

The Remains of the Body

Human tissue, competence and consent in an age of profit

Eike-Henner W. Kluge
University of Victoria

What is covered in this talk?

- Ethics and law dealing with
 - anything that is part of or that is produced by the human body, and
 - that contains any material that is genetically identical with/derived from that body
- Therefore includes all biologicals
 - cells
 - organs
 - fluids (inclusive of blood)
- Not considered
 - gametes

Issues

- Ownership
- Disposition
- Access
- Use
- Privacy

} ethical & legal

Governing legal fact

- There is no ownership in human bodies, body parts or tissues
- There is a right of disposition
- Only partially spelled out in current Canadian law
 - Feds are working on it

Right of Disposition

- Right to control use within limits otherwise set by law
- Ethical basis:
 - Human being is embodied person
 - Whatever affects human body therefore affects the embodied person
 - Person has right
 - to autonomy and self-determination
 - Conditioned by equal and competing rights of others within social context
 - to dignity

Uniform Human Tissue Donation Act (1990)

- Competent adult may give consent to retrieval and use of tissues from
 - living body
 - dead body
- Duly empowered substitute/proxy decision-maker may give consent for incompetent or dead if no previous competent consent
- Duly empowered agents (coroner, researcher, health care professionals etc.) may remove/use under specified conditions

Definition of "tissue" in *Uniform Human Tissue Donation Act*

- "tissue" means a part of a living or dead human body, but does not include
 - spermatozoa or ova
 - embryo or fetus,
 - blood or blood constituents; ("tissu")
- Corresponding legislation in all provinces
 - Some include placenta

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Some Other Relevant Acts

- Federal
 - *Canadian Centre for Occupational Health & Safety Act*, R.S.C. 1985, c. C-13
 - *Cancer Programs Act*, R.S.C. 1980 c. C-1.
- Provincial (varies provincially)
 - *The Anatomy Act*
 - *Human Tissue Gift Act*
 - *Evidence Act*
 - *Health Protection and Promotion Act* (Ont.)
 - *Cornea Transplant Act* (P.E.I.)
 - *Code Civil du Quebec*
 - Etc.

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General rule in health care

Where consent can be had, it must be had

Criminal Code of Canada

- S. 265(1) : "A person commits assault when he applies force to another person, directly or indirectly..."
- (3) For the purposes of this section, no consent is obtained where the complainant submits or does not resist by reason of
 - (a) the application of force to the complainant or to a person other than the complainant;
 - (b) threats or fear of the application of force to the complainant or to a person other than the complainant;
 - (c) fraud; or
 - (d) the exercise of authority.

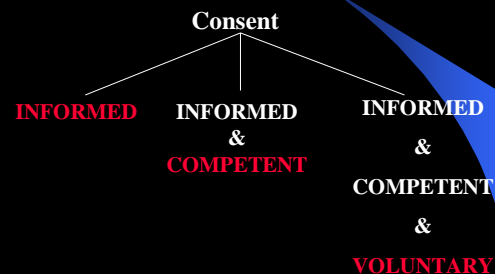
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Consent: the general part

- Short for "informed, competent and voluntary"
- Convergence of Canadian law and ethics agree on general notion of consent
- *Reibl v. Hughes* as leading case
 - standard of disclosure
 - standard of comprehension

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Conditions on Consent



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Who may give consent?

- Patient
 - assumption of competence
 - rebuttable
 - covers all areas
- Proxy/substitute
 - criteria
- Doctrine of emergency

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Order of Proxy Decision-makers

- Court-appointed
- Patient-appointed
- Spouse
 - *Mawdsley v. Austin* [1985] 1 W.W.R. 369 (B.C.S.C.).
- Child
- Parent
- Sibling
- Anyone else related by birth or adoption.

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However

- Law of consent applies only to medical interventions
- Therefore retrieval and use of human tissue not covered
- Since no ownership in human tissue,
 - commercial law does not apply
 - contract law does not apply either

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Nevertheless,

- General recognition that right of consent / disposition exists
- Captured in regulatory provisions
 - Interagency Advisory Panel
 - Tri-Council

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Interagency Advisory Panel on Research Ethics

- Collection and use of human tissues for research purposes shall be undertaken with the free and informed consent of competent donors;

In the case of incompetent donors, free and informed consent shall be by an authorized third party;

- In the case of deceased donors, free and informed consent shall be expressed in a prior directive or through the exercise of free and informed consent by an authorized third party.

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Tri-Council Guidelines for Research Involving Human Subjects

- Cover everything the Advisory Panel's statement covers
- Extend further to include
 - fluids
 - gametes

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Consent under these provisions

- Consent is necessary
- Consent must disclose
 - Proposed use
 - Potential commercial use
 - Privacy implications

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Further considerations

- Privacy rights also entail that consent must be had
- Possibly relevant legal case
 - *R. v. Dymnt* 1988, 66 C.R.(3d) 348, 45 C.C.C.(3d) 244 (S.C.C.)
 - Blood taken for one purpose may not be used for other purpose

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Therefore

- Consent must be had for retrieval and use of human tissue for research purposes
- Unless otherwise stipulated by subject, consent need not be had for destructive disposal

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Further conditions:

- Applies to previously collected as well as newly collected tissue
- Donorship cannot be a condition of treatment
- Duty to warn of results of tests
- Duty of appropriate recordkeeping
- Subject has right of access to information about subject derived from tissue

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An aside

- Presumed organ donorship in 13 countries of the EU
 - But only for transplantation purposes
- Council of Europe: Convention on Human Rights and Biomedicine, Article 22:
 - When in the course of an intervention any part of a human body is removed, it may be stored and used for a purpose other than that for which it was removed, only if this is done in conformity with appropriate information and consent procedures.
- Applies to
 - “organs and tissues proper, including blood”

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Return to Canadian scene

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Non-research use

- Presumption of right of disposition remains
- Therefore guidelines for research must be followed as well
- Doctrine of abandonment
 - Clearly intended to abandon

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Possible excuses for non-consensual recovery and use

- Doctrine of *laches*
- Doctrine of *adverse possession*
- Doctrine of abandonment
- Doctrine of *res nullius*

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Doctrine of *laches*

- Requires donor to be negligent in asserting claim
- Not applicable unless donor was apprised of rights

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Doctrine of *adverse possession*

- Requires that tissue was possessed visibly and openly in opposition to possible interest of rightful owner
- Not applicable unless donor knows of use

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Doctrine of Abandonment

- Standard view of many jurisdictions
 - MRC of UK, *Human Tissue and Biological Samples* 3.1
- Requires that donor abandoned intentionally
 - Abandonment extinguishes right of disposition
- However
 - Not in keeping with standard assumption
 - Assumption that will be disposed of in standard fashion of disposal
 - Therefore if not standard in social context, then there lies an ethical duty to inform

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Doctrine of *res nullius*

"Res nullius fit primi occupantis."

- Types of *res nullius*
 - what cannot be owned by anyone
 - what in fact is not owned by anyone but can be owned in principle
 - what is owned in common
- Does not apply to tissue because there is no ownership in human tissue

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Moreover

- Privacy rights
 - of donor
 - of third partiesare not extinguished by abandonment

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Special tissues

- Foetus
- Placenta
- Cord blood

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Status of the foetus

- Is foetus property or person?
- Is it something in-between?
- What applies to abortus?
 - *Davis v. Davis* [842 S.W.2d 588, 597 (Tenn. 1992)]

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Placenta

- Considered tissue in Europe
- Therapeutic uses
 - placenta-derived mesenchymal cells (to treat ischemic diseases)
 - Diagnostic uses
 - A convenient source of homologous material, for diagnosis and therapy of inborn errors of metabolism
- Cosmetic uses
 - Placenta Lexmo (Swiss)
 - Lanocrème (Australia)
 - Lui-21 Placenta cream (Japan)

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Cord blood

- Convention on Human Rights and Biomedicine of the Council of Europe (Oviedo Convention)
 - Convention 25
 - *The human body and its parts shall not, as such, give rise to financial gain.*
 - Convention 26
 - *The provisions of this Protocol applicable to tissues shall apply also to cells, including haematopoietic stem cells*

<http://conventions.coe.int/treaty/en/treaties/html/164.htm>

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Some relevant cases from the UK

- *R v Luff* (1960) (hair)
- *R v Rothery* [1976] RTR 550. (blood)
- *R v Welsh* [1974] RTR 478. (urine)

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Continued interest

- Cell lines
- DNA

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Special issues

- Collectivities
 - Religious
 - cultural
- Bodies
- Incompetent persons
 - Children
 - Adults
- Donated tissue
 - Access
 - Use
 - Storage
 - Identification
- Biomonitoring

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Let's start with profit: an old case

- *Moore v. Regents of U. of California* 793 P.2d 479 (Cal. 1990)
 - Splenectomy to assist treatment of hairy cell leukemia
 - established a cell line from Moore's T-lymphocytes
 - MO cell line producing G-CSF (granulocyte colony stimulating factor)
 - 2006 cost:
 - \$1,842.18 per patient (2 injections, 4 cycles)
- See reaction of Council of Europe

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