UBC Clinical Research Ethics Board (CREB)

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2008 CREB Annual Report
For the period of April 1 2008 to March 31 2009

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

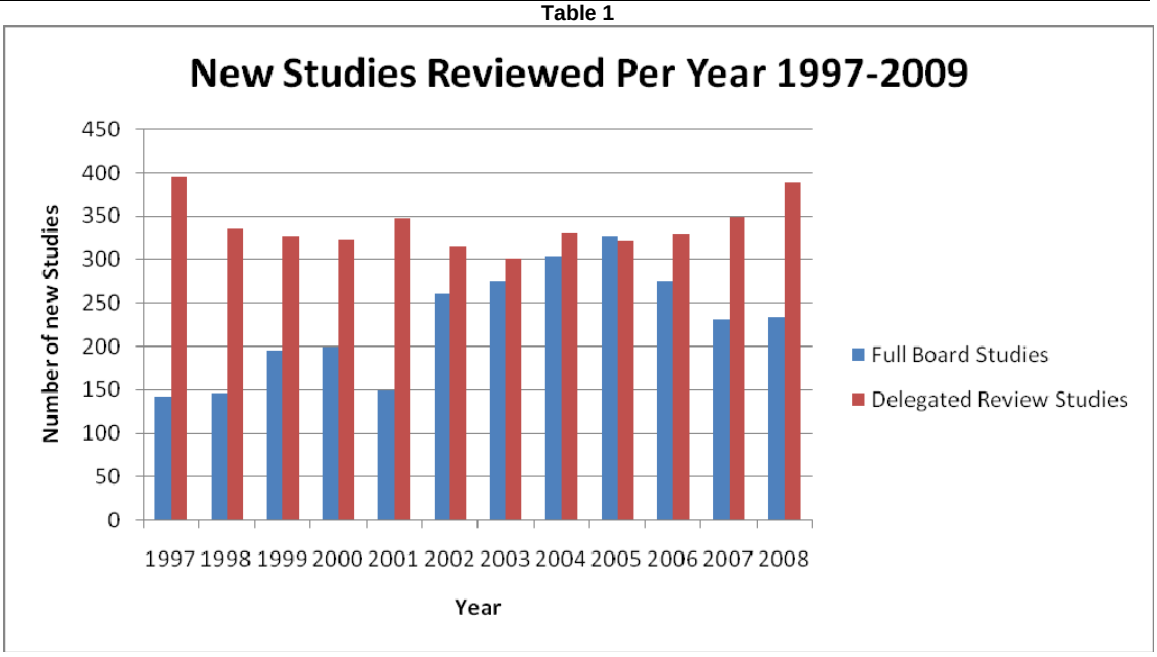
As of March 31 2009, the CREB was responsible for ethical oversight of 2055 ongoing research projects.

NEW STUDIES

623 New Studies were submitted to the CREB in the 2008 fiscal year (April 1 2008 to March 31 2009). 234 of these were sent to the Full Board for Review, 389 were Delegated Review.

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

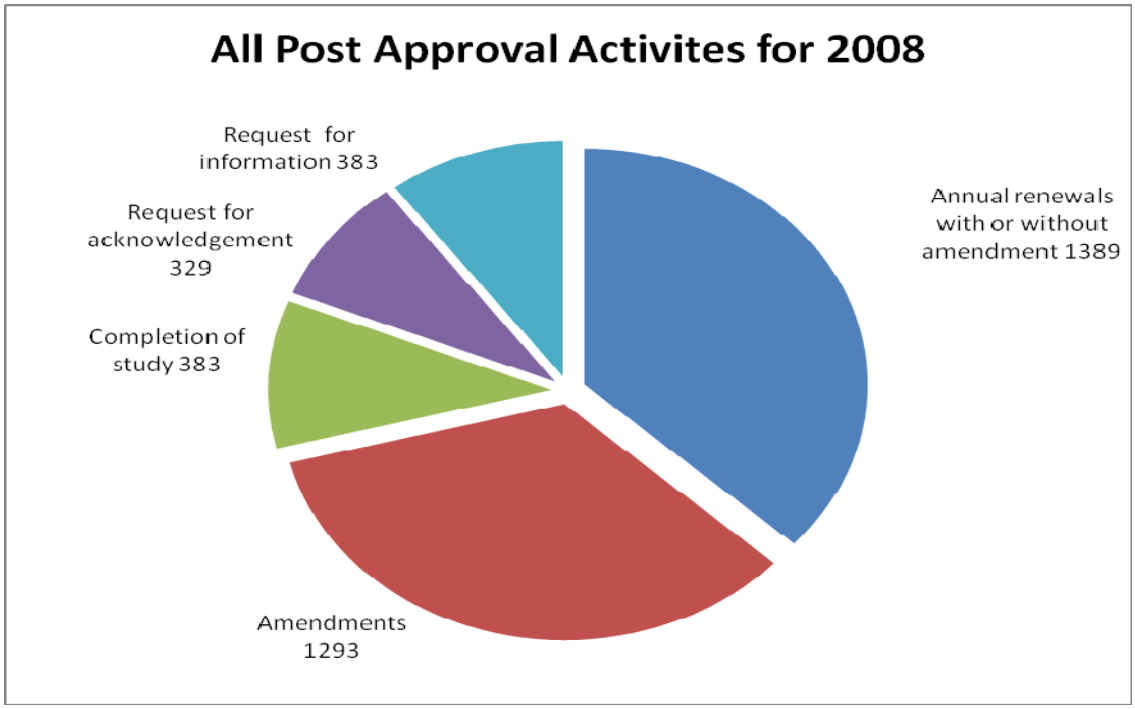
Table 1



POST APPROVAL ACTIVITIES (PAAs)

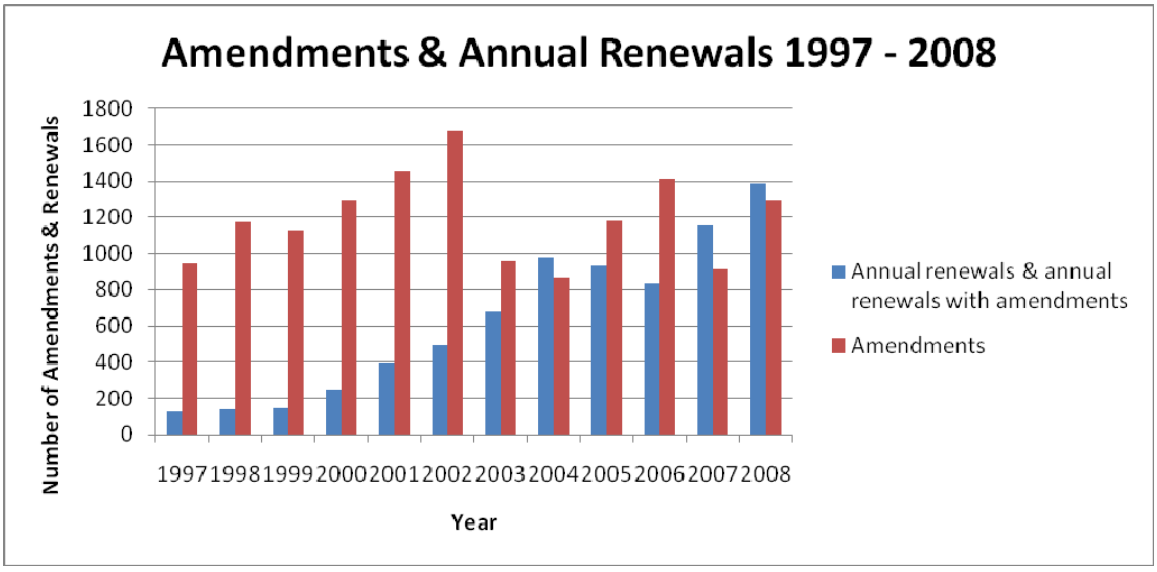
In addition to new studies, the CREB processes PAAs on ongoing studies, which include Annual Renewals, Annual Renewals with amendments, Amendments, Study Closures, Requests for Acknowledgement, and Responses to Requests for Information. In total the CREB reviewed a total of 3777 PAAs.

Table 2



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

Table 3

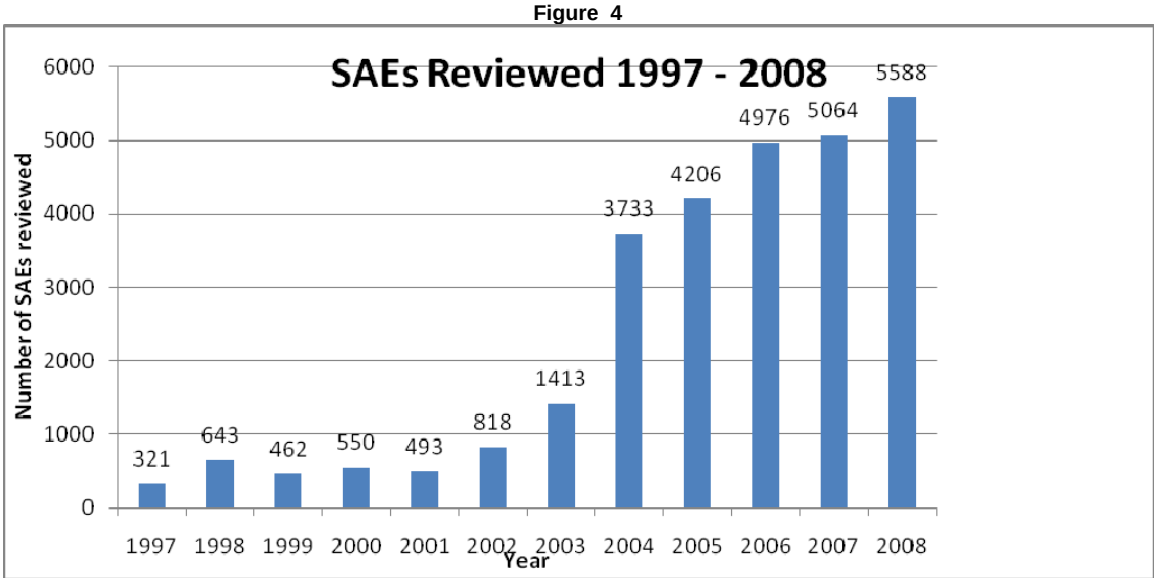


SERIOUS ADVERSE EVENT (SAE) REPORTING

The CREB continues to follow Health Canada's reporting requirements for serious and unexpected adverse drug reactions and for incidents involving medical devices. The process of SAE submissions continue to be outside of the RISe system i.e. via paper submission. These reports are reviewed by 2 nurse reviewers who log all SAE reports into the CREB SAE database, and bring to the CREB Chair's attention any SAE forms that require follow up for any reason. In 2008 the CREB received, reviewed and acknowledged 5588 SAE reports (approximately 465 per month).

The process of SAE review has been discussed by the Chair and Associate Chairs as thousands of reports of various incidents, outcomes & events are submitted which do not meet the criteria stipulated by both the ICH-GCPs and the US regulations of being serious, unexpected and related or possibly related to the study drug or procedure. As per Figure 4 it is clear that the number of SAEs are rising. Given the emerging national consensus among REBs that review of non-local SAEs in the absence of some interpretation by, for example, a Data Safety Monitoring Board or similar does little to enhance subject protection and is an increasing drain on REB resources, a revised approach to SAEs will be developed and implemented in the coming year.

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 2008 these turnaround times varied, depending on the quality & 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.

On average however, from first REBA screening of a Full Board Study to the Approved status took 80 days. From REBA screening of these Full Board Studies to the issuance of the First Provisos took 37 days ("REB days"). The other 43 days are considered "Investigator days".

On average for Delegated Review Studies the REBA screening to the Approved status took an average of 44 days with REBA screening to the issuance of the provisos approximately 23 days ("REB days"). The other 21 days are considered "Investigator days".

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 101 industry sponsored studies submitted in 2008 with fees received for all but one study. Total Revenue to 31 March 2009 = $300,000

MEMBERSHIP

As of 31st March 2009, the CREB was composed of 33 members (19 Voting members & 14 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. Gail Bellward** Female/Canadian	Chair	PhD	Pharmacology and Toxicology	Yes	B, E
2	**Dr. John Cairns** Male/Canadian	Half-time member	MD, FRCPC	Cardiology	Yes	B
3	**Lori d'Agincourt-Canning** Female/Canadian	Ad hoc Ethicist	PhD	Clinical Ethicist	Yes	B, E
4	**Dr. Doris Doudet** Female/Canadian	Half-time member	MD	Neurology	Yes	B
5	**Dr. Robert Douglas** Male/Canadian	Half-time member	MD	Ophthalmology and Visual Sciences	Yes	B
6	**Clive Duncan** Male / Canadian	Half-time Member	MBBCh, Msc,FRCSC	Orthopedic surgery, Medicine, Surgery	Yes	B
7	**Ms. Barbara Fulton** Female/Canadian	Full-time member	MA	Community Member	No	C, N
8	**Ms. Holly Harlow** Female/American	Reserve member	LLM	Law	No	L, N
9	**Dr Stephen Hoption-Cann** Male/Canadian	Associate Chair and Full-time member	PhD	Epidemiology	Yes	B
10	**Dr. Morrison Hurley** Male/Canadian	Half-time member	MD	Pediatric Nephrology	Yes	B
11	**Jo-Ann Isaacson** Female / Canadian	Ad hoc Community member		Community member	No	C, N
12	**Dr. Dean C.C. Johnston** Male/Canadian	Half-time member	MD, MHSc	Neurology	Yes	B
13	**Suzanne Kennedy** Female/Canadian	Ad hoc Lawyer	LLB	Law	No	L, N
14	**Simon Kent** Male/Canadian	Ad hoc Lawyer	LLB	Law	No	L,N
15	**Dr. Ardis Krueger**	Ad hoc member for	ND	Natural Health Products	No	H

	Female/Canadian	NHP reviews				
16	**Ms. Karen Low Ah Kee** Female/Canadian	Full-time member		Community Member	No	C, N
17	**Dr. Alexander MacKay** Male/Canadian	Half-time member	PhD	Radiology	Yes	B
18	**Dr. John Mayo** Male/Canadian	Half-time member	MD	Radiology	Yes	B
19	**Dr. Peter McComb** Male/Canadian	Half-time member	MD, FRCSC	Obstetrics and Gynaecology	Yes	B
20	**Dr. James McCormack** Male/Canadian	Associate Chair and Full-time member	Pharm.D.	Pharmaceutical Scs.	Yes	B, E
21	**Dr. Orson Moritz** Male/Canadian	Half-time member	MD	Ophthalmology and Visual Sciences	Yes	B
22	**Dr. Kishore Mulpuri** Male/Canadian and Indian	Half-time member	MD	Orthopedics	Yes	B
23	**Dr. Elton Ngan** Male/Canadian	Half-time member	MD	Psychiatry	Yes	B
24	**Dr. Robert Peterson** Male/Canadian and American	Full-time member	MD	Pediatrics	Yes	B
25	**Dr. Jerilynn Prior** Female/Canadian	Half-time member	MD	Endocrinology	Yes	B
26	**Dr. Robert Reynolds** Male/Canadian	Half-time member	MD	Infectious Diseases	Yes	B
27	**Dr. Jeremy Road** Male/Canadian	Half-time member	MD	Respirology	Yes	B
28	**Dr. John Russell** Male/Canadian	Ethicist and Associate Chair	PhD	Philosophy (Ethics)	Yes	E, L, N
29	**Dr. Robert Stowe** Male/Canadian and American	Half-time member	MD	Psychiatry	Yes	B
30	**Dr. Caron Strahlendorf** Female/Canadian	Associate Chair and Half-time member	MD	Pediatric Oncology	Yes	B
31	**Mr. Bill Sullivan, QC** Male/Canadian	Full-time member	LLB	Law	No	L, N
32	**Dr. John Tsang** Male/Canadian	Half-time member	MD, FRCPC	Critical Care Medicine	Yes	B
33	**Dr. Pearce Wilcox** Male/Canadian	Half-time member	MD	Respirology	Yes	B

* 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 2008 to 31 March 2009. 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 five full-time staff. The CREB office includes one Manager, two Managers of Pre- and Post- Review, one Administrative Clerk & one Senior Administrative Coordinator. 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 continued her appointment as CREB Chair, which began in 2005. Dr. James McCormack, Dr John Russell, Dr Caron Strahlendorf and Dr Bonita Sawatzky (stepped down in June 2008) continued their appointments as CREB Associate Chairs. The Chair and Associate Chairs group met on a monthly basis to continue discussions regarding policy, membership and administrative issues.

EDUCATION ATTENDED OR PRESENTED

- *26 April 2008* G. Bellward presented at the Fraser Health REB Educational Workshop.
- *11 July 2008* J. Russell presented *Ethics and Human Research* to the Summer Grant Writing workshop for trainees at the Life Sciences Institute at UBC.
- *23 August 2008* G. Bellward presented at the Ethics Workshop for the International Conference of Engineers in Medicine and Biology.
- *24 Sep 2008* S. Dommisse and P. Ganz presented to the Masters of Occupational Therapy Students regarding the Ethics Review Process.
- *08 October 2008* J. Ruiz presented at the VCHRI Program Evaluation Course for new Researchers.
- *12 November 2008* The REB Administrators facilitated a hands on Ethics Application session together with the RISe team.
- *16 – 19 November 2008* S. Dommisse attended the PRIM&R Conference *"Advancing Ethical Research – Balancing the Needs of Human Subjects and Science"*
- *03 Dec 2008* The REB Administrators Presented an Interactive Working Lunch to the VCHRI research coordinators *"how to review common errors in the ethics application process"*
- *28 Jan 2009* CREB members and the CREB Manager attended the E-Health & Privacy Conference arranged by the VCHRI
- *25 Feb 2009* REB Administrators presented to the UBC Division of Physical Medicine & Rehabilitation during their Brown Bag luncheon. This was an interactive question and answer session regarding the Ethics Review Process.