

Enabling Tissue Banking: Ethics, Issues and Solutions

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"Enabling medical research: Opportunities and challenges for tissue banks within health"
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National Statement

National Statement on Ethical Conduct in Human Research, NHMRC, ARC & UA, 2007

Purpose: "to promote ethically good research."

This requires that:

- Participants are accorded due respect and protection
 - Fostering of research of benefit to the community
- Broad purposes are reflected in ethical principles and chapters on ethical considerations specific to:
- Research methods or fields
 - Categories of participants

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Research use of tissue

General ethical principles apply to research with human tissue, whether from research tissue banks or from banks created for other purposes

Essential principles are those of:

- Research merit
- Beneficence
- Justice
- Respect

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Research merit

Potential benefit: knowledge, improved welfare, research skills

Appropriate methods

Prior literature

Respect for donors not compromised by aims or methods

Researchers have suitable experience, qualifications & competence

Appropriate facilities & resources

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Justice

Within scope of project, selection, exclusion & inclusion & recruitment fair
No unfair burden of research
Fair distribution of, and access to, benefits
No exploitation

Beneficence

Likely benefits justify risks
Risks minimized and clarified
If no benefits, risks lower
Suspension if risks no longer justified

Respect

Intrinsic value of humans
Regard for welfare, beliefs, perceptions, customs & heritage
Privacy & confidentiality & cultural sensitivities
Due scope to capacity to make own decisions or empowering & protecting
Respecting value of human autonomy – and protection of those with diminished decisional autonomy

Research & tissue banks

Meeting principles may present difficulties

Research merit:

- Sufficient samples?
- New questions and old banks?

Justice:

- Fair collection?

Beneficence:

- Risks from new information?
- Identifiability?

Respect:

- Donors decisions?
- Waiver?

Responses to challenges: governance

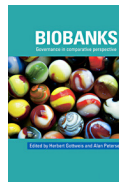
Governance structures can demonstrate that

- Research merit
- Justice
- Beneficence

are substantially addressed

Much attention to governance of public, State-owned databanks

Lessons for other databanks



Tissue banking and research with tissue samples

National Statement chapters specific to:

1. establishment and use of research databanks, e.g. in genetics or pathology
 - either with newly collected (and banked) samples
 - or with samples previously collected and banked *for research*
2. Research using human tissue samples

Research tissue banks

Chapter 3.2 of National Statement guides tissue banking for research:

- planning a databank
- consent: specific, extended or unspecified
- disclose extent of identifiability, purposes
- complying with donor's conditions
- custodian to respect privacy
- make available information relevant to welfare
- independent custodian
- guarding against harm to donors

Research using human tissue

- Chapter 3.4 of National Statement guides research with human tissue
- Institutions "should develop" policies for collection, use & disposal of tissue in research
- Policies to address
 - Information on source, nature & collection reason
 - Donor consent or waiver
 - Confidentiality, privacy
 - Access & disposal
 - Socio-cultural considerations

Research using human tissue

- Participants informed about identifiability
- Identifiability for follow-up with welfare information
- Consent: specific, extended or unspecified
- Respect wishes of deceased donor or next-of-kin
- No trade

Responses to challenges: governance

- Both chapters recognise importance of
- governance structures for tissue banks and human tissue research, and
 - participant/donor consent

Responses to challenges: consent

Processes for donation/participation can demonstrate that respect is addressed, by consent or justified waiver.

Waiver, if:

- Research is low risk
- Benefits justify risks of harm with not seeking consent
- Impracticable to obtain consent
- No reason to think participants would not have consented
- Sufficient protection of privacy
- Adequate plan to protect confidentiality of data
- Where practicable, plan for welfare information available
- Commercial possibilities not deprive of entitled benefits
- Waiver not prohibited by law

(National Statement paragraph 2.36)

Autonomy - atomistic

- Prevailing justification for consent in bioethics in recent decades is respect for autonomy
- Autonomous individual capable of rational choices that will fulfill personal goals (choosing to live one's life ordered as one desires)
- Assumes & promotes a deeply individualistic, atomistic view of humans
- Encourages language of personal control, ownership

Autonomy - relational

- Revised conception advanced (Catriona Mackenzie)
- Recognises that autonomy is learned, maintained and even constituted by the relationships in which individuals grow and live
- Autonomy is relational not atomistic
- Choices about life would, and do, reflect this relational situation
- Such an autonomous person could be expected consent to research with her human tissue because she values her autonomy relationally

Autonomy - principled

Other philosophers have advanced revised concepts of autonomy

“A person whose desires and impulses are her own and express her nature as it has developed and been modified by her own culture has character. People with character contribute to well-being of human kind so that liberty to develop that character is essential.”

Principled autonomy - that expresses principles that could be adopted by all others

(Onora O'Neill, Gifford lectures, Autonomy and Trust)

Indigenous cultures

- Indigenous cultures show less recognition of atomistic individuals
- Recognise individuals for their genealogy, their “belonging” and the responsibilities
- Australian Aboriginal and Torres Strait Islanders, New Zealand Maoris, Samoans

Re-thinking autonomy

If we adopted a relational or principled view of autonomy, or drew on indigenous culture, would that promote a more balanced view of:

- the rights and responsibilities of Australians,
- the requirements for consent to use of personal information or tissue samples, and
- the criteria for ethics committee decisions in the absence of consent?

Re-thinking autonomy

National Statement's use of specific, extended and unspecified consent, and
For waiver, HRECs to be satisfied no reason to think participants would not have consented
offer room for reliance on relational or principled autonomy as the basis for guidance, education and reassurance
that an autonomous decision need not be confined to an individualistic one

Ethics, human tissue and human research

- Is there a wider ethical and educational task that needs to be undertaken?
- To rethink & rebuild a shared ethical understanding of use of personal information or human tissue samples to build social knowledge through human research,
- From one based largely on an autonomy of atomistic independence and ownership
- To one based on revised understanding of relational or principled autonomy & community benefit
- That accepts that, in some contexts, we should treat the value of human tissue as shared.

Qualifications of decision-maker

- National Statement requires institutions that establish HRECs to:
- resource them adequately (NS 5.1.26)
 - set terms of reference (NS 5.1.27)
 - ensure members have relevant expertise, induction, continuing education (NS 5.1.28(b))
 - ensure HREC has access to “expertise necessary to enable it to address the ethical issues arising from the categories of research that it is likely to consider.” (NS 5.1.33)

Qualifications of decision-makers

What do we expect of HRECs?

Required composition of 8:

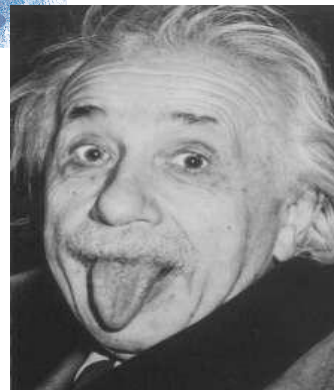
- Chair,
- Layman and laywoman
- Professional care, counselling
- Pastoral community role
- Lawyer
- Current and relevant research experience

What image represents the role and function of HRECs?



HRECs as moralists?

- Authority from asserted superior moral or ethical insight
- Decide for others
- Justification by authority alone: we are the ethics committee and we know what is acceptable and what is not



HRECs as philosophers

- Authority from learning & status
- Offer explanation and justification for all alternative decisions
- Clarify the choices and justifications available



HRECs as lawyers

- Authority from professional status
- Decide by applying rules and laws to situations
- Justification by interpretation





HRECs as coaches

- Authority from experience
- Provide strategies for others to use in deciding
- Justify advice by principles, values and experience
- Operate within boundaries set by laws



HRECs as coach

Need continuing education about

- the emerging methods in research
- guidelines, principles and values

So that decision makers sufficiently understand research, and their decisions are:

- based on guidelines
- know the principles that justify the guidelines
- recognise the range of relevant values that society draws on.