SEQ Combined HREC

Training Day

Tissue Sharing and Consent

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Overview

1. Sharing human biospecimens and the *National Statement*
2. Prospective consent
3. Waiver of the consent requirement
4. Accessing from previous research
5. Biobanks/pathology services
6. Importation/exportation
7. Research ethics review
8. Fruit of a poison tree and communication with researchers
9. Good practice for prospective collection and banking

A rose by any other name?

National discussion and thinking:

- » Human biospecimens rather than tissue
- » Research ethics review rather than ethical review
- » Consent rather than informed consent
- » Not equating research ethics review to HREC review

Human biospecimens: The *National Statement*

- Allows for access under a number of circumstances
- Recognising the ethical and integrity value of sharing
- NS discusses the ethical issues to be considered by researchers and reviewers
- Nature of existing consent (specified, extended and unspecified)
- Biospecimens collected prior to December 2013
- Imported biospecimens
- Human embryos, gametes and fetal tissue
- Legislation

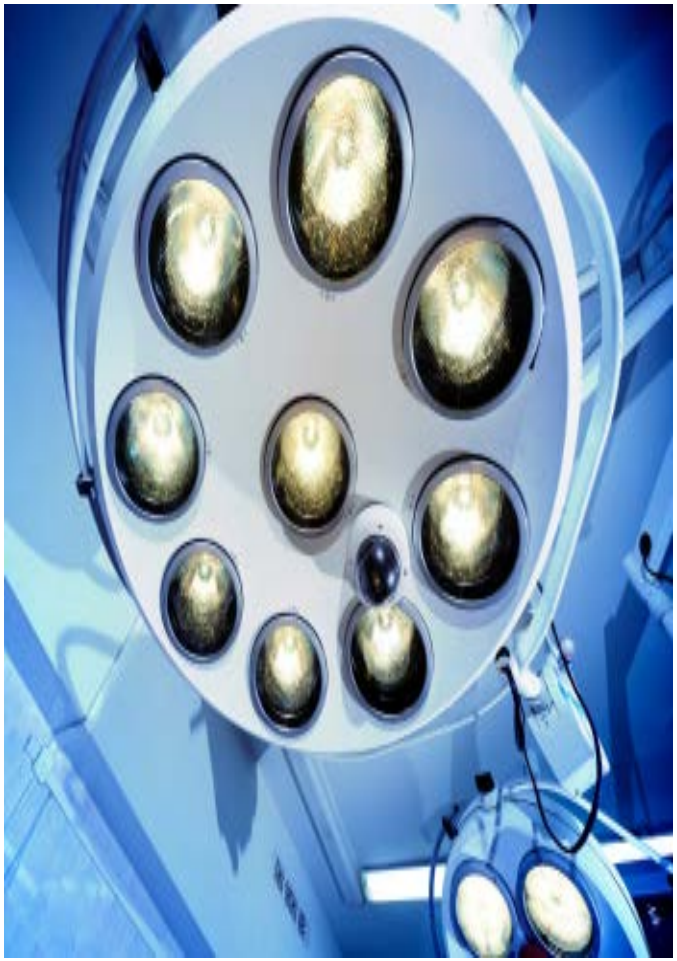
Prospective consent

- Consent mechanisms
- Specified, extended and unspecified
- Describing risks and burdens
- Confidentiality considerations
- Return of results
- Family members
- Withdrawal of consent
- Discussing reuse/sharing
- Evaluating in ethics review

Waiver of the consent requirement

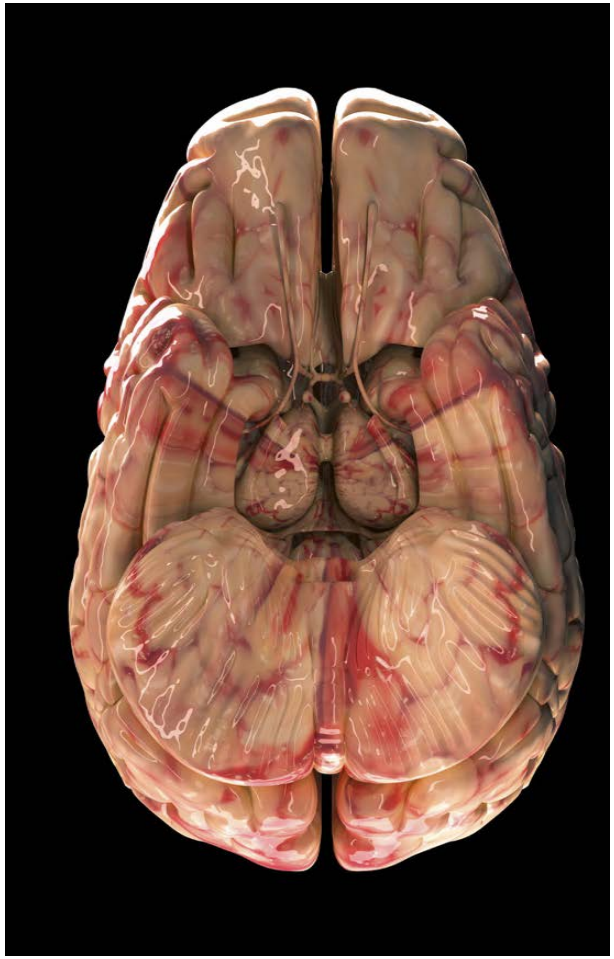
- Might be useful for work with biospecimens collected for clinical purposes banked/old biospecimens
- Discussed in NS Chapter 2.3
- Specified matter to consider discussed at NS 2.3.10
- Only for research with no more than a low risk of harm
- Public interest considerations
- Likely the donor(s) would have consented if they had been asked

Accessing from previous research/clinical work



- Appropriate collection
- Consent anticipated research use
- Consent anticipated sharing
- Access to personally identified information
- Return of results
- Specificity of consent
- Is a waiver required?

Biobanks/pathology services



- HREC approved
- Appropriate governance arrangements
- Good records with regard to consent, confidentiality and donor wishes
- Post-mortem samples
- Cultural considerations
- Family members

Importation/exportation of human biospecimens

- Obtained in a manner consistent with the NS and relevant legislation
- Otherwise **cannot** be used
- Exporting only with ethical clearance
- Exporting only when consistent with consent

Research ethics review

- Collected appropriately (e.g. management of risks)
- Consent for research use/sharing
- Was consent specified, extended or unspecified?
- Is the consent sufficient for the specific use/project?
- Waiver of the consent requirement
- Donors likely to have agreed
- Respect for person
- Remember research ethics and integrity value

Fruit of a poison tree

Biospecimens should only be used for research where:

- (Australia pre 2013) Must still be consistent with NS 3.4 and within scope of consent*
- (Australia from 2013) Must adhere to NS 3.4 and be in accord with consent*
- (Overseas) Must be established to be consistent with NS 3.4 and within scope of consent*

** Or utilise the waiver mechanism*

Good practice for prospective collection and banking

- Value of offering participants/donors more than one option
- Record keeping
- Withdrawal of consent
- Results of significance
- Personal information
- Access control

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- Blog
  - » human research ethics
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