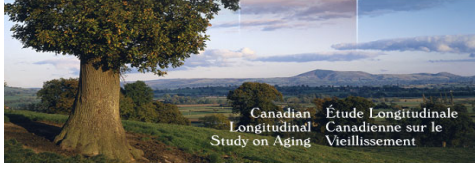




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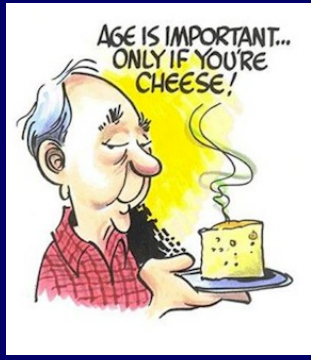


Some Ethical, Legal, Social Issues (ELSI) in the context of the Canadian Longitudinal Study on Aging (CLSA)
 Patricia Kosseim

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Age is an issue of mind over matter. If you don't mind, it doesn't matter.
 ~Mark Twain

Age is not a particularly interesting subject. Anyone can get old. All you have to do is live long enough.
 ~Groucho Marx



~ George Burns?



off the mark.com by Mark Parisi

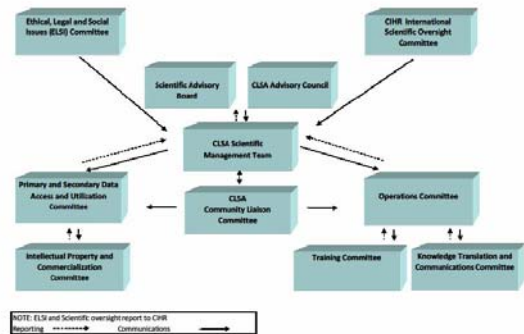
TESTING THE THEORY THAT PEOPLE ARE ONLY AS OLD AS THEY FEEL

**If life were that simple...
 You wouldn't need ELSI Committees!**

Focus today is on *some* Relevant ELSI in the context of the CLSA:

1. ELSI Governance
2. Consent
3. Capacity

1. ELSI Governance



Advisory Committee on ELSI for the CLSA - Membership

Members:

Patricia Kosseim, Genome Canada (*Co-Chair*)
 Daryl Pullman, Memorial University of Newfoundland (*Co-Chair*)
 Carman Baggaley, Office of the Privacy Commissioner of Canada
 Mylène Deschênes, Public Population Project in Genomics Canada
 Khaled El Emam, CHEO Research Institute
 Debra Grant, Information and Privacy Commissioner of Ontario
 Trudo Lemmens, University of Toronto
 Kieran O'Doherty, University of British Columbia
 Norm O'Donnell, Community Member, British Columbia
 Nola Ries, University of Alberta
 Jill Scott, Vancouver Coastal Health Authority
 Don Willison, Ontario Agency of Health Protection and Promotion

Ex officio Members:

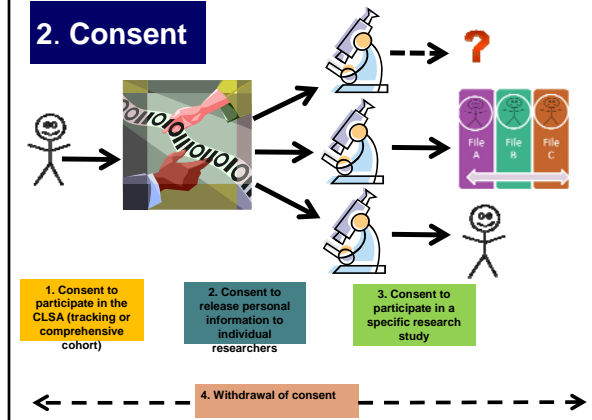
Kristiann Allen, CIHR Ethics Office
 Linda Mealing, CIHR, CLSA
 Christina Wolfson, CLSA Principal Investigator, McGill University

Terms of Reference

Mandate of the CIHR Advisory Committee on ELSI related to the CLSA is to:

1. provide independent, critical advice to the Scientific Management Team leading the CLSA on actions and best practices to address ethical, legal and social issues during the 5-year implementation phase of the CLSA;
2. contribute to the advancement of ELSI knowledge related to the CLSA and other similar population-based, longitudinal studies, databases and biobanks; and,
3. disseminate ELSI knowledge to the external community of relevant stakeholders

2. Consent



“Informed Consent”

- Current legal and ethical standard in Canada
- Tension around specific vs. broad consent continues
- Ways of “informing” consent:
 - delimiting as much as possible the broad parameters
 - putting in place governance process to ensure ongoing respect of purpose
 - disclosing the informational risks/unknowns to potential participants
 - instituting proper oversight and accountability
 - building in de-identification mechanisms and access controls
 - designing effective protections and safeguards against unauthorized use
 - creating publicly available registries of specific research projects
 - periodically reaffirming consent (in the case of longitudinal studies)
 - Providing ongoing opportunity to withdraw consent



Withdrawing Consent

- Discontinue all future contact by CLSA or other researchers?
- Discontinue all future data collection either directly or indirectly through linkage or other means?
- Discontinue all future research uses of already-collected data and biosamples?
- De-identify or destroy personal data and biosamples?

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3. Capacity

- Only participants capable of consenting at initial recruitment phase will be enrolled in the CLSA
- Interviewers will be trained professionals, able to determine a person's capacity to provide informed consent and to participate in the CLSA
- What happens as participants age, and begin to lose mental capacity?

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Underlying Ethical Principles Relevant to Issues of Capacity

- Respecting the autonomy of the individual
- Respecting the dignity and integrity of persons
- Protecting the vulnerable against possible harms, abuses or exploitation
- Allowing inclusive participation in research and equitable sharing of its potential benefits

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Legal Capacity – General

- General presumption exists in favour of adult capacity
- Capacity requires understanding of nature and consequences of proposed intervention
- Process for determining capacity (or incapacity) typically involves assessment by health provider

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Diminishing Capacity

- Capacity may diminish for some purposes (e.g. financial affairs), not others (e.g. health care decisions)
- Loss of capacity may be only partial (individual may still be capable of expressing assent/dissent)
- Loss of capacity may be only temporary (capacity may be regained, upon which legal powers of substitute decision-maker and legal effect of advance directive are extinguished)

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Substitute Decision Makers (1)

- court-appointed: guardians with broad powers to manage all of the individual's affairs, including health care);
- patient-appointed: proxies appointed in an advance directive to make health care decisions on behalf of the patient; or,
- statute-appointed: SDMs chosen in accordance with specific rank order.

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Substitute Decision-Makers (2)

- SDMs must be of adult age and capable, with no conflicting interest
- SDMs must respect express instructions of patient , as per advance directive (where there is one) or per known wishes of the individual.
- Where individual's wishes not known, SDM must decide in individual's best interests, taking into consideration mandatory criteria where these exist in law
- Mechanisms exist to review SDM decisions.

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Application to Research: Physical Intervention

- Statute: some health care consent laws include "research" subject to conditions; others prohibit SDMs from consenting to research, unless clear and unambiguous instruction to do so under AD
- Common law: still predominantly governed by concept of "best interest" of the individual
- Civil law: allows SDM for research, but under formal protection regimes
- Ethics guidelines: allows SDM to consent to research on behalf of persons who lack capacity subject to several conditions*

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Application to Research: C/U/D Personal Info

- Lack of capacity is not the same as "impracticability to obtain consent"
- Consent remains the rule, subject to possible exemption for research where conditions are met
- Substitute decision-making rules apply, either as set out directly in personal information laws, or generally imported by reference

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Conclusions



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