



UBC CLINICAL RESEARCH ETHICS BOARD (CREB)

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CLINICAL RESEARCH ETHICS BOARD ANNUAL REPORT 2011

For the period of 01 April 2011 to 31 March 2012



This is the individual report for the UBC Clinical Research Ethics Board for the fiscal year 01 April 2011 to 31 March 2012.

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 2011 to 31 March 2012.

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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. The RISe team introduced a new website 17 Feb 2012

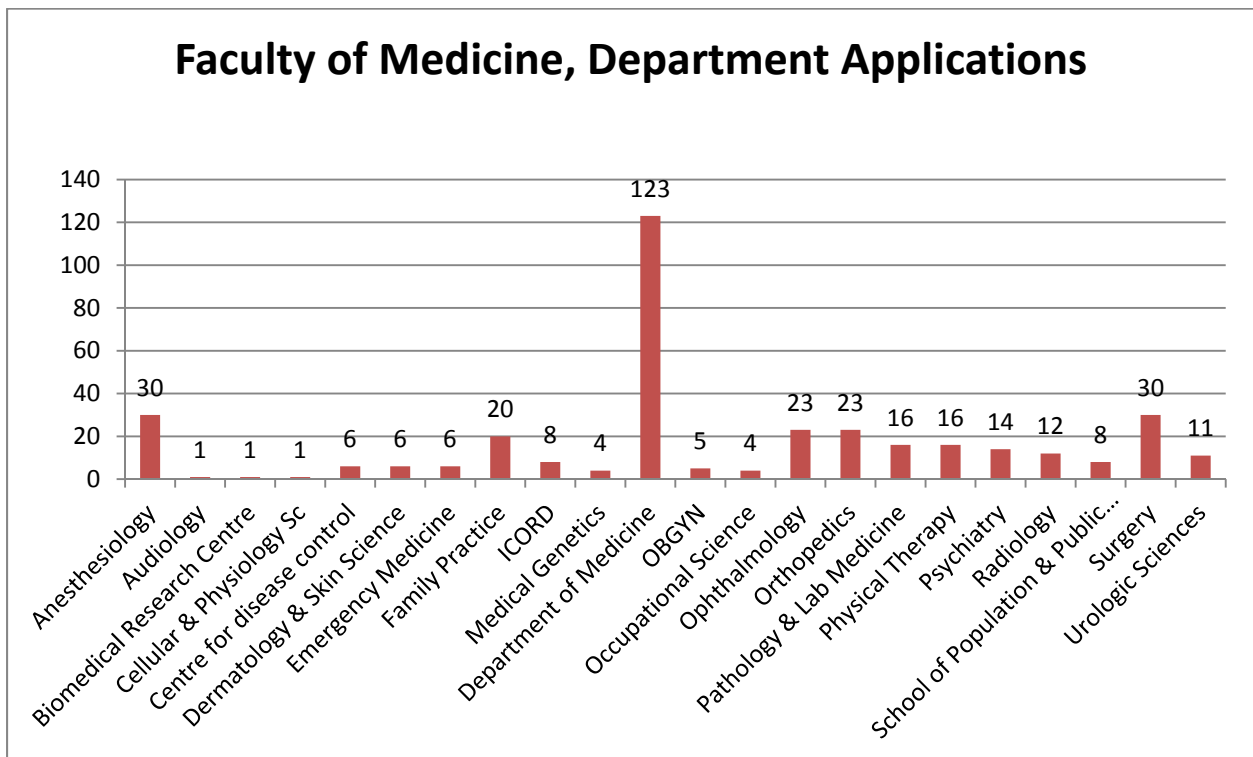
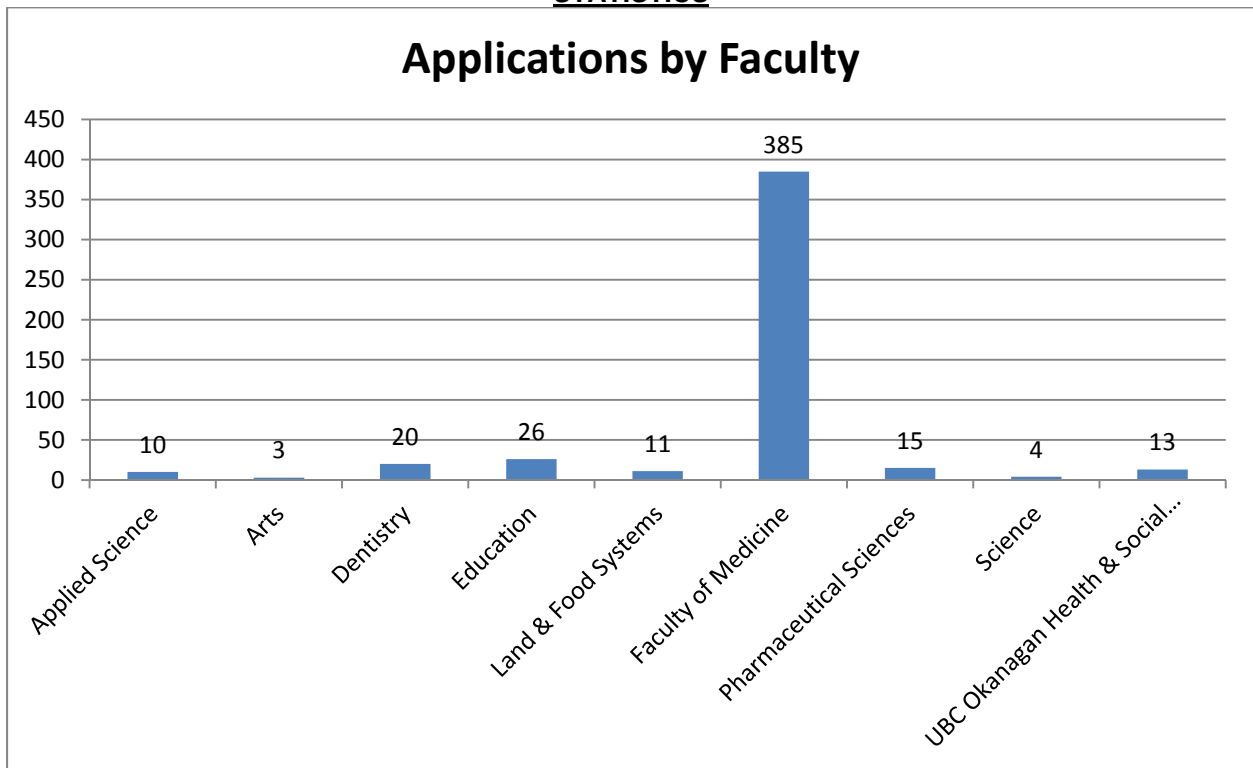
MESSAGE FROM THE CHAIR

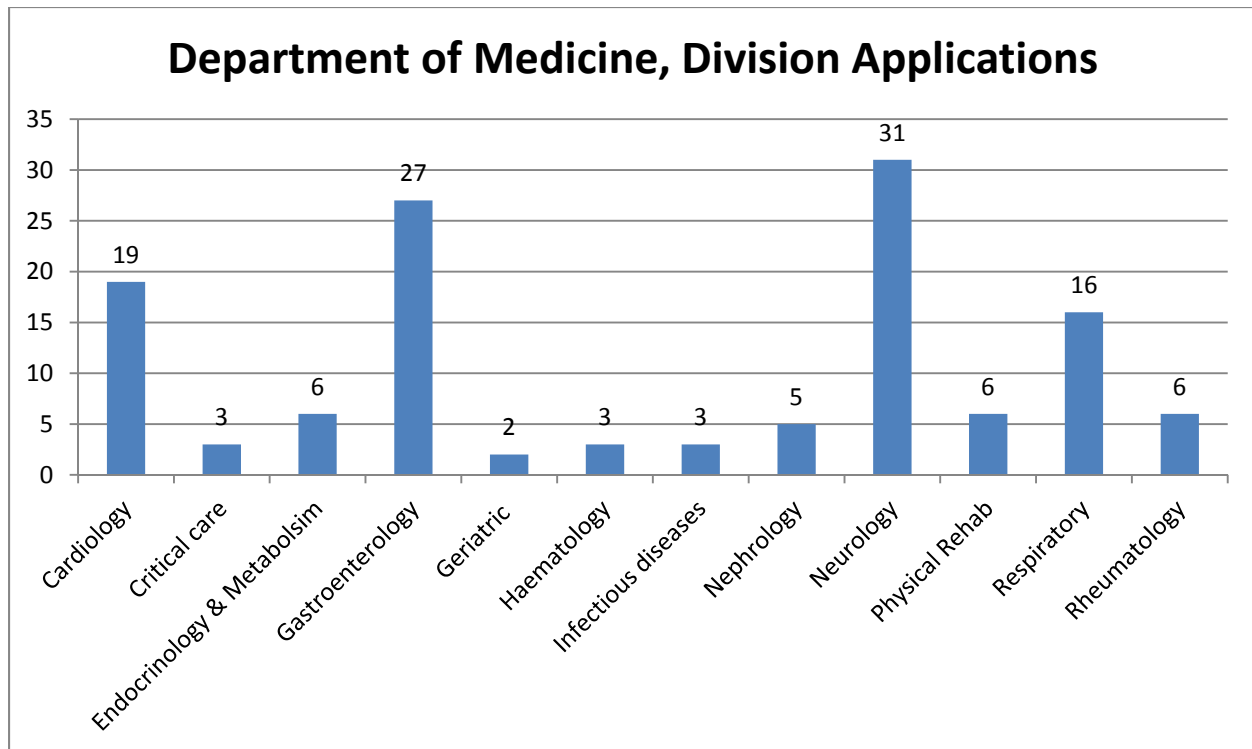
Peter Loewen

2011 was another eventful year for the CREB. During 2011 we welcomed the following new members, Dr. Emma Guns, Dr. Jaap Hamburger, Dr. Bonnie Mackenzie, Dr. Christopher Nguan, Dr. Roy Pursell and bid adieu, with our sincere thanks, to Dr. James McCormack, Holly Harlow, Kishore Mulpuri & Dr. Robert Reynolds.

The CREB developmental retreat held in October was highly successful, engaging many CREB members in vigorous learning and discussion about privacy legislation, conflicts of interest in research, and efforts to harmonize ethical review processes in BC and Canada. The CREB is grateful for the outstanding work of its members who review many complex research proposals each year and provide expert assessment and recommendations to researchers so that the rights and welfare of participants in research are protected. Thank you CREB members!

STATISTICS





TURNAROUND TIMES

There are various issues that influence the turnaround times of studies submitted to the CREB. During 2011 turnaround times varied depending on the quality and completeness of the application. i.e. incomplete applications that were missing documents such as protocols, peer reviews or consent forms that were not according to the ICF template were returned to the Investigator for revision. Certificates of approval were not released to studies that had outstanding fees.

On average (as can be seen in the charts below) the number of days from Department Approval to the issuance of the Certificate of approval for Full Board studies was 68.4 and for Delegated Review was 23.6

- 🚫 indicates that the value is worse than the previous month, 🟢 indicates that the value is better than the previous month, 🟡 indicates that the value is within .5 days of the previous month.
- The number of studies approved each month is presented as n=8(1). The number in parentheses represents the number of studies that were in the system more than 200 days and were, as a result, not included in the calculations.

Full Board Review Summary	Apr	May	Jun	Jul	Aug	Sep
	n=19	n=10(1)	n=15(2)	n=17	n=10(1)	n=14
Days from Department Approval to REB Meeting	17.63 U	15.60 U	19.18 D	18.06 U	17.70 U	20.07 D
Days from REB Meeting to Provisos Entered	4.47 D	4.80 D	4.13 U	2.82 U	2.60 U	2.71 D
Days from 1st Provisos Entered to Response to 1st Provisos	36.00 D	34.90 U	23.40 U	22.88 U	26.40 D	21.21 U
Days from Response to 1st Provisos to Cert of Approval Issued	20.68 U	22.30 D	29.67 D	16.00 U	15.40 U	12.43 U
Department Approval to Cert of Approval Issued	78.79 U	77.60 U	77.20 D	59.76 U	62.10 D	56.43 U
	Oct	Nov	Dec	Jan	Feb	Mar
	n=16	n=27	n=14	n=18(1)	n=13	n=17(1)
Days from Department Approval to REB Meeting	22.00 D	16.26 U	14.93 U	16.33 D	20.46 D	18.29 U
Days from REB Meeting to Provisos Entered	3.63 D	3.04 U	3.21 D	3.44 D	3.38 D	4.35 D
Days from 1st Provisos Entered to Response to 1st Provisos	37.38 D	26.56 U	16.36 U	28.39 D	33.62 D	36.76 D
Days from Response to 1st Provisos to Cert of Approval Issued	21.81 D	20.15 U	12.57 U	12.72 D	17.00 D	16.59 D
Department Approval to Cert of Approval Issued	84.81 D	66.00 U	47.07 U	60.89 D	74.46 D	76.00 D

Delegated Review Summary	Apr	May	Jun	Jul	Aug	Sep
	n=19(2)	n=24	n=23(3)	n=18(2)	n=24	n=24
Days from Department Approval to 1st Provisos Entered	19.47 D	7.40 U	9.32 D	8.13 U	9.62 D	8.96 U
Days from 1st Provisos Entered to Response to 1st Provisos	6.65 U	13.90 D	19.32 D	3.44 U	9.80 D	9.74 D
Days from Response to 1st Provisos to Cert of Approval Issued	5.35 U	5.30 D	3.05 U	11.81 D	6.0 U	7.61 D
Department Approval to Cert of Approval Issued	29.43 U	23.21 U	27.30 D	21.06 U	22.96 D	25.38 D
	Oct	Nov	Dec	Jan	Feb	Mar
	n=19	n=23	n=18	n=30	n=16(1)	n=28
Days from Department Approval to 1st Provisos Entered	10.63 D	7.24 U	6.75 D	6.85 D	8.54 D	9.04 D
Days from 1st Provisos Entered to Response to 1st Provisos	8.11 U	8.33 D	9.56 D	9.33 D	6.69 U	17.93 D
Days from Response to 1st Provisos to Cert of Approval Issued	6.26 U	5.81 D	3.44 U	3.93 D	2.83 U	9.41 D
Department Approval to Cert of Approval Issued	25.00 D	20.26 U	18.06 U	18.73 D	17.50 U	35.39 D

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 90 for-profit studies submitted in the fiscal year ending 31 March 2012 totaling \$270,000

YEAR	<u>Total # of for-profit studies Per Fiscal Year</u>	<u>Total CAD\$ at \$3000 per study</u>	<u>% gain or loss from previous year</u>
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%
2011	90	\$270,000.00	12.50%

FULL BOARD MEETINGS

23 Full Board meetings of the CREB were held from 01 April 2011 to 31 March 2012. Meetings are held on the 2nd and 4th Tuesday of the month. 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	<u>TOTAL</u>
New studies	42	41	39	46	32	52	44	54	40	44	43	41	518
New studies for Full Board Review	14	15	16	8	7	14	18	20	13	8	8	16	157
New studies for Delegated Review	28	26	23	38	25	38	26	34	27	36	35	25	361
Annual Renewals, Amendments Requests for Acknowledgement	237	251	250	248	259	224	256	225	227	310	263	285	3035

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:

Type of Assurance	Policy Number	Expiry Date
Federal Wide (see details)	FWA00000668	January 31, 2017
Institutional Review Board (see details)	IRB00001443	January 18, 2015

REB MEMBERSHIP

As of 04 Jan 2012, 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	Dr. Raja Abboud Male / Canadian	Voting Member (Alternate for # 2)	MD, FRCP	Respiratory Medicine	Yes	B
2	Dr. Najib Ayas Male / Canadian	Voting Member	MD	Internal Medicine (Pulmonary Critical Care Medicine)	Yes	B
3	Dr. John Cairns Male / Canadian	Voting Member	MD, FRCPC	Cardiology	Yes	B
4	Dr. Peter Choi Male / Canadian	Voting Member	MD, MSc	Anesthesia	Yes	B
5	Dr. Iain Dommissie Male / Canadian	Voting Member (Alternate for #8)	MbChB	Orthopedics	No	B
6	Dr. Doris Doudet Female / Canadian	Voting Member	MD	Neurology	Yes	B
7	Dr. Robert Douglas Male / Canadian	Voting Member	MD	Ophthalmology and Visual Sciences	Yes	B
8	Dr. Clive Duncan Male / Canadian	Voting Member	MBBCh, Msc,FRCSC	Orthopedic surgery, Medicine, Surgery	Yes	B
9	Ms. Barbara Fulton Female / Canadian	Voting member	MA	Community Member	No	C, N
10	Dr. Aziz Ghahary Male / Canadian	Voting Member	Ph.D	Plastic Surgery	Yes	B
11	Dr. Emma Tomlinson Guns Female / Canadian	Voting Member	Ph.D	Urologic Sciences,	Yes	B
12	Dr. Jaap Hamburger Male / Canadian	Voting Member	Ph.D, FESC, FRCPC	Interventional Cardiology	Yes	B
13	Dr. Alice Hawkins Female / Canadian	Voting Member (Alternate for # 32)	PhD	Applied Ethics, Political Science, Pathology	Yes	E
14	Dr Stephen Hoption- Cann Male / Canadian	Voting Member Associate Chair	PhD	Epidemiology	Yes	B
15	Dr. Morrison Hurley Male / Canadian	Voting Member	MD	Pediatrics, Nephrology	Yes	B
16	Dr. Dean C.C. Johnston Male / Canadian	Voting Member (Alternate for #6)	MD, MHSc	Neurology	Yes	B
17	Ms. Suzanne Kennedy Female / Canadian	Voting Member (Alternate for #35)	LLB	Law	No	L, N
18	Dr. Ardis Krueger Female / Canadian	Ad hoc member for NHP reviews	ND	Natural Health Products	No	H
19	Dr. Gang Li Male / Canadian	Voting Member	Ph.D	Dermatology	Yes	B
20	Dr. Peter Loewen Male / Canadian	Chair	Pharm.D	Pharmaceutical Sciences	Yes	B, E
21	Ms. Karen Low Ah Kee Female / Canadian	Voting Member (Alternate for #9)		Community Member	No	C, N
22	Dr. Alexander MacKay	Voting Member (Alternate for	PhD	Radiology	Yes	B

	Male / Canadian	#25)				
23	Ms. Bonnie MacKenzie Female / Canadian	Voting Member (Alternate for #9)		Community Member	No	C, N
24	Dr. Ian Martin Male / Canadian	Voting Member	MD	Family Medicine, Epidemiology, Emergency Medicine	Yes	B
25	Dr. John Mayo Male/Canadian	Voting Member	MD	Radiology	Yes	B
26	Dr. Peter McComb Male / Canadian	Voting Member	MD, FRCSC	Obstetrics and Gynaecology	Yes	B
27	Dr. Orson Moritz Male / Canadian	Voting Member (Alternate for #7)	MD	Ophthalmology and Visual Sciences	Yes	B
28	Dr. Elton Ngan Male / Canadian	Voting Member	MD	Psychiatry	Yes	B
29	Dr. Christopher Nguan Male / Canadian	Voting Member (Alternate for #11)	MD	Urologic Sciences	Yes	B
30	Dr. Jerilynn Prior Female / Canadian	Voting Member	MD	Endocrinology	Yes	B
31	Dr. Roy Pursell Male / Canadian	Voting Member	MD	Emergency medicine	Yes	B
32	Dr. John Russell Male / Canadian	Ethicist	PhD	Philosophy (Ethics)	Yes	E, L, N
33	Dr. Bonita Sawatzky Female / Canadian	Voting Member (Alternate for #8)	PhD	Orthopedics (Sports Medicine, Biomechanics)	Yes	B
34	Dr. Robert Stowe Male / Canadian / American	Voting Member (Alternate for #28)	MD	Neuropsychiatry	Yes	B
35	Mr. Bill Sullivan, QC Male/Canadian	Voting Member	LLB	Law	No	L, N
36	Dr. John Tsang 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

11 May 2011: The Consent Requirements under the Personal Health Information Protection Act Webinar presented by Debra Grant, Senior Health Privacy Specialist for the Information and Privacy Commissioner for the Province of Ontario (IPC)

25 May 2011: What's New in TCPS 2? Webinar presented by Susan Zimmerman, Executive Director, Secretariat on Research Ethics.

21 Sept 2011: Harmonizing Research Ethics Review in Canada presented by Jack Corman, IRB Services

16 February 2012: Suzanne Richardson and Sarah Bennett presented "CREB Interactive Workshop to Facilitate Common Challenges in your Ethics Submissions"

06 March 2012: John Russell presented "Recruitment and Retention Talk" at the VCHRI Clinical Research Symposium