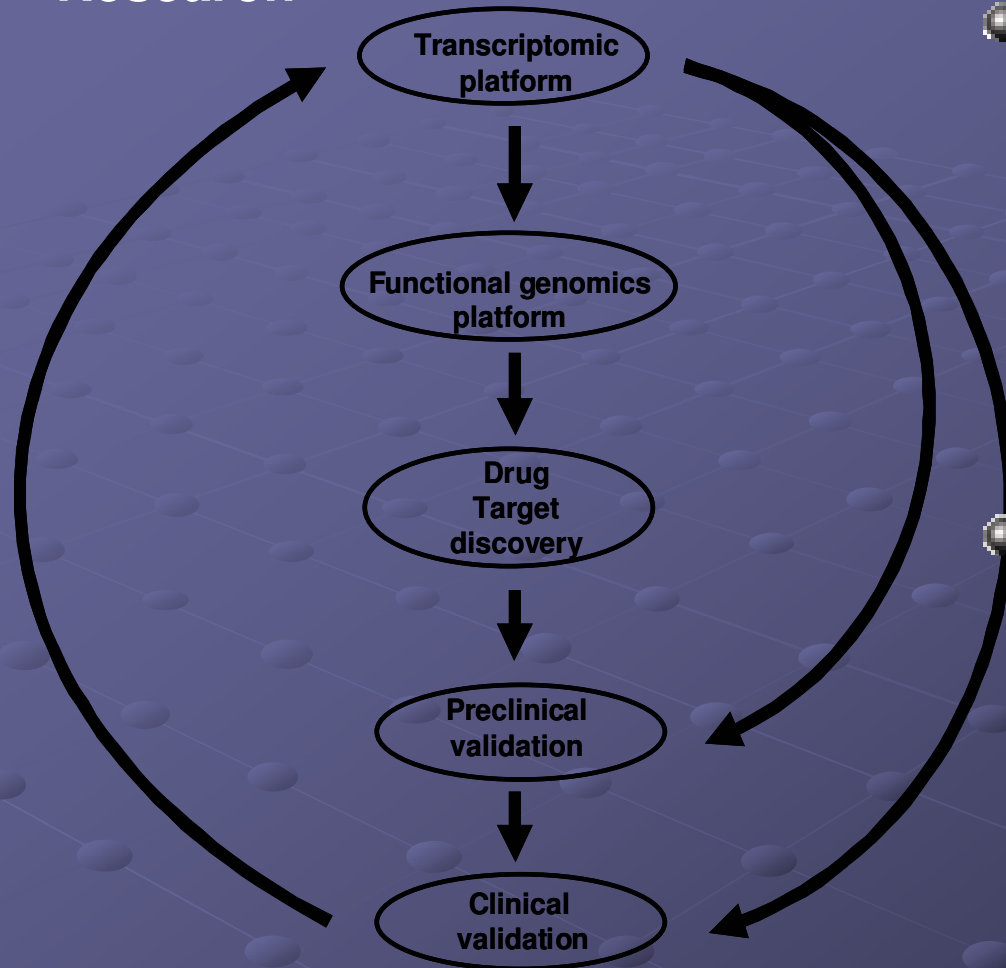


Facilitating the Sustainability of Tissue Banks & Translational Research via Harmonisation of Ethical & Regulatory Frameworks

Dr Jennifer Fleming, Chair Human Research Ethics Committee, Princess Alexandra Hospital

ABN Annual Meeting – November 2008

Sustaining Tissue Bank Contribution to the Cycle of Translational Research



● Biorepositories integral TR (drug development, early diagnostics, pharmacogenomics, & clinical validation of novel therapies)

● Future Sustainability of Tissue Banks:

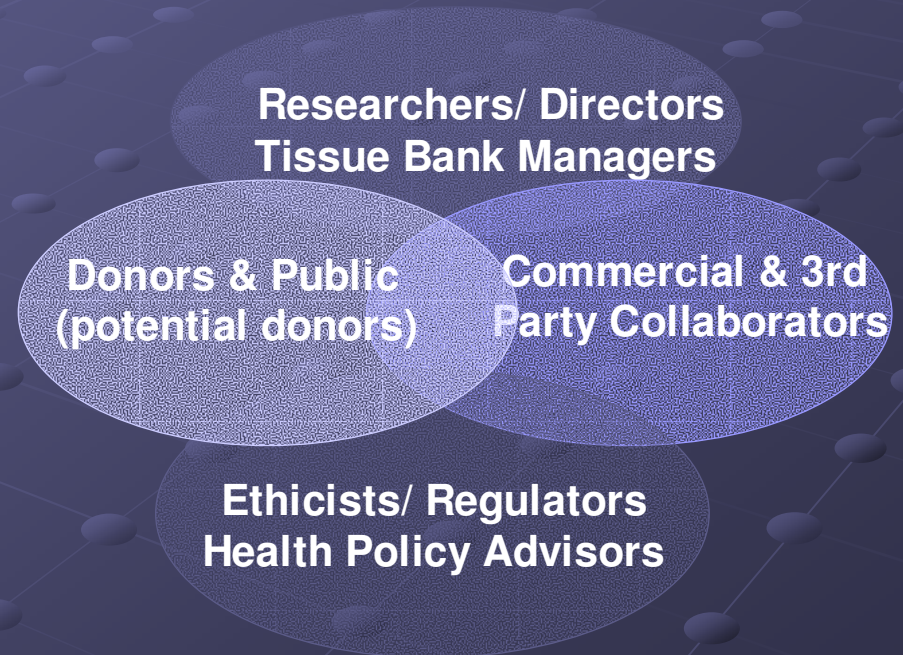
- Strengthen their position (commercial imperative).
- Sound & informed regulatory frameworks to address ELSI.
- Engender public trust

Proposed Research Questions for Future Sustainability of Tissue Banks:

- Does harmonisation benefit sustainability of tissue banks?
- What are the key attributes of models/regulations that address:
 - Commercialisation (beyond cost recovery)
 - Ownership & access, private public partnerships.
 - IP issues & the role of economic modelling.
 - Emerging duty to disclose (3rd party access)
 - Risk management strategies required to consider level of feedback (clinical validity of findings) & generic consent.

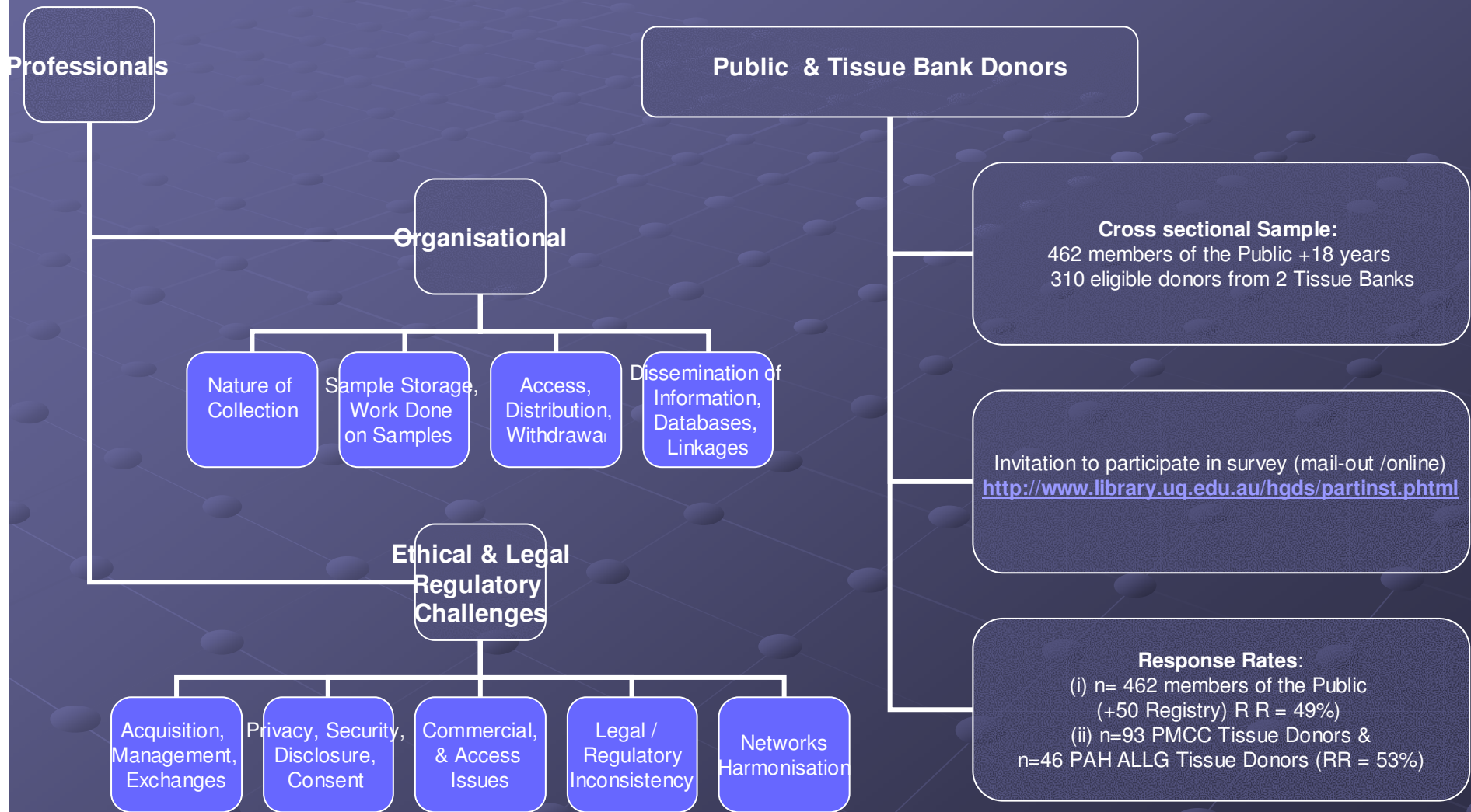
Proposed Research Strategy: Evidence Based Approach to Regulatory Reform via Empirical Studies Future Sustainability of Tissue Banks

- Compare & Contrast models.
- National Comparative Studies on perceptions professionals, tissue donors & the public on
Ethical Legal Social Implications -
 - Commercialisation
 - Duty to Disclose
 - Generic Consent
- Extend initial (PhD) research & comparative analysis of findings from public studies in Ireland & Sweden.



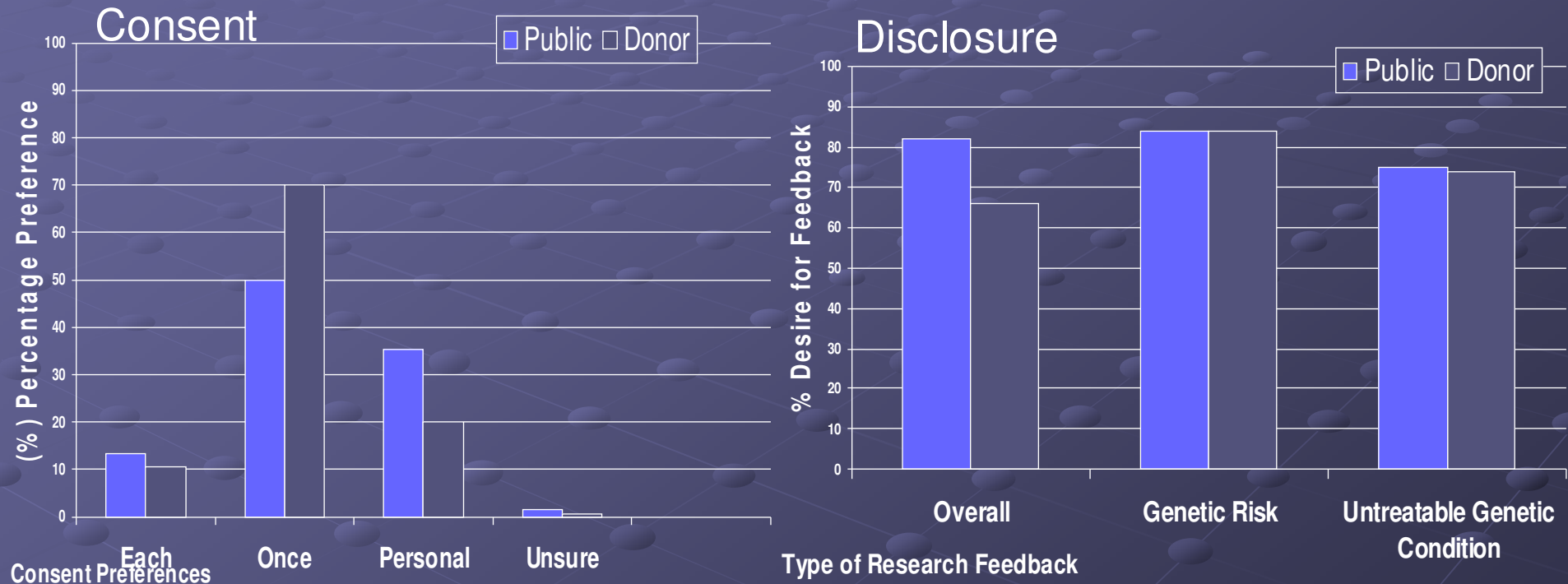
Professional Perceptions Study I Design (adopted from Hirtzlin 2003);

Public & Donor Perceptions on Tissue Banks & Generic Consent & Disclosure: Study II & III Design (adopted from Cousins 2005)



Tissue Donor & Public Preferences for (i) Generic Consent to Future Use of Stored Tissue & (ii) Disclosure of Results

(Donor sample n = 139; Public sample n = 462)



Consent - Each: permission before **each** specific study. General: permission asked **once** with subsequent unspecified studies HREC approved. Personal Choice: asked when agreeing to store tissue for future research they wish to be able to choose to **decide** on providing general or specific consent.

Future Directions

Findings indicate more liberal attitudes towards ethical issues:

- Generic consent for future unspecified use in HREC approved studies,
 - Disclosure of research results (overall, predisposition, untreatable genetic condition),
 - Linkage of tissue with other health information,
- than reflected in policy debate & current regulation.

- Conduct empirical studies to inform regulation & offer key recommendations to optimise future sustainability of tissue banks in Australia & Globally.

Acknowledgements

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- Dr Paula Marlton, Megan Ellis, ALLG Tissue Bank, PAH
- Lisa Devereux & Michelle Fleming, PMCC
- ABN Executive & Responders
- Participants – 50+ Registry - Centre of Ageing University of Queensland
- Cousins etal (2005) – Dublin University, Ireland
- Hirtzlin etal (2003) – Eurogenebank Project