NATIONAL INFORMATION GOVERNANCE BOARD FOR HEALTH AND SOCIAL CARE

NIGB

IGT for clinical research & education: NIGB and HRA perspectives

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‘Section 251’ overview

NIGB

- Access to medical records without consent
- ECC advise SofS to support / non-support, subject to conditions
- Health Service (Control of Patient Information) Regulations 2002
- Regulation 7 ‘restrictions and exclusions’:

  “…ensure that appropriate technical and organisational measures are taken to prevent unauthorised processing of that information”

- Security assessment separate process to ECC consideration

‘Section 251’ and security

NIGB

- Evolution of seeking security assurance
  - 2001 – organisational policy documents
  - 2008 – system level security policy
  - 2012 – information governance toolkit
- Role of security review in ECC considerations

NIGB perspective

NIGB

- National Commissioning Board review of IGT as an information standard
- NIGB consultation response (www.nigb.nhs.uk):

> "*not an indicator for potential data losses or broader risks arising from information use*"
>
> *"…does not provide specific information on an information flow, and it is difficult to argue that this is sufficient to make a judgement on whether that information flow is being managed to the standards required*"
>
> "*…without independent assurance to self-declared scores, the IGT response cannot be used to provide reliable accurate opinion or a confident view to support an application and undermines the ECC ability to discharge their obligation to the SofS*"

NIGB perspective (contd.)

NIGB

- A proportionate approach that does not frustrate a provisional approval
- Section 251 considerations focus on specific flow of data versus organisational view

HRA perspective

NIGB

- Time of significant organisational establishment and change
- HRA assessment
- Confidentiality Advisory Group establishment - advice
- Change to approval – HRA for research
- Build upon current business improvement activity
- Opportunity to look at processes
- Listen

Questions

NIGB

- Suitable level of assurance?
- Benefits once completed
- Alternatives?