



UBC Clinical Research Ethics Board (CREB)

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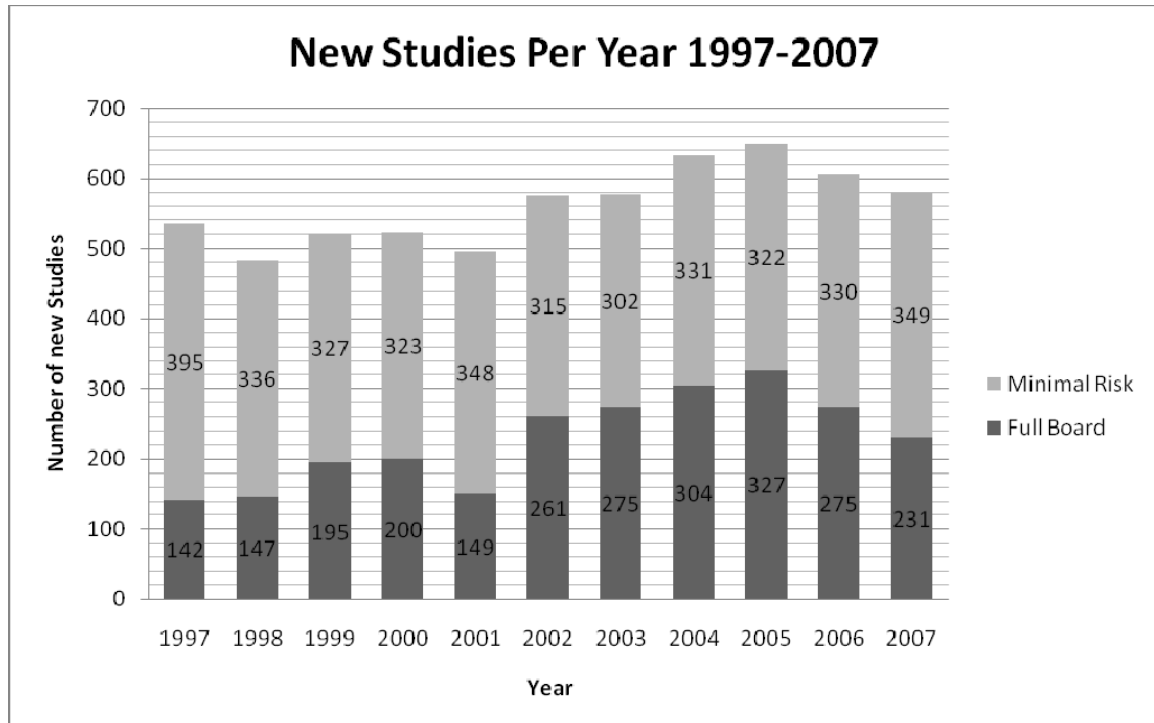
2007 CREB Annual Report For the period of April 1 2007 to March 31 2008

STATISTICS

As of March 31 2008, the CREB was responsible for ethical oversight of 1870 ongoing research projects.

NEW STUDIES

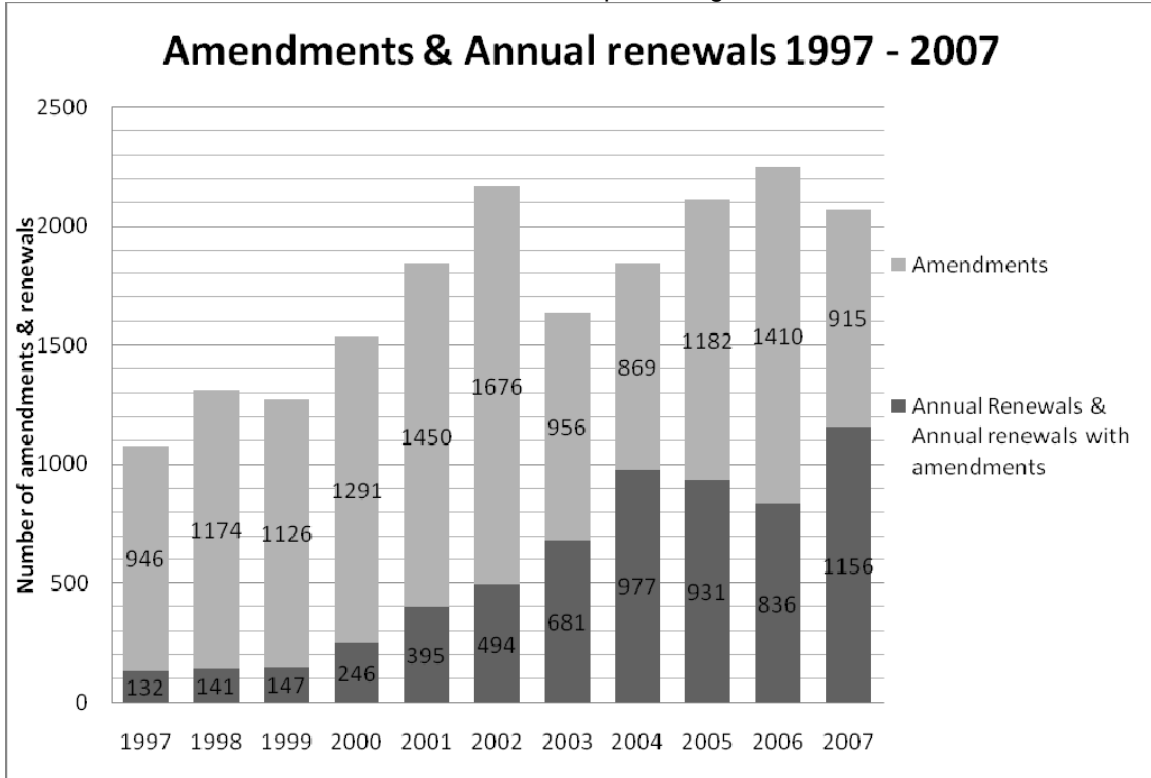
580 New Studies were submitted to the CREB in the 2007 fiscal year (April 1 2007 to March 31 2008). 231 of these were sent to the Full Board for Review, 349 were Minimal Risk Review.



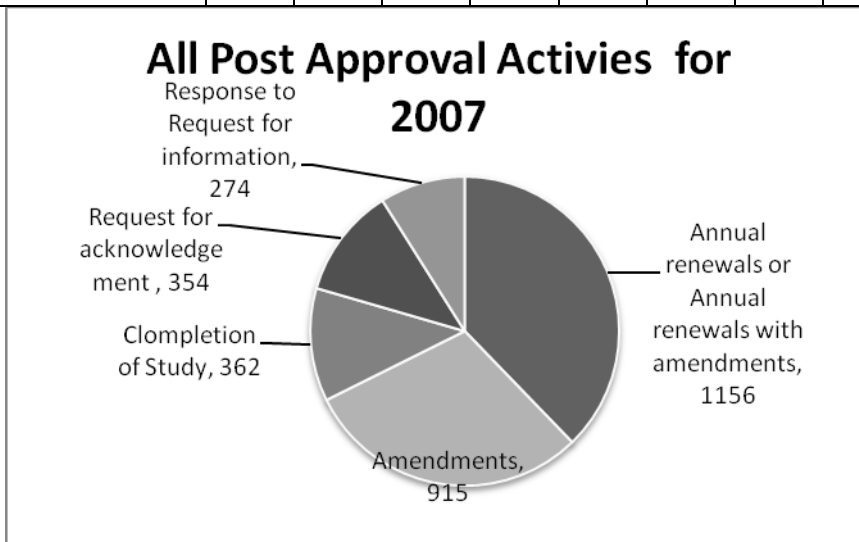
New Applications	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Full Board	142	147	195	200	149	261	275	304	327	275	231
Minimal Risk	395	336	327	323	348	315	302	331	322	330	349
Total	537	483	522	523	497	576	577	635	649	605	580

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 3061 PAAs. Due to the implementation of the new Researcher Information Services (RISe) system in 2006 the figures for amendments appears less than in the previously years as amendments attached to an annual renewal are captured together with annual renewals.

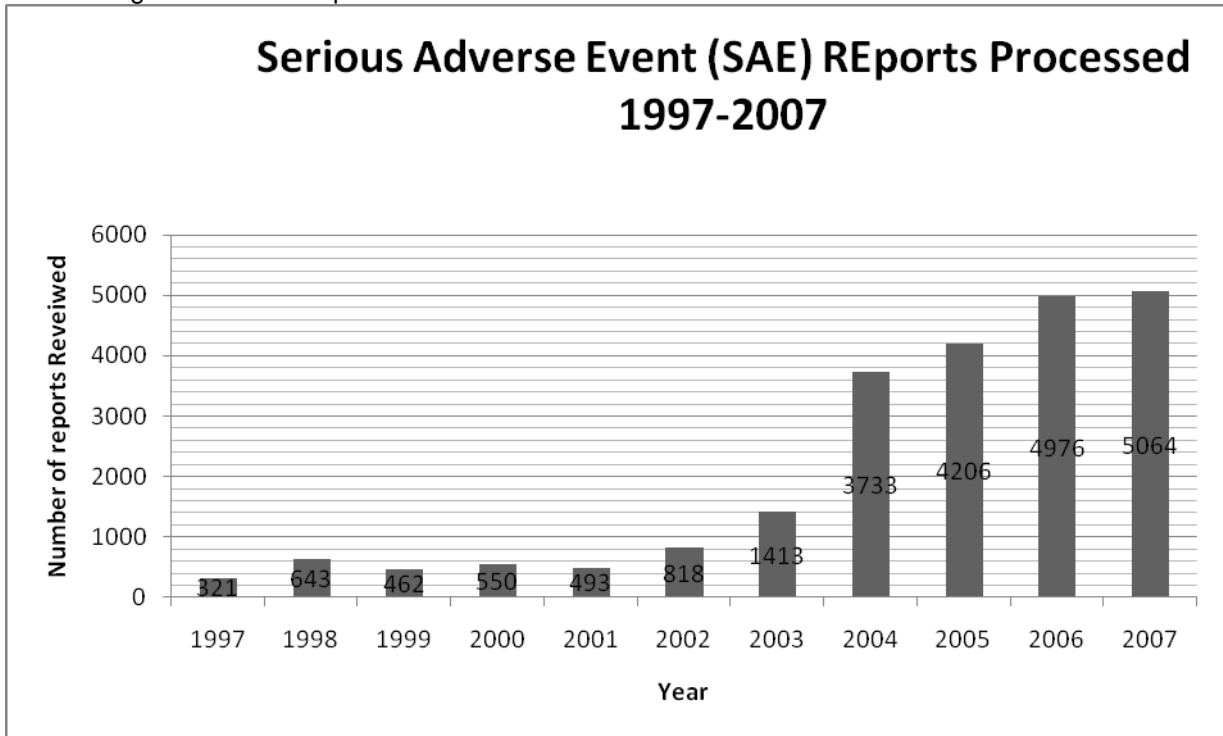


Post Approval Activities	1997	1998	1999	2000	2001	2002	2003	2004	2005	2006	2007
Annual Renewals & Annual renewals with amendments	132	141	147	246	395	494	681	977	931	836	1156
Amendments	946	1174	1126	1291	1450	1676	956	869	1182	1410	915
Total	1078	1315	1273	1537	1845	2170	1637	1846	2113	2246	2071



SERIOUS ADVERSE EVENT (SAE) REPORTING

The CREB requirements for submitting SAE reports follow Health Canada's mandatory reporting requirements for serious and unexpected adverse drug reactions and for incidents involving medical devices. The CREB continues to process submissions of SAE reports outside of the RISE system. SAE reports are submitted on paper and 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 2007 the CREB received, reviewed and acknowledged 5064 SAE reports.



TURNAROUND TIMES FOR SUBMISSIONS TO THE CREB

Depending on the quality & completeness of submissions, the turnaround times varied during 2007. Incomplete studies (that were missing documents such as protocols), or consent forms that were not according to CREB guidelines & templates are sent back to the Investigator for revision, hence delaying time to approval.

Another influencing factor in delayed turnaround was the backlog created by a lack of reviewers available to attend meetings. This led to some studies being "bumped" to a later Full Board meeting date. On average however, for properly drafted applications, including well-written protocols and consent documents, the return to the principal investigator is usually within 14 days for Minimal Risk studies and within 7 days following the meeting for Full Board studies.

REVENUE

The CREB fee of \$3,000 for ethical review applies to any new study submitted that is sponsored by a for-profit entity. There were 104 industry sponsored studies submitted in 2007.

MEMBERSHIP

As of 31st March 2008, the CREB was composed of 29 voting members (10 Full Time, 15 Half time, and 4 reserve members) of diversified specialties 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 we thank the Board members for their outstanding contributions to UBC and its affiliated institutions.

A new member training workshop was held for New Board members 11 Feb 2007.

Member name	Role(s)	Primary academic, scientific or non scientific area	Affiliated With UBC	Fulltime / halftime or Reserve
* New in 2007				
Gail Bellward, PhD	Chair	Pharmacology and Toxicology	yes	Full time
Victoria Bernstein, MD	Primary Reviewer	Cardiology	yes	Reserve
Doris Doudet, MD*	Primary Reviewer	Neurology	yes	Half time
Barbara Fulton, MA	Lay Member		no	Full time
Holly Harlow*	Lawyer		no	Reserve
Susan Harris, MD *	Primary Reviewer	Physical therapy	no	Half time
Dean Johnston, MD*	Primary Reviewer	Neurology	yes	Half time
Ardis Krueger, ND*	Primary Reviewer for Studies involving Natural Health Products	Natural Health Products	no	Reserve
Valia Lestou, PhD	Primary Reviewer	Medical Genetics	yes	Full time
Karen Low Ah Kee, CMA	Lay Member		no	Full time
Alexander MacKay, MD*	Primary Reviewer	Radiology	yes	Half time
Ian Martin, MD	Primary Reviewer	Family Medicine	yes	Half time
John Mayo, MD*	Primary Reviewer	Radiology	yes	Half time
Peter McComb, MD*	Primary Reviewer	Obstetrics & Gynecology	yes	Half time
James McCormack, Pharm.D.	Associate Chair / Primary reviewer	Pharmaceutical Scs.	yes	Full time
Kishore Mulpuri, MD	Primary Reviewer	Orthopaedics	yes	Half time
Robert Peterson, MD	Primary Reviewer	Paediatrics	yes	Full time
Jerilynn Prior, MD	Primary Reviewer	Endocrinology	yes	Half time
Robert Reynolds, MD*	Primary Reviewer	Infectious Diseases	yes	Half time
Jeremy Road, MD	Primary Reviewer	Respirology	yes	Half time
John Russell, PhD	Associate Chair / Ethicist	Philosophy (ethics)	yes	Full time
Bonita Sawatzky, MD	Associate Chair / Primary reviewer	Orthopaedics	yes	Full time
Peter Skippen, MD*	Primary	Pediatric Critical	yes	Half time

	Reviewer	Care		
Robert Stowe, MD*	Primary Reviewer	Psychiatry/Neurology	yes	Half time
Caron Strahlendorf, MD	Associate Chair / Primary reviewer	Paediatric Oncology	yes	Full time
Bill Sullivan, QC, MCL	Lawyer	Law	no	Full time
Penny Washington, LLB	Alternate Lawyer	Law	no	Reserve
David Wensley, MD	Primary Reviewer	Paediatrics	yes	Half time
Pearce Wilcox, MD	Primary Reviewer	Respirology	yes	Half time
MEMBERS WHO RESIGNED FROM THE CREB 2007-2008				
David Ansley, MD	Primary Reviewer	Anaesthesia	yes	
Harvey Coxson, PhD	Primary Reviewer	Radiology	yes	
Patrick Doyle, MD	Primary Reviewer	Microbiology	yes	
John Higenbottam, PhD	Primary Reviewer	Psychology and Psychiatry	yes	
Rob Irvine, MD	Primary Reviewer	Otolaryngology	yes	
John Jue, MD	Primary Reviewer	Cardiology	yes	
Murray Morrison, MD	Primary Reviewer	Otolaryngology	yes	

FULL BOARD MEETINGS

24 Full Board meetings of the CREB were held in 01 April 2007 to 31 March 2008.

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.

The Administrative Clerk position was filled by a number of individuals throughout 2007. The CREB Manager resigned her position in Dec 2007. This position was left vacant until the new manager was hired on 28 Jan 2008.

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 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.