

Feasibility: Ethics, Privacy, Intellectual Property

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Likely ethical issues - patient-related

➤ Privacy

➤ Consent

- To collection of data
- To use of data

➤ Risk/benefit analysis

- Who could be harmed, in what way, how can the risk of harm be minimised?
- Who could benefit, in what way, how can benefits be maximised, whilst at the same time respecting autonomy and privacy, and minimising risks?

Likely ethical issues researcher/institution-related

- Ownership of data
- Control of access to data
- Intellectual property
 - Authorship
 - Ownership of results
 - Right to use results
 - Commercialisation

The regulatory environment: Consent and Privacy

- An HREC has the power to approve a research study which involves breach of Commonwealth Information Privacy Principles stated in the *Privacy Act 1988*. State laws have similar provisions.
- In particular, it can permit personal data to be used without the person's consent (*waiver of consent*)
- There are specific conditions for this

1. Using existing data

Conditions for waiver of consent in 2007 *National Statement on Ethical Conduct in Human Research (2.3.6)*

- Low risk to “participants”
- Benefits justify risk
- Impracticable to obtain consent
- No reason to think people would say no, if asked
- Sufficient mechanisms protection of privacy
- Where results have significance for individual’s welfare, have a plan to inform them (not necessarily directly, and “where practicable”)
- If commercialised, participants will lose out on any financial benefits that they would have been entitled to

Changes from 1999 National Statement

New bits added

(have to show these to justify..)

- No reason to think people would say no, if asked
- Sufficient mechanisms protection of privacy
- Where results have significance for individual's welfare, have a plan to inform them
- If commercialised, participants will lose out on any financial benefits

Old bits missing

(can't use these to justify)

- Cause unnecessary anxiety (14.4a)
- Prejudice scientific value (14.4a)

2. Using stored tissue

2007 National Statement

- For tissue originally collected for one specific research use, do not use for other research without consent (3.4.7)
- **BUT** HREC can waive consent requirement, under exactly same conditions as for data(3.4.7)
- If research is likely to produce info relevant to individual's health, should have procedures to re-identify and follow up ("wherever possible") (3.4.6)
- No specific mention of tissue originally collected for clinical purposes

1999 National Statement –

- when using stored tissue for a purpose other than that for which it was originally collected, consent should "generally" be obtained
- Same basic idea for tissue collected in research and clinical settings, but slightly different wordings (15.6 and 15.7)
- Waiver of consent permitted under conditions very similar to those for data (15.8)

3. Collecting data/tissue prospectively

Type of consent required by 2007 National Statement

- Consent may be “unspecified” (ie blanket) (2.2.14)
(NB 1999 NS implies consent should be specific only (15.5))
- Unspecified consent may include consent to data/tissue-banking (2.2.21)
- The terms and implications of unspecified consent should be clearly explained when consent is sought (2.2.16)
- When data-banking, tissue donors must be informed of a number of issues, inc. form in which data is to be stored, what it will be used for, and what conditions on access will apply (3.2.9)

4. Data Linkage

2007 National Statement

- can use identified data for data linkage, even when consent has not been given for use of identified data, provided identifiers are removed once linkage is complete (3.2.4)

1999 National Statement - almost the same

- Identifiers may be used for data linkage, but once complete, resulting data must be coded or de-identified 14.8