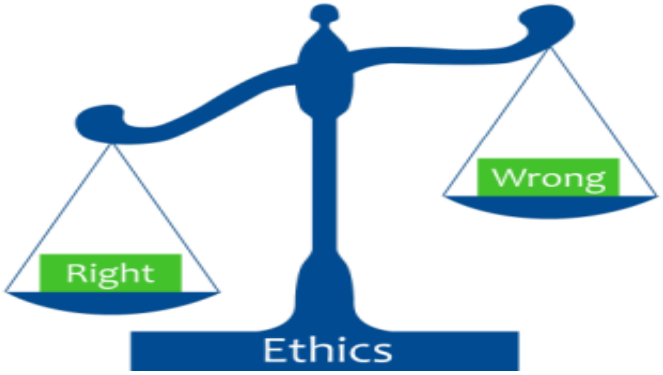
People, Tissues, Cells, & Data: Key Ethical Considerations and Resources



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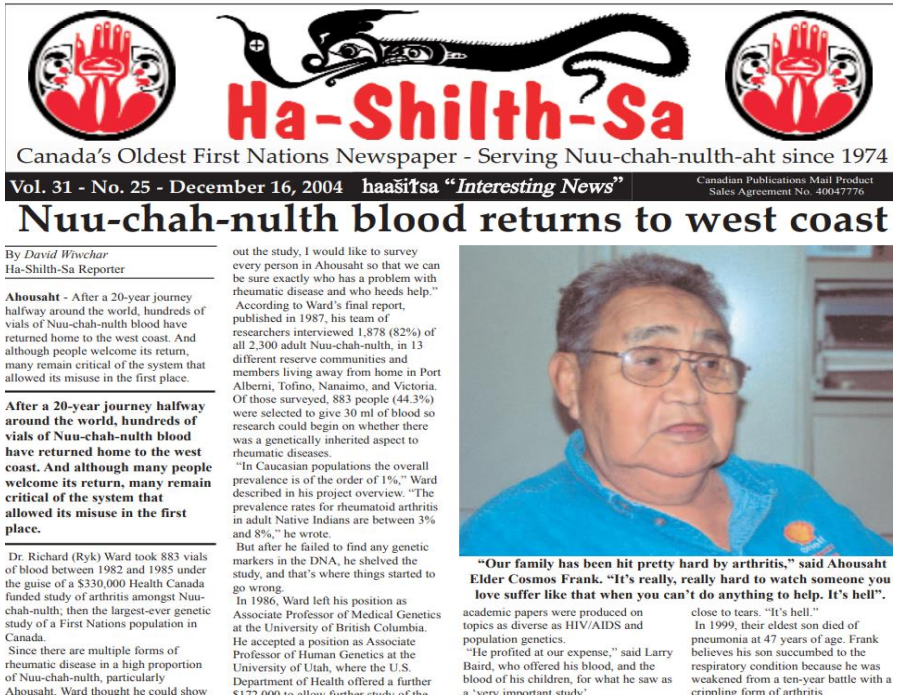
Agenda

- Why Research Ethics?
- Pop Quiz
- Consent Requirements for Secondary Use of Data/Biologics
- HSREB Ethics Application Forms
- Affiliated Hospitals Opt-Out Research Policy
- Hospital-Based Research
- Scenarios

Why Research Ethics?



Ha-Shilth-Sa

Canada's Oldest First Nations Newspaper - Serving Nuu-chah-nulth-aht since 1974

Vol. 31 - No. 25 - December 16, 2004 haašiłsa "*Interesting News*" Canadian Publications Mail Product Sales Agreement No. 40047776

Nuu-chah-nulth blood returns to west coast

By *David Wiwchar*
Ha-Shilth-Sa Reporter

Ahousaht - After a 20-year journey halfway around the world, hundreds of vials of Nuu-chah-nulth blood have returned home to the west coast. And although people welcome its return, many remain critical of the system that allowed its misuse in the first place.

After a 20-year journey halfway around the world, hundreds of vials of Nuu-chah-nulth blood have returned home to the west coast. And although many people welcome its return, many remain critical of the system that allowed its misuse in the first place.

Dr. Richard (Ryk) Ward took 883 vials of blood between 1982 and 1985 under the guise of a $330,000 Health Canada funded study of arthritis amongst Nuu-chah-nulth; then the largest-ever genetic study of a First Nations population in Canada.

Since there are multiple forms of rheumatic disease in a high proportion of Nuu-chah-nulth, particularly Ahousaht, Ward thought he could show out the study, I would like to survey every person in Ahousaht so that we can be sure exactly who has a problem with rheumatic disease and who heeds help."

According to Ward's final report, published in 1987, his team of researchers interviewed 1,878 (82%) of all 2,300 adult Nuu-chah-nulth, in 13 different reserve communities and members living away from home in Port Alberni, Tofino, Nanaimo, and Victoria. Of those surveyed, 883 people (44.3%) were selected to give 30 ml of blood so research could begin on whether there was a genetically inherited aspect to rheumatic diseases.

"In Caucasian populations the overall prevalence is of the order of 1%," Ward described in his project overview. "The prevalence rates for rheumatoid arthritis in adult Native Indians are between 3% and 8%," he wrote.

But after he failed to find any genetic markers in the DNA, he shelved the study, and that's where things started to go wrong.

In 1986, Ward left his position as Associate Professor of Medical Genetics at the University of British Columbia. He accepted a position as Associate Professor of Human Genetics at the University of Utah, where the U.S. Department of Health offered a further

"Our family has been hit pretty hard by arthritis," said Ahousaht Elder Cosmos Frank. "It's really, really hard to watch someone you love suffer like that when you can't do anything to help. It's hell".

academic papers were produced on topics as diverse as HIV/AIDS and population genetics.

"He profited at our expense," said Larry Baird, who offered his blood, and the blood of his children, for what he saw as

close to tears. "It's hell."

In 1999, their eldest son died of pneumonia at 47 years of age. Frank believes his son succumbed to the respiratory condition because he was weakened from a ten-year battle with a

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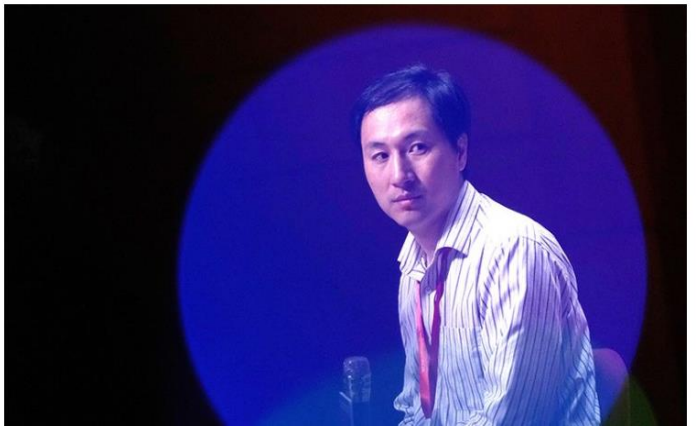
https://www.igb.illinois.edu/sites/default/files/Wiwchar%202004%20Nuu-chah-nulth.pdf

NEWS · 22 JANUARY 2019

CRISPR-baby scientist fired by university

Investigation by Chinese authorities finds He Jiankui broke national regulations in his controversial work on gene-edited babies.

David Cyranoski



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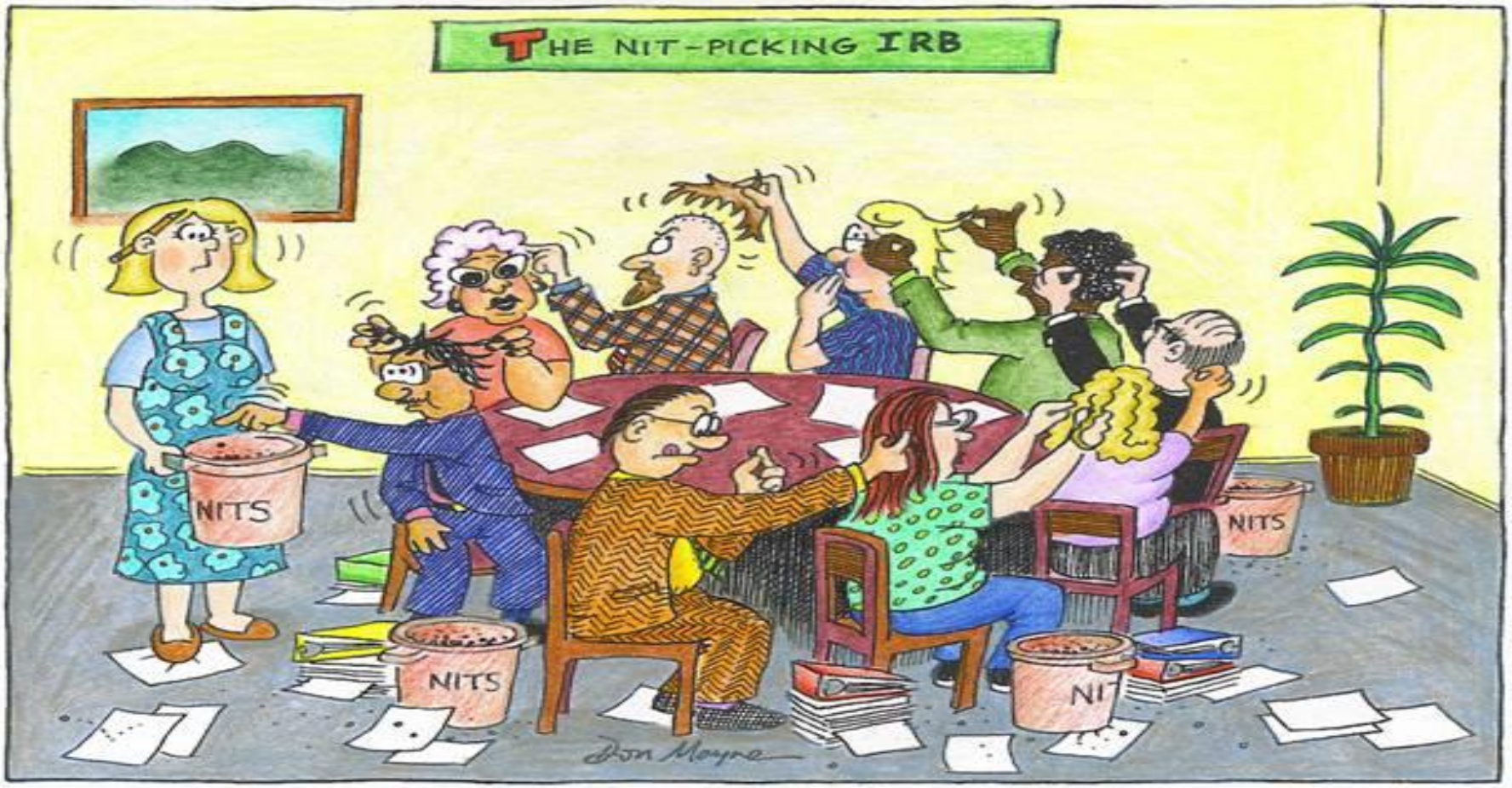
Research Ethics Boards (REBs)



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http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

Queen's University

2nd Edition of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2 2014)

Minimum standards for ethics review involving human participants:

1. Respect for Persons
2. Concern for Welfare
3. Justice - obligation to treat people fairly and equitably

Types of Information – Pop Quiz

- The information/materials never had identifiers attached to them and risk of identification of individuals is low or very low.

Types of Information – Pop Quiz

- Direct identifiers are removed from the information/materials and replaced with a code. Depending on access to the code, it may be possible to re-identify specific individuals (e.g., a principal investigator retains a key that links the coded material with a specific individual if re-linkage is necessary).

Types of Information – Pop Quiz

- The information/materials are labelled with a direct identifier (e.g., name, personal health number).
- Materials and any associated information are directly traceable back to a specific individual.

Types of Information – Pop Quiz

- Information can reasonably be expected to identify an individual through a combination of indirect identifiers (e.g. date of birth, place of residence).

Types of Information – Pop Quiz

- The use in research of information or human biological materials originally collected for a purpose other than the current research purpose.

Types of data/information – Pop Quiz

- The information/materials are irrevocably stripped of direct identifiers, a code is not kept to allow future re-linkage, and risk of re-identification of individuals from remaining indirect identifiers is low or very low.

Types of data/information – Pop Quiz

- The information/materials are either anonymous (never had identifiers), anonymized (key to the identifiers has been destroyed) or the information/material is coded but the information/material recipient/holder does not have access to the key.

What HSREB Ethics Application do I use?

1. **HSREB Standard Application Form**
   - ✓Clinical trials
   - ✓Interventional research
   - ✓Studies involving invasive contact
   - ✓The performance of a task
2. **NEW HSREB Intermediate Application Form**
   - ✓Interviews, surveys, questionnaires, focus groups/sharing circles or evaluation/assessment
3. **HSREB Non-Recruitment Application Form**
   - ✓NOT ACTIVELY RECRUITING participants
   - ✓Case reports
   - ✓Secondary use of biological samples

Do I also need participant consent for secondary use of data/biological samples?

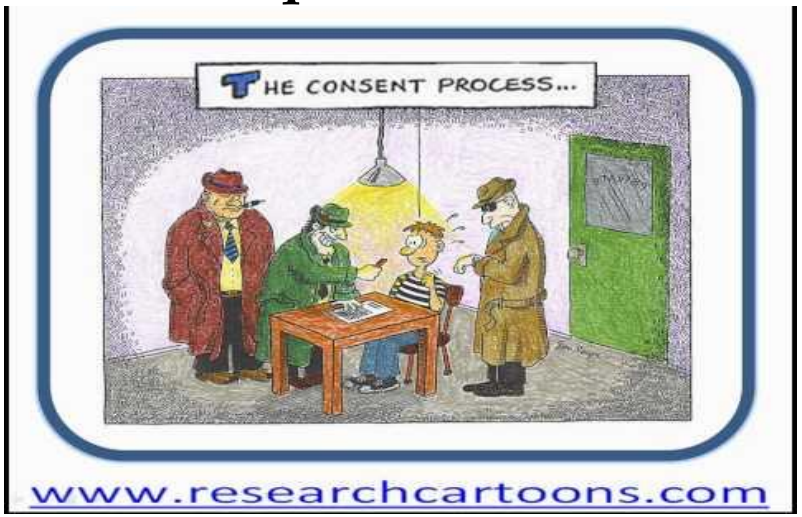
Identifiable human information or biological materials

- **TCPS 2 2014 Article 5.5A/Article 12.3A** outlines the conditions that researchers must meet for secondary use **without having to seek consent from participants**

Non-identifiable human information or biological materials

- **TCPS 2 2014 Article 5.5B/Article 12.3B** outlines that researchers must seek REB review, but are **not required to seek participant consent**

(e.g., the use of coded human biological materials where the researcher never had access to the coding key).



Affiliated Hospitals – Opt-Out Research Policy

- Affiliated hospitals display a privacy poster in various areas of the hospital (e.g., outpatient clinic areas, emergency/urgent care areas) that informs patients they have a right to opt out of research
- Patients must withdraw their consent in writing (not retroactive) Opt-Out form available from the registration staff & privacy office
- Researchers, research staff, students and trainees must verify within each medical record that consent for research has not been withdrawn by a patient if extracting patient data for research purposes
- To verify if consent for research purposes has not been withdrawn within PCS Clinical Desktop, researchers, research staff, students and trainees can follow the steps outlined in the research Roadmap titled, 'Accessing Patient Data for Research' found on the KGHRI website: http://www.kgh.on.ca/research/researchers-staff-trainees

What is Considered Hospital-Based Research?

- ✓Occurs in a hospital setting OR utilizes or requires hospital staff, space (office, clinic, lab), services and/or other resources
- ✓Obtaining or retrieving patient biological samples/specimens (including discarded tissue from surgery, outpatient clinics) from patients seen (or samples stored) at one of the hospitals for lab projects and transported to your research lab located within OR outside of the hospital (i.e. Botterell Hall, CRI)
- ✓Extracting patient data from hospital medical records
- ✓Purchasing supplies or equipment at/through the hospitals
- ✓Use of hospital services and payment to hospital departments
- ✓Funds will be held within one of the hospitals/hospital research institutes

Things to think about

- Would REB clearance be required for Queen's University?
- Would REB clearance be required at another Institution?
- Would participant consent be required?
- Would Queen's affiliated hospital approvals be required through submission of a TRAQ DSS?
- Would an Agreement be required through the Contracts Unit?
- Would a Biosafety permit be required through Environmental Health and Safety?
- Will there be any generation of identifiable information through data linkage?

Scenario #1

A. Dr. Li is a researcher from the Department of Biomedical and Molecular Sciences working in Botterell Hall at Queen's University. Dr. Li would like to order a human primary dermal fibroblast cell line from the American Tissue Culture Collection (ATCC) called HDFa. What administrative steps would Dr. Li need to take to bring this cell line into their laboratory?

B. What if Dr. Li's colleague at University of Toronto, Dr. Hernandez, has a primary dermal fibroblast cell line that was isolated from a patient and Dr. Hernandez has agreed to provide an aliquot of the de-identified cells free of charge to Dr. Li?

Scenario #2

A. Dr. Smith is a bioinformatician from the School of Computing at Queen's University. A local clinician researcher at Kingston Health Sciences Centre (KHSC) – KGH Site, Dr. James, would like Dr. Smith to analyze some de-identified data sets. The data will be from a retrospective chart review study led by Dr. James that will be completed at the Ottawa Hospital Research Institute (OHRI) by a site investigator and at the KHSC-KGH Site by Dr. James. Dr. James has agreed that Dr. Smith will be listed as a co-author on the publication. What administrative steps would Dr. James and Dr. Smith need to take to complete this research project at Queen's University?
B. What if Dr. James was sending the KHSC data set to a bioinformatician at OHRI for analysis?

Scenario #3

A. Dr. Potter is a researcher from the Department of Chemical Engineering studying regenerative medicine. Dr. Potter would like to use discarded non-identifiable adipose tissue from lipo-suction procedures at KHSC – HDH Site. Dr. Potter will use the tissue to isolate cells for analysis in their laboratory at Dupuis Hall. Dr. Potter has a clinician colleague at KHSC, Dr. Wang, that has said they would be able to help Dr. Potter acquire the tissue. What administrative steps would Dr. Potter and Dr. Wang need to take to enable this research project?
B. What if Dr. Potter was acquiring discarded adipose tissue from a hospital in Toronto?

Thanks for your time!