



Feidhmeannacht na Seirbhíse Sláinte
Health Service Executive

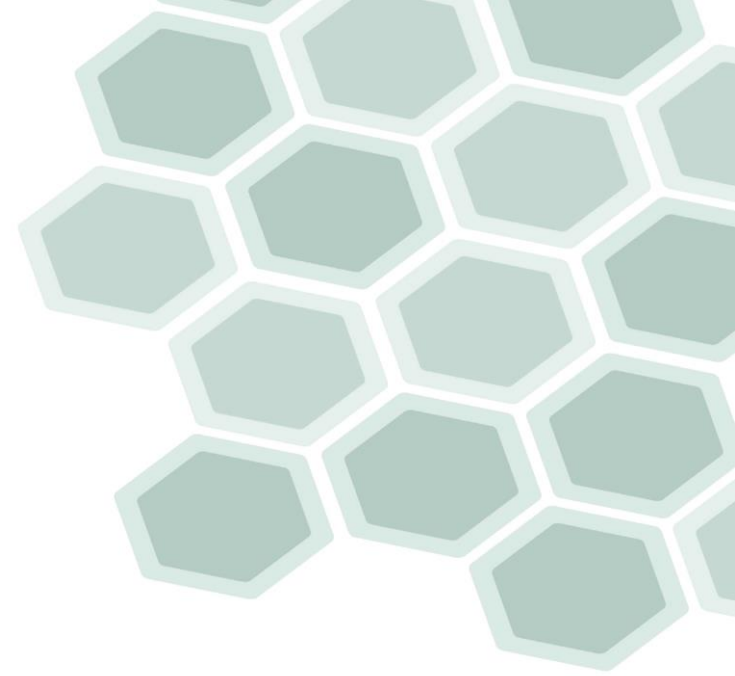
Supporting Clinical Audit

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GDPR Implementation Programme

Building a Better Health Service

CARE COMPASSION TRUST LEARNING



DPO Guidance

- Understanding the nature of the processing being done or proposed
- Assessing whether there is a lawful basis and if so how it is applied
- Determining what is necessary to ensure that the rights and freedoms of the data subject are protected

To do this the DPO must;

- Interpret the legislation and guide the organisation in protecting the data subject's rights and itself
- This involves understanding the legislation in detail and when in doubt seeking the advice and guidance of the DPC and/or legal advice

Questions Raised

- **Does Clinical Audit require Data Subject Consent?**
- **How do we ensure transparency of the Clinical Audit process?**
- **Can Clinical Audits be used for research purposes?**

Does Clinical Audit Require Data Subject Consent?

Clinical Audit

- “a clinically led, quality improvement process that seeks to improve patient care and outcomes through the systematic review of care against explicit criteria and to act to improve care when standards are not met”*
- Where standards do not exist, guidelines are referred to.
- Where guidelines do not exist, the Commission recommended that the audit may in fact establish the standards through the audit process and that these should then be recognised as such.

**The Commission on Patient Safety and Quality Assurance (2008, p.152)*

Lawful Basis

- Processing Personal Data in the absence of consent - Article 6 (1) (e)
 - We are processing the personal data on the basis that it is necessary for the performance of a task in the public interest and we are doing this in the exercise of the official authority vested in the organisation through the Health Acts
- Processing Special Category Data – Article 9 (2) (h)
 - The organisation may process the special category data in the provision of health or social care or treatment and, crucially, in the management of health and social care systems on the basis of Union or Membership law, again referring to the Health Acts.
- Applicability of Statutory Instrument No. 314 of 2018, Data Protection Act 2018 (Section 36(2)) (Health Research) Regulations 2018
 - Having considered the definition, meaning and purpose of clinical audit, the SI does not require clinical audit to have consent.

Protecting the Data Subject and the Organisation

- The organisation will ensure that patients and service users are clear that the organisation does clinical audits as a matter of routine and in exceptional circumstances.
- The organisation will assure patients and service users that their data will be protected in the course of clinical audits and any data / results produced will be anonymised / pseudonymised.
- The organisation will inform patients that it does clinical audit without seeking their consent and does so in line with the legislation.
- The organisation will ensure that only authorised personnel will perform clinical audits and will be subject to the appropriate confidentiality measures and controls

How do we ensure Transparency of the Clinical Audit Process

Privacy / Fair Processing Statement

- The new Privacy / Fair Processing Statement has been developed
- This document is primarily aimed at Acute Hospital facilities, a version aimed at community care will follow shortly
- It is an excellent document that clearly and succinctly explains data subject rights and how we will treat their personal data, including audit and research.

Can Clinical Audits be Used for Research Purposes?

Simple Answer

- Yes – IF
 - The researcher has satisfied all ethical approval requirements
 - The researcher has reviewed the clinical audit data to be used and has ensured that even where the data is anonymised / pseudonymised, that no data subject is identifiable



Working Together to Safeguard Patient and Service User Safety and Privacy