



**UNIVERSITY OF BRITISH COLUMBIA
PROVIDENCE HEALTH CARE RESEARCH ETHICS BOARD**

ANNUAL REPORT – April 1, 2008 to March 31, 2009

Statistics

Table 1 outlines statistics for applications received between April 1, 2008 and March 31, 2009.

Table 2 compares the statistics between applications submitted for the 2007-2008 fiscal years and the fiscal year April 1, 2008 to March 31, 2009.

Table 1: Statistics April 1, 2008 to March 31, 2009

Total active applications in the RISE system	616
New Applications	
Total new full board applications	68
Total new expedited (minimal risk) applications	152
Total new applications for the fiscal year	220
Total of the new applications total number that were:	
Industry sponsored	42
Not-for-profit or unfunded	178
Post Approval Activity Applications	
Total annual Renewals	395
Total amendments	397
Total study completion Notices	105
Total requests for acknowledgement	171
Total requests for information	1
Total post approval activity applications for the fiscal year	1069
Total Applications (New + Post Approval Activity) reviewed	1289

Table 2: Statistics Comparison: Fiscal Years 2007-2008 and 2008-2009

	2007-2008	2008-2009
Total new applications	222	220
Total full board new applications	61	68
Total expedited new applications	161	152
Total industry sponsored new applications	50	42
Total not-for-profit new applications	172	178
Total number of post approval activities	1139	1069
Total number of applications reviewed (all types)	1361	1289

Review of Applications Submitted to other UBC Research Ethics Boards

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, UBC C&W 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.

Review of Serious Adverse Event Reports

During fiscal year 2007-2008, the UBC PHC REB received, acknowledged and reviewed approximately 200 SAE reports per month. If the physician 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 normally issued within 7-10 days of the 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 2 weeks in the case of minimal risk studies and within 7 to 10 days of the full REB meeting for studies requiring full REB review.

Revenue

Fee for Ethical Review

The REB fee of \$3000.00 for ethical review applies to any new industry sponsored application submitted for review. This fee is a one-time fee that covers all subsequent post-approval activities such as amendments, annual renewals, acknowledgment and SAE reviews.

UBC PHC Research Ethics Board Membership

The UBC-PHC REB was pleased to welcome Dr. David Unger as ethicist and Mr. Mike Kleisinger as lawyer to the board during the period of April 1, 2008 to March 31, 2009. The addition of these members enhanced the UBC-PHC REB's ability to meet, on a consistent basis, quorum as defined by Health Canada. The following REB member resigned during this period: Dr. Alastair McLeod.

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 April 2008 to March 31, 2009 normally occurring on the last Friday of the month, with the exception of July. All scheduled meetings took place. The UBC PHC Research Ethics Board will be expanding the number of yearly scheduled full board meetings to 12, beginning January 2010.

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 fiscal year 2008-2009.

UBC REB Chairs and Managers Meetings

Laurel Evans, the Associate Director, Research Ethics, Office of Research Services the Chairs and Managers of the UBC REB's meet quarterly to discuss policies and procedures that require a common resolution, particularly now that all UBC REBs are using the RISE system. These meetings have been successful in resolving issues and promoting consistency across the UBC REB's. These meetings will continue on a regular basis.

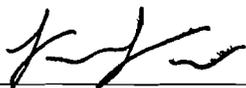
Goals for fiscal year 2009-2010

To recruit additional REB members - The UBC PHC REB would like to recruit additional physician members, specifically in the areas of nephrology, cardiology, medicine, surgery and respirology. In addition, the REB requires another community member.

To develop 'plain language' consent form templates – The REB manager will be collaborating with a plain language specialist to create consent form templates that more appropriately takes into account the literacy level of the general population. The goal is also to create a glossary of medical/technical terminology translated into plain language. It is hoped that this glossary will be useful to researchers and research coordinators.

To institute an annual REB member educational retreat – The REB Manager will develop a plan for continuing education of REB members. The agenda will include updates on current regulatory and ethical issues, as well as a presentation on a topic of interest to the members. The timing of the retreat is to be determined based on majority availability of the members.

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 Rib'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.



Dr. Kuo-Hsing Kuo, Chair, UBC PHC REB



Ms. Vivienne Bearder, Manager Ethical Reviews

30 July 2009