



## **2005 ANNUAL REPORT**

of the

# **UNIVERSITY OF BRITISH COLUMBIA CLINICAL RESEARCH ETHICS BOARD**

Issued June 2006

by

**Dr. Gail Bellward, Chair, UBC Clinical Research Ethics Board  
Ms. Erin Skrapek, Manager, UBC Clinical Research Ethics Board**

**Mission of the  
University of British Columbia  
Clinical Research Ethics Board:**

***“To protect the interests  
of human subjects by  
ensuring high ethical  
standards in clinical  
research at UBC”***

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## Introduction and Background

The UBC Clinical Research Ethics Board (CREB) was formed in 1985. Since that time, the CREB has been responsible for review and ongoing oversight of clinical research conducted by researchers based at UBC and its affiliated institutions.

The CREB supports clinical research at UBC in many ways, including:

- Ensuring adherence to national and international regulations and standards;
- Providing quality assurance for research projects (this results in increased leverage of research dollars because of increased reputation);
- Supplying ethical education to researchers who serve as Board members, and their colleagues; and facilitating educational activities for the UBC community;
- Acting as a centre to address subjects' concerns and a quick response centre for emergencies (e.g., adverse effects);
- Providing an arm's length counter-balance for projects to ensure equipoise and lack of conflict of interest; and,
- Decreasing liability and managing risk for UBC

The UBC CREB operates according to the principles and standards detailed in the Tri-council Policy Statement for Ethical Conduct for Research Involving Humans (TCPS).

In addition to clinical research conducted by investigators based on UBC's Point Grey campus, the CREB is responsible for review and oversight of research conducted within the Vancouver Coastal Health Authority (all sites and affiliated research institutes) and BC's Children's & Women's Health Centre (and affiliated hospitals and research institutes).

This report is one part of the CREB's multi-faceted effort to maintain and increase the integrity, transparency, independence and efficiency of the clinical research ethical review process at UBC.

This report reflects the activities of the CREB for the calendar year 2005. Historical data and comparisons with previous years' operations are provided in selected instances. The CREB thanks the CREB staff, Gary Ho (ORS), Patricia Tait (VCHRI), and others who contributed to the preparation of this report.

Any questions about this document may be directed to the CREB's Manager, Erin Skrapek ([erin.skrapek@ors.ubc.ca](mailto:erin.skrapek@ors.ubc.ca)) or the CREB Chair, Dr. Gail Bellward ([gail.bellward@ors.ubc.ca](mailto:gail.bellward@ors.ubc.ca)).

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## Membership

As of December 2005, the CREB was composed of 28 members, 15 of which were regular participants and the balance part-time or periodic participants.

MEMBER NAME	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
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
Barbara Fulton, MA	Lay Member		no
Anthony Fung, MD	Primary Reviewer	Cardiology	yes
Rob Irvine, MD	Primary Reviewer	Otolaryngology	yes
John Jue, MD	Primary Reviewer	Cardiology	yes
Karen Low Ah Kee, CMA	Lay Member		no
Ian Martin, MD	Primary Reviewer	Family Medicine	yes
Zubin Master, PhD	Specialty Reviewer	Stem Cell Research	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
Sydney Pilley, MD	Primary Reviewer	Ophthalmology	yes
Jerilynn Prior, MD	Primary Reviewer	Endocrinology	yes
Jeremy Road, MD	Primary Reviewer	Respirology	yes
John Russell, PhD	Ethicist	Philosophy (ethics)	yes
Bonita Sawatzky, MD	Primary Reviewer	Orthopaedics	yes
Anthony Smith	Lay Member		no
Caron Strahlendorf, MD	Primary Reviewer	Paediatric Oncology	yes
Marion E Stickland	Alternate Lawyer	Law	no
Bill Sullivan, QC, MCL	Lawyer	Law	no
Helen Tremlett, PhD	Primary Reviewer	Pharmacoepidemiology/ Multiple Sclerosis	yes
Penny Washington, LLB	Alternate Lawyer	Law	no
David Wensley, MD	Primary Reviewer	Paediatrics	yes
Pearce Wilcox, MD	Primary Reviewer	Respirology	yes
<b>Members who resigned from the Board between Jan and Dec 2005</b>			
Peter O'Brien, MD	Primary Reviewer	Orthopaedics	yes
Pierre Guy, MD	Primary Reviewer	Orthopaedics	yes

Alain Gagnon, MD	Primary Reviewer and Associate Chair	Obstetrics & Gynaecology	yes
Pratibha Reebye, MD	Primary Reviewer	Psychiatry	yes
Lynn Beattie, MD	Primary Reviewer	Geriatric Medicine	yes
Jolanda Cibere, MD, PhD	Primary Reviewer	Rheumatology/ Epidemiology	yes
Fergall Magee, MD	Primary Reviewer	Surgical Pathology	yes
Peter Loewen	Chair	Pharmacology	yes

Dr. Gail Bellward was appointed as the new CREB Chair on April 1, 2005. The previous Chair, Dr. Peter Loewen, resigned from the Board in February 2005. Dr. James McCormack, CREB Associate Chair, served as interim Chair until Dr. Bellward began her appointment. Dr. Alain Gagnon, Associate Chair, resigned from the Board in June 2005 and a replacement had still not found by the end of 2005.

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.

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## Operations

The CREB hired two new Administrative Assistants to fill existing clerical positions in 2004. Farin Ramji was hired in October 2004, and was given the portfolio of clerical administration of new Full Board and Minimal Risk applications, proviso responses and general correspondence from the Chair. Suzanne Dommissse was hired in November 2004, and was made responsible for the clerical administration of all amendments and renewals reviewed through the Expedited process, SAEs, file closures and financial administration.

In January 2005, Jonathan Doan was hired as the CREB's second Manager of Pre- and Post-Review alongside Erin Desjardine, the CREB's existing Manager of Pre- and Post-Review (hired in September 2003). In this capacity, Erin and Jonathan 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 Erin's and Jonathan's reviews is to ensure that a study's consent forms meet current CREB requirements.

Susan Chunick, CREB Manager, left the CREB in February 2005. Erin Skrapek was hired in July 2005 as the new Manager of the CREB.

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

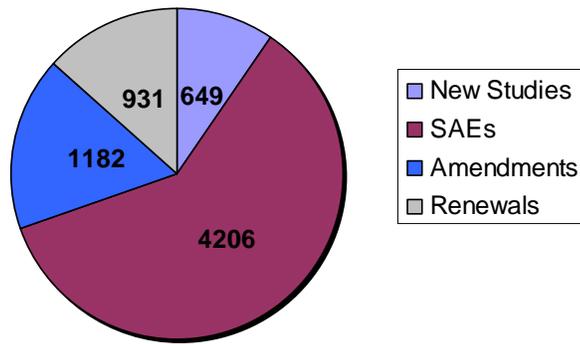
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## Statistics

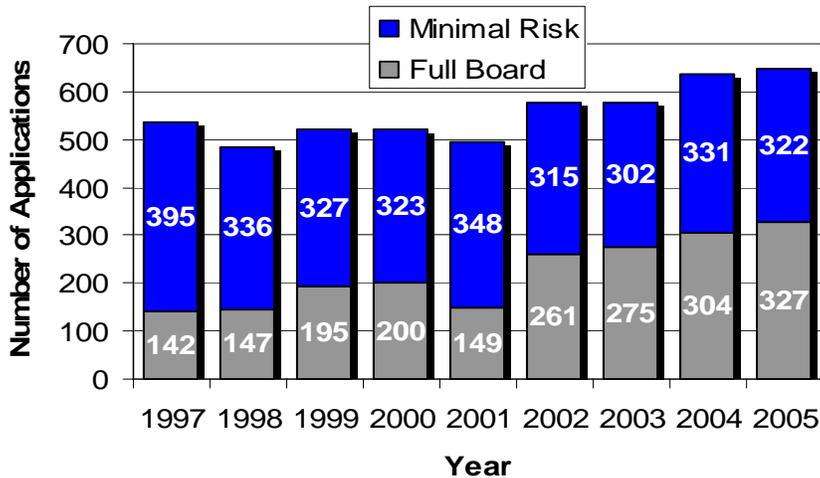
As of December 31 2005, the CREB was responsible for ethical oversight of 2,203 ongoing research projects.

The CREB handled 6,968 requests for ethical review in 2005. A breakdown of these requests is depicted in Figure 1.

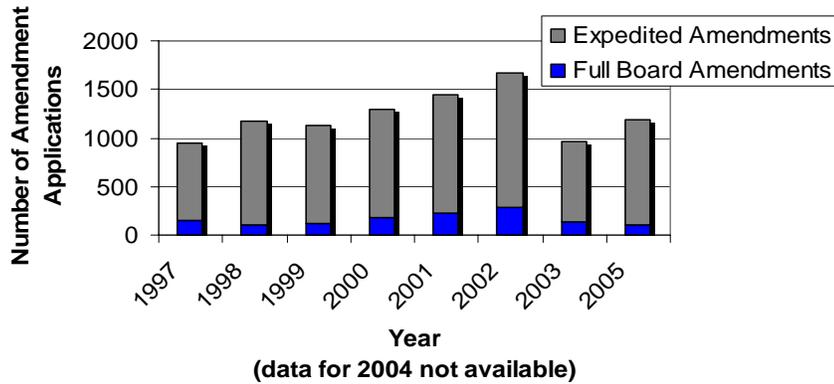
**Figure 1: Requests for Ethical Review in 2005**  
(Total = 6,968)



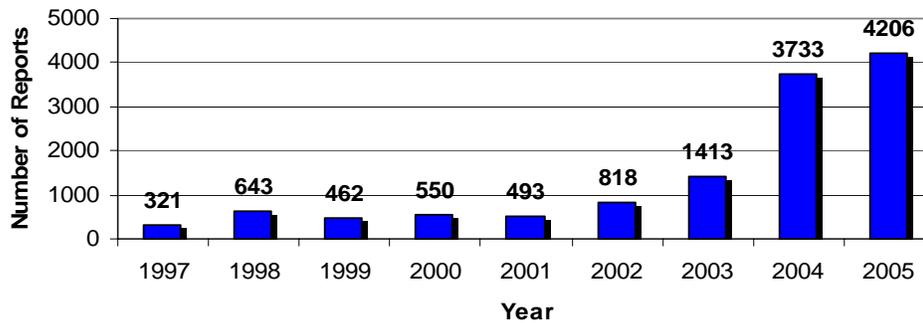
**Figure 2: New Project Applications**



**Figure 3: Applications for Amendment of Previously Approved Projects Processed**

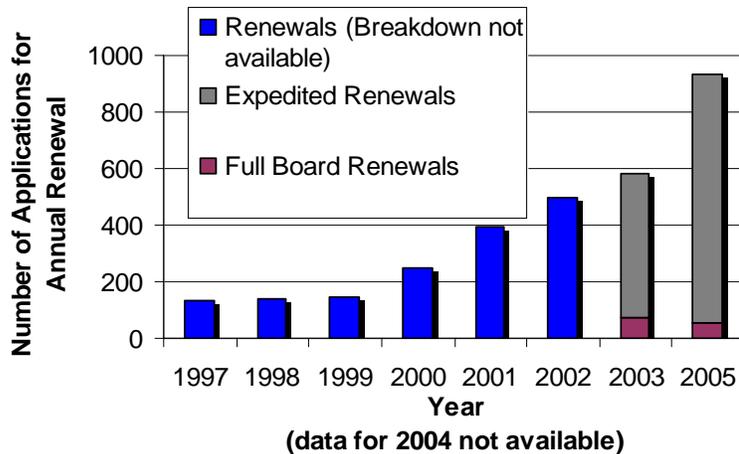


**Figure 4: Serious Adverse Event (SAE) Reports Processed**

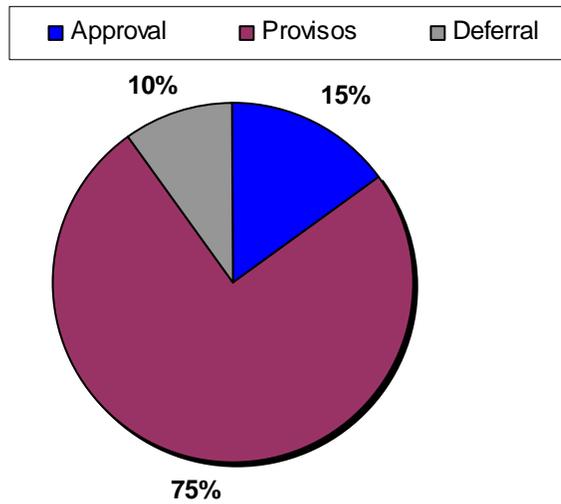


The UBC Clinical Research Ethics Board (CREB) requirements for submitting adverse event reports follow Health Canada's mandatory reporting requirements for 'serious and unexpected adverse drug reactions' and for incidents involving medical devices.

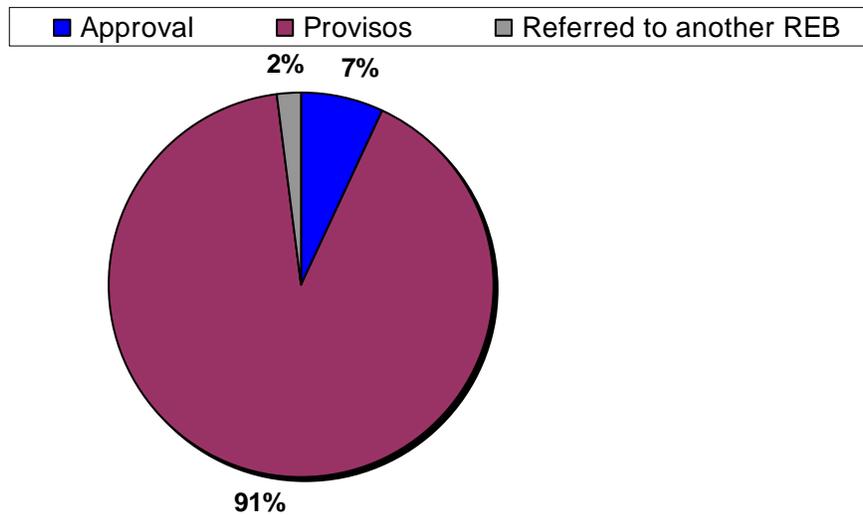
**Figure 5: Applications for Annual Renewal Processed**



**Figure 6: Breakdown of Actions on New Full Board Applications**



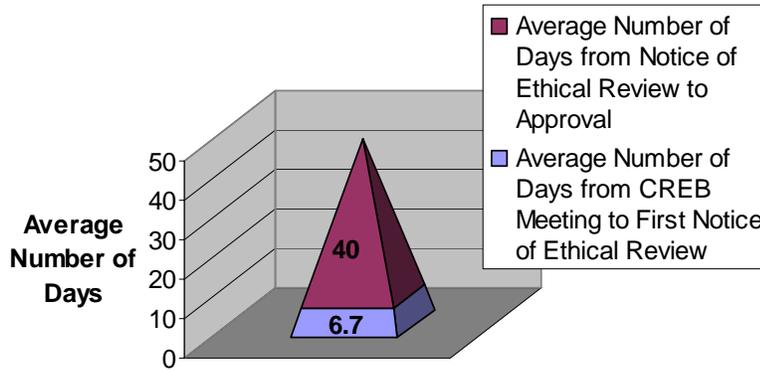
**Figure 7: Breakdown of Actions on New Minimal Risk Applications**



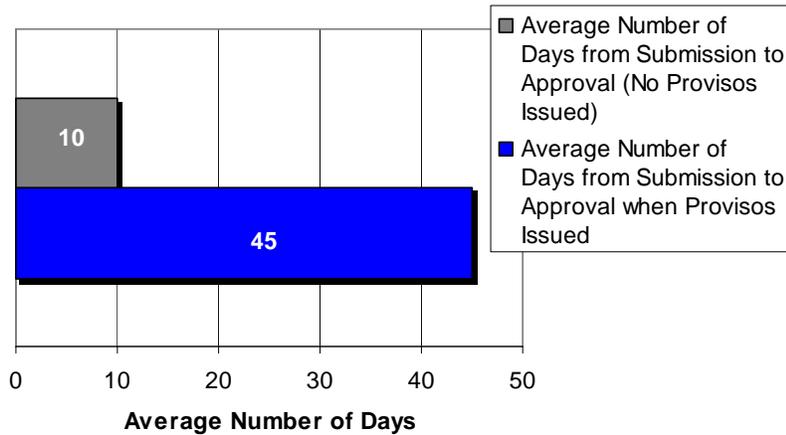
In order to decrease the large percentage of new proposals requiring changes to meet ethical or scientific requirements, the CREB strongly recommends an internal departmental review of all applications before they are submitted to the CREB for ethical review.

**Note: All Timelines are Average Number of Calendar Days (includes weekends).**

**Figure 8: Timeline from Meeting to Approval for Full Board Studies**



**Figure 9: Timeline from Submission to Approval for Minimal Risk Studies**



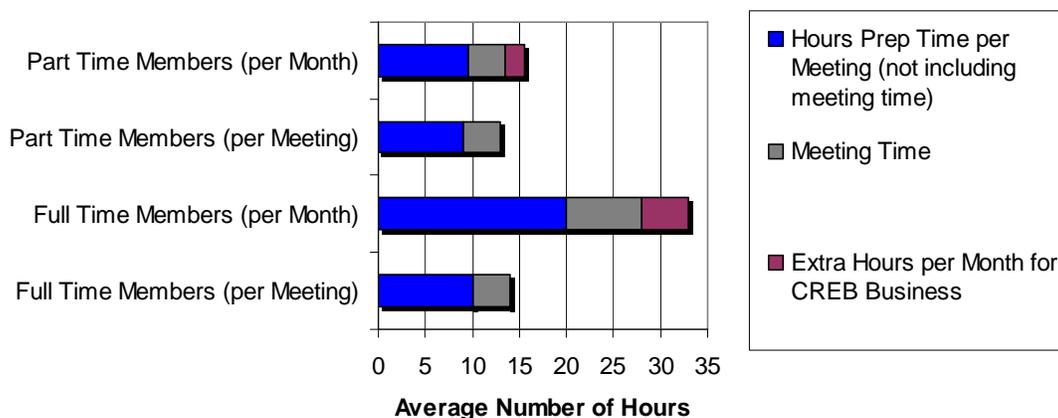
**Note: when provisos are issued, the majority of the days are “investigator days” rather than “CREB days”.**

## Review Process and Board Meetings

### Full Board Review

The CREB currently meets at 8:00 AM on the 2<sup>nd</sup> and 4<sup>th</sup> Tuesdays of the month with the exception of one meeting in August and December, for a total of 22 meetings per year. Meetings last for approximately 4 hours, and Board members spend on average from 9 to 10 hours preparing for each meeting in addition to the meeting time. Additionally, members spend an average of 3 to 4 hours per month on extra CREB-related business. In total, full-time members spend an average of 33 hours per month on CREB meetings and other business, while part-time members spend an average of 15.5 hours per month. See Figure 10 for a breakdown of this time contribution.

**Figure 10: Time Contribution by CREB Members**



### Minimal Risk Review

In addition to the full board meetings, the Chair and Associate Chairs share the task of reviewing all of the minimal risk applications, amendments, renewals and correspondence that result from the full board and minimal risk review process. In 2005, the number of reviews required was 4,180. This requires approximately 20 to 40 hours per week (split between the Chair and Associate Chairs) in addition to preparation time for the regular meetings and other CREB-related business.

### Policy Meetings and Retreat

A retreat to discuss policy and procedural matters was held for all CREB members and staff on November 19 2005 at the Seasons Bistro in Queen Elizabeth Park. Topics discussed included: format for dealing with emergency protocols; defining “minimal risk”; ensuring understanding in the consent process; standard consent form wording on high-risk toxicities; reproductive risks and the reciprocal review process with PHC-REB; quality assurance and case study reports; and stem cell research and regulations.

## Ethical Standards and Services to Investigators

### Protocol Compliance Review Committees

Since 2001, previously approved CREB studies with incomplete documentation have been referred to the CREB Protocol Compliance Review Committees for re-review. All research studies approved by CREB are now in full compliance with the TCPS and UBC Policy 89, in that each ongoing study held by the CREB contains a full and up-to-date study protocol, and consent form(s) that accurately mirror(s) the corresponding protocol in a manner consistent with current standards.

### 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 2005 in an effort to assist investigators in meeting current standards for ethical conduct of research and to increase the efficiency of ethical review.

### Clinical Trial Registration

In June 2005, the International Committee of Medical Journal Editors (ICMJE) – which represents the major health science journals worldwide – announced a new requirement that all clinical trials be registered at the start. Trials that are not registered at onset will now not be considered for publication. In response to the development and implementation of this requirement, the CREB amended its Application for Ethical Review form and corresponding Guidance Notes to inform investigators of their responsibility to register all clinical trials meeting the ICMJE's eligibility criteria, and to request that the registration numbers be provided to the CREB for tracking purposes.

### On-line Tutorial

In response to the Interagency Advisory Panel on Research Ethics (PRE) launch of the TCPS tutorial in 2004, the CREB amended its Application for Ethical Review form and corresponding Guidance Notes in December 2005. The CREB now strongly suggests that all study team members (including principal investigators, co-investigators and student researchers) must complete this tutorial before beginning research on human subjects.

### Stem Cell Research

The CIHR updated its Guidelines for Human Pluripotent Stem Cell Research in June 2005, and the CREB amended its Application for Ethical Review form and corresponding Guidance Notes in December 2005 to reflect the revised CIHR criteria.

### Assent Form Template

In September 2005, the CREB developed and adopted an Assent Form Template, primarily intended for children between the ages of 7 to 13 years who are not legally competent to consent on their own behalf but who have the capacity to assent, and related to CREB Guidance Note #36 on Assent.

### Optional Research Studies Template

In response to the need for a model consent form for optional research studies (including tissue banking, DNA testing, etc.), the CREB began the development of an Informed Consent Form Template for Optional Studies. The development of this template had not been completed by the end of 2005.

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> .

### **New Member Information Packages**

The education and training of new CREB members is essential to ensure a well-informed and efficient Board. With this in mind, in November 2005, the CREB office finalized the development of a detailed information binder for new CREB members, which includes revised member Terms of Reference and Standard Operating Procedures, copies of relevant guidelines and regulations (e.g., TCPS, GCP, CIHR Privacy Best Practices, Belmont Report, Declaration of Helsinki, etc.), and a list of internet resources.

### **Educational Outreach by Staff and Board Members**

Throughout 2005, 6 education sessions were held to update the research community on CREB policies as well as its requirements for completing application forms and formulating consent forms. These sessions are listed below:

#### **General CREB Introductory Workshops:**

- VCHA Researchers and Coordinators (October 19 2005 at VCHRI, presented by Erin Skrapek);
- New College of Medicine Researchers (October 27 2005 at C&W, presented by Margaret Shotter and Erin Skrapek)

#### **Workshops for Graduate Students:**

- Occupational Therapy MCT 547 (September 28 2005 at UBC, presented by Erin Skrapek and Shirley Thompson, BREB Manager).

#### **Other CREB Workshops:**

- CREB Decisions And Ethical Principles: Case Studies I: Understanding Value, Validity, Equipoise, And Balancing Harms And Benefits (February 9 2005 at VCHRI, presented by James McCormack and Peter Loewen)
- CREB Decisions And Ethical Principles: Case Studies II: Understanding Ethical Requirements For Recruiting And Consenting Subjects (February 16 2005 at VCHRI, presented by John Russell)
- CREB Decisions And Ethical Principles: Case Studies III: Ensuring Ongoing Subject Protection During Clinical Trials (April 28 2005 at VCHRI, presented by Margaret Shotter)

Board members also regularly provide advice to colleagues.

## Financial Statement for Fiscal Year 2005

Revenue	<i>Projected</i>	<i>Actual</i>
Fee for Review <sup>1</sup>	\$459,000 <sup>2</sup>	\$354,535 <sup>3</sup>
Contribution from Vice-President Research	\$15,000	0
<b>Total Revenue</b>	<b>\$474,000</b>	<b>\$354,535</b>

Expenses	<i>Projected</i>	<i>Actual</i>
Administrative Staff Salaries <sup>4</sup>	\$257,849	\$252,082
Committee Expenses	\$128,860	\$119,518
Office Expenses	\$35,203	\$29,140
Consultants & Contractors <sup>5</sup>	\$11,000	\$10,370
Education (attendance at conferences/workshops)	\$14,750	\$9,424
<b>Total Expenses</b>	<b>\$447,662</b>	<b>\$420,534</b>

The direct cost for ongoing administrative operations of the CREB office, including committee expenses, are recovered entirely by fees collected from industrial sponsors of research. Initially set at \$1750.00 per new application, this fee was increased to \$3000.00 per new application as of September 2003.

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 Margaret Shotter (Associate Director, Research Ethics), the development and maintenance of information technology systems and “once only” funding of initial CREB office setup costs.

<sup>1</sup> In 2005, the CREB charged a review fee of \$3,000 per application, and these fees were collected for industry-sponsored applications only.

<sup>2</sup> Projected revenue was based 153 industry-sponsored applications.

<sup>3</sup> In 2005, there were 121 industry-sponsored applications.

<sup>4</sup> Includes wages and benefits for full time and casual staff

<sup>5</sup> Includes wages for serious adverse event reviewers, Protocol Review Committee expenses and miscellaneous requests for external reviews and expertise.

## **Outlook and Challenges for 2006**

The CREB will continue to enhance the ethical oversight of research at UBC and its affiliated institutions in 2006. The primary goal of the Board and staff will continue to be to protect the interests of human subjects by ensuring high ethical standards in UBC and affiliated clinical research.

### **CREB Membership**

The CREB hopes to continue to grow and support its Board membership in 2006. It is a 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. Margaret Shotter, UBC Associate Director, Research Ethics has worked hard to recruit new members to the Board. However, the workload for Board members, who are also busy clinicians and professionals often with their own research portfolios, is heavy and thus recruitment is often a challenge.

The challenge of recruiting and retaining Board members is unlikely to be overcome without more recognition by the UBC and affiliated research community of the value of the work done by the CREB. The CREB remains hopeful that support for, and recognition of, the commendable dedication of its members will 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.

### **Enhanced Continuing Review of Ongoing Research**

In 2005, the Office of Research Services developed the position of Continuing Review Manager of Research Ethics, and Dr. Jeffrey Toward was hired into this position. The CREB looks forward to working closely with this invaluable resource to enhance the process of monitoring of ongoing research at UBC.

### **Research Ethics Education**

Ongoing education activities are being planned with Vancouver Coastal Health Authority Research Services and Children's and Women's Hospital to increase awareness of research ethics issues in the research community.

### **Electronic Application and Review System**

The CREB is set to "go live" with the new and highly anticipated Researcher Information Services (RISe) electronic submission and review system in August 2006. This system will be of great benefit to researchers, Board members and staff alike. CREB staff participated in many RISe planning sessions with staff and members of other UBC REBs and the RISe implementation team in 2005.

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