UBC Clinical Research Ethics Board (CREB)

Room 210, VGH Research Pavilion
828 West 10th Avenue
Vancouver, B.C. V5Z 1L8
Tel: 604-875-4111 x68917 or x68918 Fax: 604-875-4167
General Email: creb.rise@ors.ubc.ca
Website: http://www.ors.ubc.ca/ethics/clinical/index.htm
Office Contacts: http://www.ors.ubc.ca/ethics/clinical/c-contacts.htm
RISe: http://rise.ubc.ca

2009 CREB Annual Report
For the period of April 01 2009 to March 31 2010

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

STATISTICS

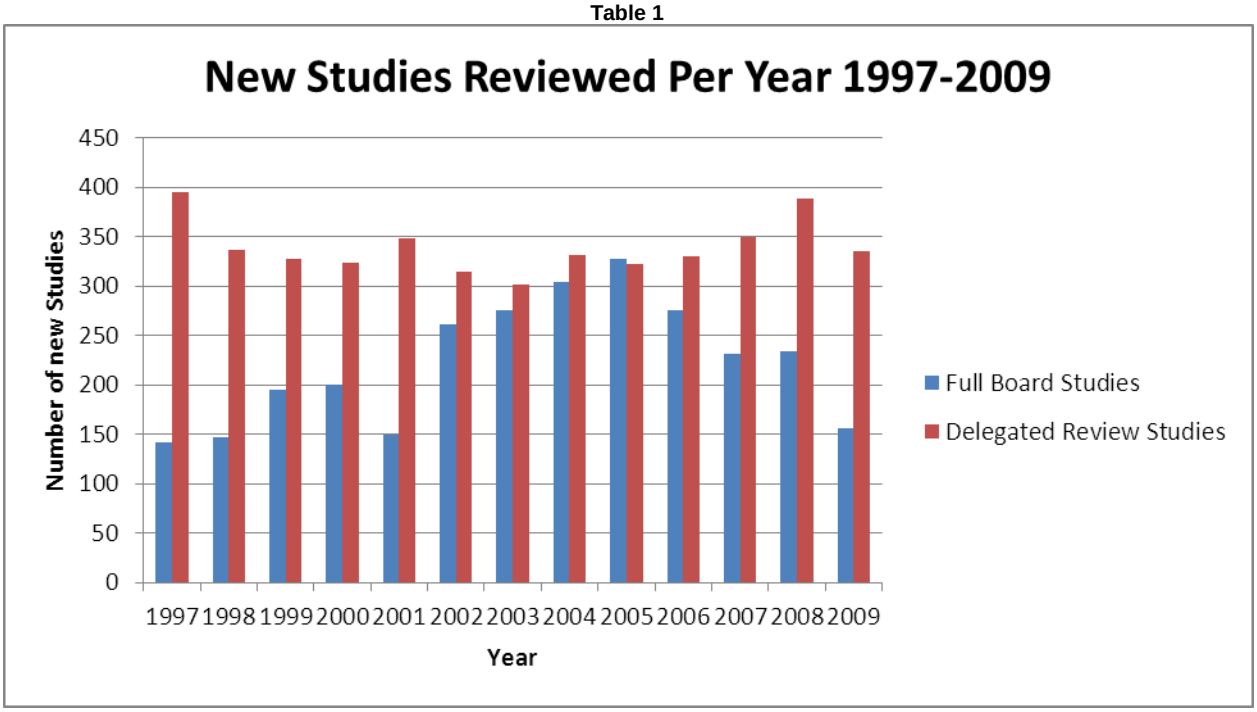
As of March 31 2010, the CREB was responsible for ethical oversight of 1547 ongoing research projects.

NEW STUDIES

491 New Studies were submitted to the CREB in the 2009 fiscal year (April 1 2009 to March 31 2010). 156 of these were sent to the Full Board for Review, 335 were Delegated Review.

New Applications	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Full Board	142	147	195	200	149	261	275	304	327	275	231	234	156
Minimal Risk	395	336	327	323	348	315	302	331	322	330	349	389	335
Total	**537**	**483**	**522**	**523**	**497**	**576**	**577**	**635**	**649**	**605**	**580**	**623**	**491**

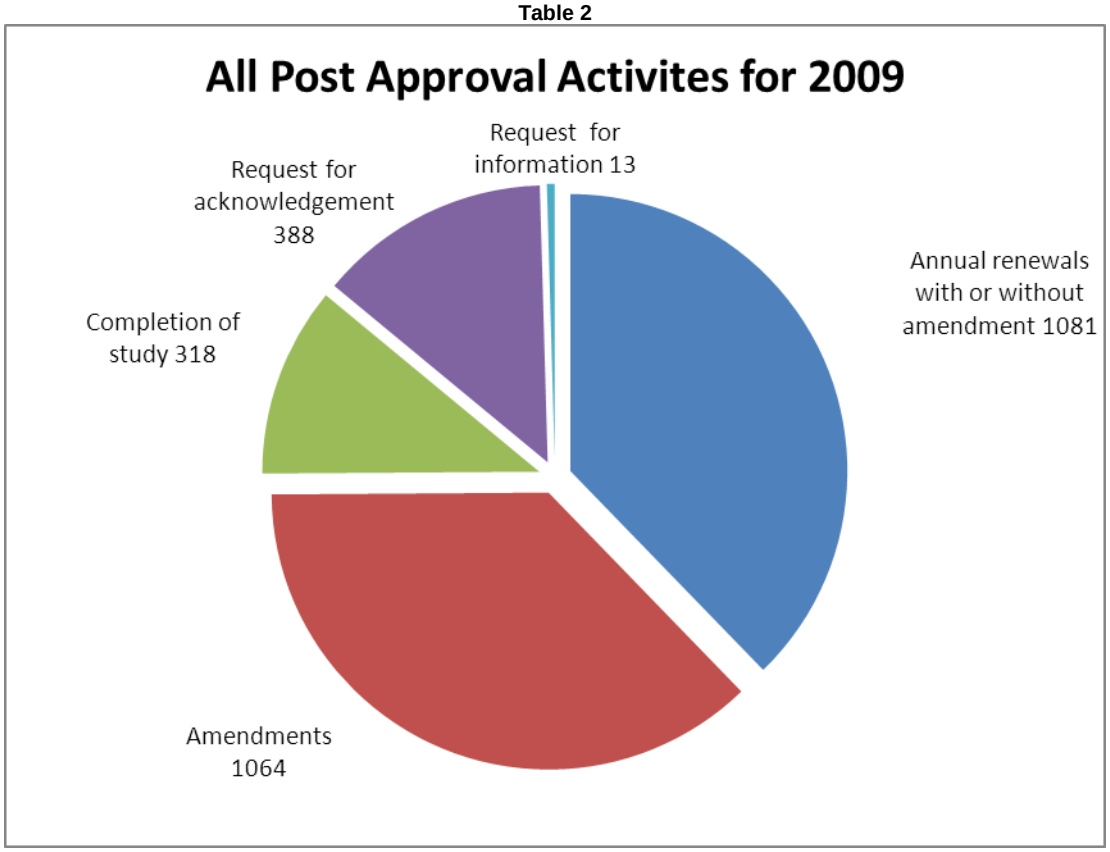
Table 1



POST APPROVAL ACTIVITIES (PAAs)

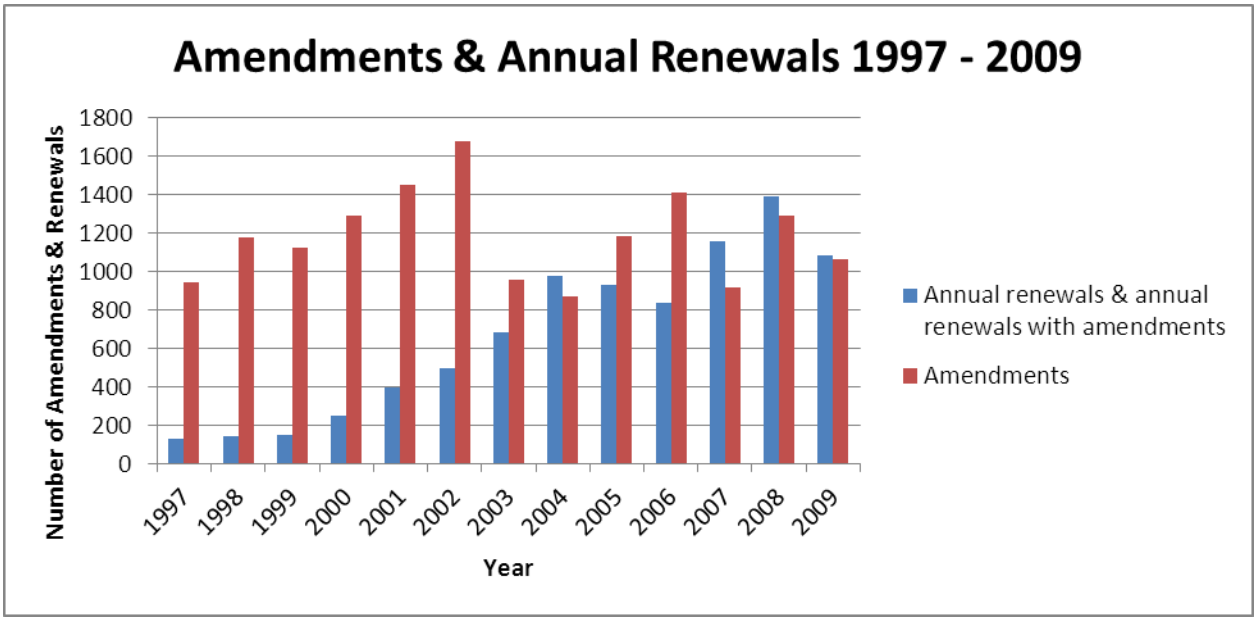
In addition to new studies, the CREB processes PAAs on ongoing studies, which include Annual Renewals, Annual Renewals with amendments, Amendments, Study Closures, Requests for Acknowledgement, and Responses to Requests for Information. In total the CREB reviewed a total of 2864 PAAs.

Table 2



Post Approval Activities	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
Annual Renewals & Annual renewals with amendments	132	141	147	246	395	494	681	977	931	836	1156	1389	1081
Amendments	946	1174	1126	1291	1450	1676	956	869	1182	1410	915	1293	1064
Total	**1078**	**1315**	**1273**	**1537**	**1845**	**2170**	**1637**	**1846**	**2113**	**2246**	**2071**	**2682**	**2864**

Table 3

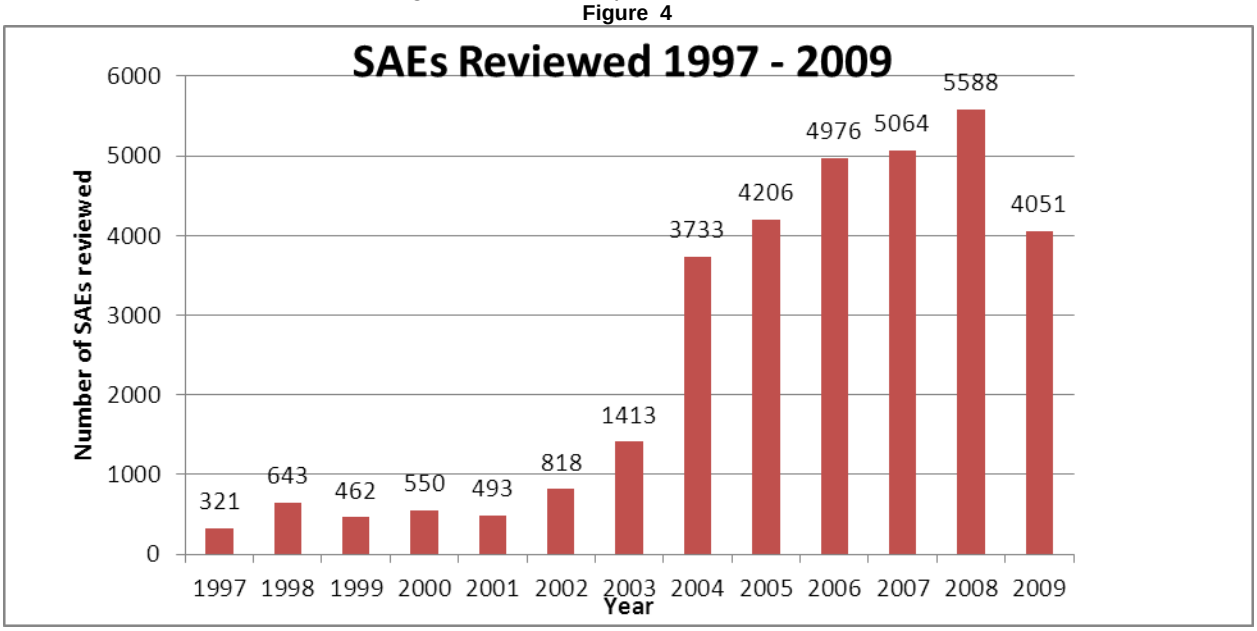


SERIOUS ADVERSE EVENT (SAE) REPORTING

On October 30, 2009, a new SAE policy was implemented by UBC's Research Ethics Boards. It was developed in response to the serious problem of over-reporting of non-local (external) serious adverse events to UBC's Research Ethics Boards, including submission of thousands of individual case reports which often included little or no information, explanation or analysis of the impact of the event on the study for which it was being reported. In response to this issue the European Commission, the US Food and Drug Administration and the Canadian Association of Research Ethics Boards have all developed Guidances endorsing summary reporting of non-local (external) SAE's, with some accompanying form of analysis of the events. The Guidances also confirm that single isolated adverse events rarely meet the requirements for reporting to REBs.

The CREB continues to follow Health Canada's reporting requirements for serious and unexpected adverse drug reactions and for incidents involving medical devices. In light of the new policy, there was a significant decrease in SAE submissions to the CREB towards the end of 2009. In total, the CREB received, reviewed and acknowledged 4051 SAE reports in 2009.

Figure 4



TURNAROUND TIMES FOR SUBMISSIONS TO THE CREB

There were numerous issues that influenced the Turnaround times of studies submitted to the CREB. During 2009 these turnaround times varied, depending on the quality and completeness of submissions. Incomplete studies that were missing documents such as protocols, peer reviews, or consent forms that were not according to CREB guidelines & templates, were sent back to the Investigator for revision, hence delaying time to approval. Certificates of Approval were not issued to studies that were approved that had outstanding fees – further delaying the final release of the Approval Certificate. A number of delays of the approval of Full Board submissions were due to the fact that fees had not yet been received. On average, however, from first REBA screening of a Full Board Study to the Approved status took 72 days. From REBA screening of these Full Board Studies to the issuance of the First Provisos took, on average, 22 days ("REB days"). The other 50 days are considered "Investigator days".

On average for Delegated Review Studies the REBA screening to the Approved status took an average of 27 days with REBA screening to the issuance of the provisos approximately 9 days ("REB days"). The other 18 days are considered "Investigator days". This is a significant decrease in turnaround times since 2008.

REVENUE

The CREB fee of $3,000 for ethical review applies to any new study that is funded by a for-profit entity. There were 91 industry sponsored studies submitted in 2009.

MEMBERSHIP

As of 31st March 2010, the CREB was composed of 38 members (22 Voting members & 16 Alternate members) 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. There was turnaround in membership during the year which is detailed on the website. The Full membership lists with REB position, Qualifications, Scientific affiliations, institutional affiliation and Quorum designation are detailed as updated on the CREB Web Page at: http://www.ors.ubc.ca/ethics/clinical/c-members.htm

UBC CREB VOTING MEMBER Gender/Citizenship		**REB POSITION** (Alternate Designation)	**HIGHEST DEGREE(S) EARNED**	**PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALITY**	**AFFILIATION WITH INSTITUTION**	**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. Anna Celler** Female / Canadian	Voting Member (Alternate for # 24)	PhD	Radiology, Nuclear Physics	Yes	B
5	**Dr. Peter Choi** Male / Canadian	Voting Member	MD, MSc	Anesthesia	Yes	B
6	**Dr. Iain Dommisse** Male / Canadian	Voting Member (Alternate for #28)	MbChB	Orthopedics	No	B
7	**Dr. Doris Doudet** Female / Canadian	Voting Member	MD	Neurology	Yes	B
8	**Dr. Robert Douglas** Male / Canadian	Voting Member	MD	Ophthalmology and Visual Sciences	Yes	B
9	**Dr. Clive Duncan**	Voting Member	MBBCh,	Orthopedic surgery,	Yes	B

	Male / Canadian	(alternate for #28)	Msc,FRCSC	Medicine, Surgery		
10	**Ms. Barbara Fulton** Female / Canadian	Voting member	MA	Community Member	No	C, N
11	**Dr. Aziz Ghahary** Male / Canadian	Voting Member	Ph.D	Plastic Surgery	Yes	B
12	**Sarah Harbottle** Female / Canadian	Voting Member (Alternate for # 38)	LL.B	Law	No	L, N
13	**Holly Harlow** Female / American	Voting Member (Alternate for #38)	LLM	Law	No	L, N
14	**Dr. Alice Hawkins** Female / Canadian	Voting Member (Alternate for # 34)	PhD	Applied Ethics, Political Science, Pathology	Yes	E
15	**Dr. Stephen Hoption-Cann** Male / Canadian	Voting Member	PhD	Epidemiology	Yes	B
16	**Dr. Morrison Hurley** Male / Canadian	Voting Member (Alternate for #37)	MD	Pediatrics, Nephrology	Yes	B
17	**Dr. Dean C.C. Johnston** Male / Canadian	Voting Member (Alternate for #7)	MD, MHSc	Neurology	Yes	B
18	**Suzanne Kennedy** Female / Canadian	Voting Member (Alternate for #38)	LLB	Law	No	L, N
19	**Dr. Ardis Krueger** Female / Canadian	Ad hoc member for NHP reviews	ND	Natural Health Products	No	H
20	**Dr. Gang Li** Male / Canadian	Voting Member	Ph.D	Dermatology	Yes	B
21	**Dr. Peter Loewen** Male / Canadian	Chair	Pharm.D	Pharmaceutical Sciences	Yes	B, E
22	**Ms. Karen Low Ah Kee** Female / Canadian	Voting Member		Community Member	No	C, N
23	**Dr. Alexander MacKay** Male / Canadian	Voting Member (Alternate for #24)	PhD	Radiology	Yes	B
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. James McCormack** Male/Canadian	Vice Chair	Pharm.D	Pharmaceutical Sciences	Yes	B, E
28	**Dr. Orson Moritz** Male / Canadian	Voting Member (Alternate for #8)	MD	Ophthalmology and Visual Sciences	Yes	B
29	**Dr. Kishore Mulpuri** Male / Canadian and Indian	Voting Member	MD	Orthopedics	Yes	B
30	**Dr. Elton Ngan** Male / Canadian	Voting Member	MD	Psychiatry	Yes	B

31	**Dr. Robin O'Brien** Female / Canadian	Voting Member (Alternate for # 21&26)	Pharm.D	Pharmaceutical Sciences, Natural Health Products	Yes	B, H
32	**Dr. Jerilynn Prior** Female / Canadian	Voting Member	MD	Endocrinology	Yes	B
33	**Dr. Robert Reynolds** Male **/** Canadian	Voting Member	MD	Infectious Diseases	Yes	B
34	**Dr. John Russell** Male / Canadian	Ethicist	PhD	Philosophy (Ethics)	Yes	E, L, N
35	**Dr. Bonita Sawatzky** Female / Canadian	Voting Member (Alternate for # 28)	PhD	Orthopedics (Sports Medicine, Biomechanics)	Yes	B
36	**Dr. Robert Stowe** Male / Canadian / American	Voting Member (Alternate for # 29)	MD	Neuropsychiatry	Yes	B
37	**Mr. Bill Sullivan,** QC Male/Canadian	Voting Member	LLB	Law	No	L, N

* All UBC CREB Members are voting members. A quorum compromises 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**

FULL BOARD MEETINGS

24 Full Board meetings of the CREB were held from 01 April 2009 to 31 March 2010. Meetings are held on the 2nd and 4th Tuesday of the month. Meeting dates & deadlines for submission to Full Board for ethics review are posted on the CREB Website at: http://www.ors.ubc.ca/ethics/clinical/c-deadlines.htm

ADMINISTRATION AND CREB LEADERSHIP

Administrative Staff (REBAs)

The administration of the CREB is undertaken by three full-time staff members and one part-time staff member. The CREB office includes one Manager, two Managers of Pre- and Post- Review, and one part-time Administrative Clerk. The CREB Managers of Pre- and Post- Review enhance the consistency and thoroughness of review of Applications for Ethical Review by being the common reviewers for all new studies and renewal applications being reviewed by the Full Board or through the Minimal Risk review process. The primary goal of these reviews is to ensure that a study's consent forms meet current CREB requirements.

CREB Chair and Associate Chairs

Dr. Gail Bellward ended her appointment as CREB Chair, which began in 2005, in March 2009. The new Chair, Dr. Peter Loewen, began his appointment in April 2009. Dr. Loewen comes from a Pharmaceutical Sciences background, and had served as CREB Chair prior to 2005.

Dr. James McCormack, Dr John Russell, and Dr Caron Strahlendorf continued their appointments as CREB Associate Chairs until May 2009, at which time the structure of delegated review for the CREB changed. Dr. James McCormack continued on as Associate Chair to the CREB, while Dr. Stephen Hoption Cann, Dr. John Cairns, Dr. Morrison Hurley and Dr. Bonita Sawatzky (who returned to the CREB in August 2009) each served as Delegated Reviewers in charge of reviewing Minimal Risk applications.

EDUCATION ATTENDED OR PRESENTED:

- *25 April 2009* Joint REB Education Session arranged by the Fraser Health Research Ethics Board *"Modernizing the Food and Drugs Act to Accommodate a Product Lifecycle Approach & Tissue Banking"* Presented by David K. Lee, Director, Office of Legislative and Regulatory Modernization Policy, Planning and International Affairs Directorate Health Products and Food Branch, Health Canada.
- *30 April - 02 May 2009* Canadian Association of Research Ethics Board (CAREB) Annual general meeting & conference in Vancouver. Attended by and organization facilitated by UBC CREB administrative staff.
- *07 May 2009* FDA Webinar and Audio conference: *How to Vet and IRB: Expose and Fix Problems Before They Threaten Your Trial*
- *20 May 2009* Webinar: Health Canada: Clinical Trial Inspections.
- *20 Oct 2009* Presentation to the Ethics Day for Program Evaluation Participants by Suzanne Richardson.
- *18 Dec 2009* CREB Office staff: Webinar: Health Canada Natural Health Products Directorate (NHPD) – *Regulatory Requirements for Natural Health Product Clinical Trial Authorizations* presented by Robin J. Marles, Ph.D, Director of the Bureau of Clinical Trials and Health Sciences at NHPD
- *04 Feb 2010* Suzanne Richardson attended the OHRP conference "*Protecting Research Participants: Ethical Challenges Within a Regulatory Framework*", hosted by the Northwest Association for Biomedical Research in Seattle, WA

Challenges / Changes to CREB during 2009:

- The Office for Human Research Protections (OHRP) performed an audit on the CREB, which was not completed until the start of the fiscal year of 2010. During this time, OHRP reviewed a few CREB studies which needed to comply with US regulations.. The audit occurred over the course of a few months and resulted in the CREB making a few procedural changes to ensure compliance.

- The CREB saw a significant change with the implementation of the Children & Women's Research Ethics Board (CW REB) in April 2009. Most studies which take place at C&W now submit to CW REB, which resulted in a decrease in workload for the CREB in 2009. Some ongoing C&W studies were also transferred to C&W during this time, which resulted in fewer Post-Approval Activities for the CREB to oversee. Some C&W studies remain under the CREB's oversight, but are expected to be transferred to CW REB as soon as appropriate.

- There were changes within the administrative structure of the CREB, both with the Chair and Associate Chairs (as previously detailed), and with the administrative staff. The Senior Administrative Coordinator position was deleted, leaving the administrative staff with a total of 3 full time members and 1 part time member. The removal of the Senior Administrative Coordinator position resulted from the reduced workload associated with the implementation of CW REB.

- The VP of Research, Dr. John Hepburn, attended the CREB meeting on January 12, 2010 as an observer in order to gain an appreciation of the workings of the Board. The CREB appreciated the opportunity to demonstrate and explain its work at this level.