BC Cancer Research Ethics

Information Session:

Bioinformatics Research Projects

May 2023

BC CANCER
Provincial Health Services Authority

RESPECT AT PHSA

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

BC CANCER
Provincial Health Services Authority

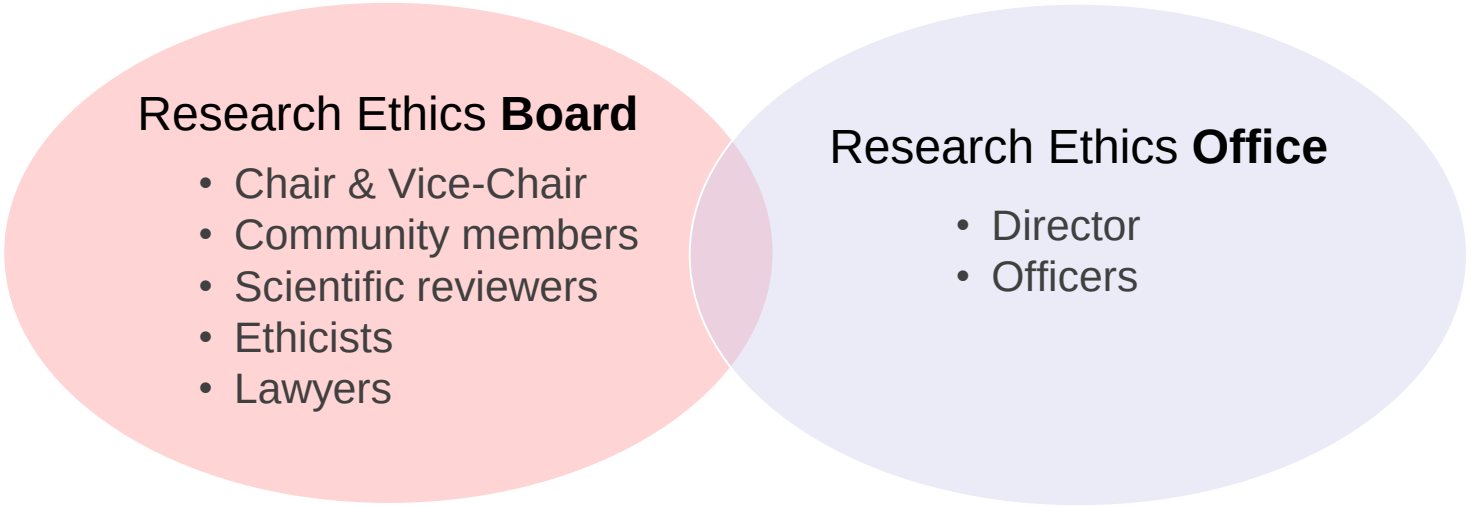
Overview

1. Research Ethics Office/REB: Who are we and what our role is
   - Core principles of ethics
   - Current ethical considerations
   - Tri-council policy statement (TCPS)
   - REB Review Structure

2. Considerations for bioinformatics research projects
   - When to submit to REB
   - Student RISe applications
   - Secondary use of data
   - Waiver of Consent
   - Publicly available data
   - Material incidental findings

3. Q&A

Research Ethics Office & REB



Independent body that is **mandated to review** and **maintain** ongoing oversight of the **ethical acceptability of all proposed or ongoing research** involving human participants on behalf of the institution by applying the Tri-Council Core Ethical Principles.

Aim to **build capacity** in ethics, **integrity**, and **compliance** through **education, advising, research, policy/guidance development, and administration**. Also responsible for administration relating to the REB.

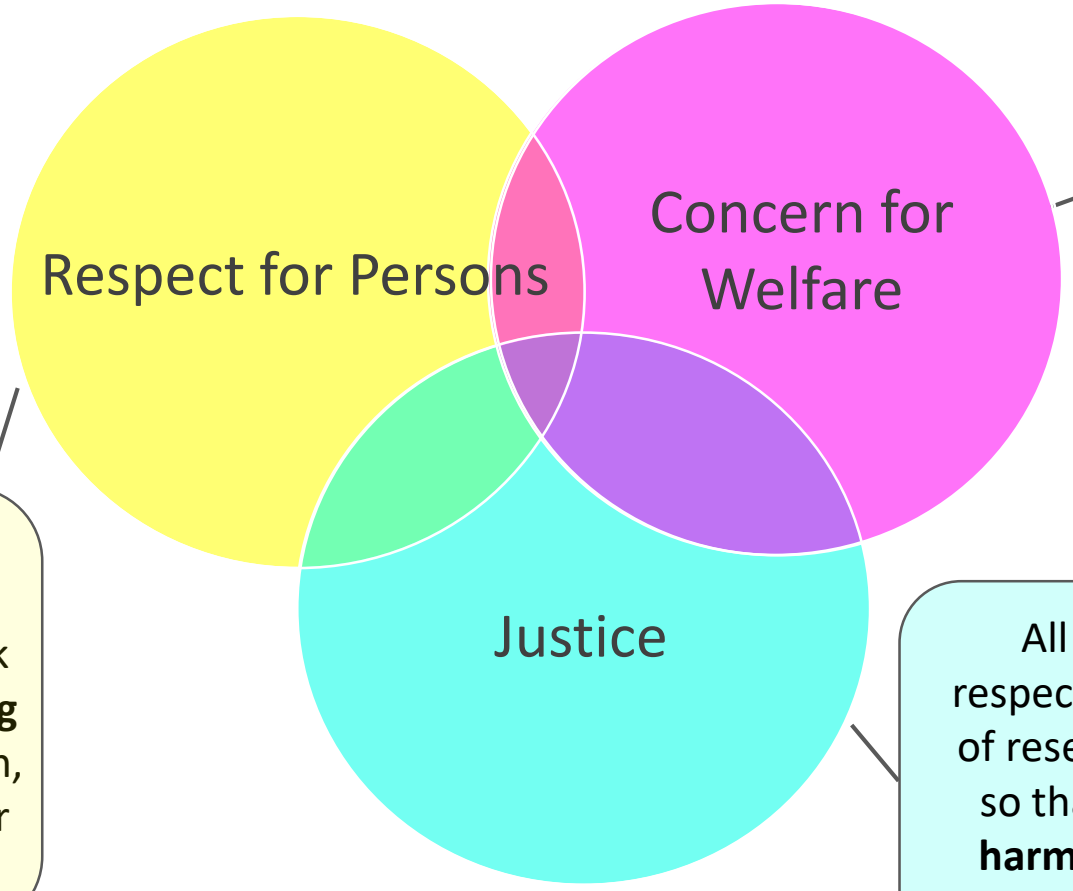
What is our main role at BC Cancer?

We provide research ethics guidance to students & researchers

- To ensure processes are in place so study participants are **adequately informed about the research**, including:
  - potential **risks** and **benefits**
  - how their **samples/data will be used**
- To **ensure research compliance** with ethical principles, legal, regulatory and policy requirements
- To **promote diversity, equity and inclusion** in research at BC Cancer
- To ensure that all research falls within what a participant agreed to in the consent document, including any **planned or unplanned future use of their samples/data**

What is Research Ethics?

Ethics framework for conducting research involving human participants follows 3 complementary and interdependent core principles:



Moral obligation to respect and protect participant autonomy through the requirement to seek their **free, informed**, and **ongoing consent to** participate in research, including the use of **their data** or **biological materials**

Protect and promote the welfare of participants by attempting to **minimize the risks** associated with any given research question. Provide participants with **enough information** to be able to **adequately assess risks and potential benefits** of research participation

All people should be treated with equal respect and concern. The benefits and burdens of research participation should be distributed so that **no group is unduly burdened by the harms of research** or **denied the benefits** of the knowledge **generated from it**

Why is Research Ethics necessary?

UNTREATED SYPHILIS IN THE MALE NEGRO

A COMPARATIVE STUDY OF TREATED AND UNTREATED CASES

R. A. VONDERLEHR, M.D.
TALIAFERRO CLARK, M.D.
O. C. WENGER, M.D.
AND
J. R. HELLER JR., M.D.
Assistant Surgeon General, Medical Director (Retired), Surgeon, and Assistant Surgeon, Respectively, United States Public Health Service
WASHINGTON, D. C.

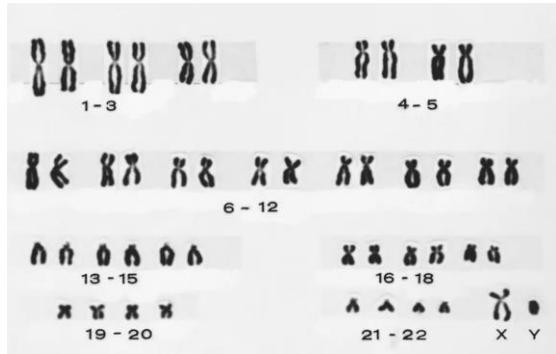
- **1932 – 1972**: **US Public Health Service** and **Tuskegee Institute** (University)
- Subjects were **not truthfully informed or consented**
- Available and effective **treatment was not offered**
- As a result, **many people died and their families, among others, were infected**

First Nations nutrition experiments

A monthly calendar vitamin pack used in a long-term study on multivitamins.
THE ASSOCIATED PRESS

- **1948 – 1952**: **Health Canada** conducted study on **1300 indigenous people and children**
- Subjects were **not informed or consented**
- Experimented with **reduced nutrient intake** in a **malnourished and vulnerable population**
- Subjects were **denied aspects of health care** as part of the study
- As a result, **subjects endured long lasting health effects, many of whom died**

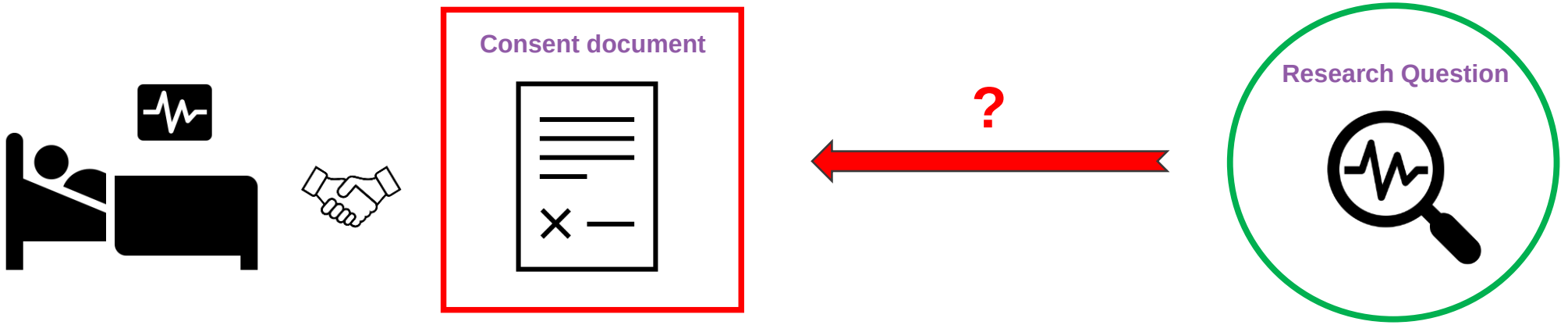
GEDmatch (Golden State Killer)



- **2018:** Detectives linked results from **GEDmatch** to the **Golden State Killer** (active 1976 - 1986)
- Detectives uploaded the suspect's DNA sample (**without consent**) to GEDmatch
- GEDmatch identified a relative of the criminal and the suspect using the **family members identifiers in the database**
- Concerns on **privacy of personal genetic information from a database** and **disclosure considerations**

https://www.cdc.gov/tuskegee/timeline.htm www.theglobeandmail.com/news/national/hungry-aboriginal-kids-adults-were-subject-of-nutritional-experiments-paper/article13246564/ https://www.nytimes.com/2018/04/27/health/dna-privacy-golden-state-killer-genealogy.html

Addressing Core Principles: Consent



- How do we ensure ethical principles are maintained in research studies? → **Informed Consent Form (ICF)**
- Consent defines the bounds of what a patient agrees to for the use of **their samples and data**
- **Not all data are created equally!** **Each dataset has parameters and restrictions** for use according to the **consent document**

Questions about parameters of a specific dataset? → **Ask the study PI**

Diversity, Equity & Inclusion (DEI) in Research

No specific individual, group or population should bear undue burden or harm of participating in research than others **nor disproportionately benefit from the outcomes** generated from it

An ethical recruitment process targets intentional or inadvertent **study exclusion based on culture, language, gender identity, race, ethnicity, age, disability, or specific groups**

- What **impact** will research have **on different groups within a population?**
- Will research **positively impact all groups** or **perpetuate existing harms?**
- Are research **conclusions accurate for all social groups**?
- Data on **Race ≠ Biology**

Test Your Knowledge!

Go to www.menti.com and use the code **7684 5327**

Is **Female** / **Male** = information on **sex** or **gender**??

Sex vs Gender: Which to use?

Q: When is it appropriate to request **sex AND gender** in research?

A: **Requesting both sex and gender can be problematic** because it can reveal individuals whose sex and gender don't align. Unless your research is specifically targeting this, we encourage thoughtful evaluation of which data is more relevant.

Q: What is **gender** and when can we request a participant's gender in research?

A: Gender refers a person's self identification as **woman, man, or gender diverse**. Including a person's gender gives information on **social behaviour, effect of power and resource distribution**, etc. This information is usually **most appropriate** for **studies not focused on biological research**.

Q: What is **sex** and when can we request a participant's sex in research?

A: Sex is used to classify humans into the categories of **female**, **male,** intersex or another. Including a patient's sex in research gives information on **biological and physiological characteristics**, such as chromosomes and hormones. This information is **present on medical records**.

Tri-Council Policy Statement (TCPS)

Tri-Council Agencies

"**Researchers** are expected, as **a condition of funding**, to **adhere to the TCPS**.

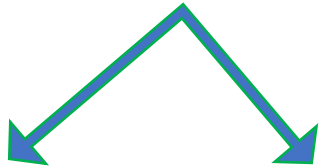
Institutions should support their efforts to do so.

That's us!

Failure to fulfill the requirements of the TCPS, by the **researcher or the institution**, may **result in recourse by the Agencies** …"

Review Structure

Initial Submission



Minimal Risk Studies

Non-interventional studies

- Secondary use of data/samples
- Chart reviews
- Interviews
- Surveys

Research Ethics Office

Communicate decision

Decision

Study Team

REB Chair & Co-Chair

Full Board Studies

Interventional studies

- Clinical Trials

Non-interventional studies with high potential impact

- Hereditary genomic studies

Research Ethics Office

Decision

REB

- REB Chair & Co-Chair
- Scientific Reviewers
- Community member
- Lawyer
- Ethicist

Communicate decision

Study Team

Considerations for Bioinformatic Studies

- Timeline of Submission to REB
- Student Research RISe Applications
- Secondary Use of Data
- Waiver of Consent
- Material Incidental Findings (MIFs)

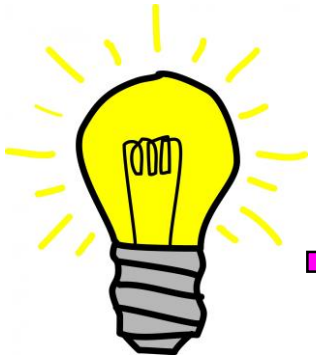
Test Your Knowledge!

Go to www.menti.com and use the code **7684 5327**

When should you submit your research project to REB?

A. After receiving data
B. During thesis completion
C. At initial project proposal
D. Before manuscript submission

When to submit to REB?



Initial project idea
(Start of grad school)

Submit project to REB as RISe application

Initial project proposal

Amend RISe application

Research Project Development

Committee meetings

New findings / project limitations

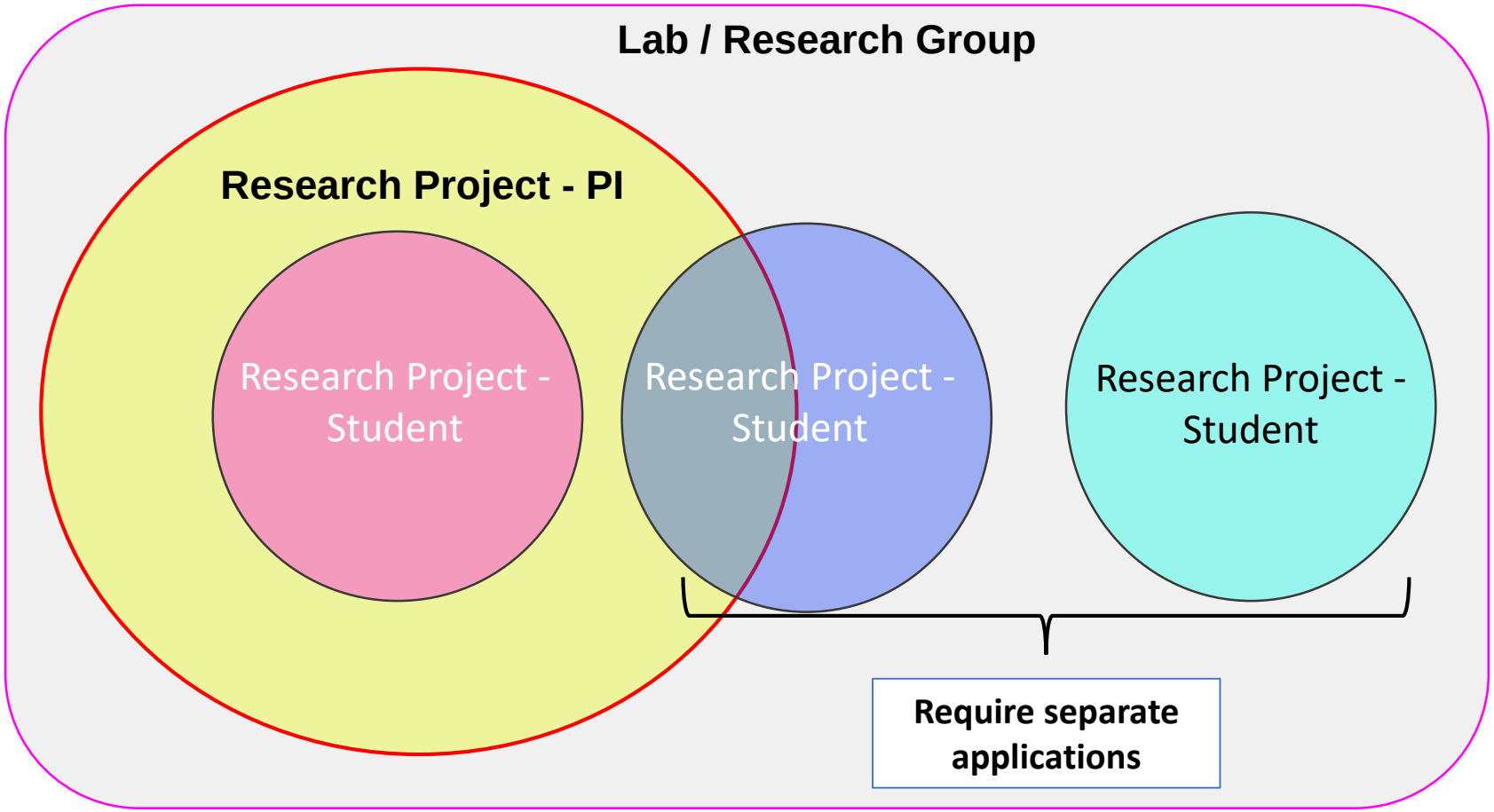
New collaborations

Technological advances

Submit project completion to REB in RISe

Project / Thesis completion

Student Research RISe Applications



** When a student is added to a RISe application, the Research Ethics office asks if the student's research project is within the scope of the approved application **

Unsure?

- Check the RISe application
- Ask your supervisor
- Contact us (**REB@bccancer.bc.ca**)
- Or **submit your research project proposal** as a study amendment to RISe

BC CANCER
Provincial Health Services Authority

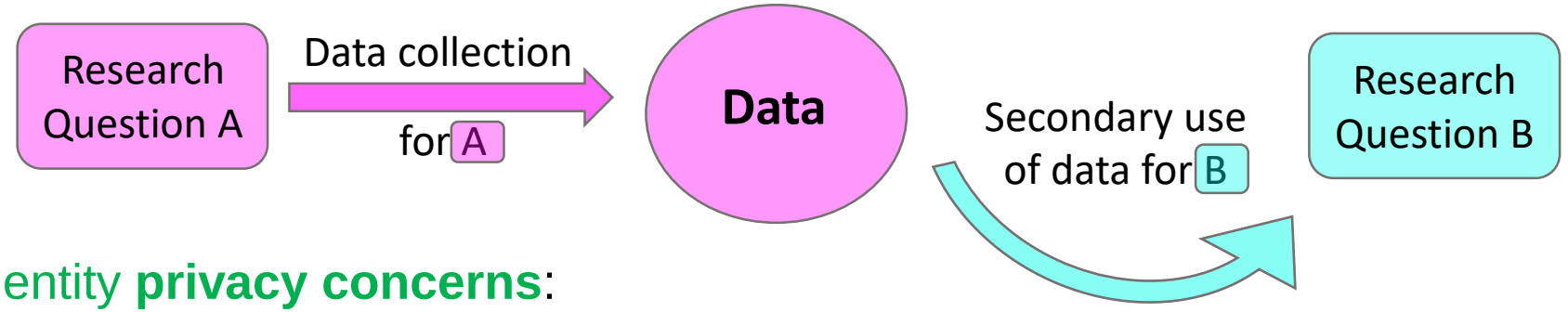
REB Review

What the Proviso?!?

Secondary Use of Data

Secondary use of data: Data use in research originally collected for a purpose other than the current research purpose (clinical and/or research data)

→ Testing new hypotheses that were not described at the time of original data collection



- Individual identity **privacy concerns**:
  - Secondary information can be linked to individuals
  - Identity can be revealed in published reports or data linkage

- Secondary use of identifiable/de-identified data: researchers must obtain consent unless requirements of a waiver of consent have been met

Types of Data

HIGH RISK → LOW RISK

Identifying Data

Data with direct or indirect identifiers

ETHICS REQUIRED

Examples:
Name, personal health number, date of birth, sex, hospital number

De-identified (Coded) Data

Direct identifiers are removed and replaced with a **unique study code**

ETHICS REQUIRED

Possible to re-identify specific individuals (e.g., a PI retains a key that links the coded data with direct identifiers)

Anonymized Data

Data are irrevocably stripped of direct identifiers, a **code is not kept** to allow future re-linkage

ETHICS REQUIRED

Anonymous Data

Never had identifiers linked to the data

NO ETHICS REQUIRED

Example:
Anonymous survey results

Genomic data is not considered anonymous

Waiver of Consent

Waiver of Consent: If a researcher **satisfies <u>all</u> the following conditions**, the **REB may approve the research without requiring consent** from the individuals to whom the information relates:

i. **Identifiable information is essential** to the research

ii. The use of identifiable information without the participants' consent is **unlikely to adversely affect the welfare of individuals** to whom the information relates

iii. The researchers will take appropriate measures to **protect the privacy of individuals** and to safeguard the identifiable information

iv. The researchers will **comply with any known preferences** previously expressed by individuals about any use of their information

v. The researchers have **obtained any other necessary permission for secondary use of information** for research purposes

vi. It is **impossible** or **<u>impracticable</u>** to seek consent from individuals to whom the information relates

Incapable of being put into practice due to a degree of hardship or onerousness that jeopardizes the conduct of the research
**** it does not mean mere inconvenience ****

Publicly Available Data

Publicly Available Information: any existing stored documentary material, records, or publications, which **may or may not include identifiable information**, and that has **no restrictions on its use or distribution**, or that may be **released under certain legal conditions**.

Research **does not require REB review** when it relies **exclusively** on data that is:

a) **Publicly available** through a mechanism set out by **regulation** and **is protected by law**

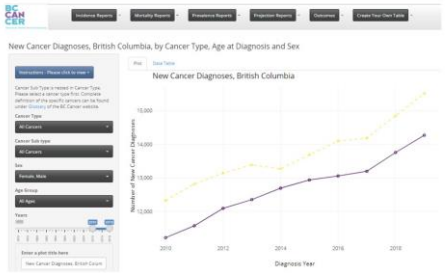
Statistics Canada Statistique Canada

OR

b) **In the public domain** and the individuals to whom the **data refers have no reasonable expectation of privacy**

cBioPortal FOR CANCER GENOMICS

Cancer Statistics Online Dashboard



Material Incidental Findings (MIFs)

Incidental Finding: A discovery about research participants that is **made during the course of research**, but is **outside the objectives of the research study**

Material: Significant welfare implications for the participant

- **Genomic data that reveals additional high risk cancer gene variant for a participant**

Rapid technological advances, evolution of research capabilities, big data & push for innovation

↓

Increased probability of incidental findings

If a MIF is encountered, this **must be reported to study PI**

Questions?!

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