BCNET

Shared IT Services for Higher Education & Research

Conference 2018

Welcome!

Ethical Decision Making in Research Privacy

A little about me

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- Research Privacy Advisor, PHSA
- Ethicist, BC Cancer REB

Conflicts of interest –None

Provincial Health Services Authority
Province-wide solutions. Better health.

Ethical decision making in research privacy

- Overview of bioethics tools, concepts, and resources
- Case study examples

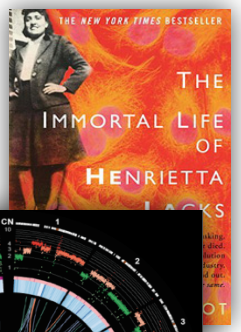
What is applied ethics?

- Many different types of applied ethics.
- What is an ethical analysis?
  - Systematic analyses of value laden areas involving “all things considered” judgments.

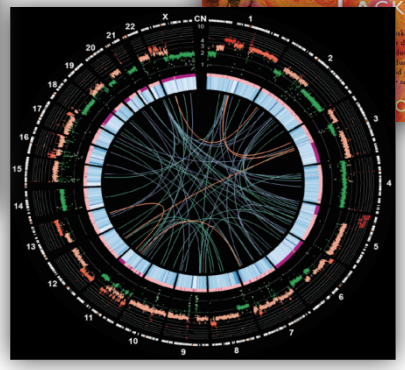
Why does research ethics matter?

Tuskegee syphilis experiment 1932-1972

Hela immortal cell line 1950-ongoing



Willowbrook Experiments on mentally disabled children deliberately infected with hepatitis over 14 years in 1956



European Molecular Biology Laboratory sequences the genome of a HeLa cell line 2013

Aboriginal nutritional experiments 1940's and 1950's

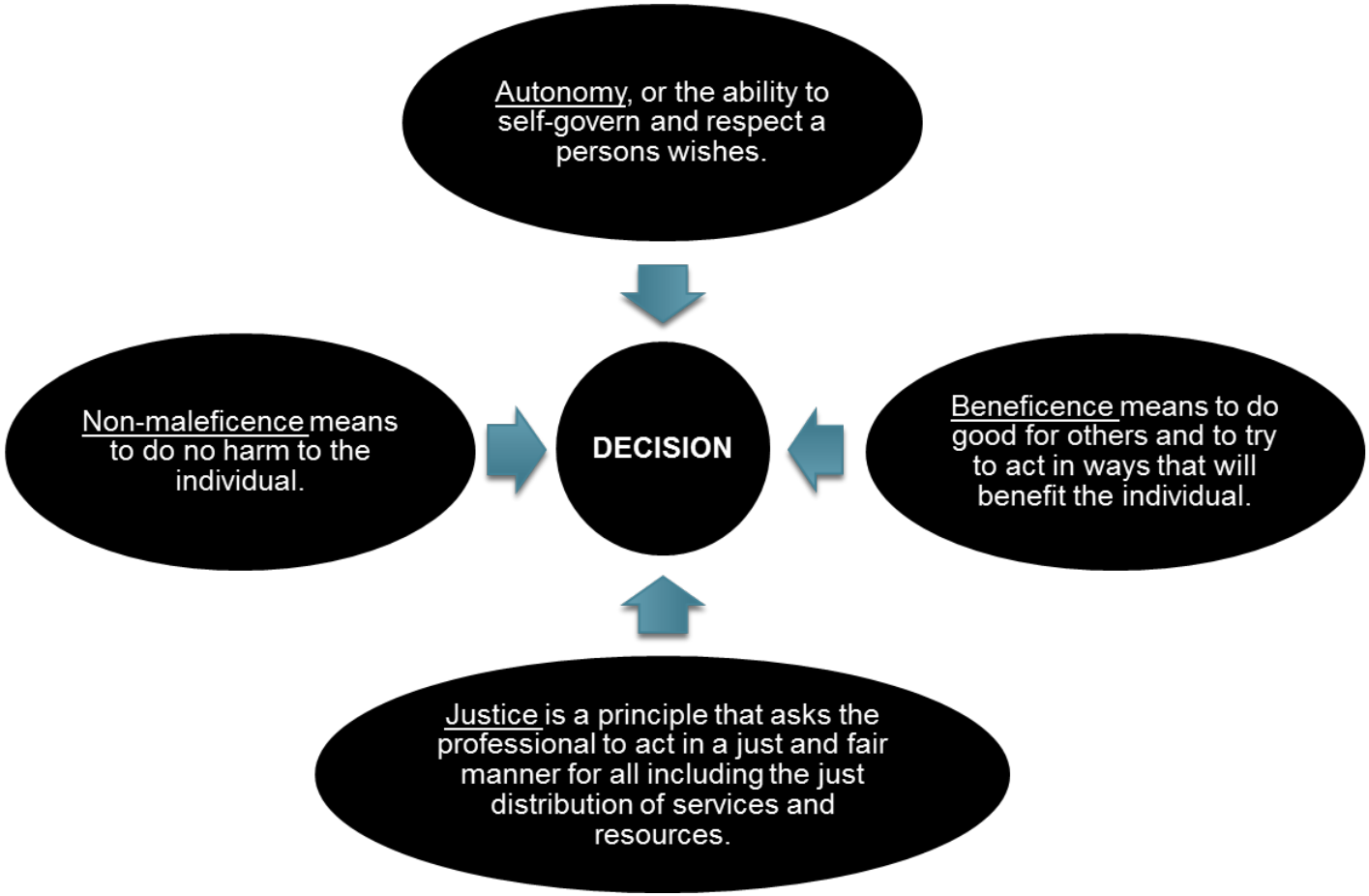
Hwang indicted on embezzlement and bioethics violations 2006

Conceptual framework (participant centered)

Substantive ethics

Procedural ethics

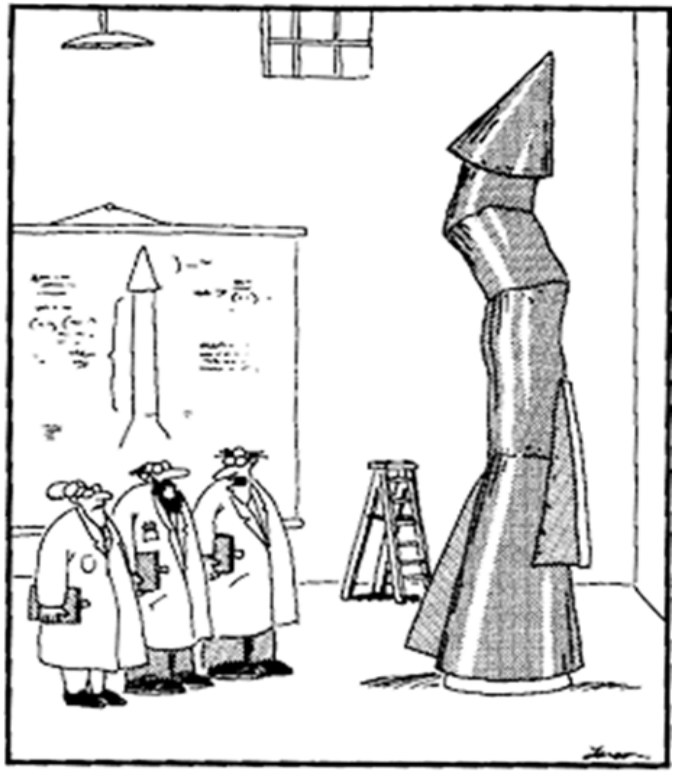
Applied ethics principles



How does research ethics relate to clinical and public health ethics?

7 requirements to make clinical research

1. Value;
2. Valid;
3. Subject selection;
4. Risk-benefit;
5. Independent review;
6. Informed consent;
7. Respect for participants.



"It's time we face reality, my friend. ... We're not exactly rocket scientists."

* Source: Emanuel, Wendler, Grady. What Makes Clinical Research Ethical? JAMA. 2000;283(20):2701-2711\

TCPS 2 (2014)— the latest edition

- TCPS is a joint policy of Canada's three federal research agencies – the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada(NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or "the Agencies."

- To be eligible to receive and administer research funds from the Agencies, institutions must agree to comply with TCPS and researchers are expected, as a condition of funding, to adhere to the TCPS.

- Principles-based guidance…
  - Respect for Persons
  - Concern for Welfare
  - Justice

What is an Research Ethics Board (REB)?

- Review studies for ethics compliance with TCPS, HC requirements, and international norms and guidance (such as ICH GCP)* and ensure scientific value
- Comprised of different experts including a community member
- Review all aspects of the study

* Good Clinical Practice and the International Conference on Harmonisation

TCPS applies to research conducted with human participants

- Research – An undertaking intended to extend knowledge through a disciplined inquiry and/or systematic investigation.



OIPC guidance regarding FIPPA and research

Ethics exceptionalism

- Calls for different procedural and substantive reviews.
  - Uncontested example: Research with Aboriginal peoples in Canada, including First Nations, Inuit and Métis peoples

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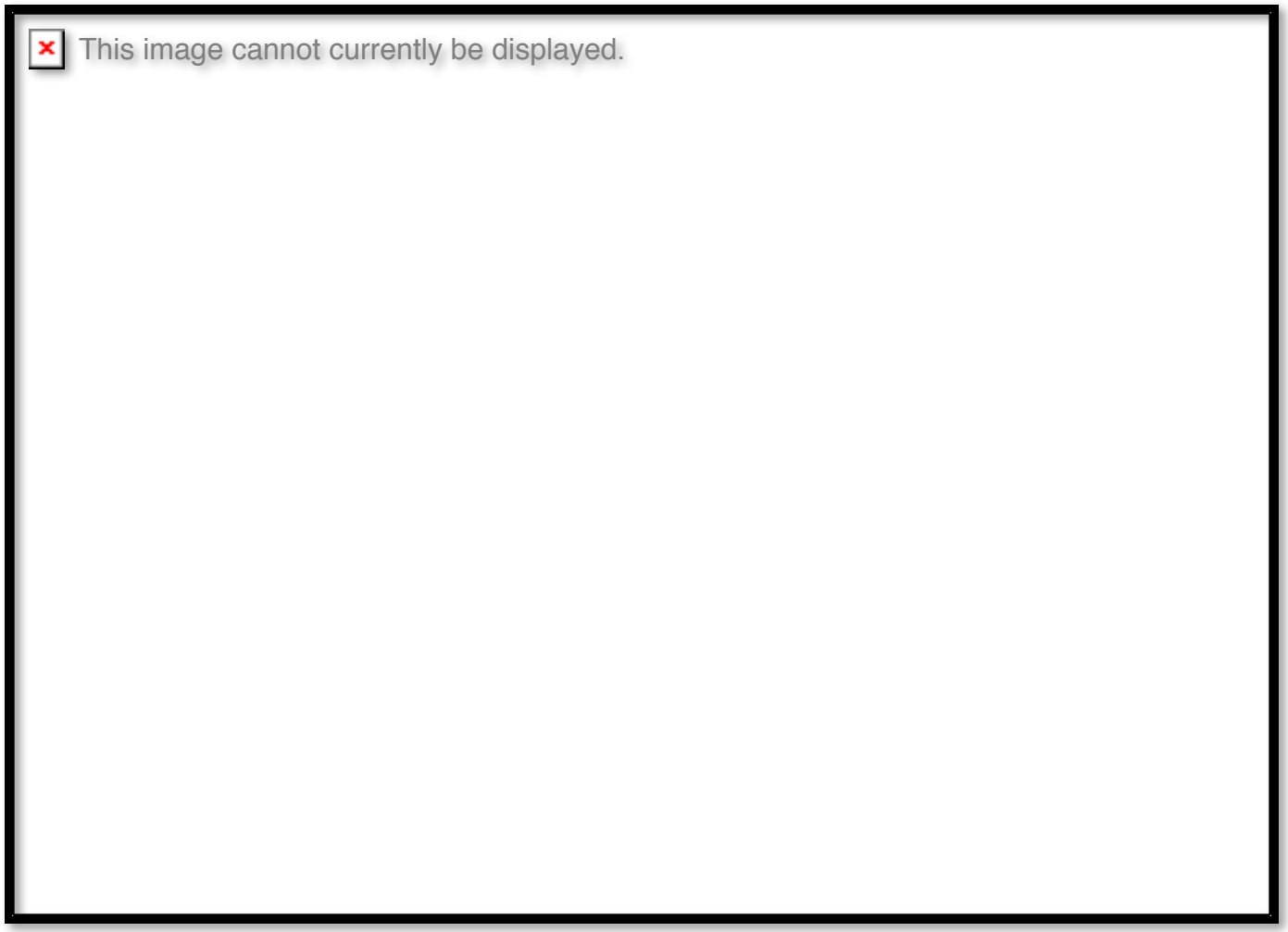
Ethics exceptionalism is not static



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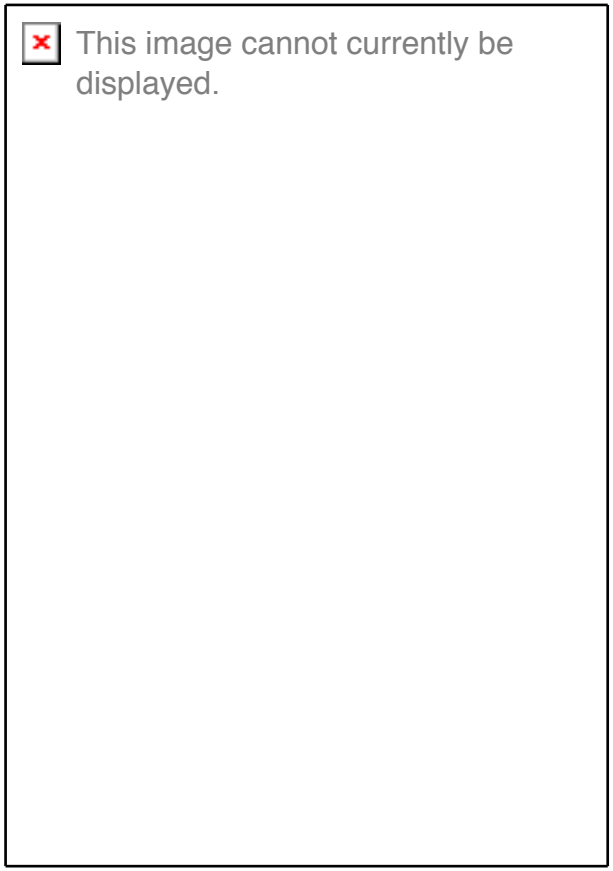
Vulnerability

The duty to protect participants

The duty to maintain confidentiality-Russel Ogden v. SFU



THE GLOBE AND MAIL

"As a master's student at Simon Fraser University in the 1990s, Mr. Ogden was awarded $34,000 and an official apology after the school refused to pay his legal bills as he fought a coroner's request that he identify the participants in his master's thesis on assisted suicide in Canada.

In 1998, Mr. Ogden left a PhD program at the University of Exeter after a protracted battle with the school's ethics committee, which backtracked on its promise to support him by granting "absolute" anonymity to more than 100 people helping terminally ill AIDS patients commit suicide in Canada, Britain, the United States and the Netherlands.

In 2003, British authorities ordered the University of Exeter to pay Mr. Ogden about $140,000 for breaking the commitment."

Case study analyses & discussions

Questions to consider …

- What are the ethical red and yellow flags?
- Can these dilemmas be mitigated? And if so, how?
- How could these dilemmas be avoided in the future?
- What are the duties of the researchers in each case (if any)?
- In what ways are these cases similar? (If at all)
- In what ways are they different? (if at all)

Case study #1: Tatiana and Krista Hogan

- Tatiana and Krista Hogan are conjoined twins who were born at B.C. Children's Hospital in 2006. They live in Vernon BC but make regular trips to BC Children's to receive health care. They are the only conjoined twins in Canada.
- As a single mother on social assistance, their mother Felicia has endured public criticism since the twins were born.
- The twins are happy and receive a lot of support from their community but struggle with financial and health issues related to their condition.
- Hollywood agent Chuck Harris has signed the family. Harris, the so-called Wizard of Odd, represents curiosities like the "Wolf Boy". Harris hopes to get them a reality TV show.
- Each child has a fully structured brain, two cerebral hemispheres, a fully formed brain stem, cerebellum, and spinal cord. There is also a bridge of tissue, through which neurological information seems to be shared; within days of their birth, it became apparent that if one twin was pricked with a needle, the other would cry. They can also see through each other's eyes.
- Researchers from around the world are very interested in their progress.

Source: Vancouver Sun -01,02,2014:
http://www.vancouversun.com/health/Through+sister+eyes+Conjoined+twins+Tatiana+Krista+were+extraordinary+from+beginning/7449226/story.html

Let’s discuss!!!

- Should researchers be permitted to work with the twins? Why or why not?
- What ethics and other issues should be considered?
- Under what circumstances could research be conducted with the twins in an ethical manner?

Autonomy and informed consent

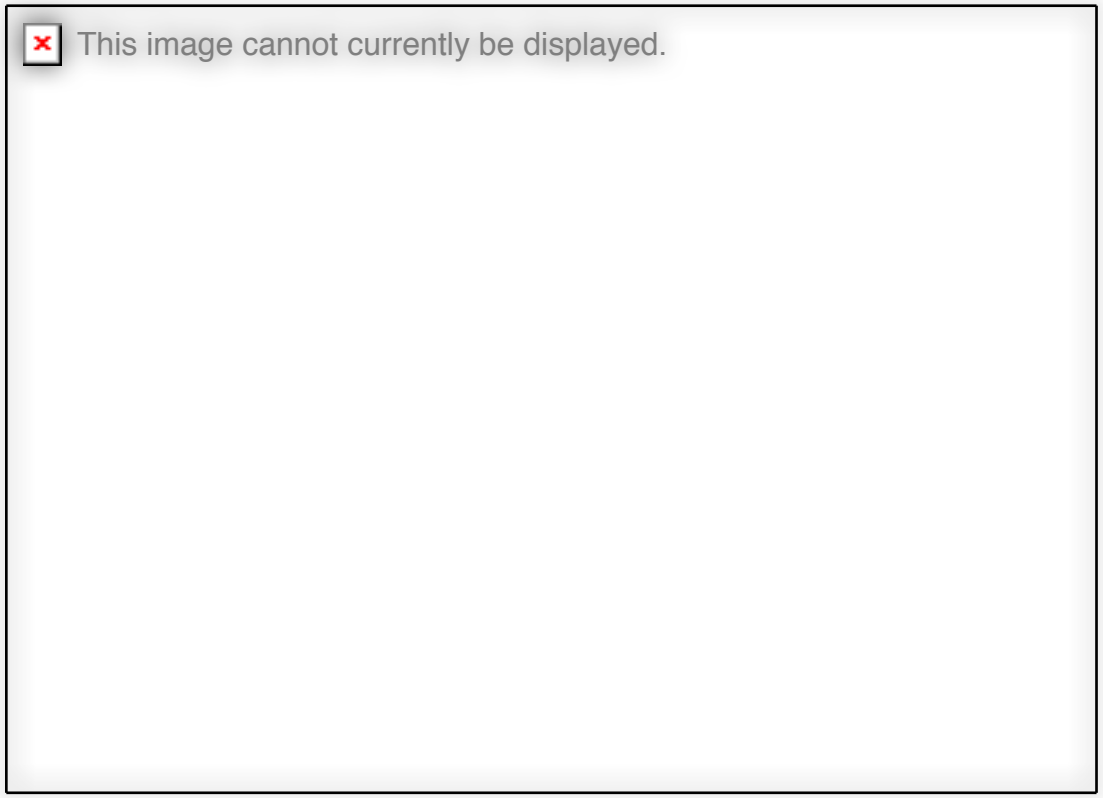
➡ Full disclosure, individualistic models or consent to good governance?

"My view is that the focus on consent in contemporary biomedical research has become the modern equivalent of a fetish“

- Barbara A. Koenig

Informed consent

- Broad/blanket, study by study, re-consent, group/community consent, dynamic consent, pragmatic consent



Centering the human participant in REB review:

Consent relationship is intended to be a flexible process and participant specific

Determining capacity to consent (third party consent always second best)

- Pediatrics: Rule of Sevens
- Adults:
  - Testing cognitive capacity (Mini Mental State Examination or MMSE)
  - Substitute decision makers, LARs, research directives, BC Health Care (Consent) and Care Facility (Admission) Act –health care includes medical research that must be reviewed by a *designated* REB.
    - Also talks about the *presumption of capability* and capacity cannot be determined solely through an adult's way of communicating with others.

<u>Other important ethical considerations:</u>

- Dissent
- Direct/therapeutic benefit and overriding assent or dissent
- Fluctuations in consent in longitudinal studies
- Regaining capacity

Material incidental findings (MIFs)

- Article 3.4 Researchers have an obligation to disclose to the participant any material incidental findings discovered in the course of research.
- Application: In some areas of research, such as medical and genetic research, there is a greater likelihood of material incidental findings. When material incidental findings are likely, researchers should develop a plan indicating how they will disclose such findings to participants, and submit this plan to the REB. If there is uncertainty as to whether a research project warrants such a plan, researchers and REBs can make this determination on a case-by-case basis. When necessary, researchers should direct participants to a qualified professional to discuss the possible implications of the incidental findings for their welfare. Insome cases, incidental findings may trigger legal reporting obligations and researchers should be aware of these obligations (see Article 5.1). A researcher may request an exception to the obligation to disclose material incidental findings, based on the impracticability or impossibility of disclosing such findings to the participant. “Impracticable” refers to undue hardship or onerousness that jeopardizes the conduct of the research; it does not mean mere inconvenience. Disclosure may be impossible or impracticable (see Glossary) when the group is very large or its members are likely to be deceased, geographically dispersed or difficult to track. The onus is on the researcher to justify to the REB the need for the exception. REBs should decide whether exceptions apply on a case-by-case basis.

- **Key points: Actionable findings, the right not to know, MIF plans, team expertise to analyze, interpret, and communicate the MIF, new Canadian The Genetic Non-Discrimination Act.**

Is this process protecting human research participants?

Empirical data-the bad news ☹

- "Recent study conducted by Kaiser Permanente Colorado found that while the majority of those approached (69%) would be willing to participate in a biobank and 84% correctly understood that they would not receive personal results from studies, some issues were not as well understood (e.g., only 32% correctly understood that their sample would be linked to their medical record)."

  (Virani and Longstaff, 2014)

Waver of consent -data

Article 5.5A Researchers who have not obtained consent from participants for secondary use of identifiable information shall only use such information for these purposes if they have satisfied the REB that:

(a) identifiable information is essential to the research;

(b) the use of identifiable information without the participants' consent is unlikely to adversely affect the welfare of individuals to whom the information relates;

(c) the researchers will take appropriate measures to protect the privacy of individuals, and to safeguard the identifiable information;

(d) the researchers will comply with any known preferences previously expressed by individuals about any use of their information;

(e) it is impossible or impracticable (see Glossary) to seek consent from individuals to whom the information relates; and

(f) the researchers have obtained any other necessary permission for secondary use of information for research purposes

Article 5.5B Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of non-identifiable information

Waiver of consent-tissue

Article 12.3A Researchers who have not obtained consent from participants for secondary use of identifiable human biological materials shall only use such material for these purposes if they have satisfied the REB that:

(a) identifiable human biological materials are essential to the research;

(b) the use of identifiable human biological materials without the participant's consent is unlikely to adversely affect the welfare of individuals from whom the materials were collected;

(c) the researchers will take appropriate measures to protect the privacy of individuals and to safeguard the identifiable human biological materials;

(d) the researchers will comply with any known preferences previously expressed by individuals about any use of their biological materials;

(e) it is impossible or impracticable to seek consent from individuals from whom the materials were collected; and

(f) the researchers have obtained any other necessary permission for secondary use of human biological materials for research purposes

Article 12.3B Researchers shall seek REB review, but are not required to seek participant consent, for research that relies exclusively on the secondary use of nonidentifiable human biological materials.

Case study #2: Moral permissibility of not knowing or informing

The condition: Autosomal dominant arrhythmogenic right ventricular cardiomyopathy (ARVC)

The facts:

- Very high chance of inheriting the condition where one parent affected
- 50% of affected males die in the absence of treatment by 40 years and 80% by 50 years, with corresponding risks for females of 5% and 20%
- Effective primary prevention of potentially lethal condition is available with implantable cardioverter defibrillator therapy
- In their report, Pullman and Hodgkinson explain that at the outset of the research there was no known genetic location for the condition under study; however, it later became “clear that DNA testing could define disease status pre-symptomatically” (p.200).

The following case arose within this context:

- A female individual at 50% a priori pedigree risk participated in genetic linkage analysis research.
- There was no experience in immediate family of serious symptoms of ARVC, even though multiple sudden cardiac death in young people in the extended pedigree;
- Research revealed woman had a high-risk DNA haplotype [ie affected]. Nevertheless, this subject refused to learn her DNA results or to receive further clinical testing;
- The woman in question had eight adult children, including five males who were between 20 and 40 years of age.

* Case from Pullman and Hodgkinson. (2006). Genetic knowledge and moral responsibility: ambiguity at the interface of genetic research and clinical practice. Clin Genet 2006: 69: 199–203.

Let's discuss!!!

- What would you do if you were the researcher? What are your moral obligations and to whom?
- What ethics and other issues should be considered?
- How could this dilemma be avoided in the future?

Good governance in research is proportionate

Good governance is about managing risk and lowering it where possible (the REB's risk benefit ratio). The threshold in TCPS2 is minimal risk or above minimal risk according to the daily life test not zero risk.

It is participant centered!!!!

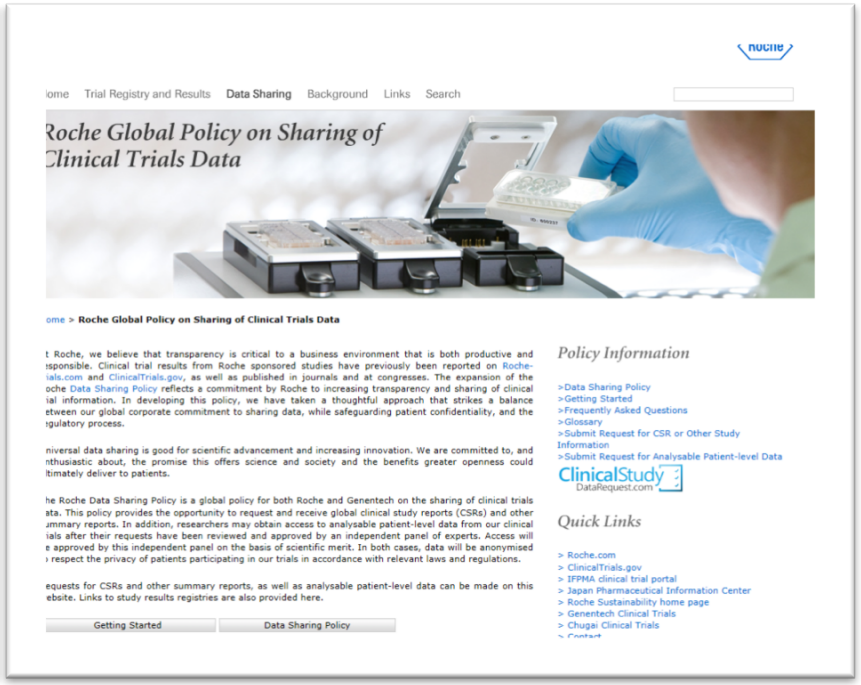
- Zero risk studies or studies that lack scientific uncertainty can be unethical
  - Junk science cannot be ethical. All risk and inconvenience with no benefit plus unjustified use of resources and services
  - Clinical equipoise- There must be genuine uncertainty regarding treatment options (e.g., comparing study arms in clinical trial). If preferences are known then it is not ethical to withhold that treatment or expose subject participants to research risks
- Increasing individual privacy risks is a necessary trade-off to achieve the collective good in most research studies
- Participants can agree to accept risks and trade-off privacy to support the collective good in research (and even without consent it can still be ethical-common practice)

The reality: Silos and the compliance police

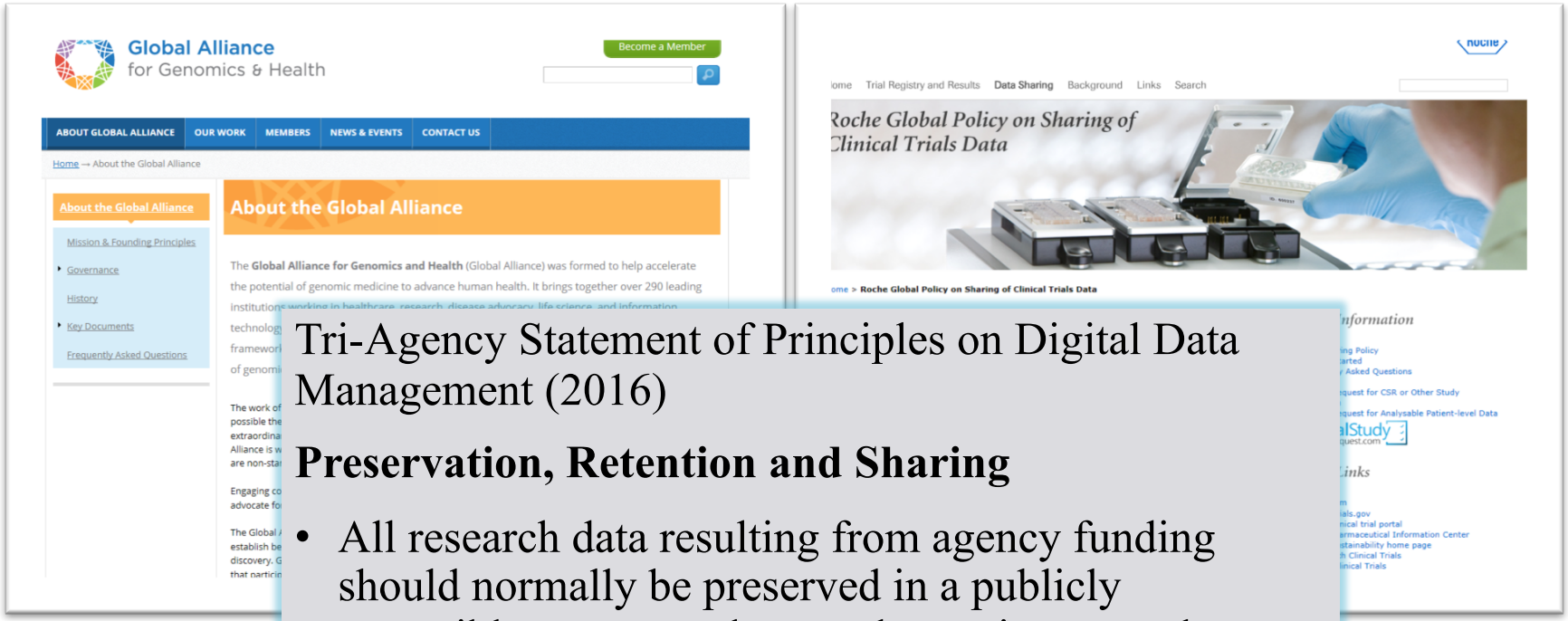
CTV news photo Published Saturday, June 2, 2012

Thoughts on rule following…

Big data & international harmonization efforts: The expectations



Big data & international harmonization efforts: The expectations



Tri-Agency Statement of Principles on Digital Data Management (2016)

Preservation, Retention and Sharing

- All research data resulting from agency funding should normally be preserved in a publicly accessible, secure and curated repository or other platform for discovery and reuse by others.

The price of ignoring substantive and procedural ethics

Loss of public trust

- Nuu-chah-nulth blood scandal at UBC where samples were used for purposes not in line with donors objectives
- Texas blood spots used without informed consent of donors eventually led to the destruction of approximately five million samples
- Gymrek 2013 study in which researches were able to breach the anonymity of genetic databases in order to recover participant surnames

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Risk to patient care

- Need data driven empirical research and QI/QA studies to inform and improve care and service for patients
- Innovate data sharing and privacy or get left behind (Facebook plan to share hospital data only “on hold”)

Research privacy in BC: Key points

- Break down the silos that lead to “creeping” and compliance gaps.
- Refocus on proportionality and value added to the lifecycle of scientific research.
- Consider the benefits of research to the health care system and patients. Inaction is not value neutral.

Research privacy in BC: Current state

- It can take years to compile required data from various data sources (if they ever get it).

- Researchers are often forced to pull data together in an ad hoc way, reduce the scope of their studies, modify their research questions, or exclude data from certain patient groups that are difficult to access.

- Not unusual for the informed consent of participants or REB decisions to be disregarded.

Accessing Health and Health-Related Data in Canada (2015) Key Findings
(Council of Canadian Academies Expert panel)

Case study #3: The murder of Angie Dodge

- 18 year old Angie Dodge was stabbed to death in 1996 in Idaho City.
- Police gather DNA from the scene and submit it for testing and conduct hundreds of interviews to find her killer.
- In 2014, police decide to search the public DNA database, Ancestry.com.
- Investigators used a technique known as familial searching, which seeks to identify the last name of potential suspects through a DNA analysis focusing on the Y chromosome. A promising “partial match” emerged between the semen sample and the genetic profile of Michael Usry Sr. -a finding that excluded the father but strongly suggested one of his relatives had a hand in the young woman’s murder.
- Only one, his son, a New Orleans Filmmaker named Michael Usry Jr., fit the mold of a plausible suspect, according to an application for a search warrant.
- Detectives traveled to New Orleans and had a magistrate judge sign a search warrant ordering Usry Jr. to provide his DNA for comparison. For about a month, Usry lived in a state of suspense.
- The result turned out to be a false positive. His sample did not match the DNA from the Dodge murder.
- The Idaho Falls Police Department has released an image of what Angie Dodge’s killer could look like based on the collected DNA.

Note: In the US, the most notable use of familial searching was the case of the notorious Grim Sleeper. An alleged serial killer, Lonnie Franklin, was indicted in 2011 on 10 counts of murder in Los Angeles after authorities found similarities between crime scene evidence and the DNA of Franklin’s son, who recently had been jailed on a weapons charge.

Sources: KBOI News, the New Orleans Advocate, and Dateline NBC

Let's discuss!!!

- Suppose a social science researcher wanted to use data from a public bank to help develop criminal profiles for law enforcement. Under what circumstances would that be acceptable (if any)?

- Suppose that a clinical researcher wanted to use tissue from a public bank to study genetic determinants in criminal activity for certain racial groups? Under what circumstances would that be acceptable (if any)?

Research Privacy at PHSA website

- You may wish to consult the “Research Privacy Tip Sheet: Common Terms and Tips to Reduce the Risk of Exposing Identifiable Personal Information.”
- This Tip Sheet references guidance from key Canadian documents that must be followed when conducting research within PHSA supplemented with advice from a range of data experts from both within and outside of PHSA.
- You can find the document on the Sharing Data page under the third bullet for Resources: http://www.phsa.ca/researcher/ethics-approvals/research-privacy-at-phsa/sharing-data

Questions/comments?

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