GDPR Assessment Table - to assist in determining if you are conducting Clinical Audit, Service Evaluation, Research, Healthcare Record Review or collecting data for a Clinical Register and how the purpose relates to GDPR, Data Protection Act 2018 (including the Research Regulations 2018)

	Clinical Audit	Service Evaluation	Health Care Record Review	Clinical Registers	Research
Definitions	'Clinical audit is a clinically-led quality improvement process that seeks to improve patient care and outcomes through systematic review of care against explicit criteria, and acting to improve care when standards are not met. The process involves the selection of aspects of the structure, processes and outcomes of care which are then systematically evaluated against explicit criteria. If required, improvements should be implemented at an individual, team or organisation level and then the care re-evaluated to confirm improvements.' DOHC (2008)	'Service evaluation seeks to assess how well a service is achieving its intended aims. It is undertaken to benefit the people using a particular healthcare service and is designed and conducted with the sole purpose of defining or judging the current service'. Shorten & Twycross (2014 p.65)	A Healthcare Record Review is where pre-recorded, person-centred data are used to answer one or more questions. The review is not part of direct patient care. A healthcare record review may be carried out for a number of purposes including clinical audit, research, or incident review. The purpose will dictate the governance structures to be followed. It may be also be referred to as a chart review or case review.	'A registry (in a clinical setting) is described as a system which collects a defined minimum data set from patients with a particular disease, undergoing a particular procedure or therapy, or using a health care resource'. Hoque et al (2019)	Research is designed and conducted to generate new generalisable or transferrable knowledge. It includes both quantitative and qualitative studies that aim to generate new hypotheses as well as studies that aim to test existing or new hypotheses'. HRB (2019)
Assessment Criteria	Did care meet the standard yes/no? • Measuring against explicit standards Non randomised population (all patients meeting criteria of audit) • No allocation to intervention - change to care of the patient	Did the service meet your expectations e.g. Patient Experience Survey • No explicit standards • Non randomised population (all patients meeting criteria of audit)	Why are you going into the chart? • Assessing the context of care, peer review, look back review, incident review, judging the context of care • The purpose will dictate the assessment steps to be followed.	System for collecting data on patients who meet criteria of register • List of patients who meet criteria for the register. Their consent status and their clinical information • Non randomised population	A research question exists that may generate new knowledge • Can be randomised • The outputs from clinical audit and/or service evaluation do not answer the research question without further analysis or additional information from other sources

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GDPR and DPA 2018 **Legal Basis**	• Article 6(1)(c) GDPR "processing necessary for performance of contract" with the data subject, or Article 6(1)(e) – 'processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller, or Article 6(1)(f) – processing is necessary for the purposes of legitimate interests. • Article 9(2)(h) GDPR– 'processing is necessary for the purpose of preventative…medicine…the provision of health or social care or treatment or the management of health or social care systems and services…' or Article 9(2)(i) – 'processing is necessary for reasons of public interest in the area of public health, such as…ensuring high standards of quality and safety of health care…' • Consent is not required if there is another other legal basis more appropriate to use • Data Protection Act 2018, Section 52(1) (a) – 'for the purposes of preventative or occupational medicine', Section 52(1) (d)' for the provision of medical care, treatment or social care' and/or Section 52(1)(e) for the management of health or social care systems and services' which allows patient information to be used for clinical audit provided that appropriate measures are taken to safeguard the fundamental rights of the data subject. • Data Protection Act 2018, Section 53(b) – 'ensuring high standards of quality and safety of health care…'			Consent is required unless a mandatory register with an opt out option	Consent is required unless HRBCDC exemption received
Research regulations	Not applicable in gathering the data for Clinical Audit	Not applicable in gathering the data for Service Evaluation	Yes - Depends on the purpose the health care record review is performed	Not applicable in gathering the data for Clinical Register	Yes
Research Ethics Committee (REC) Approval	Not required	Not required	As above	Not required	Yes
Presenting findings	Findings should be aggregated and not identify individuals				As per Research Ethics Committee Approval
Using the Data collected for Clinical Audit, Service Evaluation for Research?	• If data is totally anonymous then GDPR and/or Research Regulations do not apply as the data is no longer considered personal data. • If the data is held in pseudonymised format then consideration needs to be given to who holds the key (link back) to identify the patients. If the person carrying out the research has access link datasets or to re-identifying the patients then this would fall under the Research regulations and consent or consent exemption would be required. • If data is identifiable then GDPR and Research Regulations do apply.				