



# How to Prepare for Ethical Review by the Fraser Health Research Ethics Board

Presented by: Susan Chunick  
Director, Research Administration and Development  
April 29, 2009



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Better health.  
Best in health care.

# Objectives:



By the end of the workshop, you will be able to:

1. Submit an application for initial ethical review that meets the requirements of the FH ethics review process;
2. Prepare an application that takes into account the ethical principles considered in the ethical review by the FH Research Ethics Board [REB];
3. Understand the decision-making process used by the FHREB in conducting an ethical review;
4. Understand the differences between a Full Board versus an Expedited Review of initial applications, amendments, renewals and serious adverse events;
5. In general, describe the standard wording requirements for consent forms;
6. Design a consent form using the FH standard template, and;
7. Describe the fundamental differences in consent forms used for genetic studies and incompetent subjects.



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## THE NIT-PICKING IRB



# But first, some background:



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2008/02/12

# WHO IS THE FH REB?

Meets TCPS & Health Canada quorum requirements



Research Ethics Co-ordinator:

Rosa Haywood

Ex-officio:

Susan Chunick

# WHO IS THE FH REB?

Meets TCPS & Health Canada quorum requirements



## Co-Chairs:

- Dr. Allan Belzberg [SMH nuclear medicine]
- Dr. Marc Foulkes [RCH anaesthesia]

## Clinical Experts:

- Aaron Tejani, PhD [SMH Pharmacy]
- Michael Vince, PhD [retired FH biochemist]
- Dr. Anton Grunfeld, MD [Emergency, Medical Director]
- Dr. Sonia Singh, MD [Family Practice, Emergency]
- Dr. Amin aminbakhsh, MD [Cardiology]
- Arun Chockinglam, PhD [SFU Faculty Health Sciences]

# WHO IS THE FH REB?



## Ethicist:

Lindsay Meredith, Ph.D [SFU]

## Statistician:

Michael Wasdell, M.A. FH Research Administration and Development

## Legal Representation: non-FH

Ms. Camille Ciarniello [LLB]

Ms. Mara Stickland [LLB]

## Lay member:

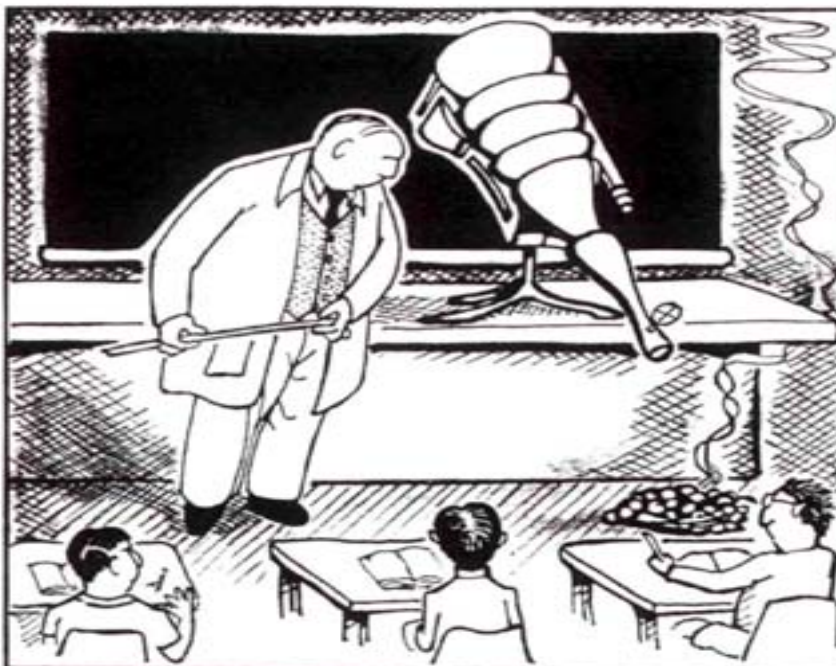
Mrs. Nancy Magnee

Mrs. Maryellen Gillen

# WHAT IS THE SCOPE OF THE FHREB?



Research versus Evaluation



The class was unusually quiet. Gribbins fingered his cane and coughed just once. Chalk dust or asthma, nobody could tell. What was left of Jimmy Worthington sizzled quietly on the floor in front of the new excimer laser.



Gribbins fought to suppress a smile as he felt that warm glow of accomplishment he last remembered having had as an undergraduate. *Once again, he thought, and after all these years.....physics is fun!*

# WHAT IS THE SCOPE OF THE FHREB?



## What is Research?

Research involving human subjects is defined as any systematic investigation (including pilot studies, exploratory studies, and academic course work assignments) designed to contribute to generalizable knowledge.

Generalizable knowledge consists of facts, theories, principles or relationships, or the accumulation of information on which they are based, that can be corroborated by accepted scientific methods of observation and inference.

Generalizable means knowledge that can be applied beyond the specific situation in which the work was conducted.

[Government of Canada. Refinements to the Proportionate Approach to Research Ethics Review in the TCPS, December 2005]

# WHAT IS THE SCOPE OF THE FHREB?



- **Clinical Research**

- Includes research on \*animal models of human disease, clinical trials and other therapeutic interventions.
- E.g. Testing the effectiveness of a new medication, a new rehabilitation treatment, a new pharmacy intervention, a new assessment tool

# WHAT IS THE SCOPE OF THE FHREB?



- **Health Services/Systems Research**
  - Multidisciplinary field
  - Aims to improve the efficiency and effectiveness of health professionals and the health care system.
  - Interventions at the level of practice and policy.
  - i.e. Evaluating a new intervention for improving patient flow.

# WHAT IS THE SCOPE OF THE FHREB?



- **Population Health Research**

- Studies the impact of social and environmental factors on the health of populations/subpopulations.
- May examine social, cultural, environmental, occupational, and economic factors that determine health status.
- Research data is used to identify areas where the health of a population can be improved.
- i.e. Statistics Canada Community Health Survey.

# WHAT IS THE SCOPE OF THE FHREB?



## What is Evaluation?

"the systematic application of social research procedures for assessing the conceptualization, design, implementation, and utility of ... programs."

Source: J. Krajnak: Rossi and Freeman (1993)

# WHAT IS THE SCOPE OF THE FHREB?



Clarification of Ethical Review Requirements for  
Studies Involving Quality  
Assurance/Improvement, Program Evaluation,  
Operational Review and Product Evaluation

- Approved by FH Executive Committee: 2005/09/27

# RESEARCH ETHICS BOARD

## STATUS REPORT 01 April 2009

### Total Studies 558

(From 2005 September 01 to Date)

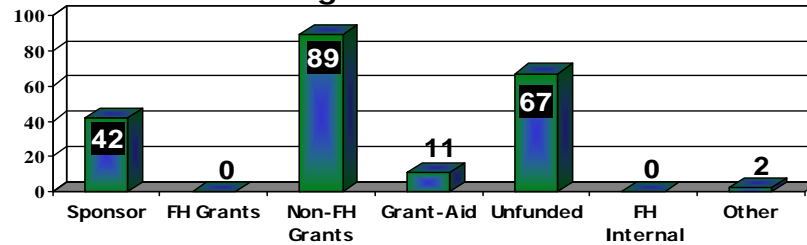
**ACTIVE STUDIES = 211**

**PENDING APPROVAL = 18**

**Type of Ethics Review for ACTIVE Studies**



**Funding for ACTIVE Studies**



**Active Studies by Department Area**

Access & Utilization	1	Family Medicine	4	Multiple Sclerosis	9	Physiotherapy	4
Acute Programs	2	Food & Nutrition	3	Nephrology	4	Professional Practice	4
Administration	1	Gastroenterology	1	Nursing	8	Psychiatry	17
Assisted Living	1	Geriatric	2	Obstetrics	7	Psychology	1
Cardiology	32	Health Services	4	Occupational Therapy	2	Public Health Prevention	1
Chronic Care	1	Infectious Diseases	1	Oncology	8	Residency Facility	2
Critical Care (ICU)	8	Information Management	1	Orthopaedics	17	Respiratory	2
Decision Support Services	1	Internal Medicine	1	Palliative Care	2	Social Work	4
Dentistry	1	Laboratory	2	Pathology	1	Surgery	2
Diversity Services	1	Material Management	1	Pediatrics	6	Workplace Health	9
Emergency	4	Medicine	4	People Services	1		
Environmental Health	2	Mental Health	6	Pharmacy	15		

# WHAT IS THE SCOPE OF THE FHREB?



Degree of FHREB Oversight in Proportion to Probability & Magnitude of the Risk of Harms

Continuum of risk of harms can encompass the following determinants, e.g.:

- Invasiveness of intervention
- Intrusiveness of data collection
- Toxicity of intervention
- Vulnerability of subjects
- Sensitivity of information
- Availability of risk mitigation strategies
- Potential for conflict of interest – i.e. industry sponsored

# WHAT IS THE SCOPE OF THE FHREB?



Degree of FHREB Oversight in Proportion to Probability & Magnitude of the Risk of Harms

Harms can include potential for:

- Physical injury/adverse event
- Emotional or psychological injury
- Social harm [e.g. loss of insurance, employability]
- Financial harm
- Breach of confidentiality
- Loss of trust

# WHAT IS THE SCOPE OF THE FHREB?



## Degree of FHREB Oversight in Proportion to Probability & Magnitude of the Risk of Harms

- Delegated Review for 'minimal risk' studies.
  - Review delegated to FHREB co-Chair
  - FHREB co-Chair may refer to FHREB

# WHAT IS THE SCOPE OF THE FHREB?



Delegated Review for Minimal Risk Studies involving 'Vulnerable' Subjects

- Secondary Sources of Data:  
Retrospective Chart review – no consent required
- Prospective Observational research:  
Primary sources of data – consent required

# WHAT IS THE SCOPE OF THE FHREB?



Ethics Review and Approval **BEFORE ANY** contact with prospective subjects and/or **ANY** data collection begins.

# Keeping the Risks to a Minimum!



# WHAT IS THE SCOPE OF THE FHREB?



Ethics Review and Approval Required  
UNTIL ALL subject contact AND/OR  
data collection is completed

# Obligations of the FHREB:



- The Ethical Review Process is transparent and meets obligations according to international and national guidelines and legislation, provincial legislation and FH policies.
- Researchers meet their obligations according to international and national guidelines and legislation, provincial legislation and FH policies.

# Obligations of the FHREB:



What are the main FHREB obligations?

- To protect human subjects
- To preserve rights of human subjects

## **ALL CANADIAN RESEARCH:**

TCPS = The Tri-council Policy Statement on Ethical Conduct for Research Involving Human Subjects [1998 + updates]

<http://www.pre.ethics.gc.ca/english/policystatement/policystatement.cfm>

**ALL CANADIAN CLINICAL DRUG/DEVICE TRIALS:** Health Canada = Food and Drug Act Regulations

[http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/acts-lois/index\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/prodpharma/legislation/acts-lois/index_e.html)

# Why Should We Worry About Protecting Human Subjects?



## The Recent Past:

[2002] Ryan Lucio – Children's Hospital-Ottawa

[2001] Ellen Roche – Johns Hopkins

[1999] Jessie Gelsinger – U Penn

[1998] Hoiyan Wan – U Roch

[1997-2001] Nancy Olivieri – U of Toronto

# The Distant Past:



- Nuremberg NAZI Doctors Trial
- PHS Syphilis Study – Tuskegee, Tennessee

# Governing Legislation, Guidelines



## WORLD MEDICAL ASSOCIATION /INTERNATIONAL

- 1964 Declaration of Helsinki
- 1997 ICH Good Clinical Practice Guidelines

## UNITED STATES for U.S. Government Funded Studies

- 1979 Belmont Report: 45 CFR 46; 21 CFR 50,56
- 1983 45 CFR 46: Subpart D (children)
- 1991 Common Rule: 17 U.S. Agencies
- 2001 Association of American Universities Conflict of Interest Guidelines

# ...Con't Governing Legislation, Guidelines



## CANADA

- 1998 Health Canada: Food & Drug Act Medical Device Regulations
- 1998 Tri-Council Policy Statement on Ethical Conduct for Research Involving Humans
- 2001 Health Canada: Regulations Amending the Food & Drug Act – Clinical Trials
- 2002 FOIPPA – Freedom of Information and Protection of Privacy (B.C.) Section 35 Amendment re "[Disclosure for research or statistical purposes](#)"
- 2002 Health Canada: CIHR Requirements for Ethical Review of Pluripotent Stem Cell Research
- 2004 Health Canada: Natural Health Products Regulations Part 4 – Clinical Trials
- 2004 Personal Information Protection Act of BC (PIPA)
- 2004 Canada: Personal Information Protection and Electronic Documents Act (PIPEDA)

# FH POLICIES AND GUIDANCES:



## **2005 April 12; Revised 2007 Jan and 2007 June**

- "Ethical Conduct of Research & Other Subjects Involving Human Subjects"

## **2005 June 21:**

- "FH Research"\* **\*Revised 2007 Jan:**
- "The Collection, Use and Disclosure of Personal Information for Research-related Purposes"
- The Provision of Research-related Services to Non-Researchers

## **2007 January:**

- Research Integrity Policy

## **FHREB GUIDANCE NOTES and POLICIES**

# Some Definitions



## APPLICATION FORMS

<http://www.fraserhealth.ca/Professionals/Research/Pages/Forms%20and%20Templates.aspx>

1. Initial Application: one application regardless of study type
2. Amendment Application for Previously Approved Research:  
Changes to a protocol:
  - genetic testing, new genetic tests or tissue banking where genetic testing may or will be performed;
  - open label extension phase following a randomized trial;
  - emergency amendments
  - change in drug dosing/duration of exposure/intervention
  - decrease in monitoring [esp. clinical trials],
  - change in recruitment technique
  - change in experimental procedure or study population.

## APPLICATION FORMS con't

3. Request for Annual Renewal Form
4. Close-out Forms [Non-clinical & Clinical]

### \*Clinical Trial specific

5. Serious Adverse Events Forms [Local & International]
6. Protocol Deviation

# Some Definitions



## RESEARCHER RESPONSE FORM

<http://www.fraserhealth.ca/Initiatives/Research/Forms+and+Templates.htm>

1. Revision of Research Studies for Removal of Modifications Required or Deferred Status
  - a. IF Modifications Required:
    - Does not require Full Board review
    - Reviewed & approved under Expedited Review
  - b. IF Study Deferred:
    - Requires resubmission to Full Board for review\*

# FEES



- \$2500 fee required for studies that are industry-sponsored ONLY
- Grant funded and unfunded studies are exempt

# The Ethical Review Process



Full Board Review: Greater Risk	Delegated Review: Minimal Risk
<p><b>Schedule:</b> All board members meet 2<sup>nd</sup> Tuesday of every month</p> <p><a href="http://www.fraserhealth.ca/Professionals/Research/Ethics/Pages/default.aspx">http://www.fraserhealth.ca/Professionals/Research/Ethics/Pages/default.aspx</a></p>	<p><b>Schedule:</b> Reviews conducted weekly by <u>one</u> of the FHREB co-chairs, i.e. no 'meeting'</p>
<p><b>Meeting Agenda:</b></p> <ul style="list-style-type: none"> <li>•New applications,</li> <li>•Amendments &amp; renewals that require FB review [regulated clinical trials only or co-Chair refers from Expedited Review]</li> <li>•Researcher's responses to Deferral memo</li> <li>•Policy, procedures, education</li> </ul>	<p><b>Review Agenda:</b></p> <ul style="list-style-type: none"> <li>•New applications,</li> <li>•Amendments &amp; renewals that do not require FB review</li> <li>•Serious adverse events,</li> <li>•Protocol deviations</li> <li>•Researcher's responses to modifications memo</li> </ul>
<p><b>Application Process:</b></p> <ul style="list-style-type: none"> <li>•Mail in 14 copies of all documents 2 weeks before meeting date to Rosa Haywood</li> <li>•Pre-review** conducted</li> <li>•Documents sent to members 1 week before meeting for their review and analysis</li> </ul>	<p><b>Application Process:</b></p> <ul style="list-style-type: none"> <li>•Email the documents [i.e. one copy only] in at any time to Rosa Haywood; Signature page may be faxed</li> <li>•Pre-review** conducted prior to review</li> <li>•Documents received 1 business day before the review date will be reviewed</li> </ul>

# The Ethical Review Process



Full Board Review: Greater Risk	Delegated Review: Minimal Risk
<p><b>Meeting Process:</b></p> <ul style="list-style-type: none"> <li>•Discuss &amp; approve protocol*, Investigator's Brochure**, consent forms, questionnaires, recruitment notices, other documentation</li> <li>•Input from clinical experts, lawyer, ethicist, lay person.</li> </ul>	<p><b>Review Process:</b></p> <ul style="list-style-type: none"> <li>•Co-chair reviews protocol*, consent forms, questionnaires, recruitment notices, other documentation</li> <li>•Summary document sent to FHREB with decision for 'approval'.</li> </ul>
<p><b>Decisions:</b></p> <ul style="list-style-type: none"> <li>•Modifications Required*** <b>92%</b></li> <li>•Deferral**** <b>8%</b></li> <li>•Deferral with External Peer Review</li> </ul>	<p><b>Decisions:</b></p> <ul style="list-style-type: none"> <li>•Approval <b>52%</b></li> <li>•Modifications Required <b>48%</b></li> <li>•Referral to Full Board</li> </ul>
<p><b>Decision Criteria:</b></p> <ul style="list-style-type: none"> <li>•<u>Study Deferred</u> Poor Science: if research design/statistical design/sample size incapable of answering research question, if information re risks/risk mitigation is insufficient.</li> <li>•<u>Modifications Required</u> if clarifications required are not substantive in nature, i.e. application/consent form inconsistencies &amp;/or inaccuracies.</li> <li>•<u>External Peer Review</u> if additional scientific/clinical expertise required.</li> </ul>	<p><b>Decision Criteria:</b></p> <ul style="list-style-type: none"> <li><u>Modifications Required</u> if research design/statistical design/sample size incapable of answering research question.</li> <li><u>Modifications Required</u> if clarifications required that are not substantive in nature, i.e. application/consent form inconsistencies &amp;/or inaccuracies.</li> <li><u>Referral to Full Board</u> if additional expertise required.</li> </ul>

# The Ethical Review Process



<b>Full Board Review: Greater Risk</b>	<b>Expedited Review: Minimal Risk</b>
<p data-bbox="146 401 587 439">Timelines [business days]:</p> <p data-bbox="146 454 836 492">Email of Decisions: 5 days <span style="float: right;">92%</span></p> <p data-bbox="146 561 921 599">Meeting to Approval [median] <span style="float: right;">39.5 days</span></p>	<p data-bbox="967 401 1408 439">Timelines [business days]:</p> <p data-bbox="967 454 1663 492">Email of Decisions: <span style="float: right;">3 days</span></p> <p data-bbox="967 561 1688 599">Review to Approval [median] <span style="float: right;">4.5 days</span></p>

# Full Board Review:



## **DR. FRANK ERVIN [RMH]:**

IMPROVE IT - Improved Reduction of Outcomes: Vytorin Efficacy International Trial: A multicentre, double-blind, randomized study to establish the clinical benefits and safety of Vytorin (Ezetimibe/Simvastin tablet) vs. Simvastin monotherapy in high-risk

ACUITY - A Randomized Comparison of Angiomax (bivalirudin) vs. Heparin (unfractionated heparin or enoxaparin) in Patients Undergoing Early Invasive Management for Acute Coronary Syndrome Without ST-Segment Elevation

## **DR. GERALD SIMKUS [RCH]:**

PLATO - A Randomized, Double-Blind, Parallel Group, Phase 3, Efficacy and Safety Study of AZD6140 Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST Elevation Acute Coronary syndrome (ACS)

## **DR. SEAN KEENAN [RCH]:**

DECRA - Multi-Centre Prospective Randomised Trial of Early Decompressive Craniectomy in Patients with Severe Brain Injury

## **DR. GALINA VOROBAYCHIK [BH]:**

A 12-month, Double-blind, Randomized, Multicenter, Active-Controlled, Parallel-Group Study Comparing the Efficacy and Safety of 0.5 mg and 1.25 mg Fingolimod (FTY20) Administered Orally Once Daily Versus Interferon b-1a (Avonex®) Administered i.m. Once Weekly

# Expedited Review – Minimal Risk



DR. DANTE MANYARI [SMH]

Canadian Congestive Heart Failure Network National Registry Database

emphasize

DR. SONIA SINGH [PAH]

Mechanism of Falls in the Elderly

HOLLY KENNEDY-SYMONDS [BH]

Evaluation of Novel Balistocardiograph Analysis Methods

JOAN ARNOLD [RCH]

Consumption of a Liquid Meal Replacement in Hospitalized Patients: An Anonymous Observational Study

# SUBMISSION PROCESS:



Refer to Guidance Notes for specific guidance related to the application form

<http://www.fraserhealth.ca/Professionals/Research/Pages/Forms%20and%20Templates.aspx>

# Initial Application Requirements: Problem Areas



## APPLICATION FORM FOR INITIAL ETHICAL REVIEW

- ✓ Application form information must be consistent with protocol, subject consent form(s) & other documentation

Pages 1 & 2:

- Primarily administrative
- Signatures must be obtained BEFORE review.
- Document version # and dates must be included.
- \*New requirement: Clinical Trial Registration
- Contact information

# Application Requirements: Problem Areas



## Recruitment methods

- see Guidance Note 17

## Risks

- See Guidance Note 22
- use template provided
  - quantify all measurable risks
  - can include psychological and social risks of harm

# Application Requirements: Problem Areas



**Confidentiality: Guidance Note 28**

**Competency, Consent and Assent:**

**Competency:** TCPS states that competence (capacity to consent) consists in "the ability of prospective subjects to give informed consent in accord with their own fundamental values. It involves the ability to understand and to appreciate the potential consequences of a decision..."

**Appreciation:** assumes adequately developed adult capacities for forming and revising personal values.

**Understanding:** ability to discern in significant measure the nature of the research and the consequences of choosing/forgoing participation in it.

No legal age of 'consent' for research in B.C.

# Application Requirements: Problem Areas



## **Children under 7 :**

parental/temporary substitute decision maker

## **Children between 7 and 13:**

- assent form &
- parental/temporary substitute decision maker consent form

## **Children 14 and older:**

- parental/temporary substitute decision maker
- statement of signed assent in the consent

# ETHICAL PRINCIPLES & REB Obligations



- Pre-study implementation: Study Value
- Subject recruitment
- Consenting Process
- Study Implementation
- Data Analysis

# ETHICAL PRINCIPLES & REB Obligations



*Study Value:*

*Ethical Principle: Beneficence*

*'Maximize possible benefits and minimize possible harms'*

# ETHICAL PRINCIPLES & REB Decisions



**Does the science have value??**

**For experimental research: Is there clinical equipoise?**

- Literature review
- Testable hypothesis/endpoints/outcomes specified
- Placebo justification
- Adequacy of peer review (FB only)
- Sufficient sample size (power)
- Do benefits outweigh possible risks?

# Mike Wasdell: Consultation for Research Proposal Development



## Recruitment

### *Ethical Principle: Distributive Justice*

*“fairness in distribution” of the risk of harms and benefits among the population*

# ETHICAL PRINCIPLES & REB Decisions



- Inclusion Criteria
  - Do inclusion criteria unfairly put one group at risk of harm versus other potential subjects?
- Exclusion Criteria
  - Do exclusion criteria provide valid reasons for excluding subjects based on for e.g. culture, religion, language, race, sex, age, mental or physical capacity?

# ETHICAL PRINCIPLES & REB Decisions



## Recruitment

*Ethical Principle: Respect*

*“treat individuals as autonomous agents”*

# ETHICAL PRINCIPLES & REB Decisions



- Subject Identification
  - Protect privacy [FOIPPA]
  - Section 35 prohibits using personal information for contact if collected for a non-research purpose, i.e. medical records
- Initial Contact
  - If Principal Investigator is primary caregiver, ensure non-coercive contact
  - No inducements: subjects must not be encouraged to trade incentives for risks

## Obtaining Consent:

“The consent form is not meant to reassure the subject, quite the contrary, it is meant to raise every possible concern that might be relevant to the subject’s participation.”

- Time 2002 April 22

# Mistakes Can, [but shouldn't] Happen!



"Went in for a simple blood test and got cloned by mistake."

# The Consent Form:



## Three basic elements:

1. Complete and Accurate Information
1. Readable
  - well organized
  - lay terms
  - grade 7 level
3. Voluntary
  - avoid coercion and undue influence

FH REB Consent Form Templates at

<http://www.fraserhealth.ca/Professionals/Research/Pages/Forms%20and%20Templates.aspx>

## Main Consent Form

- Optional Research, e.g. genetic testing
- Assent Form
- Consent to Screen
- Consent to Contact

## Consenting to Participate

***Ethical Principle:** Respect for free and informed consent throughout the study*

*“treat individuals as autonomous agents”*

# ETHICAL PRINCIPLES & REB Decisions



- Ensure Non-coercive Consent Process
  - Time to consent > 24 hours
  - CF: Voluntary decision
  - CF: Informed decision:
    - Opportunity to ask questions
    - Full disclosure\* of all information in lay terms including alternatives if therapy
    - Opportunity to withdraw at any time

## During the Study: Ongoing Consent

***Ethical Principle:***

***Non-maleficence***

*“duty to avoid, prevent, or minimize  
harms to others”*

# ETHICAL PRINCIPLES & REB Decisions



## Risk of Harms:

## Full Board Review of Clinical Trials:

“The risk of harms to the subject of participating in the study has been evaluated by the FHREB. The FHREB agrees that the foreseeable harms to this subject population do not outweigh the anticipated benefits to society and that the foreseeable harms are documented in the written consent form compared to the **review of the Investigator’s Brochure for this study**. In addition, the FHREB agrees that the risk management strategies described in the consent form to prevent, mitigate and/or manage the occurrence of harms are reasonable and reflect current medical practice.”

# ETHICAL PRINCIPLES & REB Decisions



- Minimize Harms
  - Provide stopping rules; rescue medication
  - CF: Emergency contact information
  - CF: New information re harms
  - CF: Compensation for research-related harms
  - CF: Legal rights
  - CF: How to withdraw
  - CF: Subject rights

## Data Analysis

*Ethical Principle: Respect*

*“ do not harm ”*

# ETHICAL PRINCIPLES & REB Decisions



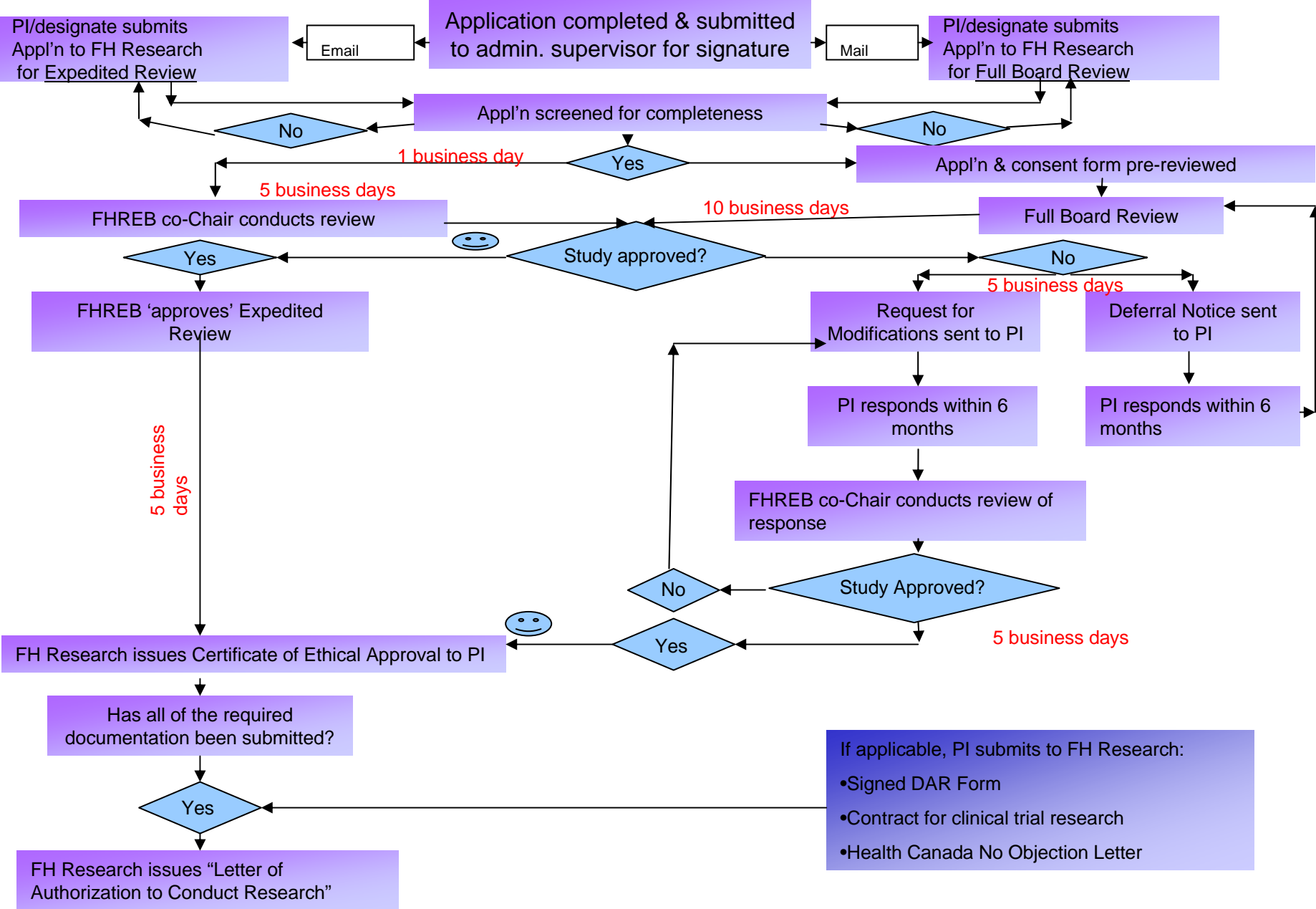
- Is collection of personal data limited to essential information for study purposes?
- Is consent obtained for collection/use of data?
- Are subjects informed about possible uses of research data?
- How is confidentiality of subject data maintained?
  - Removal of personal identifiers, i.e. initials, name, PHN, etc.
  - Secure storage of data [preventing breach of confidentiality]

# Consent Form Review



- Divide into groups of 4
- Each group review 1 page of the informed consent
- Each group compare their assigned page to the standard consent form template and critique
- Report back

# FH RESEARCH REVIEW PROCESS



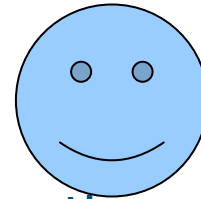


# Last But Not Least



## The Letter of Authorization to Conduct Research:

- FHREB initial approval
  - consent
- Health Canada Letter of No Objection
- Clinical Trial Agreement
- Department Agreement for Providing Research-related Services
- Clinical Trial Registration #
- Grant Agreement start date



# Last but not least



## HAVE FUN!



*THANK YOU !!!*

*Susan Chunick*

*604-587-4681*

*Rosa Haywood*

*604-587-4436*