Legal and ethical issues

Graeme Laurie

The remit

- "…*creating*, *curating*, and *using* brain image banks, including research uses"

- The importance of relationships, compare:
  - Health care professional/patient
  - Researcher/participant
  - Data custodian/data subject

- Duties, rights and expectations

Creating

- Consent: valid as to informedness, voluntariness, and capacity

- Broad consent: "…to participate in research"

- Capacity: cf 'benefits' v 'best interests"

- Social licence and public engagement

Creating, capacity and research

- Mental Capacity Act 2005 and Adults with Incapacity (Scotland) Act 2000:

- Potential for real and direct benefit

- No comparative effectiveness with consent

- Informed on rights and does not object

- Necessary authorisation (proxy or committee)

- Prior wishes respected

Curating in the public interest

- Royal Society, *Science as an Open Enterprise*, (2012)
- "Intelligent Openness"
  - Intelligibility
  - Verifiability
  - Accessibility
- Two caveats: (i) commercial confidence, and (ii) personal privacy

THE UNIVERSITY *of* EDINBURGH
Edinburgh Law School

mi
mason institute for medicine,
life sciences & the law

Curating in the private interest

- Data Protection Act 1998 and common law duty of confidence
- Key responsibility is "data controller"
- "processing" of "personal data" – identifiability is key (now or in the future)
- Consent or anonymise paradigm
- ICO's Code on Anonymisation (2012): "motivated intruder"
- "Authorisation": PAC (Sc) and CAG (Eng & Wales)

Using in the public interest

- Care Act 2014: Health Research Authority has duties to protect *and promote* ethical research
- The importance of good governance of access
- Transparency, accountability, and engagement
- *Proportionate* risk-based governance

THE UNIVERSITY *of* EDINBURGH
Edinburgh Law School

mason institute for medicine,
life sciences & the law

Using in the private interest

- Incidental Findings: Is there a duty to disclose?

- Ethical or legal question?

- Clinical utility, nature and magnitude of threat

- Duty of Care:
  - dr/patient or researcher/participant?
  - a reasonable standard of care (relative to profession)
  - Breach of duty was cause of the harm

Consensus statement

- The role (and the limits) of consent in *creating*

- Broad consent + good proportionate governance

- Intelligence Openness for responsible *curating*

- Protection *and* promotion when *using*

- Professional role in setting and policing standards of care