



Shared IT Services for Higher Education & Research

Conference 2018

Welcome!

Ethical Decision Making in Research Privacy

A little about me

Holly Longstaff, PhD

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

Conflicts of interest –None



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.

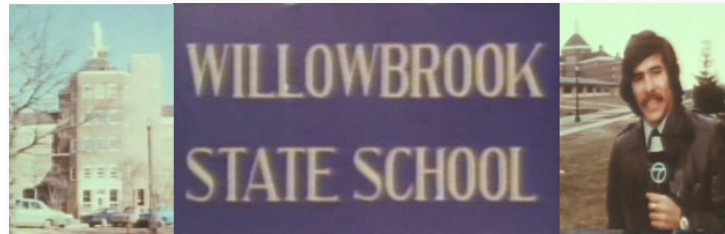
Why does research ethics matter?



Tuskegee syphilis
experiment 1932-1972

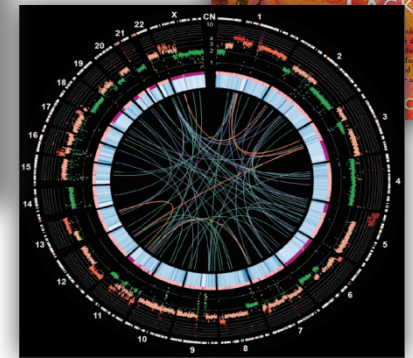
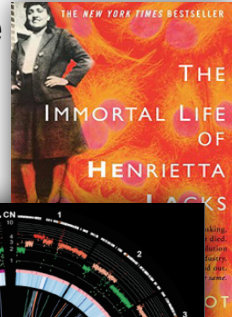


Aboriginal nutritional
experiments 1940's and
1950's



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

Hela immortal cell line
1950-ongoing



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



Hwang indicted on embezzlement
and bioethics violations 2006

Conceptual framework (participant centered)

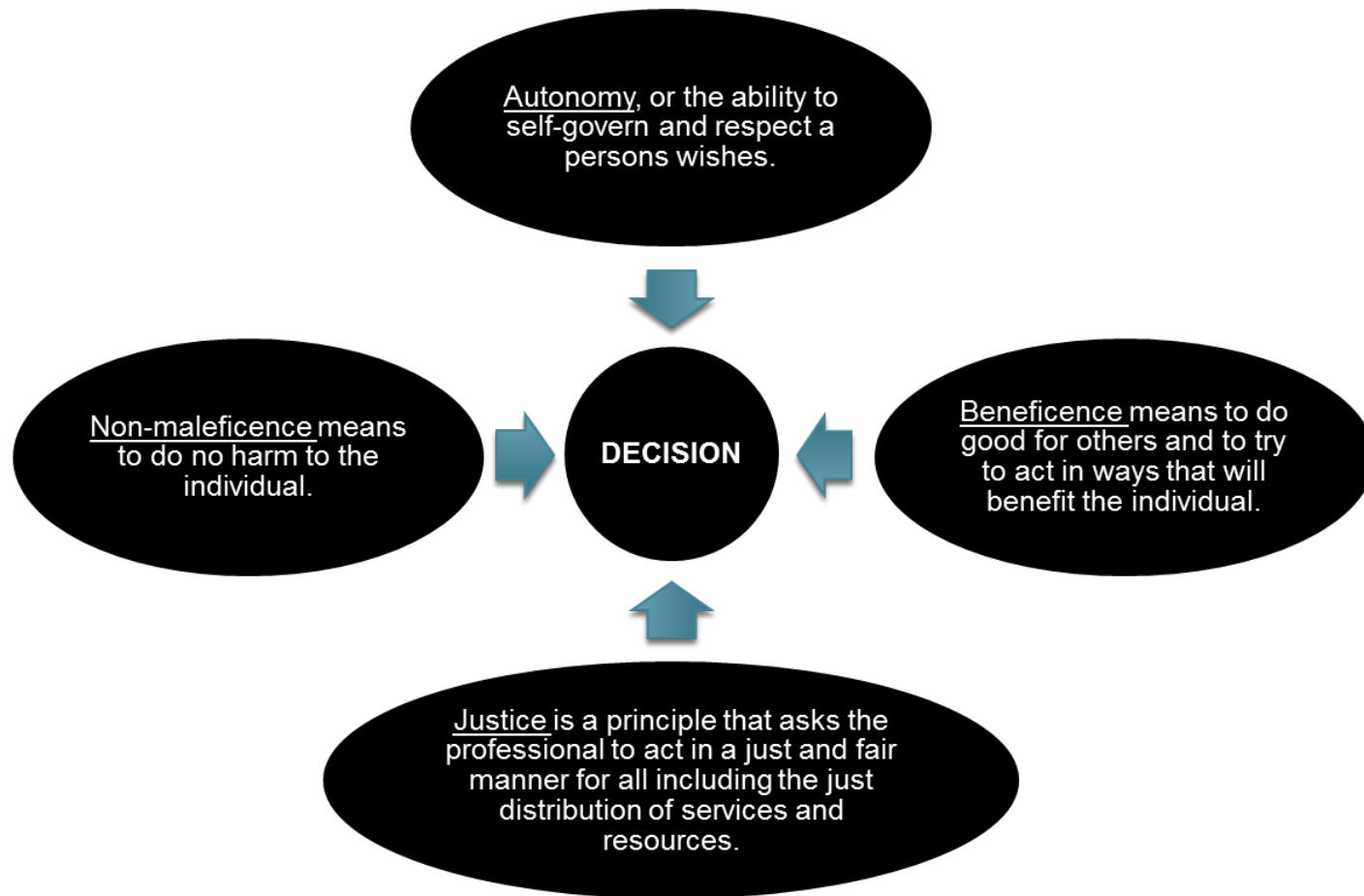


Substantive ethics



Procedural ethics

Applied ethics principles

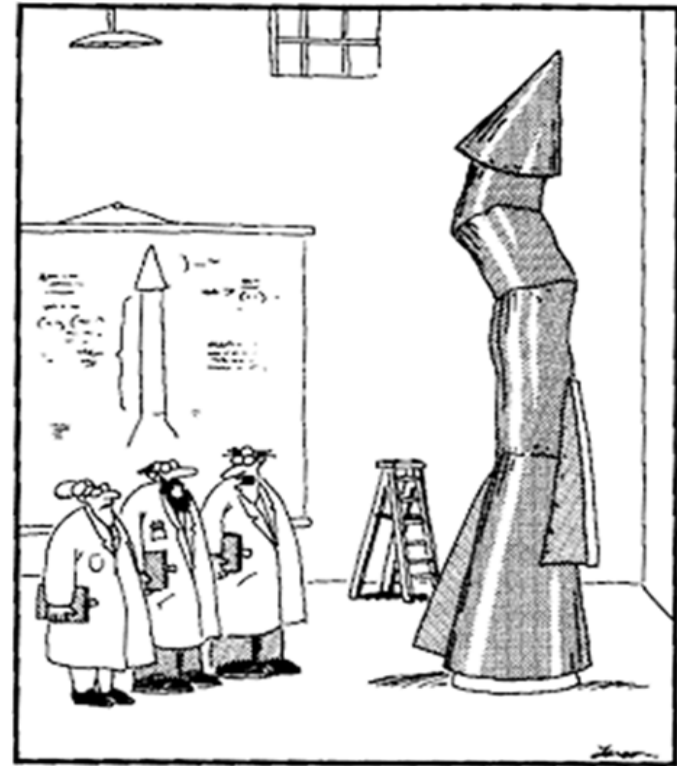


How does research ethics relate to clinical and public health ethics?



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




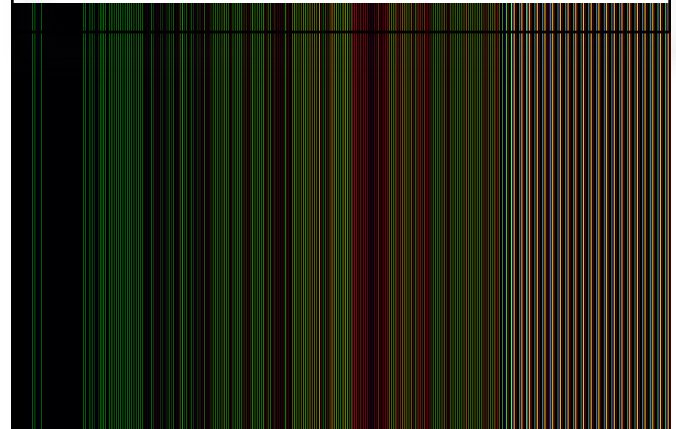
Ethics exceptionalism

- 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

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The duty to protect participants

The duty to maintain confidentiality-Russel Ogden v. SFU

THE GLOBE AND MAIL 



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“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



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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.

Other important ethical considerations:

- 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. In some 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.



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

**Global Alliance**
for Genomics & Health

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About the Global Alliance

[Mission & Founding Principles](#)

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[History](#)

[Key Documents](#)

[Frequently Asked Questions](#)

About the Global Alliance

The **Global Alliance for Genomics and Health** (Global Alliance) was formed to help accelerate the potential of genomic medicine to advance human health. It brings together over 290 leading institutions working in healthcare, research, disease advocacy, life science, and information technology. The partners in the Global Alliance are working together to create a common framework of harmonized approaches to enable the responsible, voluntary, and secure sharing of genomic and clinical data.

The work of the Global Alliance is critical to realizing the potential of recent technological advances that make possible the large-scale collection of data on genome sequencing and clinical outcomes. To seize this extraordinary opportunity, it is often necessary to ask questions that span individual datasets. The Global Alliance is working to alter the current reality where data are kept and studied in silos, and tools and methods are non-standardized and incompatible.

Engaging collaboratively with its stakeholders, the Global Alliance works to establish, broadly disseminate, and advocate for the use of interoperable technical standards for managing and sharing genomic and clinical data.

The Global Alliance acts as a convener, bringing together global stakeholders across sectors to share and establish best practices and to cross-pollinate ideas and learning, fostering a culture of innovation and discovery. Global Alliance stakeholders work together to promote the highest standards for ethics, ensuring that participants have the choice to responsibly and securely share their genomic and clinical data to advance



HomeTrial Registry and ResultsData SharingBackgroundLinksSearch



[Home](#) > [Roche Global Policy on Sharing of Clinical Trials Data](#)

At Roche, we believe that transparency is critical to a business environment that is both productive and responsible. Clinical trial results from Roche sponsored studies have previously been reported on [RocheClinicalTrials.com](#) and [ClinicalTrials.gov](#), as well as published in journals and at congresses. The expansion of the Roche Data Sharing Policy reflects a commitment by Roche to increasing transparency and sharing of clinical trial information. In developing this policy, we have taken a thoughtful approach that strikes a balance between our global corporate commitment to sharing data, while safeguarding patient confidentiality, and the regulatory process.

Universal data sharing is good for scientific advancement and increasing innovation. We are committed to, and enthusiastic about, the promise this offers science and society and the benefits greater openness could ultimately deliver to patients.

The Roche Data Sharing Policy is a global policy for both Roche and Genentech on the sharing of clinical trial data. This policy provides the opportunity to request and receive global clinical study reports (CSR) and other summary reports. In addition, researchers may obtain access to analysable patient-level data from our clinical trials after their requests have been reviewed and approved by an independent panel of experts. Access will be approved by this independent panel on the basis of scientific merit. In both cases, data will be anonymised to respect the privacy of patients participating in our trials in accordance with relevant laws and regulations.

Requests for CSRs and other summary reports, as well as analysable patient-level data can be made on this website. Links to study results registries are also provided here.

[Getting Started](#)[Data Sharing Policy](#)

Policy Information

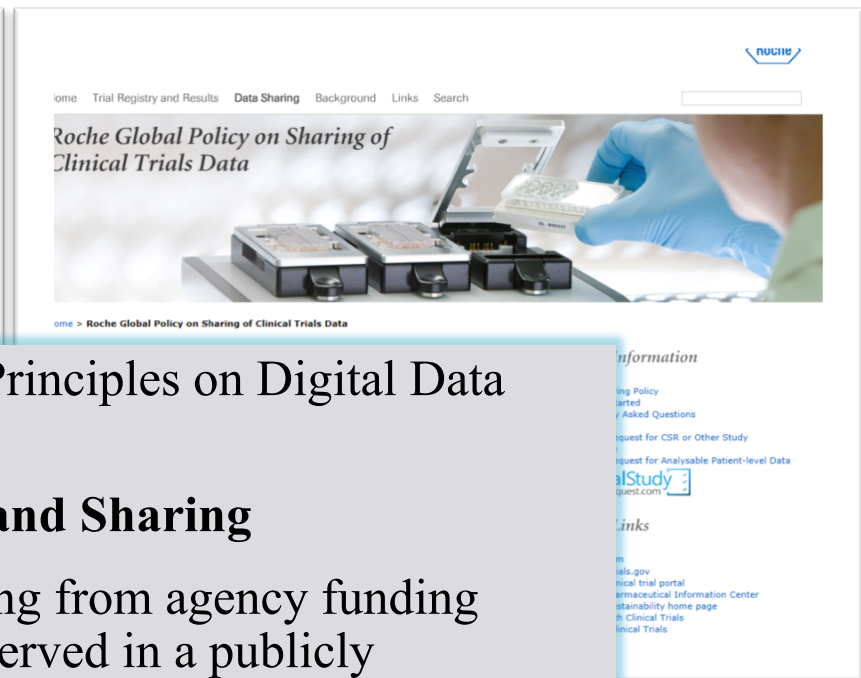
- > Data Sharing Policy
- > Getting Started
- > Frequently Asked Questions
- > Glossary
- > Submit Request for CSR or Other Study Information
- > Submit Request for Analysable Patient-level Data

[ClinicalStudy](#)
DataRequest.com

Quick Links

- > Roche.com
- > ClinicalTrials.gov
- > IPFMA clinical trial portal
- > Japan Pharmaceutical Information Center
- > Roche Sustainability home page
- > Genentech Clinical Trials
- > Chugai Clinical Trials
- > Feedback

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.





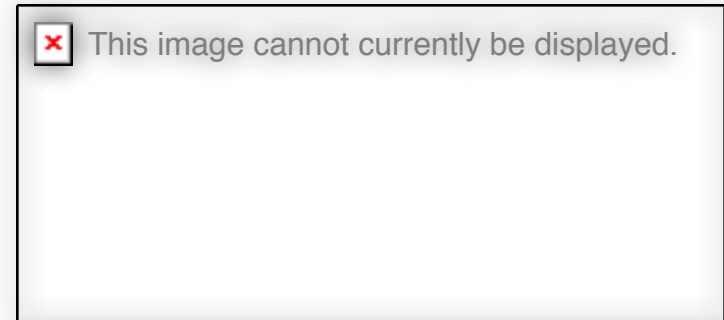
The price of ignoring substantive and procedural ethics

Loss of public trust

- Nuuchahnulth 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 researchers were able to breach the anonymity of genetic databases in order to recover participant surnames

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.

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>

The screenshot shows the PHSA Research Administration & Services website. The page is titled "Research Privacy at PHSA" and is part of the "Research Administration & Services" section. The page includes a search bar, a navigation menu with options like "Ethics & Approvals", "Resources & Support", "Education & Development", "Technology Development", and "Research Making a Difference". The main content area is titled "Research Privacy at PHSA" and contains a paragraph about resources available to help clarify privacy considerations for research. Below this, there is a section titled "Changes to the Privacy Review Process" which explains that research studies are no longer required to complete a privacy review intake form or undergo a Privacy Impact Assessment (or PIA) at the PHSA Information Access and Privacy Office. Instead, the Research Privacy Advisor will now conduct a privacy review, when necessary, at the same time as the Research Ethics Board (REB) review and the privacy review will be included with your other ethics documents on [PISA](#) (the online ethics application submission system). This new process is intended to streamline the privacy review process and reduce bureaucracy while also ensuring that research conducted at PHSA is carefully reviewed for privacy considerations. Below this, there is a section titled "Which research studies need a privacy review?" which states that not all research studies require a privacy review. Only studies that use or link personal information or have significant privacy concerns are reviewed by the Research Privacy Advisor. Researchers are encouraged to review our [checklist](#) of activities that lead to significant privacy concerns for research studies. Below this, there is a section titled "Check out our online resources!" which states that if you have questions about this new process, please contact the [Research Privacy Advisor](#) or visit our [FAQ's](#) and other privacy tips on the sidebar menu of this page. On the right side of the page, there is a sidebar titled "In this section" which lists various links: "Research Privacy at PHSA", "FAQs", "Sharing Data", "Conducting Surveys", "New Initiatives to Facilitate Research", "Helpful Tips", "Common Pitfalls to Avoid", "Helpful Resources", and "Real-Life Resolutions". Below this, there is a section titled "Need privacy support or have suggestions for this page?" which includes a "Contact" section with the name "Holly Longstaff, PhD", her title "Research Privacy Advisor", her department "Research & Academic Services", her organization "Provincial Health Services Authority", her hours "Hours: 8:30am-4:30pm", her address "700-1380 Burrard Street, Vancouver, BC, V6Z 2H3 Canada", her phone number "Phone: 604-675-7435", and her email "Email: holly.longstaff@phsa.ca". Below this, there is a section titled "Important Links" which includes links to "BC Freedom of Information and Protection of Privacy Act" and "Tri-Council Policy Statement 2 (2014)".

Research Administration & Services

Ethics & Approvals | Resources & Support | Education & Development | Technology Development | Research Making a Difference

Menu | Ethics & Approvals / [Research Privacy at PHSA](#)

Research Privacy at PHSA

Resources are available to help clarify privacy considerations for research, and help ensure ethical, regulatory and institutional requirements are met, as well as the requirements of funders.

Changes to the Privacy Review Process

Some of you may have noticed that we changed the way privacy reviews are done for research studies at PHSA in April 2017. Research studies are no longer required to complete a privacy review intake form or undergo a Privacy Impact Assessment (or PIA) at the PHSA Information Access and Privacy Office. Instead, the Research Privacy Advisor will now conduct a privacy review, when necessary, at the same time as the Research Ethics Board (REB) review and the privacy review will be included with your other ethics documents on [PISA](#) (the online ethics application submission system). This new process is intended to streamline the privacy review process and reduce bureaucracy while also ensuring that research conducted at PHSA is carefully reviewed for privacy considerations.

In some cases, your REB will notify the Research Privacy Advisor to determine if a privacy review is required. However, you are also welcome to send your study to the Research Privacy Advisor before it is submitted to the REB if you think you might need a privacy review or if you need some privacy-related advice.

Which research studies need a privacy review?

Not all research studies require a privacy review. Only studies that use or link personal information or have significant privacy concerns are reviewed by the Research Privacy Advisor. Researchers are encouraged to review our [checklist](#) of activities that lead to significant privacy concerns for research studies.

Check out our online resources!

If you have questions about this new process, please contact the [Research Privacy Advisor](#) or visit our [FAQ's](#) and other privacy tips on the sidebar menu of this page.

In this section

Research Privacy at PHSA
FAQs
Sharing Data
Conducting Surveys
New Initiatives to Facilitate Research
Helpful Tips
Common Pitfalls to Avoid
Helpful Resources
Real-Life Resolutions

Need privacy support or have suggestions for this page?

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Important Links

[BC Freedom of Information and Protection of Privacy Act](#)
[Tri-Council Policy Statement 2 \(2014\)](#)

Questions/comments?

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<http://www.phsa.ca/researcher/ethics-approvals/research-privacy-at-phsa>

*Office hours on Thursdays
with TDO at BCCRC and C&W*