



UNIVERSITY OF BRITISH COLUMBIA PROVIDENCE HEALTH CARE RESEARCH ETHICS BOARD

**ANNUAL REPORT - April 1, 2007 to March 31, 2008**

**STATISTICS**

The UBC PHC REB annual report will hereafter outline statistics according to the fiscal year (April 1 to March 31), rather than the calendar year as reported prior to 2007.

Table 1 outlines statistics for applications received between April 1, 2007 and March 31, 2008.

Table 2 compares the statistics between applications submitted for the 2006 calendar year and for the fiscal year April 1, 2007 to March 31, 2008. Although not a direct comparison due to the change in reporting parameters (i.e. fiscal year versus calendar year), it is included to give an approximate description of REB activity. The period of activity between January 1 2007 and March 31, 2007 is not therefore recorded in this report.

New Submissions

Table 1: UBC PHC REB Statistics April 1, 2007 to March 31, 2008

Active applications to date	551
New applications for the fiscal year	222
Number of new full board applications	61
Number of new expedited (minimal risk) applications	161
Number of new applications sponsored by Industry	50
Number of new applications not-for-profit	173
Number of Certificates of Approval issued (new applications) <sup>1</sup>	173
Number of Post Approval Activity applications	1139
Annual Renewals	353
Amendments	406
Study Completion Notices	121
Requests for Acknowledgement	259
Total number of applications reviewed (all types)	1361

<sup>1</sup> The difference in stats between 'New applications for the fiscal year' and 'Number of Certificates of Approval issued (New Applications)' is due to non response of investigators to REB provisos during this time period.

Table 2: Comparison Between Calendar Year 2006 and April 1, 2007 to March 31, 2008

	2006 -2007	2007-2008
Total new applications	215	222
New applications that were full board	79	50
New applications that were expedited (minimal risk)	138	173
Total number of post approval activities	605	1139
Total number of applications reviewed (all types)	820	1361
New Applications sponsored by Industry	79	50

The number of new minimal risk reviews has increased by approximately 21% over the past year, and the number of post approval activities (all types) has doubled.

#### Review of Applications Submitted to UBC Research Ethics Boards Outside PHC REB

Under the UBC REB of Record process, the PHC Research Ethics Board conducts a review of applications submitted to the other UBC research ethics boards (UBC CREB, UBC BREB, and UBC BCCA REB) that indicate that use of PHC facilities, services, or access to patients or staff is required. This review process is consistent with the process described under the March 27, 2007 letter to John Hepburn, UBC VP of Research, signed by each of the UBC REB Chairs.

The UBC PHC REB Manager of Ethical Reviews is responsible for ensuring that a PHC Institutional Certificate of Final Approval signed by the PHC VP of Research is issued for each application reviewed and approved by any of the other UBC REBs. If there is any question or concern about any of these applications (i.e. concern about issues related to catholic policy), the UBC PHC REB Manger of Ethical Reviews refers the application to the UBC PHC REB Chair. If there are no concerns, the process for obtaining institutional departmental approvals is undertaken, after which, if all institutional approvals are in place, the final certificate to conduct the research at PHC is issued.

For the period of April 1, 2007 to March 31, 2008, the approximate number of these applications reviewed by the UBC PHC REB was 53.

#### Review of Serious Adverse Event Reports

During 2007, the UBC PHC REB received, acknowledged and reviewed approximately 250 SAEs per month. A physician REB member who has served on the board form more than 3 years reviews the SAE reports. If the reviewer requires additional information not included in the SAE report (e.g. request for a copy of the latest Data Safety Monitoring Board (DSMB) report), the reviewer notifies the UBC-PHC REB Manager Ethical Reviews. The UBC-PHC REB Manager Ethical Reviews contacts the principal investigator/designate by email and requests a copy of the DSMB report or other documentation requested by the reviewer. This process is continued until any issue is resolved and the reviewer is satisfied with the response.

#### REB Review Times for Submissions

Turnaround times for UBC PHC REB submissions cannot be summarized in a single statistic. Some studies arrive at the UBC PHC REB with well-written protocols and are accompanied by well-crafted consent documents that closely follow the UBC PHC 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 UBC PHC 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 UBC PHC 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 2007 this goal was usually attained.

Currently there are no statistical reports available in RISE that will allow the UBC REBs to determine turn-around time. However, the UBC REB Managers and the RISE programmers have been in discussion about parameters required for such reports, and it is believed that these statistics will be available in the future.

## **REVENUE**

### **Fee for Ethical Review**

The REB fee of \$3000.00 for ethical review applies to any new study submitted 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, acknowledgment and SAE reviews.

## **RESEARCH ETHICS BOARD MEMBERSHIP**

The UBC-PHC REB was pleased to welcome Dr. Kuo-Hsing Kuo, Ms. Sarah Harbottle and Ms. Lynne Connell to the board during the period of January 2007 to March 31, 2008. The addition of these members enhanced the UBC-PHC REB's ability to meet, on a consistent basis, quorum as defined by Health Canada.

Dr. Jill Kernahan and Dr. Kuo-Hsing Kuo agreed to act as Associate Chair of the board, and Dr. Kuo-Hsing Kuo agreed to act as REB Chair when Dr. Ingrid Fedoroff expects to step down from that position at the end of 2008.

The following REB members resigned during this period: Ms. Lori Williams, Dr. John Boone, Dr. James Kennedy and Mr. B. Maxwell.

The Board and the University of British Columbia are grateful and indebted to all members for their valuable service to the Board and the Providence Health Care research community.

## Full Board Meetings

11 full board meetings were scheduled for the period of January 1 2007 to March 31, 2008 normally occurring on the last Friday of the month, with the exception of August. All scheduled meetings took place.

## ADMINISTRATION

### Administrative Staff (REBA)

One permanent full time manager of ethical reviews and one permanent full time research ethics coordinator supported the UBC PHC REB during 2007. The UBC PHC REB was without permanent administrative assistance during the period of July 2007 to December 31, 2007, however, temporary staffing was employed periodically throughout this period. The vacant administrative secretary position (ethics) was never filled and a non-contract ethics review coordinator was hired in January 2008.

### REB Chair/Associate-Chairs

One Chair and two Associate Chairs support the UBC PHC REB.

### 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. Following the resignation of Ms Margaret Shotter in 2007, Ms. Laurel Evans was appointed the position of UBC Associate Director of Research Services. Ms. Evans has continued the practice of these REB Managers and Chairs meetings. These meetings have been successful in resolving issues and promoting consistency across the UBC REB's and the plan is continue meeting on a regular basis.

## OUTLOOK AND CHALLENGES FOR 2008-2009

The UBC-PHC 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 UBC-PHC 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.