



UBC Clinical Research Ethics Board (CREB)

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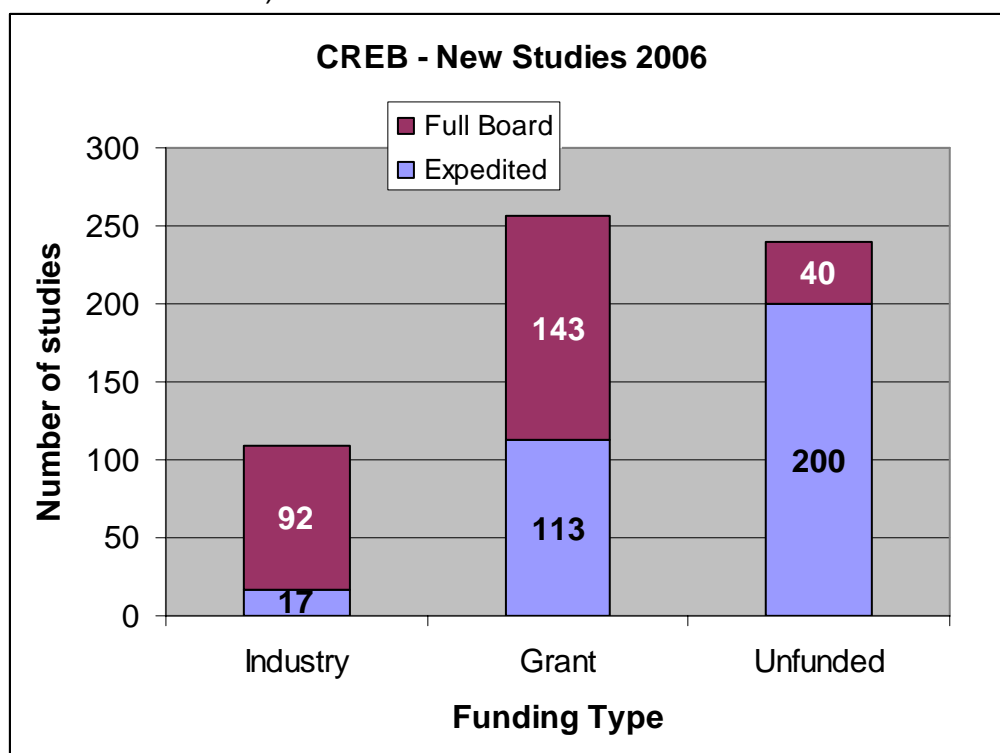
2006 CREB Annual Report For the period of April 1 2006 to March 31 2007

STATISTICS

As of March 31 2007, the CREB was responsible for ethical oversight of 2,106 ongoing research projects.

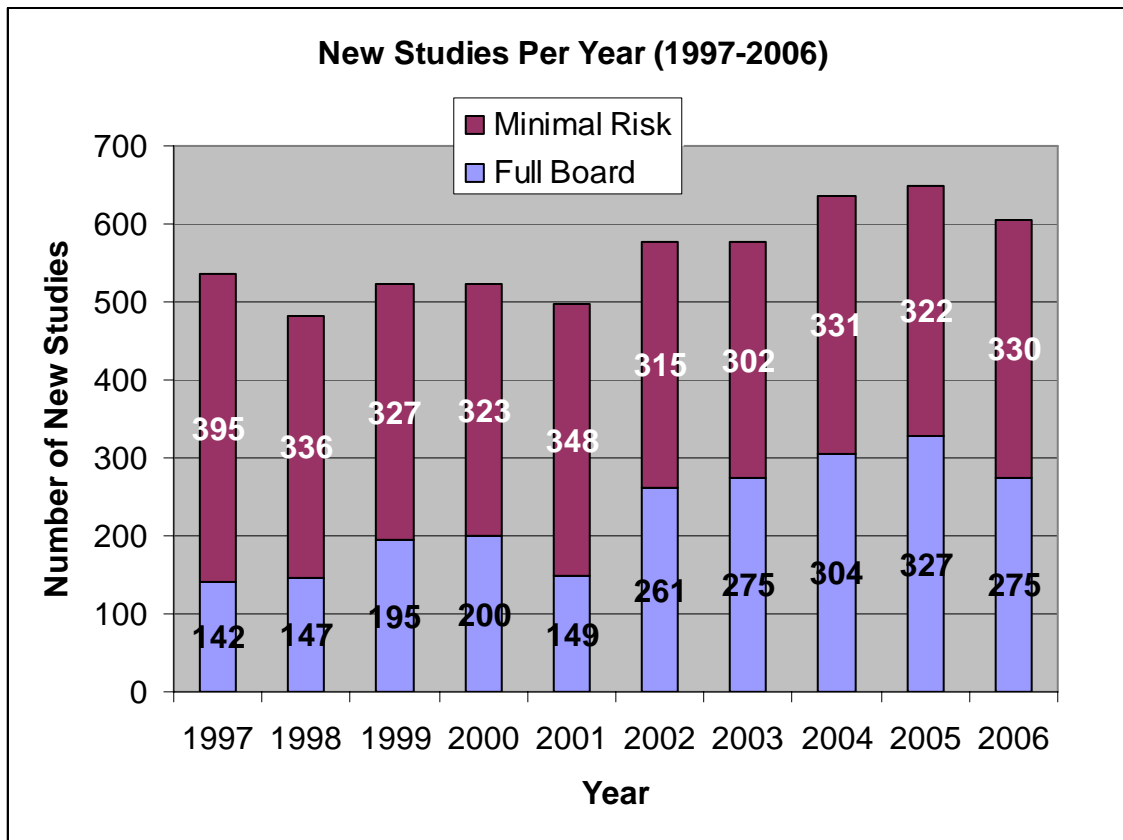
New Studies

605 New Studies were submitted to the CREB in the 2006 fiscal year (April 1 2006 to March 31 2007).



| | Expedited (Minimal Risk) | Full Board | All New Studies |
|--------------------|-----------------------------|------------|-----------------|
| Industry-Sponsored | 17 | 92 | 109 |
| Grant-Funded* | 113 | 143 | 256 |
| Unfunded | 200 | 40 | 240 |
| TOTAL | 330 | 275 | 605 |

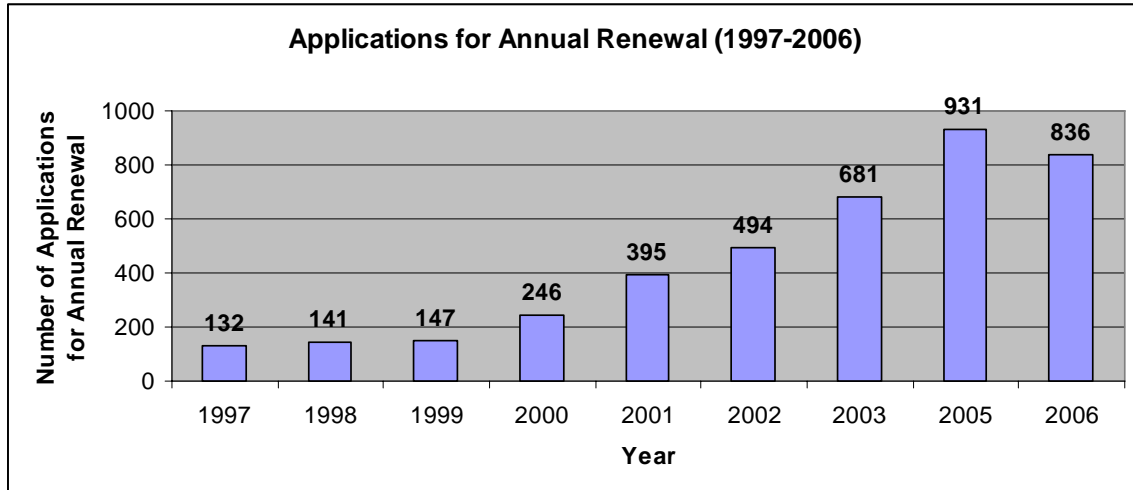
*Note: Grant-funded studies include funding from granting agencies, foundations, internal UBC funding, and grants-in-aid



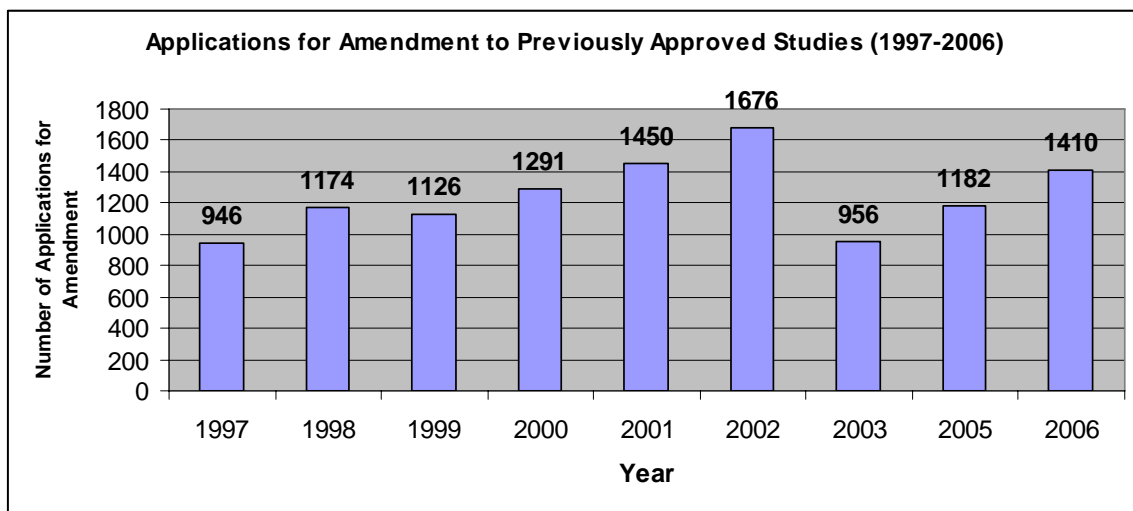
| New Applications | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2004 | 2005 | 2006 |
|------------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|------------|
| Full Board | 142 | 147 | 195 | 200 | 149 | 261 | 275 | 304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

Post Approval Activities (PAAs)

In addition to new studies, the CREB processes Post Approval Activities (PAAs) on ongoing studies, which include amendments, renewals, requests for acknowledgement and requests for study closure. Due to the implementation of the new Researcher Information Services (RISe) system, accurate statistics for all PAAs are not available for the entire 2006 fiscal year. However, it is estimated that, since RISe was implemented in August 2006, the CREB processed approximately **836 applications for Annual Renewal and 1410 applications for Amendments.**



| Renewals | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2005 | 2006 |
|----------|------|------|------|------|------|------|------|------|------|
| Total | 132 | 141 | 147 | 246 | 395 | 494 | 681 | 931 | 836 |

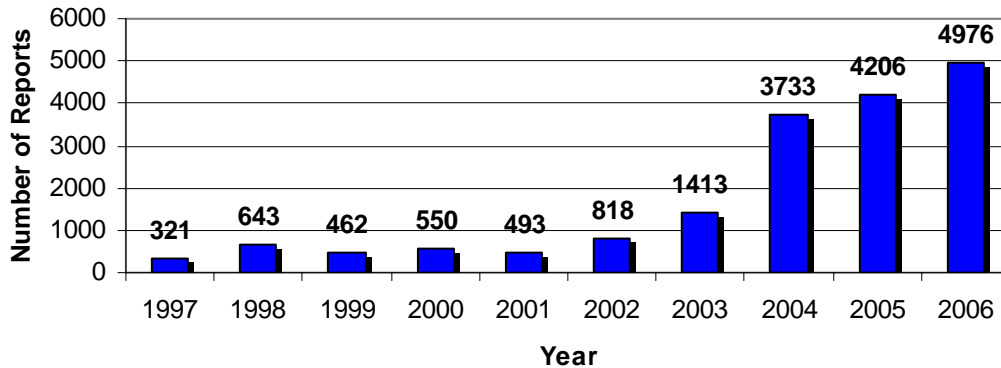


| Amendments | 1997 | 1998 | 1999 | 2000 | 2001 | 2002 | 2003 | 2005 | 2006 |
|------------|------|------|------|------|------|------|------|------|------|
| Total | 946 | 1174 | 1126 | 1291 | 1450 | 1676 | 956 | 1182 | 1410 |

Serious Adverse Event Reporting

The CREB requirements for submitting Serious Adverse Event (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 three nurse reviewers, who log all SAE reports into the CREB SAE database, and bring to the CREB Manager's and/or Chair's attention any SAE forms that require follow up for any reason. **In 2006, the CREB received, reviewed and acknowledged 4,976 SAE reports.**

Serious Adverse Event (SAE) Reports Processed 1997-2006



Turnaround Times for Submissions to the CREB

Turnaround times for submissions to the CREB cannot be summarized in a single statistic. Some studies arrive at the CREB with well-written protocols that have been subjected to rigorous scientific review prior to submission, and are accompanied by well-crafted consent documents that closely follow the CREB consent form templates and include all CREB standard wording. When such studies involve minimal risk to subjects, they undergo review through an expedited review process and a decision from the CREB is generally issued within 14 days from the time of initial submission. When such studies require Full Board review, they are usually discussed at the next meeting, and a decision from the CREB is generally issued within 7 days of that meeting.

Some studies arrive at the CREB with major deficiencies in the protocol and/or consent documents. These are returned to the principal investigator as quickly as possible, with a full review and recommendations for revision. This can usually be done within the same time frame as described above, but may take longer for very poorly written proposals.

The goal of the CREB is for properly drafted applications, including well-written protocols and consent documents, to be returned to the principal investigator within 14 days for Minimal Risk studies and within 7 days following the meeting for Full Board studies. Throughout 2006, this goal was usually attained. However, there were periods in which the CREB fell several weeks behind its usual turnaround time. In 2006, these instances included the months surrounding the implementation of the RISE system, periods of being short-staffed in the CREB office, and months in which only one Full Board meeting occurred (August and December 2006, due to usual meeting scheduling, allowing for vacation time for CREB members). The full implementation of the

RISe system, staffing of vacant positions in the CREB office, and additional screening procedures to identify deficient submissions and return them for revision prior to Minimal Risk or Full Board review, should allow for an improvement in CREB turnaround time statistics in 2007.

REVENUE

The CREB fee for ethical review applies to any new study submitted to the CREB that is sponsored by a for-profit entity. This is a one-time fee of \$3,000 that covers the initial review, as well as all subsequent PAAs (including amendments, renewals, requests for acknowledgement, study closures, and submissions of SAE reports). The direct cost for ongoing administrative operations of the CREB office, including committee expenses, are generally recovered entirely through fees charged for ethical review.

Financial Statement for Fiscal Year 2006

| Revenue | Projected | Actual |
|--|------------------------|------------------------|
| Fee for Review | \$363,000 ¹ | \$286,866 ² |
| Contribution from Vice-President Research and UBC GPOF | \$149,000 | \$299,414 |
| Total Revenue | \$512,000 | \$586,280 |

| Expenses | Projected | Actual |
|--|------------------|------------------|
| Administrative Staff Salaries ³ | \$267,533 | \$273,946 |
| Committee and Contractor Expenses ⁴ | \$195,000 | \$223,222 |
| Office and Computer Expenses | \$42,350 | \$45,333 |
| Education and Professional Development | \$15,000 | \$5,000 |
| Total Expenses | \$519,883 | \$547,501 |

The CREB gratefully acknowledges the one-time support received from the UBC General Purpose Operating Fund via Dr. John Hepburn, Vice-President Research, in 2006.

The CREB gratefully acknowledges the ongoing “in kind” support it receives from the Vancouver Coastal Health Research Institute through the provision of office and meeting space.

In addition, as one of the UBC’s Research Ethics Boards, the CREB is supported by the University’s continued funding of the Associate Director, Research Ethics,

¹ Projected revenue was based 121 industry-sponsored applications.

² In 2006, there were 97 industry-sponsored applications.

³ Includes wages and benefits for full time and temporary/casual staff

⁴ Includes honoraria for Board Chair, Associate Chairs and members, wages for serious adverse event reviewers, and miscellaneous requests for external reviews and expertise.

the development and maintenance of information technology systems and the RISE team, and “once only” funding of initial CREB office setup costs.

MEMBERSHIP

As of March 2007, the CREB was composed of **27 voting 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.

| MEMBER NAME * NEW IN 2006 | ROLE(S) | PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALITY | AFFILIATED WITH UBC? |
|------------------------------|--|--|----------------------|
| David Ansley, MD | Primary Reviewer | Anaesthesia | yes |
| Gail Bellward, PhD | Chair | Pharmacology and Toxicology | yes |
| Victoria Bernstein, MD* | Primary Reviewer | Cardiology | yes |
| Harvey Coxson, PhD* | Primary Reviewer | Radiology | yes |
| Patrick Doyle, MD* | Primary Reviewer | Microbiology | yes |
| Barbara Fulton, MA | Lay Member | | no |
| John Higenbottam, PhD* | Primary Reviewer | Psychology and Psychiatry | yes |
| Rob Irvine, MD | Primary Reviewer | Otolaryngology | yes |
| John Jue, MD | Primary Reviewer | Cardiology | yes |
| Ardis Krueger, ND* | Primary Reviewer for Studies involving Natural Health Products | Natural Health Products | no |
| Valia Lestou, PhD* | Primary Reviewer | Medical Genetics | yes |
| Karen Low Ah Kee, CMA | Lay Member | | no |
| Ian Martin, MD | Primary Reviewer | Family Medicine | yes |
| James McCormack, Pharm.D. | Primary Reviewer and Associate Chair | Pharmaceutical Scs. | yes |
| Murray Morrison, MD | Primary Reviewer | Otolaryngology | yes |
| Kishore Mulpuri, MD | Primary Reviewer | Orthopaedics | yes |
| Robert Peterson, MD | Primary Reviewer | Paediatrics | yes |
| Jerilynn Prior, MD | Primary Reviewer | Endocrinology | yes |
| Jeremy Road, MD | Primary Reviewer | Respirology | yes |
| John Russell, PhD | Ethicist and Associate Chair | Philosophy (ethics) | yes |
| Bonita Sawatzky, MD | Primary Reviewer and | Orthopaedics | yes |

| | | | |
|---|--|---|-----|
| | Associate Chair | | |
| Anthony Smith | Lay Member | | no |
| Caron Strahlendorf, MD | Primary Reviewer and Associate Chair | Paediatric Oncology | yes |
| Bill Sullivan, QC, MCL | Lawyer | Law | no |
| Penny Washington, LLB | Alternate Lawyer | Law | no |
| David Wensley, MD | Primary Reviewer | Paediatrics | yes |
| Pearce Wilcox, MD | Primary Reviewer | Respirology | yes |
| MEMBERS WHO RESIGNED FROM THE CREB 2006-2007 | | | |
| Lorne Brown, DTCM | Primary Reviewer for Studies involving Natural Health Products | Traditional Chinese Medicine | no |
| Caroline Calmettes, BSc | Non-primary Reviewer | Sponsored Research Agreements | yes |
| Anthony Fung, MD | Primary Reviewer | Cardiology | yes |
| Zubin Master, PhD | Specialty Reviewer | Stem Cell Research | yes |
| Sydney Pilley, MD | Primary Reviewer | Ophthalmology | yes |
| Marion E Stickland | Alternate Lawyer | Law | no |
| Helen Tremlett, PhD | Primary Reviewer | Pharmacoepidemiology/ Multiple Sclerosis | yes |

FULL BOARD MEETINGS

22 Full Board meetings of the CREB were held as scheduled in 2006. Meetings were held on the second and fourth Tuesday of every month, with the exception of the months of August and December, in which only one meeting was held.

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, and two Administrative Assistants. 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 CREB Administrative Assistants handle the clerical administration of the office by processing new Full Board and Minimal Risk applications, applications for Amendment and Annual Renewal of

previously approved studies, proviso responses, SAEs, file closures and financial administration.

The CREB experienced significant turnover of staff in 2006. In June 2006, Erin Desjardine, Manager of Pre- and Post- Review with the CREB since 2002, left the CREB and was replaced by Farin Ramji, previously CREB Administrative Assistant. Nesa Khareghani was hired to fill the position of Administrative Assistant vacated by Farin Ramji.

In January 2007, Jonathan Doan, Manager of Pre- and Post- Review with the CREB since January 2005, left the CREB and was replaced by Suzanne Dommissie, previously a CREB Administrative Assistant. Svitlana Franchuk was hired in March 2007 to fill the position of Administrative Assistant vacated by Suzanne Dommissie.

In February 2007, Farin Ramji, Manager of Pre- and Post- Review with the CREB since June 2006, left the CREB and was replaced by Jean Ruiz.

Erin Skrapek, hired in July 2005, continued in her role as the Manager of the CREB in 2006.

Three nurse reviewers, Michelle Jones, Karen MacDonald and Sandy MacLeod, were engaged on a part time basis to carry out review of Serious Adverse Event (SAE) reports.

CREB Chair and Associate Chairs

In 2006, Dr. Gail Bellward continued her appointment as CREB Chair, which began in 2005, and Dr. James McCormack continued his appointment as CREB Associate Chair, which began in 2003. In addition, the CREB appointed three new Associate Chairs. Dr. John Russell, CREB Ethicist, was appointed Associate Chair for Policy and Education. Dr. Caron Strahlendorf, CREB Primary Reviewer, was appointed Associate Chair with the mandate to review all new Minimal Risk studies. Dr. Bonita (Bonnie) Sawatzky, CREB Primary Reviewer, was appointed Associate Chair with the mandate to review all new Minimal Risk Post-Approval Activities in partnership with Dr. James McCormack. Beginning in December 2006, the Chair and Associate Chairs group have held monthly meetings to discuss ongoing policy, membership and administrative issues.

POLICY AND PROCEDURES

RISe (Researcher Information Services – Ethics)

On August 21, 2006 the UBC Clinical Research Ethics Board (CREB) implemented the Researcher Information Services (RISe) system. RISe is a secure, internet-based, all-electronic system that allows REBs and researchers

to securely apply for ethical approval and track research applications through the approval process, as well as manage all post-approval activities (including amendments and annual renewals). RISE is now operational for the UBC Animal Care Committee and all four of the UBC REBs. The UBC REBs are working together, with the RISE management and programming team, to maintain and improve the content, data, and functionality of the new system.

Chairs and Managers Meetings

In September 2006, under the direction of Ms. Margaret Shotter, Associate Director, Ethics, Office of Research Services, the Chairs and Managers of the UBC REBs began meeting on a monthly basis to discuss policies and procedures that require a common resolution, in particular now that all UBC REBs are using the RISE system. The meetings have been successful in resolving issues and promoting consistency among UBC REBs, and the plan is to continue these meetings on a monthly or bi-monthly basis.

Continuing Review

In November 2006, Dr. Jeffrey Toward, Continuing Review Manager, Office of Research Services, presented the results of a pilot project for the internal review of 14 randomly selected studies at Providence Health Care and Children & Women's Hospital with regard to compliance standards for ethical research on human subjects. The CREB is utilizing Dr. Toward's internal review reports to work with the investigators to address specific areas of non-compliance or concern in the reviewed studies.

Application Forms, Guidance Notes and Templates

Numerous updates, clarifications, and additions to the CREB's Application Forms, Guidance Notes and Consent Form Templates were made throughout 2006 in an effort to assist investigators in meeting current standards for ethical conduct of research and to increase the efficiency of ethical review. The CREB Guidance Notes, Application Forms and Templates are available on the CREB website at: <http://www.ors.ubc.ca/ethics/clinical/c-forms.htm> .

EDUCATIONAL OUTREACH

Throughout 2006, 10 education sessions were held to update the research community on CREB policies as well as its requirements and application processes on RISE. These sessions are listed below:

General CREB Introductory Workshops:

- VCHA Researchers and Coordinators (October 19 2006 at VGH, presented by Erin Skrapek);
- VCHA Program Evaluation Course (January 10 2006 at VGH, presented by Erin Skrapek)

RISe Introduction and Demonstration Sessions:

- VCHA Researchers (August 1 2006 and August 10 2006 at VGH, presented by Erin Skrapek, Monika Garg, RISe Manager, and Jonathan Doan)
- C&W Researchers (August 3 2006, presented by Erin Skrapek, Monika Garg, RISe Manager, and Suzanne Dommissie)
- UBC Researchers (August 17 2006 at UBC, presented by Erin Skrapek, Monika Garg, RISe Manager, and Farin Ramji)

Workshops for Graduate Students and Residents:

- CIHR Training Program in Rehabilitation and Quality of Life (July 14 2006, presented by Erin Skrapek)
- Health Research Methods for Rehabilitation Sciences, Nutrition Sciences and Human Kinetics RHSC/HUNU 500 (September 19 2006 at UBC, presented by Erin Skrapek)
- Occupational Therapy MCT 547 (September 20 2006 at UBC, presented by Erin Skrapek and Shirley Thompson, BREB Manager).
- VCHA Neurology Residents (February 8 2006 at VGH, presented by Erin Skrapek and Monika Garg, RISe Manager)

Board members also regularly provide advice and make presentations to colleagues and the research community.

OUTLOOK AND CHALLENGES FOR 2007

The CREB will continue to work with UBC and its affiliates, as well as the other UBC REBs, to ensure high ethical standards in research at UBC and its affiliated institutions in 2007. The CREB staff and members remain committed to the goal of the protection of human subjects of clinical research, and to achieving this goal through the improvement of processes, meeting of compliance standards, and assistance to researchers in meeting regulatory requirements.

In 2007, the CREB will continue to focus on working with the UBC REBs and the RISe team to make improvements to the content and functionality of RISe for researchers, CREB staff and Board members. A considerable amount of time is required to attend to these issues and to facilitate training of new users.

The CREB hopes to continue to grow and support its Board membership in 2007. It is an ongoing challenge to maintain the membership needs of the CREB to comply with all relevant national and international requirements and legislation by which UBC is governed, such as the Tri-Council Policy Statement and Health Canada legislation for regulated clinical trials. There is a need for a multidisciplinary membership with a broad spectrum of expertise and experience. Ms. Margaret Shotter, UBC Associate Director, Research Ethics, and Dr. Gail Bellward, CREB Chair, have worked hard to recruit new members to the Board. Dr. John Hepburn, UBC Vice-President Research, has also worked diligently to provide support for, and recognition of, CREB members. However, the workload

for CREB members, who are also busy clinicians and professionals often with their own research portfolios, is at maximum capacity due to a high volume of applications being submitted, and thus recruitment and retention of members is an ongoing challenge. The CREB remains hopeful that support for, and recognition of, the commendable dedication of its members will continue to grow to a degree proportionate to the amount of work and commitment they contribute to the UBC and its affiliates. Without ensuring a sustainable and efficient ethical review process, the UBC stands to jeopardize its reputation as a major centre of scientifically rigorous and ethical research.

Educational outreach activities for 2007 are being planned with Vancouver Coastal Health Authority, UBC Office of Research Services, and Children's and Women's Hospital to increase awareness of research ethics issues in the research community. The CREB thanks the staff of Vancouver Coastal Health Research Institute and the Child and Family Research Institute for their ongoing partnership and support in implementing these educational initiatives.