



Research Ethics

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History of Research Ethics

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- Nazi war crimes

- Nazi experiments on prison camp inmates were declared “crimes against humanity”

- Tuskegee Syphilis Study

- The lie that treatment was being administered prevented subjects from otherwise seeking medical treatment for their disease, and proven treatments, including penicillin, were withheld

- Willowbrook Study

- Profoundly mentally impaired children were infected with the hepatitis virus at the time of admission to Willowbrook State School in order to study the course of disease from the earliest stages of infection

Some Guiding Declarations

- Nuremberg Code, 1947
- Declaration of Helsinki, first adopted by the World Medical association in 1964 and regularly amended
- Belmont Report, 1979

Canada: The TCPS

- *Tri-Council Policy Statement, Ethical Conduct for Research Involving Humans (TCPS)*
- A great resource is the TCPS tutorial available at:
<http://pre.ethics.gc.ca/english/tutorial/>

Underlying Principles of the TCPS

- Moral Imperative: Respect for Human Dignity
 - Concern for Welfare
 - Respect for Autonomy
 - Respect for the Equal Moral Status of all Humans

VIHA Research Ethics Requirement

- Human research that is conducted by members of VIHA or that involves VIHA facilities, patients, residents, clients, staff, resources, databases, stored tissues, or genetic materials requires research and ethical approval from a VIHA Research Ethics Board prior to commencement.
- *Ethical approval ensures that all human research complies with ethical principles and standards.*

What is "Research"?

- Is your project a "Research" Project, or is it quality improvement (QI), quality assessment (QA), or program evaluation (PE)?
- Ask: What is the purpose of this project?
 - To increase the state of knowledge?
 - To inform future VIHA decision making?
 - What will be done with the results?
 - Publication? Conference?
 - VIHA Team meeting?
- When in doubt, phone the Ethics Office!

VIHA Research Ethics Boards

- Clinical Research Ethics Board (CREB)
- Health Research Ethics Board (HREB)
- Joint UVic/VIHA Research Ethics Subcommittee

Research Ethics Review Process



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graph TD; A[Application received by Research Ethics Office] --> B[Application is sent for review]; B --> C[Letter from the Board is sent to the researcher identifying areas in need of further clarification or comment]; C --> D[Researcher responds to the Board's letter. Any issues requiring further clarification or comment are addressed.]; D --> E[Researcher is sent Certificate of Approval and research can begin!];
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Application received by Research Ethics Office

Application is sent for review

Letter from the Board is sent to the researcher identifying areas in need of further clarification or comment

Researcher responds to the Board's letter. Any issues requiring further clarification or comment are addressed.

Researcher is sent Certificate of Approval and research can begin!

Research Ethics Review

- Proportionality
- Weighing the risks and benefits
- Ensuring that subjects are fully informed and autonomous
- Ensuring that privacy and confidentiality is respected
- Ensuring VIHA infrastructure support is available

Autonomy and Informed Consent

"Free and informed consent lies at the heart of ethical research involving human subjects,"
TCPS, 1st edition

- Subjects must be fully informed about the research prior to commencement so that they can make a free and informed decision as to whether to participate
- Reimbursement/Compensation
- Power-over issues

Privacy and Confidentiality

- Recruitment
 - Neutral 3rd party?
 - Snowballing
- Data storage, security, and retention
- Data analysis and summary of findings
- Dissemination of research findings

Further Points to Consider

- The Research Ethics Boards cannot grant retroactive approval for research that has already begun.
- If you have questions, please check out our website:
http://www.viha.ca/rnd/research_ethics/
or contact the Research Ethics Office at,
phone: 250-370-8620

Resources

- The VIHA Research Ethics website: http://www.viha.ca/rnd/research_ethics/, phone: 250-370-8620
 - The website contains the forms and policies for the various Boards as well as links to research ethics resources.
- The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) website: <http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
 - The TCPS tutorial is available at: <http://pre.ethics.gc.ca/english/tutorial/>
- Included for your reference is the VIHA HREB application and the VIHA informed consent template and the informed consent checklist – all are available on the Research Ethics website.
- Also included for your reference: the “Screening Tool for Determining the Appropriate Route for Ethics Review”, (i.e. is your project “research”), from the *Alberta Research Ethics Community Consensus Initiative* (ARECCI). Remember, if you are unsure of whether your project is “research” or not, please contact the Ethics Office.

References

1. For more information on *The Belmont Report*, see: Department of Health, Education, and Welfare. April 18, 1970. *The Belmont Report: Ethical Principles and Guidelines for the protection of human subjects of research*. Retrieved April 15, 2009 from <http://ohsr.od.nih.gov/guidelines/belmont.html>
2. For more information on the Nuremberg Code, see: http://www.ushmm.org/research/doctors/Nuremberg_Code.htm
3. For more information on the Declaration of Helsinki, see: <http://www.wma.net/e/policy/b3.htm>
4. Much of the information in this presentation was taken from: Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. 1998 (with 2000, 2002 and 2005 amendments).
 - The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) website: <http://pre.ethics.gc.ca/english/policystatement/policystatement.cfm>
 - As well as, The TCPS tutorial, available at: <http://pre.ethics.gc.ca/english/tutorial/>