# Medical Imaging Data Access and Sharing Meeting

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Information Governance Session

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# Feedback

- Requirements
- Obstacles
- Possible solutions (existing/proposed)
- Action Plan and key people

‘It is important to note that it is in the public interest both to encourage good medical research and to protect patient privacy’

*NHS NSS Privacy Advisory Committee, Guiding Principles and Policy for Decision-making and advice*

# What is information governance?

- '….the umbrella term that brings together the statutory requirements, best practice and standards that apply to the handling of information…that includes:
  - **Confidentiality and the Caldicott requirements**
  - **Data Protection**
  - Freedom of Information
  - **Information security**
  - Records Management'
- Information Governance standards part of the NHS Quality Improvement Scotland Clinical Governance and Risk Management (CGRM) standards

# Data Protection Act permits the use of personal health data for research purposes:

1. Must not support measures or decisions with respect to particular individuals
2. Must not cause substantial damage or distress to an individual
   - May be kept indefinitely if above 2 points apply
   - Subject access rights do not apply so long as first 2 points apply and resulting output not personally identifiable
3. Substantial public interest
4. Use of identifiable data is necessary
5. Proportionality
6. Comply with the remaining 'Data Protection Principles' including 'fair processing', data quality, data security

# Confidentiality

- Seek permission or de-identify (anonymise) before making use for a research purpose

- Confidentiality is not an absolute right, therefore it is possible to proceed without either of the above conditions in specific limited circumstances e.g.
  - Benefits to an individual or society of disclosure outweigh the public and the individual's interest in keeping the information confidential
  - Caldicott Guardians, ethics advisors

# Confidentiality – the question of consent (1)

- Requirement of the common law
- NHS Scotland policy
  - 2002 Recommendations of the Confidentiality and Security Advisory Group for Scotland
  - NHS Scotland Code of Practice on protecting patient confidentiality
- *Medical Research Council* Personal Information in Medical Research guidance '….in most cases…is practicable'
- *Information Commissioner's Office* (Academy of Medical Sciences 24 June 2006 legal symposium) '…clinical health services should work harder to inform patient about the uses and benefits of research using personal information and to ask patients for their consent to use their data for such purposes'

# Confidentiality – the question of consent (2)

- Challenging where research use is ‘secondary’:
  - Consent for consent
  - Subjective standard
  - Capacity issues
  - Resource intensive
  - Duration

# Information Security

- Confidentiality, Integrity, Availability
  - Access controls
  - Secure data storage and transfer mechanisms
  - Back-up
  - Audit trail and monitoring
  - …

# Information Governance and Data Sharing

- When personal information is shared between data users there is a need for clarity on how information governance obligations are to be discharged:
  - Custodianship of the data
  - Informing/ consent
  - Data Security controls
    - Monitoring
    - Incident reporting and investigation

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