for routine care or service (but not always). May involve comparing data on treatments, samples or investigations additional to routine care. May involve data collected from interviews, focus groups and/or observation.	Usually involves analysis of existing data but may also include administration of interview(s) or questionnaire(s).	Usually involves analysis of existing data but may include administration of simple interviews or questionnaires.	May involve analysis of existing routine data supplied under licence, agreement or administration of interview or questionnaire to those in the population of interest. This includes collection of data on hazards, exposures and other data to enable interpretation of issues relevant to the population rather than the individual. May also require evidence review.
PARTICIPANT ALLOCATION	Quantitative research study design may involve allocating patients/service users/healthy volunteers to an intervention. Purely qualitative research does not usually involve allocating participants to an intervention.	No allocation to intervention: the care professional and patient/service user have chosen intervention independently of the service evaluation / improvement / development.	No allocation to intervention: the care professional and patient/service user have chosen intervention before audit.	Not applicable. Collects data on issue of concern <i>in situ</i> . May involve allocation to control group to assess risk and identify source of incident, but no allocation to intervention.
RANDOMISATION	May involve randomisation.	May involve randomisation for sampling, but not for treatment/ care/ intervention.	May involve randomisation for sampling, but not for treatment/ care/ intervention.	May involve randomisation for sampling, but not for treatment/ care/ intervention.
NHS REC review required?	Normally requires NHS REC review but not always. Refer to <u>http://hra-</u> <u>decisiontools.org.uk/ethics/</u> for more information.	Does not require REC review.	Does not require REC review.	Does not require REC review.

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*The UK Policy Framework for Health and Social Care Research defines research as:

"3.1 For the purpose of this policy framework, research is defined as the attempt to derive generalisable or transferable¹ new² knowledge to answer or refine relevant questions with scientifically sound methods³. This excludes audits of practice and service evaluations. It includes activities that are carried out in preparation for or as a consequence of the interventional part⁴ of the research, such as screening potential participants for eligibility, obtaining participants' consent and publishing results. It also includes non-interventional health and social care research (i.e. projects that do not involve any change in standard treatment, care or other services), projects that aim to generate hypotheses, methodological research and descriptive research. Projects whose primary purpose is educational to the researcher, either in obtaining an educational qualification or in otherwise acquiring research skills, but which also fall into the definition of research, are in scope of this policy framework. Activities that are not research according to this definition should not be presented as research and need not be conducted or managed in accordance with this framework. A decision tool that provides a definitive answer about whether a project counts as research under this policy framework is available at <u>www.hra-decisiontools.org.uk/research</u>.

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¹ NB This definition involves an attempt at generalisability or transferability, i.e. the project deliberately uses methods intended to achieve quantitative or qualitative findings that can be applied to settings or contexts other than those in which they were tested. The actual generalisability or transferability of some research findings may only become apparent once the project has been completed.

² Including new knowledge about existing treatments or care.

³ Projects that are not designed well enough to meet this definition are not exempt from this policy framework – see paragraph 9.10.a.

⁴ This means the part of the research where a change in treatment, care or other services is made for the purpose of the research. It does not refer to other methodological 'interventions', e.g. issuing a postal survey.