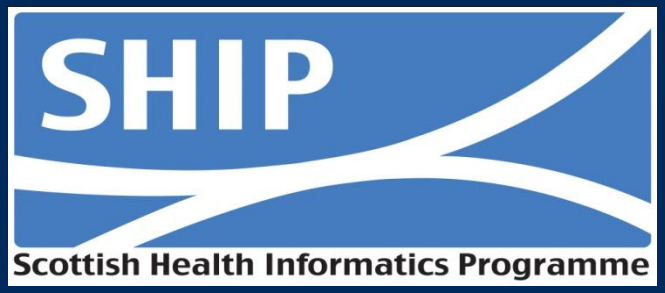


wellcome trust

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# SHIP: Governance
# Researcher Engagement Workshop
# 13 December 2010

**Graeme Laurie**
**Edinburgh Law School**


Arts & Humanities
Research Council

# The benefits of SHIP

- Improved efficiency, transparency & security
- Clarity on governance and processes
- Improved data security and less data travel
- Dedicated research coordinators to assist approved researchers with projects
- High standards and best practices

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# Improving governance for all

- Reducing uncertainty & increasing transparency
- Setting standards: Principles & Best Practices
- Responsibilities: Data Flows & Data Controllers
- Seeking buy-in from stakeholders
- Next steps? Regulatory joined-up-ness…

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# Governance: our work to date

- **Identify** governance solutions across the range of SHIP activities
- **Secure** buy-in from key stakeholders, e.g. Caldicott Guardians
- **Be ambitious** in the potential reach of SHIP:
  - Data linkages/transfers both inside and beyond health service
  - Consider wider challenges on the tissue/data continuum
- **Learn lessons** from positive experiences elsewhere:
  - Cooperation between Directors of Public Health
  - OECD Guidance on human genetic databases (2009)
- **Concrete and workable outputs** to steer SHIP forward

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# Principles and Best Practices document

- **Principles**: foundational starting points for deliberation and action
- **Best practice**: instances of implementation of principles to a high standard
- **Content:**
    - Public interest and the importance of research
    - Privacy/Anonymisation/Consent/Data Protection
    - Authorising/advisory bodies
    - Governance/Access
    - Trusted Third Parties (where appropriate)
    - Clinical Trials
    - Cross-sector sharing and sharing agreements
    - Public engagement and benefit sharing

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# Principles and Best Practices examples

## 1. Public interest

### Principles

Scientifically sound and ethically robust research is in the interest of protecting the health of the public.

The responsible use of health data should be a stated objective of all organisations adhering to this instrument.

### Best Practice

It is the data controller's responsibility to ensure the development of *transparent* policies that demonstrate their understanding of public interest and the basis upon which they will use and disclose health data;

# Principles and Best Practices examples

## 3. Consent

### Principles

Personal data must not be used without consent unless absolutely necessary…

Where obtaining consent is not possible/practicable, then (a) anonymisation of data should occur as soon as is reasonably practicable and/or (b) authorisation from an appropriate oversight body/research ethics committee should be obtained.

### Best practices

Where there is the prospect of future use of data that is unknown at the time of consent, then data subjects should be informed of the broad purposes for which the data might be used. These purposes will delimit the appropriateness of any future use…

Where consent is not to be obtained, the reasons for this must be clearly articulated and adequately justified.

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# Principles and Best Practices examples

## 11. Cross-sector sharing

### Principles

Where ethical & legal standards are met, data should be made accessible to trusted researchers across disciplines. The value of such cross-sector sharing should be recognised.

Along with the potential benefits, risks should also be identified and appropriately addressed. In particular, assurance of reciprocal privacy standards across sectors is necessary.

The unnecessary duplication of approval procedure(s) and governance mechanisms should be avoided. Mutual recognition of equivalent standard and procedures should be sought.

### Best practice

Clear and easy to understand specifications covering confidentiality, security and privacy, and which define roles and protocols, should be agreed prior to cross-sector data sharing taking place.

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# Data Flows and Data Controllers

1) When does one become (and stop being) a data controller?

2) What flexibilities exist for the assumption of, or agreement on, data protection responsibilities?

3) Is there a meaningful distinction between *data disclosure* (surrender responsibility) and *data sharing* (share responsibility)?

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# Seeking stakeholders input and buy-in

- What are the top two governance challenges you face as a researcher?
- What does good governance look like for you?
- What are your thoughts on the role of (a) consent, (b) anonymisation and (c) authorisation in legitimating your research?

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# Next steps?

- Identifying further governance challenges and solutions
- Engaging the range of stakeholders and refining the model(s)
- Suggestions?

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