HRA and IG – IG Workstream of HRA Approval

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R&D Conference

11:40 – 12.10  Tuesday 24th May 2016
Overall Aim:

• HRA Approvals is to provide single review of the information governance aspects of research studies currently duplicated across the NHS in England.

• Provide authoritative assurance to NHS organisations about the suitability, compliance and quality of research proposals.

• Currently individual NHS organisations and their staff interpret the requirements of data protection legislation and information governance codes of practice. Sometimes in different ways.

• Each trust will be able to accept the HRA Approval and therefore will not need to ask further questions about the information governance aspects of a study.
Scope

- Information Governance may be understood to cover a number of domains including Common Law Duty of Confidentiality, DPA, FOI, Records Management, Security (technical and organisational), and Information Quality.

- The inclusion of different domains within the IG workstream is intended to reflect the extent to which each is currently subject to local trust review.

- If it is not currently reviewed at a local level, then there is no immediate need to review as part of the unified process – but need to take account of developments e.g. DFC Report; GDPR; etc.
Objectives

(1) To develop questions to capture the information required to enable central, unified, review of the IG requirements currently subject to local trust review.

(2) To establish the criteria applied in assessing the answers and to provide appropriate question specific guidance.

(3) To provide assurance to Trusts and Caldicott Guardians that IG requirements are subject to appropriate review.
Work So Far

- Invitation to participate sent to Caldicott Guardians
  – Meeting in Edinburgh
- Invitation to participate NHS HE IG WG
- Invitation to participate MRC Research Governance Forum
- Workshop 1, June 2015
- Invitation to participate NHS Trust IG leads
- Workshop 2, September 2015
- Invitation to participate to Research Champions, January 16
- Invitation to participate to DA (Operational leads), January 16
- Email Discussion Group
  – Third iteration for comment
- Meetings with ICO, ongoing.
- Testing with Researchers (MRC assistance), Now
Next steps and current considerations

- Development of QS Guidance and FAQs
- Further testing with researchers and CGC
- Testing and development with RECs/ CAG
- Testing in Use (parallel to IRAS)
- Safe Harbour / Privacy Shield
- GDPR
- DFC Report and Gov’t Response