

*Navigating the Research Ethics Application Process*

Presenter:  
**Lynn Cummings**, MN, Nursing Research Facilitator,  
Chair VIHA Health Research Ethics Board (HREB)



RHSRNBC Research Skills Workshop  
June 15<sup>th</sup> 2012

---

---

---

---

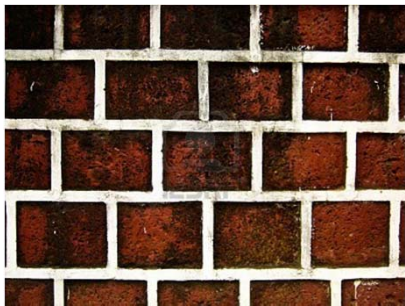
---

---

---

---

Do you feel like this...?



2

---

---

---

---

---

---

---

---

**Objectives**

- Provide background and context for an ethical approach to research
- Identify significant elements of a typical ethics application and common issues encountered
- Consider general "tips" to assist with a successful review process
- Provide a brief overview of the VIHA Research Ethics Office and REB process

3

---

---

---

---

---

---

---

---

## Putting Ethics Review in Context

Ideals

- Promote health research that serves the public good
- Respect the interests and rights of research participants
- Merit the trust of participants and the public

4

---

---

---

---

---

---

---

---

## Who is supposed to do this?

- Researchers,
- Research institutions,
- Research sponsors – public, private, and not for profit
- Research workers
- Research ethics boards

5

---

---

---

---

---

---

---

---

## Why?

- Inhumane Practices:
  - Nazi war crimes: experiments on prison camp inmates were declared “crimes against humanity”
- Unethical Research:
  - Inducement
  - Intolerable risk
  - Uninformed or active deception
  - Residual after effects

6

---

---

---


---

---

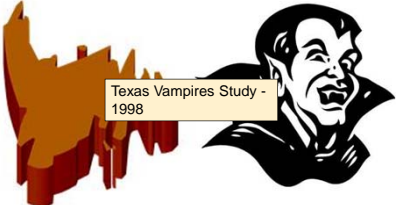
---

---

---



Stanford Prison Experiment - 1973



Texas Vampires Study - 1998

7

---

---

---

---


---

---

---

---

### Ethics Framework



- Respect for Persons
- Concern for Welfare
- Justice

8

---

---

---

---

---

---

---

---

### Tri-Council Policy Statement (v2): Ethical Conduct for Research Involving Humans

- Canadian Institutes of Health Research (CIHR);
- Natural Sciences and Engineering Council of Canada (NSERC); and,
- Social Sciences and Humanities Research Council of Canada (SSHREC). (revision: Aug, 2010)

Useful Links:

1. Tri-Council Policy Statement(v2):
  - <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-epts2/Default/>
2. Canadian Association of Research Ethics Boards:
  - <http://www.careb-accer.org/>



9

---

---

---

---

---

---

---

---

## Does the Project Need an Ethics Review?

Is it "Research", or ...?

- Program Development,
- Quality Improvement (QI),
- Quality Assurance (QA),
- Program Evaluation (PE)

*When in doubt, check with the Research Ethics Office!*

---

---

---

---

---

---

---

---

## Scope of a Research Ethics Review

- Proportionate review
- Minimal risk
- Above Minimal Risk

---

---

---

---

---

---

---

---

## UBC REB Minimal Risk Matrix

Group Vulnerability	Research Risk		
	Low	Medium	High
High	Full	Full	Full
Medium	Minimal Risk Review	Full	Full
Low	Minimal Risk Review	Minimal Risk Review	Full

UBC REB Matrix, 2012

---

---

---

---

---

---

---

---

### Research Ethics Lifecycle

1. Priority setting
2. Education (science and ethics)
3. Protocol design
4. Funding review
5. Ethics Review (ACC, SCOC, REB)
6. Recruitment
7. Informed consent
8. Ongoing review / D&SM
9. Study termination
10. Data analysis
11. KT
12. QA / QI

Anderson, J.A; Sawatzky-Girling, B.; McDonald, M; Pullman, D.; Saginur, R.; Sampson, H.A.; Willison, D.J. (2011), "Research Ethics Broadly Writ: Beyond REB Review", *The Health Law Review*, 19, 2.  
(soon on line)

13

---

---

---

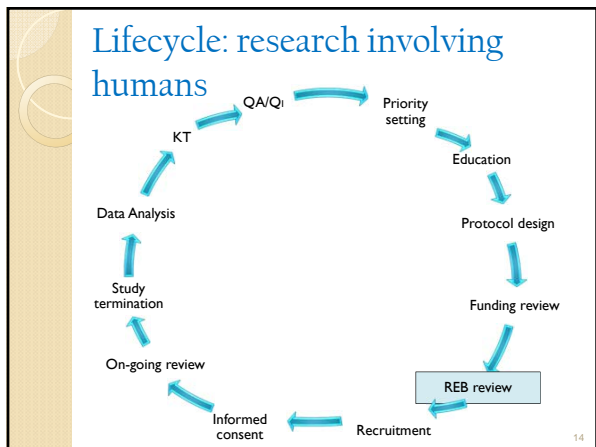
---

---

---

---

---



---

---

---

---

---

---

---

---

### General Considerations

- Organizational Impact & Administrative Approval
  - Impact on departmental resources and operations
  - Practicality i.e. is there adequate budget, resources, timeline
  - Expectation of in-kind resources
- Scientific Review

15

---

---

---

---

---

---

---

---

### General Considerations ....(2)

- Privacy & Security
  - Recruitment- access & contact
  - What is collected
  - Data release & security
  - Potential for identification (de-identification and anonymization will be contextual)
  - Reporting findings & dissemination (sample size, Patriot Act)

Freedom of Information and Protection of Privacy Act, Section 35, May 9, 2012

16

---

---

---

---

---

---

---

---

### General Considerations ....(3)

- Data Security
  - Extraction logistics
  - Data protection
  - Transfer/transport/handling (electronic or physical)
  - Storage
  - Data destruction
  - Rapid technology expansion & complexities

**Remember: Privacy is more than confidentiality**

17

---

---

---

---

---

---

---

---

### Sample Data Collection, Use & Disclosure Table

	Data Type	Source	Collection Method (Direct or Indirect)	Data Use (this initiative)	Degree of Identifiability	Disclosed to whom?	Authority to Collect, Use, Disclose*
1.	Demographic Data						
2.	Clinical personal health Data						
3.	Other Provider Information						
4.	Service or administrative data						

18

---

---

---

---

---

---

---

---

### Health Authority Considerations

- Local site PI identified
- Forms & templates (see website)  
[http://www.viha.ca/rnd/research\\_ethics/forms\\_page.htm](http://www.viha.ca/rnd/research_ethics/forms_page.htm)
- Recruitment adaptations i.e. geography, resources or participant access requirements
- HA data stewardship requirements; PIA required?
- Organizational sign-offs e.g. Lab, Health Records, Diagnostics etc.

19

---

---

---

---

---

---

---

---

### REB Common Issues

- Scientific review;
- Ambiguity & inconsistency between application and protocol;
- Conflict of interest/Power over;
- Possible risks of harm/inconvenience
- Privacy & Data security

20

---

---

---

---

---

---

---

---

### REB Common Issues cont'd...

- Unclear budgets i.e. who bears the cost?
- Administrative sign offs, business contracts incomplete;
- Dissemination strategies
- Incomplete applications

21

---

---

---

---

---

---

---

---

### Tips for Smooth Sailing

- TCSP 2 Tutorial
- Consult when in doubt
- Do your upfront work
- Peer reviewed if appropriate
- Use data and business flow charts where applicable
- Check application for completeness



22

---

---

---

---

---

---

---

---

### And now a little about us...



23

---

---

---

---

---

---

---

---

### VIHA REB Structure

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

24

---

---

---

---

---

---

---

---



### VIHA CREB: Process

- Meets monthly
- CREB Ethics Application – Forms & Templates;
- Full Board Review;
- Response Letters;
- Response from Investigators;
- Amendment(s);
- SAE's;
- Regulations: Health Canada sign-off;
- PI & Co-PI and Departmental signatures

25

---

---

---

---

---

---

---

---

### VIHA HREB & Joint Process

- Forms/Templates:  
[http://www.viha.ca/rnd/research\\_ethics/forms\\_page.htm](http://www.viha.ca/rnd/research_ethics/forms_page.htm)
- Delegated reviews
- Collated response letter
- Expected timelines

26

---

---

---

---

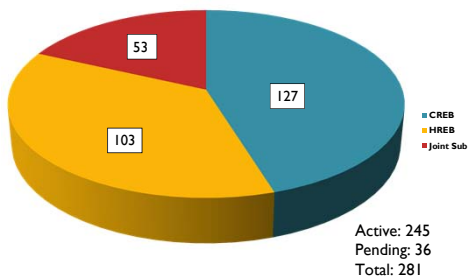
---

---

---

---

### Active and Pending Studies by VIHA REBs



27

---

---

---

---

---

---

---

---

## Helpful Links and Resources

1. VIHA Research Ethics Office
  - ✓ [http://www.viha.ca/rnd/research\\_ethics/](http://www.viha.ca/rnd/research_ethics/)
2. UVIC Research Ethics Office
  - ✓ [ethics@uvic.ca](mailto:ethics@uvic.ca).
3. VIHA Privacy Office
  - ✓ [http://www.viha.ca/info\\_privacy](http://www.viha.ca/info_privacy)
  - ✓ VIHA IM/IT
4. TCPS 2 website
  - ✓ <http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/>

28

---

---

---

---

---

---

---

---

## Questions/Comments



29

---

---

---

---

---

---

---

---