
Consent, sharing and banking tissues

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Outline

- Basic principles
 - Autonomy, consent and the law
 - Consent exemption
 - Generic consent
 - Nature of consent process
-

Basic Principles

Individual

- Beneficence
- Non-maleficence
- Fidelity and trust
- Personal dignity
- Autonomy

Community

- Beneficial research
- Human advancement
- Wastage of valuable resource

Autonomy

- informed, voluntary, competent decision making (consent)
 - the privacy of personal information
 - ‘ownership’ of own body parts
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Who 'owns' the tissues?

- Purist view
 - Individuals
 - Cannot be used without informed consent
 - Opposing view
 - Individuals when the tissues are integral to them
 - No one when in isolation
 - Clinical surplus tissues
 - 'abandoned' property
 - informed consent is primarily important to respect the right to bodily integrity or privacy
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Human Tissue Act 2004

- Consent required for use of relevant material in research
 - Lawful to use (but not remove) tissues for research without consent providing
 - there is ethical approval
 - samples are anonymised
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Main categories of tissues and consent

Research project (RP)

Project specific consent

**Consent for storage and future use
(generic and enduring consent)**

Research tissue bank (RTB)

**Consent for use in specified
programme of research**

**Consent for storage and future use
(generic and enduring consent)**

Diagnosis/treatment & RP

Clinical consent

Project specific consent

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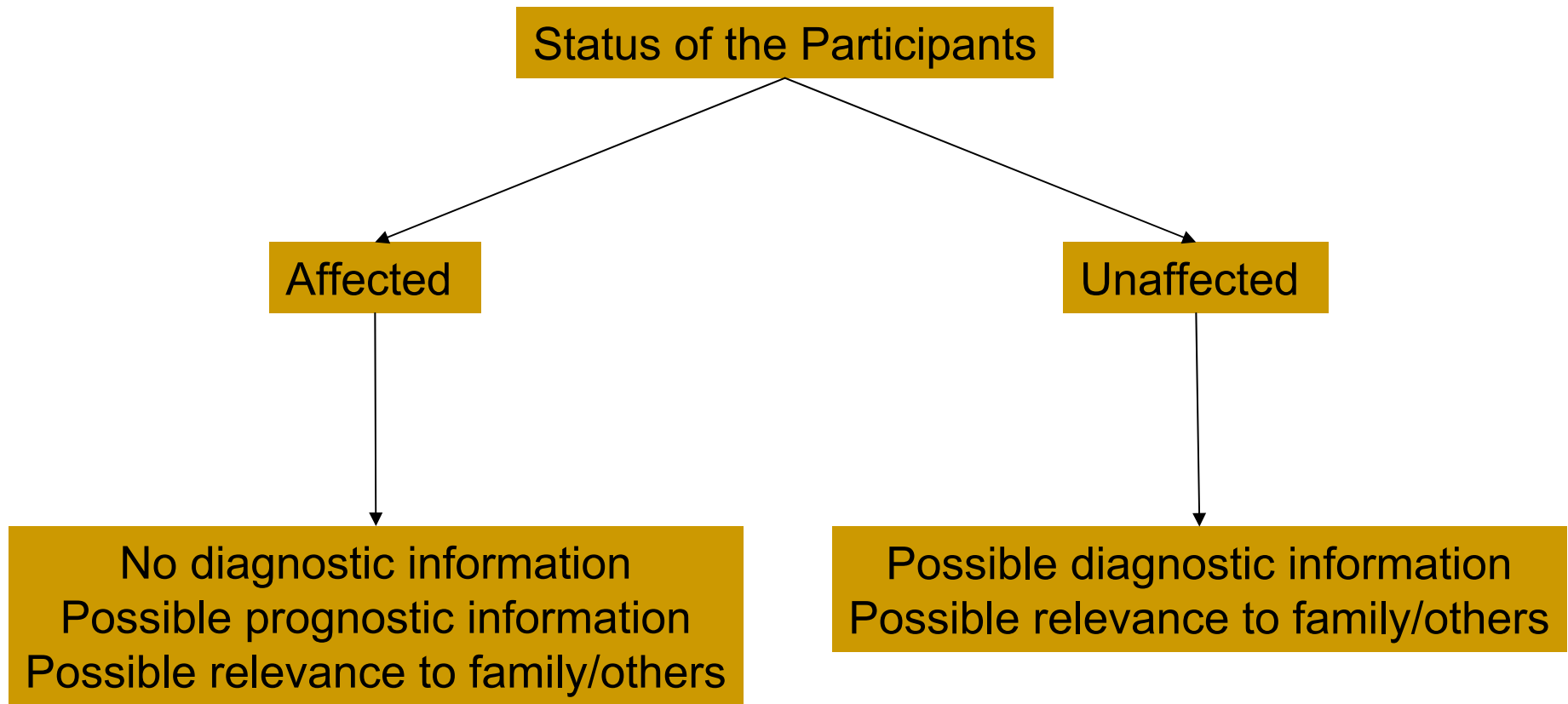
Existing clinical archival
tissues

Consent exemption

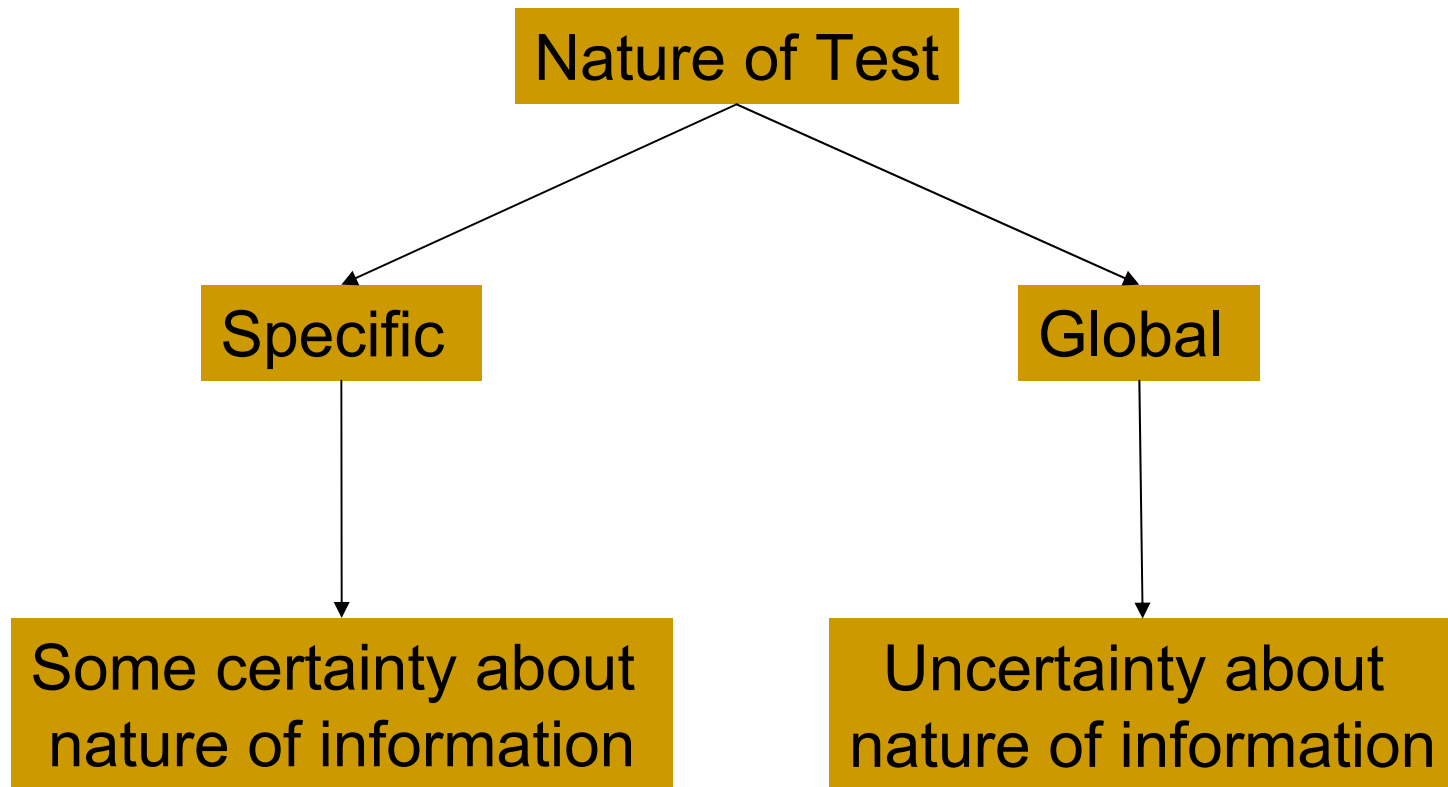
Consent exemption - what do RECs consider?

- Balanced view of risks and benefits
 - Risks to privacy and wellbeing of the donors
 - Benefit of the research
 - Difficulty or intrusiveness of obtaining consent
 - Possibility of anonymising the tissue
 - Nature of the research tests and findings
 - Possibility of commercial exploitation
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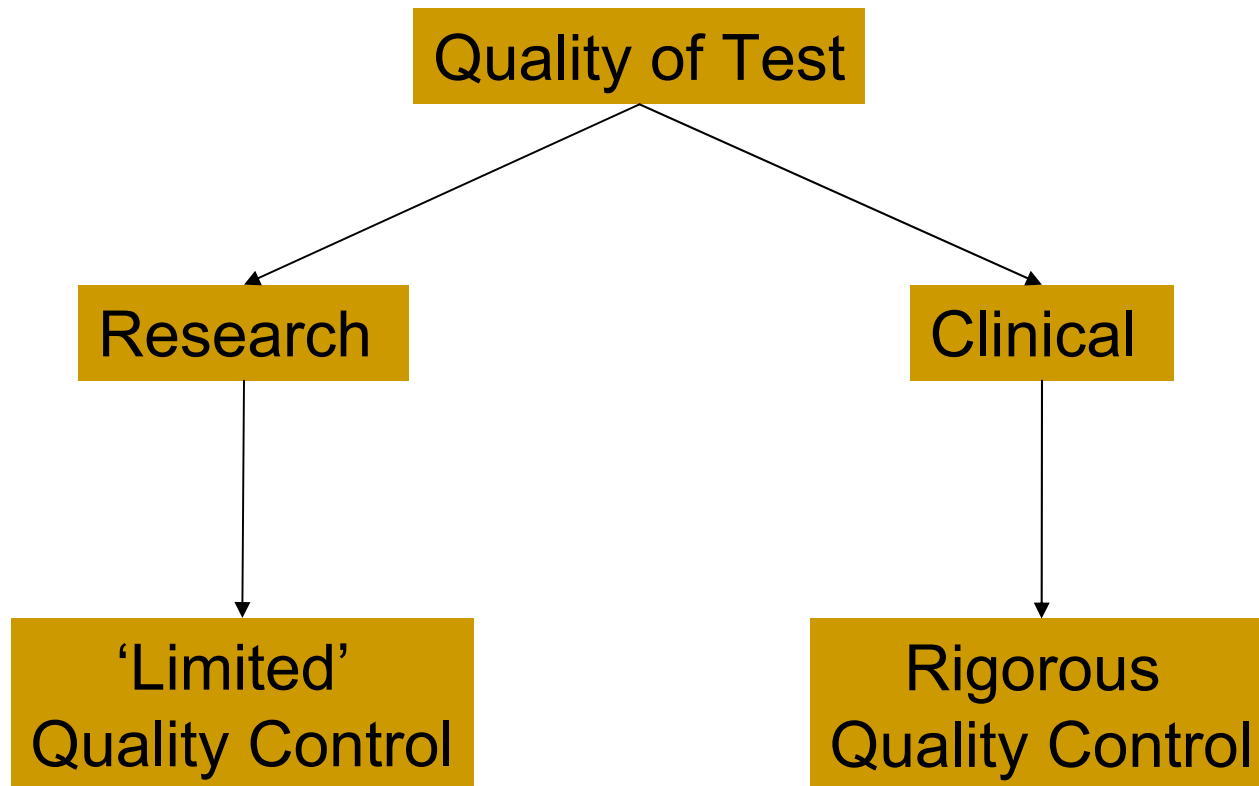
Value of Information From Testing



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Main Categories of Tissues and Consent

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Existing clinical archival tissues

Consent exemption

IS THIS
“INFORMED”
CONSENT?

'Fully Informed' Consent

- Unrealistic and limited in most cases
 - Consent can be given for a course of action only as described in a specific way
 - Description cannot be exhaustive
 - Thus, consent is almost always for incompletely described or understood action
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Consent is 'Defeasible'

- Having a presupposition in its favour but open to revision if countervailing evidence becomes known
 - Consent requirements are not met wherever anything rebuts or defeats the presumption of consent e.g.
 - coercion
 - misrepresentation
 - lack of appropriate disclosure
 - misdescription
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'Generic' Consent

- Consent to permit use of the tissue
 - with knowledge of any planned future research use
 - with knowledge that one cannot be fully informed about all
 - possible future uses of the tissues
 - possible outcomes (including commercial exploitation)
 - with appropriate checks and balances
 - research ethics review
 - sponsor governance oversight
 - compliance with an HTA licence
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Generic Patient Information

- Proportionate
 - Balance between
 - Brevity, readability and accessibility
 - Completeness of information
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Generic Patient Information - 1

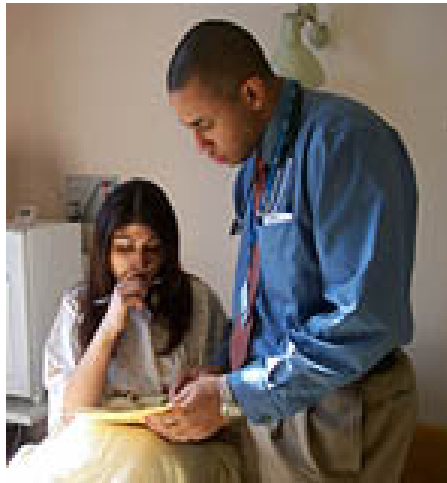
- Why: broad description of research benefits
 - What & how:
 - Samples and personal/health data
 - Type of samples
 - Procedures
 - Retention and disposal
 - Who:
 - Sharing policy
 - Researchers & organisations likely to use samples
 - Geographical constraints of research work
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Generic Patient Information - 2

- Right to withdraw
 - Benefits and risks
 - Nature of analysis if known
 - Highlight any possible ‘ethically sensitive’ research (animals, ESC, etc)
 - Clear statement if future use is unknown
 - Value of the information derived and feedback policy
 - Checks and balances – further ethics review etc
 - Commercial use and waiver of financial and property rights
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Nature of Consent Process

- Single event vs. ongoing process
- Other means of informing and raising awareness of potential participants



Summary

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Main Categories of Tissues and Consent

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Existing clinical archival tissues	Consent exemption

Pathology Archives as Research Tissue Banks (RTBs)

- Pathology archives can receive NRES ethics approval to operate as RTBs
 - Require an HTA Licence
 - Pathology archive
 - consists of existing collection of diagnostic tissues
 - is continually expanded by prospectively collected samples
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Pathology Archive RTB – Consent

Samples already in the pathology archive

1. Consent withheld

- Samples cannot be used

2. Generic Consent

- Anonymised samples can be used
 - Project specific approval
 - Research tissue bank generic approval

3. No indication either way

- As for (2)
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Pathology Archive RTB – Consent

Samples prospectively added to the pathology archive

Is consent required for use of tissues for research?

- Legally, not necessary if samples released in non-identifiable form with RTB ethics approval
 - Ethically, the patient is now seen as a potential donor and consent should be sought
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