



## UBC CLINICAL RESEARCH ETHICS BOARD (CREB)

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RISe: <http://rise.ubc.ca>

## CLINICAL RESEARCH ETHICS BOARD ANNUAL REPORT 2010

For the period of 01 April 2010 to 31 March 2011



This is the individual report for the UBC Clinical Research Ethics Board for the fiscal year 01 April 2010 to 31 March 2011.

The UBC Office of Research Ethics will provide a combined UBC REB annual Report encompassing all UBC affiliated REBs for the fiscal year 01 April 2010 to 31 March 2011.

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The UBC Research Ethics Boards are established and empowered under the authority of the Board of Governors through the Vice-President Research at the University. UBC requires that all research projects involving humans as subjects or human material be reviewed and approved by a UBC REB including any properly constituted REB as described in Policy 89, Authorized Procedures, prior to initiation of any research related activities, including recruitment and screening activities.

### **PURPOSE**

The REB's purpose is to protect the rights and welfare of human subjects participating in research conducted at UBC. The UBC REBs review and oversee such research to assure that it meets ethical principles and that it complies with all applicable regulations and standards pertaining to human subject protection. These include but are not limited to Health Canada's Food and Drugs Act, the International Conference on Harmonization Good Clinical Practice: Consolidated Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, UBC Policy 89 and where and to the extent applicable, US Federal Regulations.

### **GOVERNING PRINCIPLES**

The REB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, as follows:

- Respect for a person's right for self-determination and autonomy
- Not harming others nor violating a person's fundamental rights of liberty and privacy
- Doing good to others, including society, research participants, researchers, sponsors and institutions
- Recognizing the duty of researchers to disseminate the analysis and interpretation of any significant results to the research community, since silence on negative outcomes may foster potentially harmful clinical practices or wasteful duplication
- Equitable distribution of the benefits and burdens of research

### **REB AUTHORITY**

- The UBC REBs are established to review all research involving human subjects that is conducted by UBC faculty, staff and students, or anyone conducting research at or under the auspices of the University of British Columbia.
- The REB has the authority to ensure that all research conducted under the auspices of UBC is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research subjects. Specifically:
  - The REB has the authority to approve, require modification in, or disapprove, any research activity that falls within its jurisdiction.
  - The REB has the authority to conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research subjects. Continuing review activities include, but are not limited to,
    - Review of regular progress reports
    - Review of changes in the design or conduct of the study prior to implementation
    - Review of Serious Adverse Events
    - Monitoring to determine that the study is conducted as approved
    - Observation of the informed consent, and
    - Any other review procedure as deemed to be necessary to protect the rights and welfare of human subjects
    - The REB may suspend or terminate approval of a study
    - The REB may place restrictions on a study

### **ONE BOARD OF RECORD AGREEMENT (UBC Affiliated REBs)**

The UBC C&W REB is one of six UBC affiliated Research Ethics Boards for human subject research.

- UBC Clinical REB (CREB)
- UBC Children & Women's (C&W REB)
- UBC Behavioural REB (BREB)
- UBC Okanagan (UBC-O)
- UBC Providence (PHC)
- UBC BC Cancer Agency REB (BCCA)

The UBC affiliated REBs noted above agree that all **new** research projects reviewed by one of the UBC affiliated REBs should have a single REB of Record **when the same Principal Investigator is conducting the same research project at more than one institution under the jurisdiction of more than one UBC REB**. The purpose is to avoid the requirement for multiple formal ethical reviews of the same research study. The UBC REB that initially reviews and approves the research project will be the Board of Record for the study. To ensure that institutional specific REB ethics requirements are met, the Chair of the UBC REB for an institution that is involved in the conduct of the study (but is not the Board of Record), may view the application and study documents approved by the Board of Record. If the institutional UBC REB Chair has questions or concerns, these will be directed to the Chair of the Board of Record for resolution.

### **RESEARCHER INFORMATION SERVICES SYSTEM (RISe)**

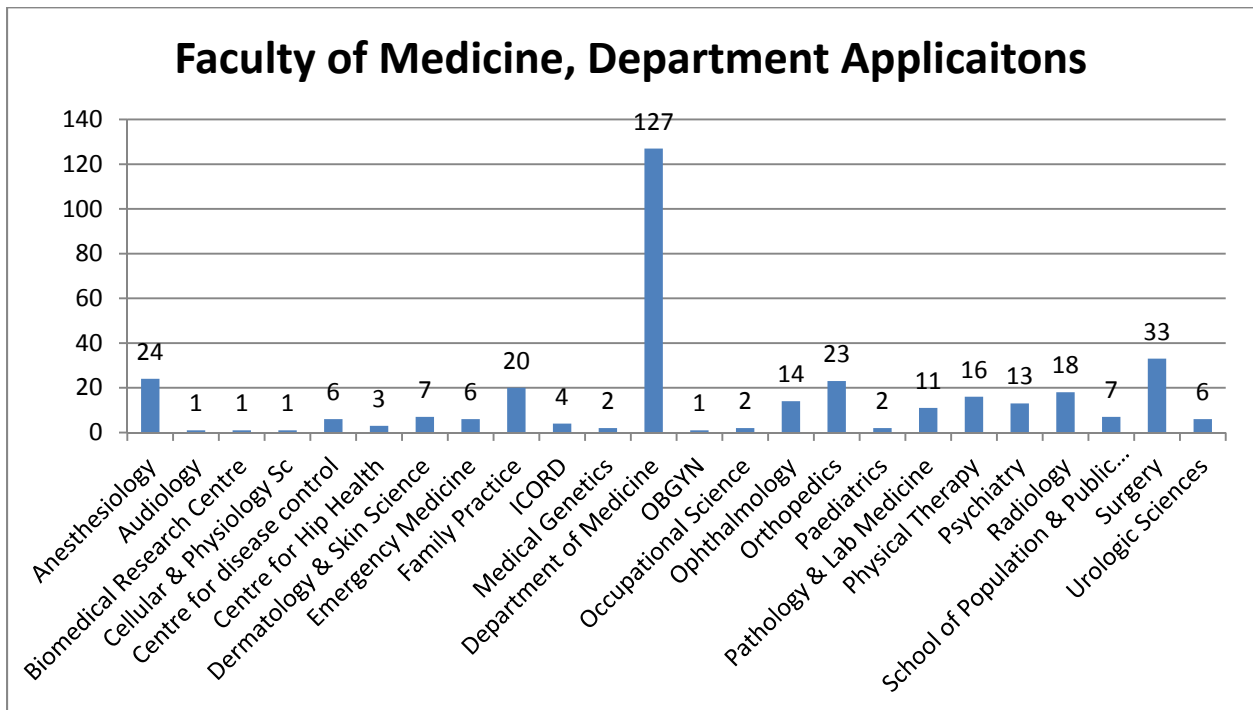
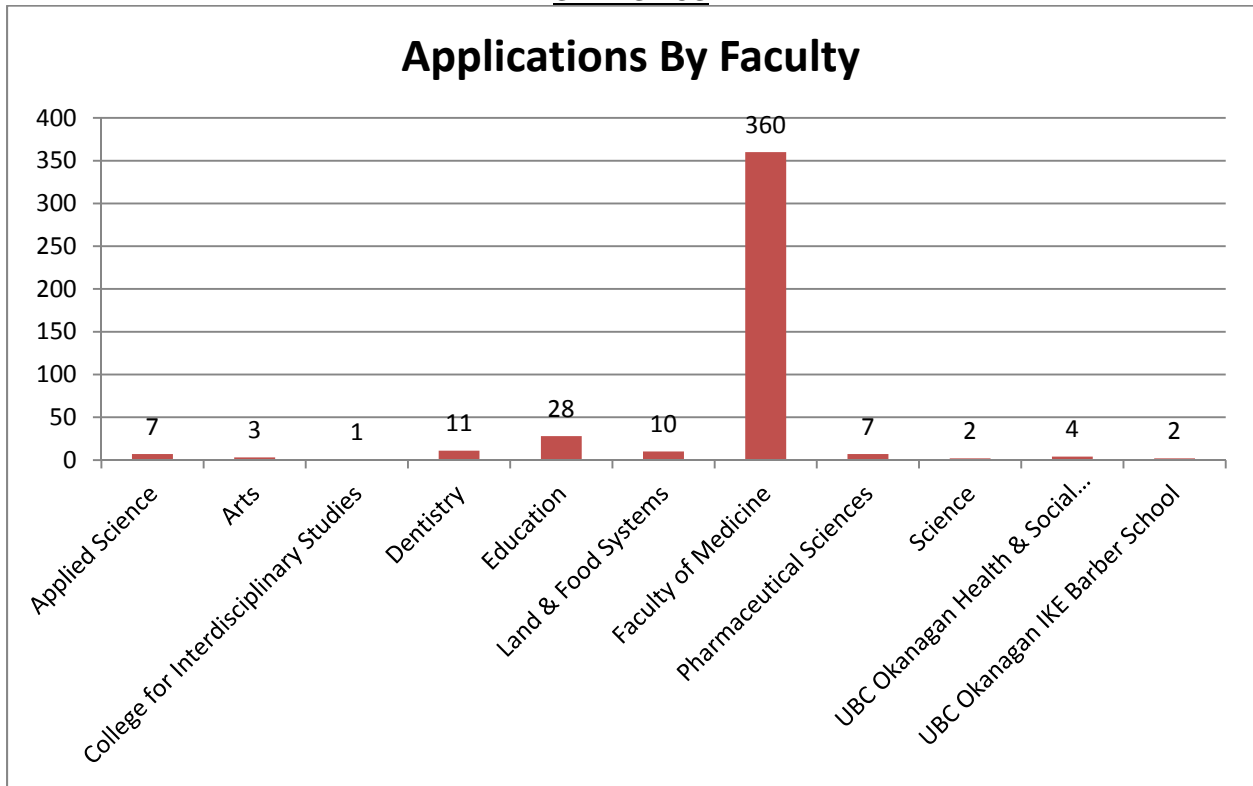
Throughout this report frequent reference is made to "RISe". RISe is an online research administration tool that allows researchers and administrators to manage applications online through the process that can be tracked to approval, certification or awarding of funds. As a collaborative online tool, RISe allows researchers to interact with their research teams, administrators, and reviewers; the system also sends auto-notifications and reminders to individuals regarding the status of their project or application. The UBC-affiliated REBs continue to work together and with the RISe team of programmers to maintain and improve the content, data, and functionality of the system.

### **MESSAGE FROM THE CHAIR**

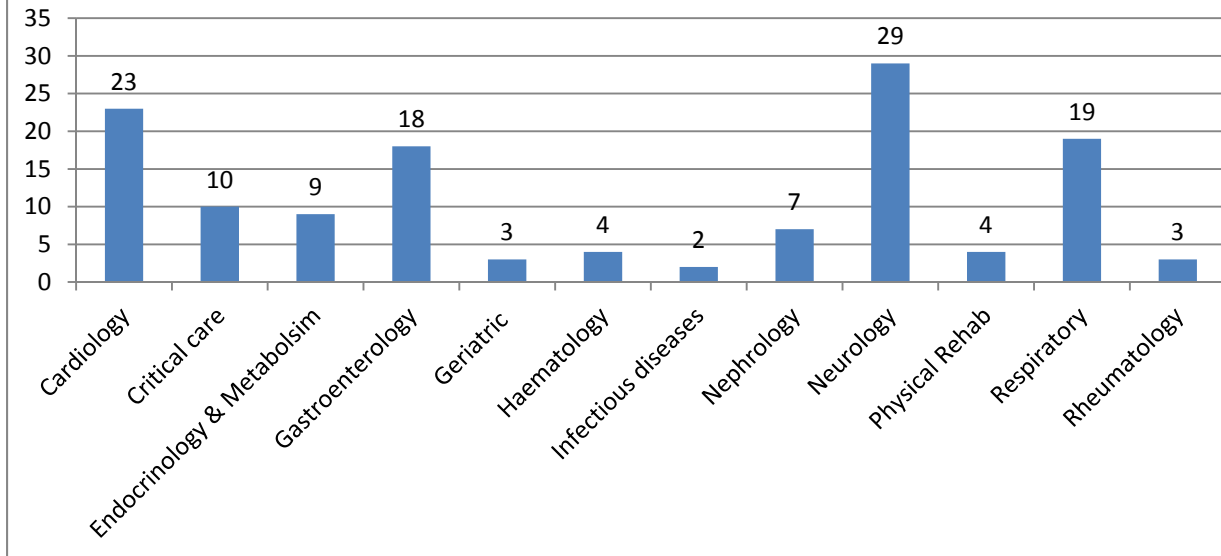
Dr. Peter Loewen

The CREB Board members provide an essential service to the research community at UBC. It is an onerous role, entailing thorough scientific, clinical and ethical scrutiny of many studies each year. Our members are highly motivated and hard-working, clearly interested in ethical principles and concepts and the many regulations that are considered. The CREB, through its staff and members, supports clinical research in many ways, providing quality assurance, ethics education, responses to subjects' concerns, and direct help to researchers so they can achieve their goals. This expertise and time is greatly appreciated and each member is a valuable asset to the CREB. Thank you CREB members and staff!

## STATISTICS



## Department of Medicine, Division Applications



### **REVENUE**

The CREB fee of \$3,000.00 for the ethical review of new applications applies to studies that are funded by a for-profit / industry sponsor. There were 80 for-profit studies submitted in the fiscal year ending 31 March 2010 totaling \$240,000

YEAR	<b><u>Total # of for-profit studies Per Fiscal Year</u></b>	<b><u>Total CAD\$ at \$3000 per study</u></b>	<b><u>% gain or loss from previous year</u></b>
2007	102	\$306,000.00	
2008	97	\$291,000.00	-4.90%
2009	85	\$255,000.00	-12.37%
2010	80	\$240,000.00	-5.88%

### **CHALLENGES / CHANGES DURING 2010**

The UBC Office of Research Ethics was completely updated February 2011, and the link to the CREB changed to <http://research.ubc.ca/ethics/clinical-research-ethics-board>. This has allowed for smoother application to the website of important changes that occur from time to time.

The RISE system underwent a major milestone April 2011 with an entire system upgrade that updated the platform as well as Click Commerce version 5.3 to version 5.7.

29 November 2010: the presidents of the 3 research funding agencies (CIHR, NSERC & SSHRC) approved the 2<sup>nd</sup> edition of the TCPS. After 2 years involving consultations across Canada TCPS2 replaces the initial policy adopted in 1998. TCPS2 is the official human research ethics policy of the agencies. Substantive changes are reflected in the Policy including a new set of core principles, clarified definitions, simplified articles and new chapters including Qualitative Research, and Research involving Aboriginal Peoples. The final TCPS2 was released February 2011.

## **FULL BOARD MEETINGS**

22 Full Board meetings of the CREB were held from 01 April 2010 to 31 March 2011. Meetings are held on the 2nd and 4th Tuesday of the month. The second meeting in August was cancelled and there is only the first meeting in December. Meeting dates & deadlines for submission to Full Board for ethics review are posted on the CREB Website at: <http://research.ubc.ca/ore/creb-meeting-dates-deadlines>

	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	<b>TOTAL</b>
New studies	36	37	40	39	29	41	45	42	45	32	38	35	<b>459</b>
New studies for Full Board Review	11	13	19	12	12	10	19	13	14	5	10	10	<b>148</b>
New studies for Delegated Review	25	24	21	27	17	31	26	29	31	27	28	25	<b>311</b>
Annual Renewals, Amendments Requests for Acknowledgement	268	250	256	259	258	246	247	257	225	296	232	284	<b>3078</b>

## **US Federal Wide Assurances (DHHS-OHRP)**

Under the United States Department of Health and Human Services (DHHS) Code of Federal Regulations 45: Part 46 A Protection of Human Subjects [Section 46.103](#), every institution engaged in human subjects research supported or conducted by any United States Federal Department or Agency must have assurance of compliance approved by the United States Office for Human Research Protections (OHRP). The Assurance formalizes the institution's commitment to protect human subjects. OHRP Federalwide Assurance (FWA) and Institutional Review Board (IRB) assurance have been obtained for UBC and the CREB (REB is the Canadian terminology for an IRB). Click on the type of assurance below for more information:

<b>Type of Assurance</b>	<b>Policy Number</b>	<b>Expiry Date</b>
Federal Wide ( <a href="#">see details</a> )	FWA00000668	January 31, 2017
Institutional Review Board ( <a href="#">see details</a> )	IRB00001443	January 18, 2015

## **CREB MEMBERSHIP**

As of 05 May 2011, the CREB was composed of 32 members (22 Voting members & 9 Alternate members, 1 ad hoc) of diversified specialties as well as from the community.

All appointments to the Board are made by the UBC Vice-President Research. The depth and breadth of knowledge required, the time commitment and the stress of the responsibility are onerous, and the Board members are thanked for their outstanding contributions to UBC and its affiliated institutions. The Full membership lists with REB position, Qualifications, Scientific affiliations, institutional affiliation and Quorum designation are detailed and updated on the CREB Web Page at:

<http://research.ubc.ca/ethics/members>

	UBC CREB VOTING MEMBER Gender/Citizenship	REB position (Alternate Designation)	Highest Degree	Primary or Non-scientific speciality	UBC Affiliation	Quorum Designation
1	<b>Dr. Raja Abboud</b> Male / Canadian	Voting Member (Alternate for # 2)	MD, FRCPC	Respiratory Medicine	Yes	B
2	<b>Dr. Najib Ayas</b> Male / Canadian	Voting Member	MD	Internal Medicine (Pulmonary Critical Care Medicine)	Yes	B
3	<b>Dr. John Cairns</b> Male / Canadian	Voting Member	MD, FRCPC	Cardiology	Yes	B

4	<b>Dr. Peter Choi</b> Male / Canadian	Voting Member	MD, MSc	Anesthesia	Yes	B
5	<b>Dr. Iain Dommissie</b> Male / Canadian	Voting Member (Alternate for #8)	MbChB	Orthopedics	No	B
6	<b>Dr. Doris Doudet</b> Female / Canadian	Voting Member	MD	Neurology	Yes	B
7	<b>Dr. Robert Douglas</b> Male / Canadian	Voting Member	MD	Ophthalmology and Visual Sciences	Yes	B
8	<b>Dr. Clive Duncan</b> Male / Canadian	Voting Member	MBBCh, Msc, FRCSC	Orthopedic surgery, Medicine, Surgery	Yes	B
9	<b>Ms. Barbara Fulton</b> Female / Canadian	Voting member	MA	Community Member	No	C, N
10	<b>Dr. Aziz Ghahary</b> Male / Canadian	Voting Member	Ph.D	Plastic Surgery	Yes	B
11	<b>Dr. Alice Hawkins</b> Female / Canadian	Voting Member (Alternate for # 28)	PhD	Applied Ethics, Political Science, Pathology	Yes	E
12	<b>Dr Stephen Hoption-Cann</b> Male / Canadian	Voting Member	PhD	Epidemiology	Yes	B
13	<b>Dr. Morrison Hurley</b> Male / Canadian	Voting Member	MD	Pediatrics, Nephrology	Yes	B
14	<b>Dr. Dean C.C. Johnston</b> Male / Canadian	Voting Member (Alternate for #6)	MD, MHSc	Neurology	Yes	B
15	<b>Ms. Suzanne Kennedy</b> Female / Canadian	Voting Member (Alternate for #31)	LLB	Law	No	L, N
16	<b>Dr. Ardis Krueger</b> Female / Canadian	Ad hoc member for NHP reviews	ND	Natural Health Products	No	H
17	<b>Dr. Gang Li</b> Male / Canadian	Voting Member	Ph.D	Dermatology	Yes	B
18	<b>Dr. Peter Loewen</b> Male / Canadian	Chair	Pharm.D	Pharmaceutical Sciences	Yes	B, E
19	<b>Ms. Karen Low Ah Kee</b> Female / Canadian	Voting Member		Community Member	No	C, N
20	<b>Dr. Alexander MacKay</b> Male / Canadian	Voting Member (Alternate for #22)	PhD	Radiology	Yes	B
21	<b>Dr. Ian Martin</b> Male / Canadian	Voting Member	MD	Family Medicine, Epidemiology, Emergency Medicine	Yes	B
22	<b>Dr. John Mayo</b> Male/Canadian	Voting Member	MD	Radiology	Yes	B
23	<b>Dr. Peter McComb</b> Male / Canadian	Voting Member	MD, FRCSC	Obstetrics and Gynaecology	Yes	B
24	<b>Dr. James McCormack</b> Male/Canadian	Vice Chair	Pharm.D	Pharmaceutical Sciences	Yes	B, E
25	<b>Dr. Orson Moritz</b> Male / Canadian	Voting Member (Alternate for #7)	MD	Ophthalmology and Visual Sciences	Yes	B
26	<b>Dr. Elton Ngan</b> Male / Canadian	Voting Member	MD	Psychiatry	Yes	B
27	<b>Dr. Jerilynn Prior</b> Female / Canadian	Voting Member	MD	Endocrinology	Yes	B
28	<b>Dr. John Russell</b> Male / Canadian	Ethicist	PhD	Philosophy (Ethics)	Yes	E, L, N
29	<b>Dr. Bonita Sawatzky</b> Female / Canadian	Voting Member (Alternate for # 8)	PhD	Orthopedics (Sports Medicine, Biomechanics)	Yes	B
30	<b>Dr. Robert Stowe</b> Male / Canadian / American	Voting Member (Alternate for # 26)	MD	Neuropsychiatry	Yes	B
31	<b>Mr. Bill Sullivan, QC</b>	Voting Member	LLB	Law	No	L, N



	Male/Canadian					
32	<b>Dr. John Tsang</b> Male/Canadian	Voting Member	MD, FRCPC	Critical Care Medicine	Yes	B

All UBC CREB Members apart from the Ad hoc member for NHP reviews, are voting members. A quorum comprises a minimum of five separate members from groups 1-4, with:

- 1) at least two members with broad expertise in biomedical research (Scientific): **B**
- 2) at least one member knowledgeable in the ethics of scientific research: **E**
- 3) at least one member knowledgeable in law relevant to scientific research: **L**
- 4) at least one member from the community who has no affiliation with the institution (Lay Member): **C**
- 5) at least one member whose specialty is non-scientific (may also be from groups 1-4): **N**
- 6) at least one member knowledgeable in therapeutic natural health products (ad hoc, for quorum only for review of therapeutic natural health products): **H**

**EDUCATION ATTENDED / WORKSHOPS PRESENTED**

15 Oct 2010: Suzanne Richardson & Sarah Bennett attended the Vancouver Coastal Health Research Institute (VCHRI) Research Symposium

17 February 2011: Jean Ruiz & Sarah Bennett attended the TCPS2 BC regional Workshop and BC Ethics Harmonization Initiative Open House at SFU