University of British Columbia - British Columbia Cancer Agency Research Ethics Board
(UBC BCCA REB)

UBC BCCA Research Ethics Board
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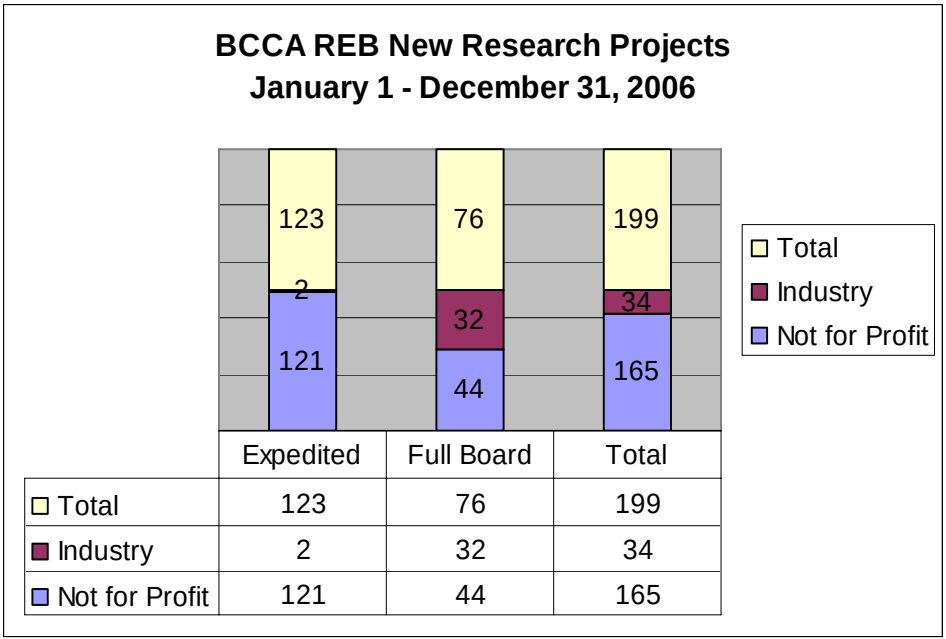
2006 ANNUAL REPORT

STATISTICS

199 New Projects between January 1 – December 31, 2006



	Expedited	Full Board	Total
Total	123	76	199
Industry	2	32	34
Not for Profit	121	44	165

State Of New Projects	**199**
Approved	163
Pending Approval	31
Withdrawn (3 Withdrawn Post-full board review) (1 Withdrawn Pre-full board review – processed by REB Admin) (1 Withdrawn Pre-expedited review – processed by REB Admin)	5

Post Approval Activities (PAA's)

In addition to new projects, the UBC BCCA REB processed post approval activities for ongoing studies such as amendments, annual renewals and acknowledgments. Due to an increase in submissions to the REB, limited resources, and the implementation of the new Researcher Information Services (RISe) system, accurate statistics for post approval activities for 2006 are not available for the entire fiscal year. However, it is estimated that since RISe was implemented between **April 3, 2006 to December 31, 2006** the REB processed approximately **682 post approval activities** (this does not include serious adverse event reporting which is processed outside of the RISe system, see below).

Serious Adverse Event Reporting

The UBC BCCA REB continues to use a fully searchable electronic Access database maintained on the BC Cancer Agency secure computer network for reporting serious adverse events. This database is accessible only by data managers, principal investigators, REB members and the REB staff and is maintained in a secure password protected computer environment. **During 2006 the REB received, acknowledged and reviewed approximately 300 SAEs per month plus an average of two follow-up reports for each SAE.**

The workload of the REB continues to increase reflecting the major commitment of the BCCA and BCCRC to conduct translational research.

Turnaround times for REB submissions

Turnaround times for BCCA REB submissions cannot be summarized in a single statistic. Some studies arrive at the BCCA REB with well written protocols that have been subjected to rigorous scientific review before submission and are accompanied by well crafted consent documents that closely follow the BCCA REB consent template. When such studies involve minimal risk to subjects they receive expedited review and are returned to the principal investigator in less than one week. When such studies require full REB review they are usually discussed at the next meeting and a proviso is issued within 7-10 days of that meeting.

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

The goal of the BCCA REB is for properly drafted protocols and consents to be reviewed and returned to the principal investigator within one week in the case of minimal risk studies and within 7 to 10 days of the full REB meeting for studies requiring full REB review. Throughout 2006 this goal was usually attained. Periodically, such as around the time when the RISe system was initially implemented and during December through January when large numbers of studies are often submitted coincident with a skipped meeting in December, the BCCA REB has not been able to meet those goals falling several weeks behind. The full implementation of the RISe system and additional screening procedures to identify deficient proposals and return them for revision before consideration at full REB meetings should allow us to improve these turnaround statistics during 2007.

REVENUE

Fee for Ethical Review

The REB fee for ethical review applies to any new study submitted to the REB that is sponsored by a for-profit entity. This fee is a one-time fee that covers all subsequent post-approval activities such as amendments, annual renewals, and acknowledgments.

Fee Applicable	**Fee Waived**	**Full Refund** (Withdrawn Pre-Review)	**Partial Refund** (Withdrawn Post Review)	**TOTAL REVENUE**	**Paid**	**Outstanding**
34	**2**	**1**	**3**			
$102,000.00	(6,000.00)	(3,000.00)	(3,000.00)	**90,000.00**	(65,000.00)	**$25,000.00**

Fee for Serious Adverse Event Reporting

In August, 2006 the REB announced a new policy effective November 1, 2006. The REB will begin charging a fee for Serious Adverse Reporting. This fee will be billed separately and in

addition to the REB Fee for Ethical Review (a waiver for exemption of trials sponsored by a not-for-profit entity will be available). The new fee is necessary due to the increasing number of SAE's reported. It is no longer sustainable for this work to be supported by the funds from the initial REB ethical review fee as the REB is devoting at least 80 hours per month of personnel time to process SAE reports, safety letters and updates. There will be a $25 fee for each initial SAE report processed which will cover all subsequent follow-up reports for that initial SAE report. The revenue from the SAE fee will be used to support the hiring of a pharmacist who will assume the processing of all SAE reports, billing and tracking of SAE fees, and maintenance of the SAE database. This pharmacist will devote approximately one half of a full time position to these tasks. This pharmacist will work in the BCCA Vancouver Centre pharmacy under the professional supervision of the head of pharmacy and be responsible to the REB for the SAE reporting process. As at December 31st, the process for billing and tracking the SAE fees is being established and recruitment of the pharmacist/SAE reviewer is pending.

MEMBERSHIP

In 2006, the Board experienced several changes of members. Dr. Lori d-Agincourt-Canning (ethicist) accepted a position at Children & Women's Hospital and resigned from the BCCA REB. Dr. Peter Battershill (ethicist and General Practitioner in Medical Oncology at BCCA Vancouver Island Centre) joined the REB. Dr. Mira Keyes, Radiation Oncologist at the BCCA Vancouver Centre also joined the REB. Dr. Robin O'Brien joined the REB to fulfill the requirement for a member knowledgeable in Complementary and Alternative Medicine to attend on an ad hoc basis when a study that involves a therapeutic natural health product requires review.

The Board is now comprised of **24** voting members of diversified specialties from the community and each of the four BC Cancer Agency centres:

(Chair)	Dr. Joseph Connors	(Medical Oncology/EthicsVancouver Centre)
(Vice-Chair)	Dr. Lynne Nakashima	(Pharmacy/Ethics/Vancouver Centre)
(Second Vice-Chair)	Dr. Ken Swenerton	(Medical/Gyne Oncology/Vancouver Centre)
	Dr. Paul Hoskins	(Medical/Gyne Oncology/Vancouver Centre)
	Dr. Hagen Kennecke	(Medical Oncology/Vancouver Centre)
	Dr. Kevin Song	(Hematology/Medical Oncology/Vancouver Centre)
	Dr. Caroline Lohrisch	(Medical Oncology/Vancouver Centre)
New	Dr. Mira Keyes	(Radiation Oncology/Vancouver Centre)
	Dr. Frances Wong	(Radiation Oncology/Fraser Valley Centre)
	Dr. Paul Blood	(Radiation Oncology/Vancouver Island Centre)
	Dr. Maxine Alford *(nee: Mueller)*	(Qualitative Research/Nursing/Vancouver Isl. Centre)
New	Dr. Peter Battershill	(Medical Oncology/Vancouver Isl. Centre)
	Dr. Susan Ellard	(Medical Oncology/Centre for the Southern Interior)
	Dr. Sanjay Rao	(Medical Oncology/Centre for the Southern Interior)
	Dr. John Spinelli	(Statistics/ Epidemiology/Vancouver Centre)
	Dr. Nhu Le	(Statistics/ Epidemiology/Vancouver Centre)
	Dr. Chris Bajdik	(Statistics/ Epidemiology/Vancouver Centre)
	Dr. Maria Cristina Barroetavena	(Qualitative Research/Symptom Mgmt./VC)
*	Mr. Chris Bardon	(Law/ Non-Scientific/Community/Vancouver)
*	Ms. Katherine Arnold	(Law/ Non-Scientific/Community/Vancouver)
*	Ms. Joan Rush	(Law/ Non-Scientific/Community/Vancouver)
*	Ms. Jo-Ann Isaacson	(Non-Scientific/Community/Vancouver)
New*	Ms. Lori Phillet	(Non-Scientific//Community/Vancouver)
New*	Dr. Robin O'Brien	(Oncology Pharmacy/Complimentary & Alternative Medicine/Vancouver)

**Member unaffiliated with BCCA*

Full Board Meetings

22 full board meetings were scheduled during 2006 occurring on the second and fourth Tuesday of each month with the exception of August and December when only one meeting was scheduled. All scheduled meetings were held.

ADMINISTRATION

Administrative Staff (REBA)

The UBC BCCA REB has been supported by one permanent full time coordinator, one temporary full time coordinator, and a casual part-time Clerk. The permanent full time coordinator position was reclassified to Manager to be in line with the UBC REB's and the temporary full time coordinator position has been posted as a permanent position, which is pending finalization. A part-time (half-time) pharmacist for the REB Serious Adverse Event review process (noted above) is also pending hire.

REB Chair/Vice-Chairs

The UBC BCCA REB is supported by a part time chair and two part time vice-chairs. A proposal was forwarded to the BC Cancer Agency Executive in November 2004 for funding for a new staff position at BCCA that would be authorized with one-half time responsibility to Chair the BCCA REB and the other half with any of the BCCA departments preferably located within either Radiation or Medical Oncology and based at the Vancouver Center. This proposal was accepted and recruitment has been undertaken. The current REB Chair, Dr. Joseph Connors agreed to bridge the position until February 28, 2007 and effective March 1, 2007 will assume the role of REB Vice-Chair.

Space

The REB administrative office will move to a larger office space in the Fairmont Medical Building to accommodate the increase in staff. The office moved to a temporary location in March, in the Vancouver Centre and the move date to the new location is still pending as at December 31, 2006.

POLICY and PROCEDURES

The UBC BCCA REB and the UBC Clinical Research Ethics Board (CREB) continues to keep the research oversight processes as consistent as possible. The BCCA REB has established and maintained processes specific to the BCCA REB utilizing the BCCA REB website and network to convey these to BCCA researchers.

RISe (Researcher Information Services-Ethics)

The UBC BCCA REB was the pilot for the UBC REB's for human subjects to implement the new RISe system effective April 3, 2006. Over the remainder of the year each of the UBC REB's also implemented the RISe system. The secure internet based all electronic system allows the REB and researchers to securely apply for and track research applications through the approval process as well as manage amendments and annual renewals. The UBC REB's are working together and with the RISe team of programmers to maintain and improve the content, data, and functionality of the new system.

UBC REB Chairs and Managers Meetings

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

Continuing Review

In November 2006, Jeffrey I. Toward, Ph.D., Continuing Review Manager, Research Ethics, UBC 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 research ethics for human subjects.

CONTINUING EDUCATION AND EVENTS

The REB members and staff participate as much as possible in research ethics workshops and conferences that are offered free of charge and consideration by the REB is given to sponsor individual members for conferences that require registration fees and travel.

National Council on Ethics in Human Research (NCEHR) Conference
Nov-17 & 18: Training in Research Ethics; Biomedical Program / Social and Behavioural Sciences and Humanities Program
The REB sponsored Ms. Joan Rush to attend the above two-day conference held in Calgary, Alberta.

BCCA Annual Cancer Conference
In November 2006, the BCCA REB participated for the first time in the BCCA Annual Cancer Conference. REB member, Dr. Peter Battershill organized the REB presentation. The volunteer presenters included Dr. Peter Battershill, Dr. Joseph Connors, Ms. Joan Rush, Ms. Katherine Arnold and the BCCA REB former ethicist Dr. Lori D'Agincourt-Canning. Feedback from those who attended was very positive. The REB plans to participate again next year.

BCCA Ethics Survey
REB Members, Dr. Peter Battershill and Ms. Joan Rush participated in a BCCA agency-wide series of anonymous ethics surveys, contributing their knowledge and expertise in the area of (research or non-research related) ethics. The survey consisted of a description of hypothetical situations to which anonymous responses were collected, and then posted for staff to read with a response to each scenario from Dr. Peter Battershill and Ms. Joan Rush.

OUTLOOK AND CHALLENGES FOR 2007

The BCCA REB will focus on improvements to the content and functionality of RISe. A considerable amount of time is required to attend to these issues and to facilitate training of new users.

The BCCA REB also recognizes the substantial contribution of its Board members. There have been several new members who joined in 2006, and a new member is planning to join in early 2007 along with possibly 3 planned resignations and recruitment of a new REB Chair. This is a significant number of changes to the membership and it is hoped that the membership will then remain stable for a period of time while new members become familiar with the REB processes and the RISe system.

The UBC BCCA REB will continue to facilitate ethical oversight of human research in affiliation with the UBC Office of Research Services and the UBC REB's. The BCCA REB remains committed to improving its processes, to protect human subjects participating in research projects, to assist researchers in meeting regulatory requirements, and ensure the REB itself meets compliance standards.