Open Access / Data Management Plans / Secondary Use of Data

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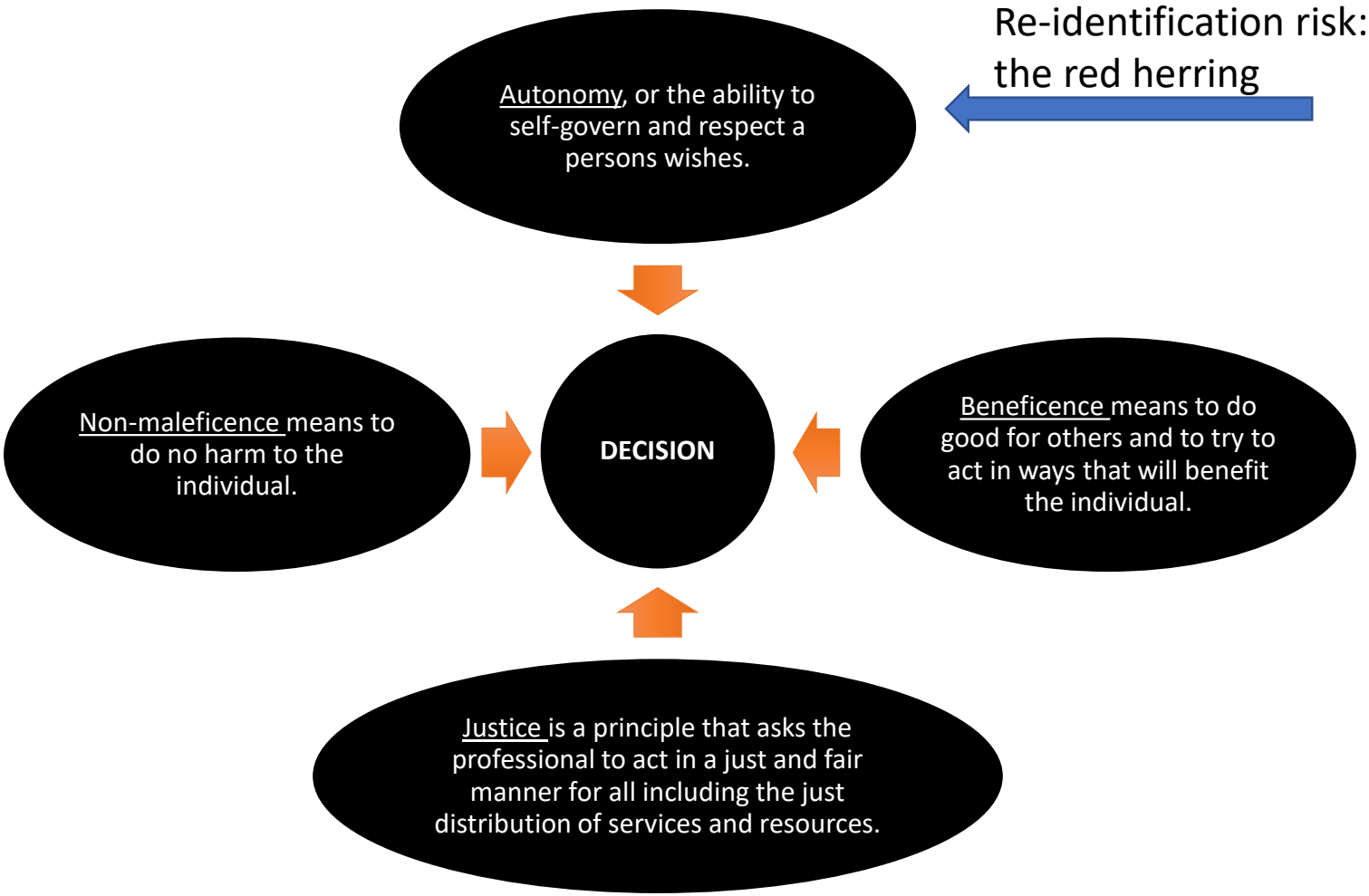
Back to basics:

Applied ethics principles (all things considered judgments)



Move towards consent to good governance and new emphasis on the right to benefit and the production of good science

Ethics of Genomic Data Sharing:

An Interview with Bartha Maria Knoppers

Federal context

- The Organisation for Economic Co-operation and Development's Declaration on Access to Research Data from Public Funding (2004)
- The Open Government Declaration (2011)
- and the G8 Science Ministers Statement (2013)
- Fostering access to the results of research funded by the Tri-Agencies is also discussed in Canada's Action Plan on Open Government (2014-16)

Data sharing expectations

Tri-Agency Research Data Management Policy (Draft), Sponsors, Journals, Patients, Publics

Story about Cornell researcher Brian Wansink

Local engagement activities

- BioBanking Participation Workshops 2018 Report by Vercauteren et al., “Giving patients, the public, and health-care providers a voice in pediatric biobanking”

- Ho et al.2018. Data Access and Usage Practices Across a Cohort of Researchers at a Large Tertiary Pediatric Hospital: Qualitative Survey Study. JMIR Med Inform. May 14;6(2):e32. doi: 10.2196/medinform.8724.

Data Deliberation BC | Public engagement on data, privacy and access

Secondary use of data: Compliance in BC

- FIPPA is actually a research facilitating document. Many different ways to share unconsented identifiable information-consent, section 35, etc.
- TCPS2-Waivers of consent articles
  - Data: 5.5 A(identifiable) and B (non-identifiable)
  - Tissue: 12.3 A (identifiable)and B (non-identifiable)
- New MoH policy instrument "Access to health data for research" (Sept, 2018)
  - "de-identification" means a process that removes, or transforms, direct and indirect identifiers in a record using methods that can include generalization, suppression, aggregation and randomization, and for unstructured data can include redacting or severing, with de-identification processes resulting in partial de-identification or anonymization;
  - "partial de-identification" means a de-identification process that removes direct identifiers and manages the indirect identifiers that could potentially be combined to identify an individual. Partially de-identified records contain personal information. Therefore, the disclosure of partially de-identified records would require appropriate authorization under Part 3 of Freedom of Information and Protection of Privacy Act;
  - "direct identifiers" means information that identifies an individual without additional information, with examples including an individual's name or a unique identifier such as a personal health number;
  - "indirect identifiers" means information that is not a direct identifier but which may identify an individual when it is connected with other pieces of information to single out an individual, with indirect identifiers being considered personal information if they can be combined together to identify an individual, due to what is commonly referred to as the mosaic effect;

Seeking clarity: The OIPC myth busting report

Secondary use of data: US Common Rule changes

IRBs gearing up for changes that must take place on Jan 21,2019 (except for single IRB review-Jan 20,2020). These changes will dramatically impact our ability to compete in the international clinical trial environment if we do not modernize and become more participant focussed in Canada

- New exemption 8: Use of identifiable data and identifiable biospecimens obtained with broad consent for secondary use when an IRB conducts a limited IRB review (IRB not required to consider all of the IRB approval criteria).

  * Remember that de-identified data has not been considered a human subject under the Common Rule and this continues to be the case.

- New informed consent rules –must be concise, contain only key information, information that a reasonable person would want to know

Data sharing efforts across BC

- Many examples: https://www.popdata.bc.ca/projects/BCSUPPORTUnit
- PopData plays a central role

Challenges ahead require an interdisciplinary approach

- How to follow the OCAP principles in community engaged Indigenous research (ownership, control, access, possession)
- How to encourage different models of consent (integrated (verbal)consent in the clinic) that reduce burden on patients and staff
- How to manage unspecified future use in genetics topics like WGS with special populations
- How to ensure meaningful, continued public engagement to support the good governance of data sharing
- How to modernize compliance mechanisms within institutions to keep up with research and patient preferences and those of publics