







Research Ethics Board  
2005-06 Annual Report



Annual Report

For the period  
April 1, 2005 - March 31, 2006

Issued May 2007  
Dr. Elan Paluck, Chair  
Research Ethics Board

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# I Purpose of the Research Ethics Board

The Research Ethics Board (REB) of the Regina Qu'Appelle Health Region (RQHR) reviews research proposals for scientific soundness and adherence to ethical guidelines as established by the Region and in accordance with professional standards. Established in 1997, the REB functions to protect the rights and welfare of research participants and to ensure the conduct of ethical research practices within the RQHR.

The REB is responsible for the review and ongoing oversight of research conducted within a RQHR institution or by a RQHR-affiliated investigator. The RQHR REB meets the standards outlined by Canada's Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans and has been approved by the Saskatchewan Minister of Health for the purposes of Section 29 by the Health Information Protection Act.

## II Background

The RQHR REB is responsible for the review of biomedical and behavioural research projects. Biomedical research involves protocols with medically invasive procedures, pharmaceutical testing, physical interventions, surgical procedures including the collection of blood or other specimens, and the use of permanent health records in accordance with provincial legislation. Behavioural research involves non-invasive interventions including interviews, surveys, focus groups, or psychological/behavioural interventions.

Meetings are held once a month to review research protocols that are considered to carry "more than minimal risk" for potential research subjects. These studies typically involve the use of medical tests, procedures, or drugs that go beyond the standard care a patient would receive for a particular clinical condition. Any decision regarding moderate-to-high risk research projects must receive the approval of 75% of the Board members. Voting cannot take place without a quorum, which has been set at 60% of the REB members. Minimal risk studies such as chart audits, for example, are reviewed through an expedited process using the Chair and/or a sub-committee of REB members.

### III Membership

The REB includes nine members with collective expertise in the areas of research, patient care, ethics, and law. The Chair, a research scientist within the Regina Qu'Appelle Health Region, appoints members to the Board. Members of the 2005/06 REB are listed below.

Dr. Elan Paluck, BSP, MSc, PhD  
Research Scientist, Regina Qu'Appelle Health Region  
*REB Chair*

Ms. Marilee Allerdings, MA  
Manager, Knowledge Exchange/Performance Support  
Regina Qu'Appelle Health Region

Ms. Jordana Buchan  
Regional Director, Canadian Diabetes  
Association

Rev. Dan Cooper, BA, MDiv(Hons)  
Chaplain, Palliative Care Services  
Regina Qu'Appelle Health Region

Dr. William Semchuk, BSP, MSc, PharmD,  
FCSHP  
Manager, Clinical Pharmacy Services  
Regina Qu'Appelle Health Region

Dr. Krishna Kumar, MB, MS, FRCS (C), FACS  
Head, Section of Neurosurgery  
Regina Qu'Appelle Health Region

Mr. Timothy J. MacLeod, BA, LLB  
Senior Counsel, Saskatchewan Government  
Insurance

Dr. David Elliott, PhD  
Associate Professor, Department of Philosophy  
& Classics  
University of Regina

Ms. Val Davies, RN, Dip Critical Care, BEd, MSc  
Executive Director, Specialty Care Administration  
Regina Qu'Appelle Health Region

#### **Alternate RQHR Research Ethics Board Members**

Dr. Tejal Patel, BScPharm, PharmD  
Clinical Pharmacy Specialist, Pharmacy Services  
Regina Qu'Appelle Health Region

Mr. Eric Greenway  
Community Development Coordinator, Canadian  
Diabetes Association

Dr. S. S. Mann  
Medical Director, MEDEC  
Regina Qu'Appelle Health Region

Mr. Mitchell Miller, B.Comm, BA, LLB  
Chief Ethics and Privacy Officer, Saskatchewan  
Government Insurance

Rev. Mary Brubacher  
Director, Spiritual Care  
Regina Qu'Appelle Health Region

Ms. Ali Bell, MSc  
Analyst, Knowledge Exchange /Performance Support  
Regina Qu'Appelle Health Region



*2005/06 RQHR Research Ethics  
Board Membership List (as of March 31, 2006)*

## IV Statistics

### a. Total Requests for Ethical Review

The RQHR REB processed a total of 744 requests for ethical review in 2005/06. These requests included the review of 71 new applications, renewal of 63 ongoing projects, 134 amendments to the protocol of ongoing projects, and 476 reviews of adverse event (AE) reports. Since many studies require more than one year to complete, the Region was actively involved in 134 studies during 2005/06, a number that has almost doubled since 2000 (Figure 1).

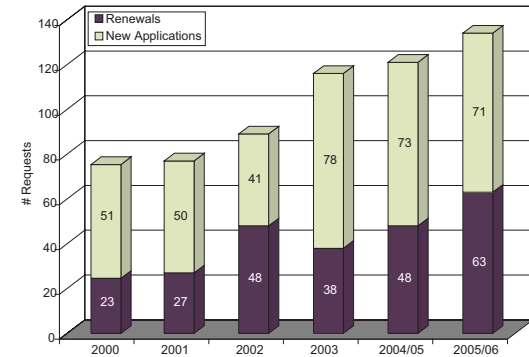


Figure 1: Requests for Ethical Review Over Time

### b. Description of New Project Applications

The REB received 71 new project applications in 2005/06. Relative to 2004/05, there was a slight decrease in the number of biomedical applications received and a slight increase in the number of behavioural applications (Figure 2). Four of the 71 new applications submitted were exempt from requiring RQHR REB approval. Of the remaining projects, full *Approval* was granted to 12 (18%) studies after their initial review. Most studies (72%), however, were granted *provisional approval*, requiring minor modifications to the protocol or consent form before receiving final approval. Seven applicants (10%) were asked to resubmit the entire protocol and provide additional information for a second full review of their project by the Board.

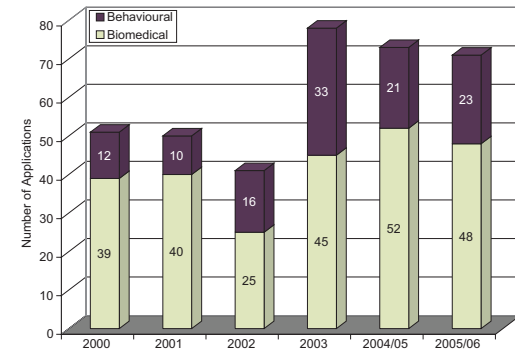


Figure 2: Types of New Project Applications

New applications are reviewed according to the level of risk that a research subject could experience as a result of the research procedures being employed. Minimal risk studies receive an expedited review by the REB Chair while moderate- to high-risk studies are reviewed by the full Board. Figure 3 reveals that the number of studies qualifying for an expedited review has increased steadily over the last four years. A complete list of the new project applications received by the REB in 2005/06 is included in the appendix.

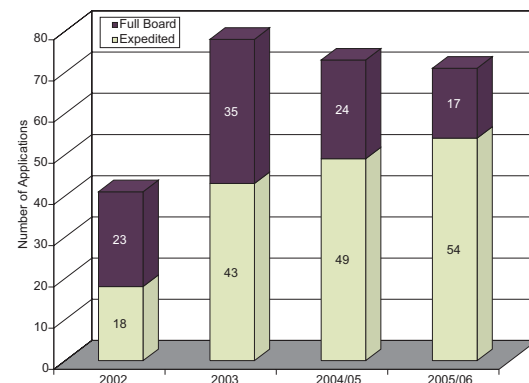


Figure 3: Level of Review Required for New Project Applications

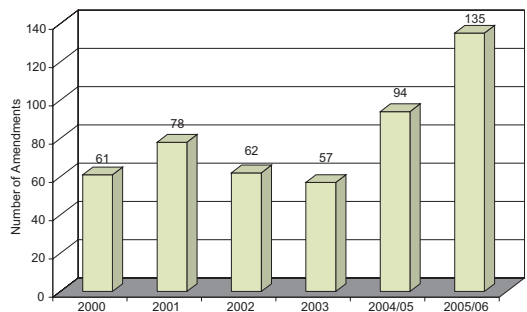


Figure 4: Number of Protocol Amendments Reviewed

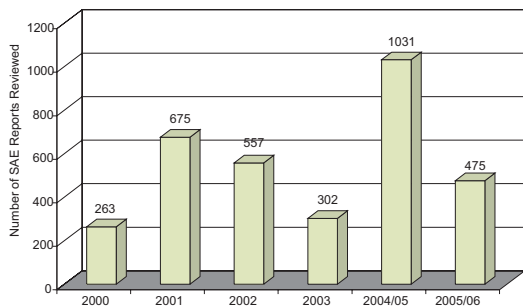


Figure 5: Number of AE Reports Reviewed

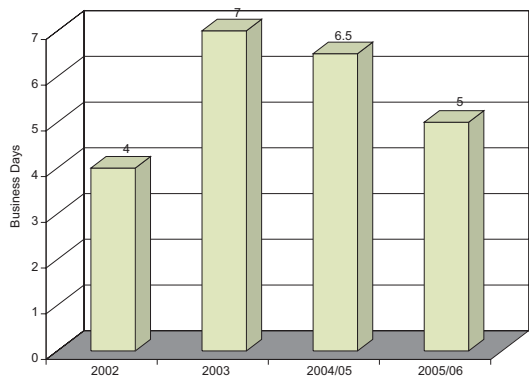


Figure 6: Median Number of Business Days from Full Board Review to Notice of Ethical Review

### c. Protocol Amendments

Once a study has been granted ethical approval, any changes to the protocol must be reviewed and approved by the REB. The number of protocol amendments submitted for review increased dramatically in 2005/06 (Figure 4), and all were classified as minor amendments receiving approval through an expedited process.

### d. Adverse Event Reports

Adverse Events (AEs) are any unfavourable or unintended medical occurrences experienced by a research subject. An AE may be expected or unexpected, and may or may not share a causal relationship to the study drug or intervention. When an AE results in death or is life-threatening requiring hospitalization, it is referred to as a Serious Adverse Event (SAE). Like AEs, SAEs are not necessarily causally linked to the study drug or intervention, and may be expected or unexpected. During the course of a study, all AEs and SAEs must be reported to the appropriate regulatory authorities.

In 2005/06, 475 AEs were processed and reviewed by the RQHR REB (Figure 5). Of these AEs, 59 (12.4%) occurred within the RQHR, and only one was deemed to be possibly related to the study drug or therapy. This event was not unexpected and no changes to the consent form or study protocol were deemed necessary.

### e. Timeline for Studies Reviewed at Full Board Meetings

In 2005/06, the median number of business days from when a study was reviewed by the Board to when the investigators were issued a *Notice of Ethical Review* (NER) was reduced to 5.0 (Figure 6). The median value represents the mid-point figure, such that 50% of the values fall above that value and 50% are lower than the value.

**f. Timeline for Studies Receiving an Expedited Review**

The median number of business days for a minimal risk study to be reviewed and issued a NER was 4.0 in 2005/06 (Figure 7). This value represents an average length of 3.0 days for the study to be reviewed, and 1.0 day for a NER to be issued. These values remain unchanged from 2004/05.

**g. Proportion of Projects Receiving Notice of Ethical Review within Five Days**

Receiving timely information from the REB regarding the status of an application under review is of paramount importance to researchers. The RQHR has adopted the standard of ensuring that a NER is issued within 5.0 working days.

Figure 8 reveals that 89% of the applications reviewed by the RQHR REB in 2005/06 received a NER within five working days. This is an area of improvement from 2004/05, where 67% of applicants received notification within that same time period.

**h. Financial Summary Financial Summary for 2005/06**

The majority of research conducted in the RQHR is reviewed at no expense to the investigative team. However, research funded by a for-profit agency is charged \$1000. The exception to this policy pertains to industry sponsored research that is coordinated through the Saskatchewan Drug Research Institute (SDRI). SDRI-affiliated studies pay the REB review fee to the University of Saskatchewan Biomedical Research Ethics Board.

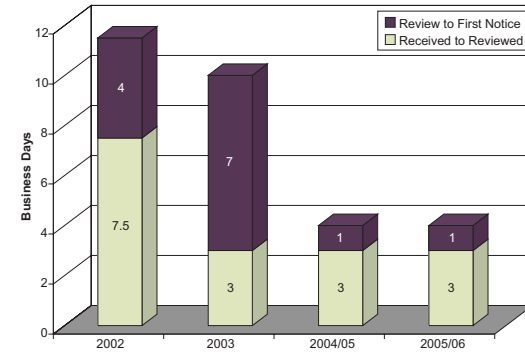


Figure 7: Median Number of Business Days Required for an Expedited Review

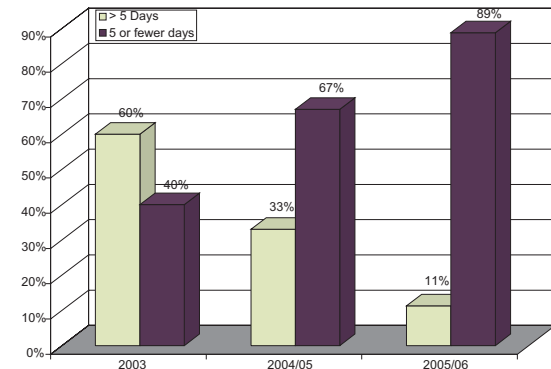


Figure 8: Proportion of Investigators Issued a Notice of Ethical Review within Five Business Days

Revenue	2002	2003	2004/05	2005/06
Fees Collected	\$10,500	\$3,000	\$9,000	\$10,478

## V. Overview of Research in the Regina Qu'Appelle Health Region

### a. The Changing Face of Research

In 1997, most of the research being conducted in the RQHR was industry-sponsored clinical drug trials (73%), and only one-quarter (27%) was lead by a researcher from an academic institution (e.g., University, SIAST), or an internal staff member, resident or intern. Over the last decade, however, research has evolved to include a balance of industry, academic, internal, and resident research (Figure 9).

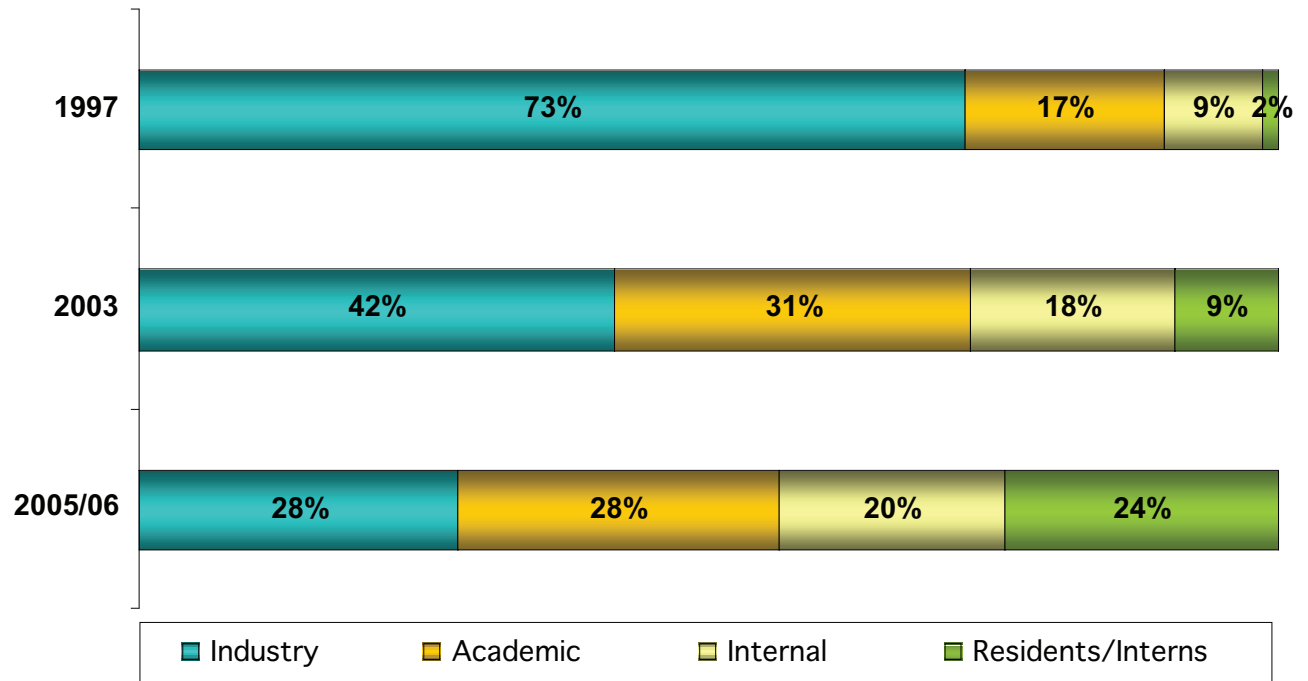


Figure 9: Changes in the Types of Research Being Conducted in the RQHR

### b. Clinical Areas in Which Research is Being Conducted

The 71 new studies submitted to the REB in 2005/06 represented more than 21 clinical specialties (Figure 10). The areas of cardioscience, obstetrics/gynecology, neurology, nutrition & food services, and psychology were most active with each initiating six new studies.

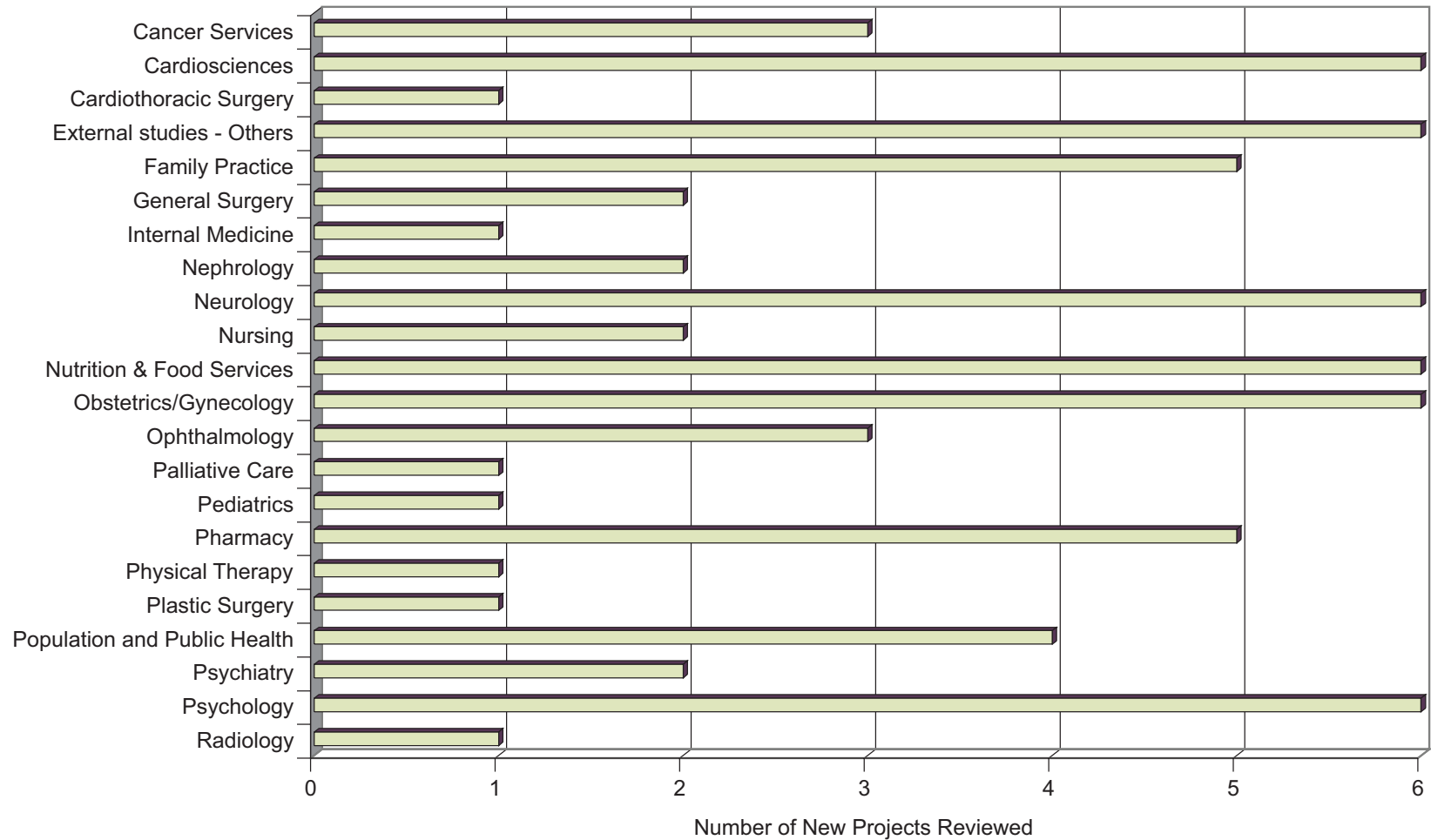
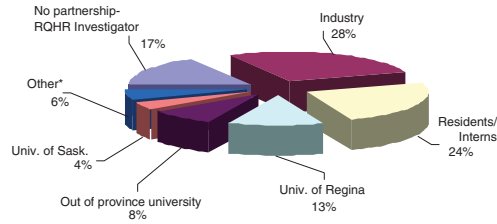


Figure 10: Number of New Research Projects Initiated by Clinical Specialty in 2005/06

### c. Research Partnerships

Establishing partnerships with community groups and organizations is critical in producing and sustaining clinically relevant research in the RQHR. In 2005/06, the Regina Qu'Appelle Health Region partnered with both local and out of province universities, the Health Quality Council, pharmaceutical companies, plus numerous residents and interns from the University of Saskatchewan to conduct many important studies. Figure 11 displays the proportion of research being conducted in the Region involving partnerships with non-RQHR staff or employees.



\*Health Quality Council, Allan Blair Cancer Centre

Figure 11 Proportion of 2005/06 Research Conducted Within the RQHR Involving Partnerships

### d. Funding Sources

The funding sources of the 71 projects received in 2005/06 are displayed in Figure 12. Four primary categories are noted:

- **Grants:** include funding from non-profit, peer-reviewed agencies such as Canadian Institute of Health Research, Canadian Health Services Research Foundation, National Institutes of Health, etc.
- **For-profit funding sources:** include pharmaceutical/medical device companies, biotechnology companies, etc.
- **Internally funded projects:** include those being wholly funded by the sponsoring RQHR department or principal investigator, including resident research projects.
- **Other:** includes projects not covered in the above categories (e.g., Health Quality Council projects, University of Regina student projects, grants in aid for non-peer reviewed projects).

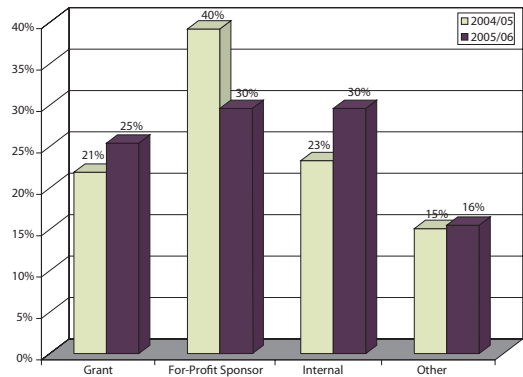


Figure 12: Funding Sources of Research Conducted in the RQHR

Approximately one-third (21) of the studies initiated in the Region in the 2005/06 fiscal year were funded by for-profit agencies, while 18 (25%) of the projects received peer-reviewed grant funding. Relative to 2004/05, a greater proportion of research is funded internally by the Regina Qu'Appelle Health Region.

## APPENDIX: Summary of 2005/06 Research Projects

**REB-05-09: A long-term, multicenter, open-label safety study with oral 20 or 40 mg/d doses of KW-6002 (istradefylline) as treatment for Parkinson's Disease.** *Investigator: Dr. F. Veloso (Neurology).*

**REB-05-12: Developing and piloting cross-cultural curriculum for delivery and utilization of End of Life health care services.** *Investigators: Dr. M. Hampton, Dr. A. Baydala, R. Boekelder (Aboriginal Health).*

**REB-05-13: Cardiac resynchronization therapy: cardiopulmonary and psychological effects.** *Investigators: Mr. C. Tomczak, and Drs. R. Haennel, G. Asmundson, and S. Korkola (Cardiosciences).*

**REB-05-14: Micronutrient intake of exclusively tube fed clients in long term care.** *Investigators: J. DeRoose, D. D'Ottavo (Nutrition).*

**REB-05-15: Decreasing time spent in ICU and/on mechanical ventilation through drainage of pleural effusions.** *Investigators: Drs. D. Jones, S. Lala, A. Lafontaine (Respiratory Medicine).*

**REB-05-16: Warfarin and coronary calcification.** *Investigator: Dr. H.A. Mohamed (Cardiosciences).*

**REB-05-17: An open-label extension study examining the safety and tolerability of memantine in patients with moderate to severe dementia of the Alzheimer's type having completed Study no. 10158.** *Investigators: Drs. F. Veloso, G. Asmundson, D. Larsen (Neurology).*

**REB-05-18: Creutzfeldt-Jakob Disease Surveillance System (CJD-SS).** *Investigators: Drs. N. Cashman, G. Jansen, C. Bergeron, M. Coulthart, D. Westaway (Centre for Infectious Disease Prevention and Control, Public Health Agency of Canada).*

**REB-05-19: Assessing and improving continuity of care.** *Investigators: Dr. H. Hadjistavropoulos, S. Garatt (Psychology).*

**REB-05-20: Professional role transition into acute-care by newly graduated baccalaureate female registered nurses.** *Investigators: J. Boychuk Duchscher, J. Profetto-McGrath (Nursing).*

**REB-05-21: A new approach to the earlier diagnosis of prostate cancer: a pilot project.** *Investigators: Dr. E. Paluck, Dr. A. Verma, J. Slater (Radiology).*

**REB-05-22: Menstrual function following hysteroscopic tubal occlusion with the Essure micro-coil system.** *Investigators: Drs. J. Thiel, H. Kamencic (Obstetrics/Gynecology).*

**REB-05-23: An investigation into the use of dexamethasone in palliative medicine by means of a retrospective chart study of 200 consecutive discharges.** *Investigator: Dr. L. Clein (Palliative Care).*

**REB-05-24: An international evaluation of the burden of illness of subfoveal, exudative age-related macular degeneration.** *Investigator: Dr. R. Garcia (Ophthalmology).*

**REB-05-25: A multicenter, randomized, open-label, assessor-blind, non-inferiority study comparing the efficacy and safety of once-weekly subcutaneous idraparinux (SR34006) with adjusted-dose oral vitamin-K antagonists in the prevention of thromboembolic events in patients with atrial fibrillation.** *Investigators: Drs. R. Zimmermann, G. Garbe (Cardiology).*

**REB-05-26: A 12-week, double-blind, placebo-controlled, parallel group study to assess the efficacy and safety of ropinirole XR (extended release) in patients with restless legs syndrome.** *Investigator: Dr. G. Sridhar (Neurology).*

**REB-05-27: Patient perspectives on acceptable waiting times for hip and knee replacement surgery.** *Investigators: Dr. T. Noseworthy, Dr. B. Conner-Spady, Dr. C. Sanmartin (Orthopaedics).*

**REB-05-28: The accuracy of patient weights used for the dosing of weight-based pharmacologic agents in acute coronary syndrome.** *Investigators: Dr. W. Semchuk, A. Marcil, N. Bidwell, A. Slopek, O. Siwic, A. Reaume (Pharmacy).*

**REB-05-29: Innovations in nurse retention and patient centred care.** *Investigators: Dr. D. Bournes, Dr. M. Ferguson-Pare, D. Larrivee (Nursing).*

**REB-05-30: Palliative patients and their health services utilization in the Regina Qu'Appelle Health Region.** *Investigators: Dr. A. Leis, J. Porter (Palliative Care).*

**REB-05-32: Implementation of a Diabetic Care Flow Sheet to improve adherence to the 2003 Diabetic Care Guidelines.** *Investigators: Drs. L. Irvine, B. Oroz, J. Kuzmich (Family Practice).*

**REB-05-33: Functional impact assessment of disability study.** *Investigators: Dr. R. MacLennan, H. Switzer, J. Redekop, T. Blackmore (Psychology).*

**REB-05-34: Stop spit! An interactive spit tobacco education and cessation resource for Saskatchewan grade 9 students.** *Investigators: C. McConnell, G. Ford, B. Ing, L. Leugner, J. Tejszerski (Public Health).*

**REB-05-35: Metabolic efficiency with ranolazine for less ischemia in non-ST elevation acute coronary syndromes: an randomized, double-blind, parallel-group, placebo-controlled, multinational, clinical trial to evaluate the efficacy and safety of ranolazine versus placebo in patients with non-ST segment elevation acute coronary syndromes.** *Investigators: Drs. R. Zimmermann, R. Mikhail (Cardiosciences).*

**REB-05-36: Exploring strategies for work/life balance in health care employees in Canada.** *Investigators: J. Okroj, and Drs. K. Dorsch, A. Hayford, L. Hoeber (Public Health).*

**REB-05-37: Evaluation of energy and protein requirements for surgery, sepsis, and inflammatory bowel disease.** *Investigators: J. Bunney, L. Hilkewich, H. Reimer, J. Striha, R. Nasser (Nutrition).*

**REB-05-38: Admission of individuals to the Regina General Hospital with an acute stroke: a retrospective chart audit of adherence to the 2003 Canadian Diabetes Association Guidelines for Type 2 Diabetes in those individuals admitted with an acute stroke and who also have type 2 diabetes.** *Investigators: Drs. C. Dumitrescu, A. Bibi, C. Zagozeski (Family Practice).*

**REB-05-39: Clinical evaluation of tissue oxygenation and flap viability in patients undergoing pedicled and free microvascular skin flap harvest and transplantation using the ODISsey Tissue Oximeter.** *Investigator: Dr. P.S. Chang (Plastic Surgery).*

**REB-05-40: Improving the quality of drug management of Saskatchewan seniors in long-term care: evaluation of a quality improvement initiative.** *Investigators: Dr. G. Teare, T. Verrall, L. Gander (Pharmacy).*

**REB-05-41: What are the unspoken team values of the Regina General Hospital Pharmacy operations that allow it to operate as a high performing team?** *Investigators: D. Sellinger, K. Maas (Pharmacy).*

**REB-05-42: TRIGR Ancillary Study.** *Investigator: Dr. G.D. Carson (Obstetrics/Gynecology).*

**REB-05-43: Predictable results and experience in diabetes through intensification and control to target: an international variability evaluation.** *Investigator: Dr. S. Lwanga (Family Practice).*

**REB-05-44: A 52-week, open-label study to assess the long-term safety of ropinirole extended release (XR) in patients with Restless Legs Syndrome (RLS).** *Investigator: Dr. G. Sridhar (Neurology).*

**REB-05-45: Cardiovascular effects of NSAIDs/COX2s in patients with serious coronary heart disease (SR 05-007).** *Investigators: Dr. M. Stang, C. Varas, W. Ray, L.A. Garcia Rodriguez (Population Health).*

**REB-05-46: Public health managers' perspectives on the use of social marketing among public health nurses in Saskatchewan.** *Investigators: K. Knibbs, L.L. Stampler (Public Health).*

- REB-05-47: Prescribing and monitoring of warfarin during the transition of care from the hospital to the community.** *Investigators: A. Reaume, L. Sulz, A. Marcil, Dr. W. Semchuk (Pharmacy).*
- REB-05-48: Review of perforated duodenal ulcers treated non-operatively at RGH.** *Investigators: Drs. G. K. Kaban, S. Bharadwaj, R. Cameron (General Surgery).*
- REB-05-49: Incidence, detection, and management practices of gastric GISTs in the RQHR.** *Investigators: Drs. R. Cameron, S. Bharadwaj (General Surgery).*
- REB-05-50: Zinc supplementation and weight gain in anorexia nervosa patients.** *Investigators: J. Bert, M. Classen, A. Kapp (Nutrition).*
- REB-05-51: A clinical trial evaluation of a pain management program for seniors with dementia.** *Investigators: Dr. T. Hadjistavropoulos, P. Hunter (Psychology).*
- REB-05-52: Age-based norms and psychometric data for measures of pain related disability and interference.** *Investigator: Dr. R. Martin (Psychology).*
- REB-05-53: Wegener's granulomatosis and cardiac manifestations.** *Investigator: Dr. J. Fitzgerald (Internal Medicine).*
- REB-05-54: The effect of a public smoking ban on prevalence, behaviours, and attitudes in Saskatchewan.** *Investigators: Dr. T. Diener, Dr. M. Hennink, Dr. Z. Abbas, P. Greaves, J. Ayer (Public Health).*
- REB-05-55: Birth control usage and failure in women presenting for termination of pregnancy.** *Investigators: Drs. T. Banerjee, J. Guillemain (Obstetrics/ Gynecology).*
- REB-05-56: Comparison of the safety and efficacy of a unique intravenous iron preparation (VIT-45) versus oral iron in the treatment of anemia in non-dialysis dependent chronic kidney disease.** *Investigators: Drs. S. Karunakaran, M. Abdulhadi (Nephrology).*
- REB-05-57: Open label extension study evaluating the long term safety, tolerability and efficacy of an iron maintenance dosing strategy utilizing intravenous VIT-45 in the treatment of anemia in non-dialysis dependent (NDD) chronic kidney disease (CKD).** *Investigators: Drs. S. Karunakaran, M. Abdulhadi (Nephrology).*
- REB-05-58: A 52-week multicenter, open-label, observational study to evaluate the effect of losartan 50 mg, losartan 100/12.5 mg, losartan100-25 on plasma glucos metabolic parameters, blood pressure and safety in hypertensive patients with metabolic syndrome.** *Investigators: Dr. S. Arndt, Dr. G. Achyuthan (Family Practice).*
- REB-06-01: A phase 3 study to evaluate the efficacy and safety of TAK-390MR (60 mg QD and 90 mg QD) and an active comparator, lansoprazole (30 mg QD) on healing of erosive esophagitis.** *Investigators: Drs. S. Arndt, G. Achyuthan, K. Kontsiotis, D. Cutts (Family Practice).*
- REB-06-02: A phase 3 study to evaluate the safety and efficacy of TAK-390MR (60 mg QD and 90 mg QD) compared to placebo in maintenance of healing in subjects with healed erosive esophagitis.** *Investigators: Drs. S. Arndt, G. Achyuthan, K. Kontsiotis, D. Cutts. (Family Practice).*
- REB-06-03: Improving the care pathways of breast cancer patients in Saskatchewan.** *Investigators: Dr. K. Willoughby, M. Rathgerber, B. Chan (Diagnostic Imaging).*
- REB-06-04: A survey to assess quality of life after radiation therapy of prostate cancer patients treated at Saskatchewan Cancer Agency (SCA) and review of retrospective data.** *Investigator: Dr. K. Jones Joseph (Cancer Services).*
- REB-06-05: Evaluation of effectiveness of a heparin nomogram utilized in the treatment of stroke.** *Investigators: S. Poulin, N. McGill, T. Patel (Pharmacy).*
- REB-06-06: Coping with anxiety while waiting for hip replacement surgery.** *Investigators: J. Janzen, Dr. H. Hadjistavaropoulos (Psychology).*
- REB-06-07: Evaluation of stress factors for energy and protein requirements in patients with burns, HIV/AIDS, and short bowel syndrome currently used in the RQHR.** *Investigators: R. Nasser, J. Granquist, B. Mansuy, J. Bert, K. Karst (Nutrition).*

**REB-06-08: Critical evaluation of stress factors, energy and protein requirements in patients with leukemia, head and neck cancer, lung cancer, and hepatic failure currently used in the RQHR.** *Investigators: R. Nasser, L. Allan, A. Gibb, D. Vanleuken (Nutrition).*

**REB-06-09: Pragmatic randomized trial of risperdal\* costa\* versus oral atypical antipsychotics in poorly adherent subjects with schizophrenia in a routine care setting.** *Investigator: Dr. D. Natarajan (Psychiatry).*

**REB-06-10: Electronic Schizophrenia Treatment Adherence Registry (e-STAR) Study.** *Investigator: Dr. D. Natarajan (Psychiatry).*

**REB-06-11: Extension of the OASIS 5 timing of intervention sub-study for patients included after enrolment to the main OASIS 5 study ends: An international randomized trial of early versus delayed invasive strategies in patients with non-ST segment elevation acute coronary syndromes.** *Investigator: Dr. R. Zimmermann (Cardiology).*

**REB-06-12: Abdominal Compartment Syndrome: a review of cases at the Regina General Hospital.** *Investigators: Drs. K. Kvinlaug, R.D.A. Cameron, S. Meiers (Surgery).*

**REB-06-13: Number of Essure coils within the uterine cavity at the time of placement and success of ultrasound determination of coil position at 3 months post-procedure.** *Investigators: Drs. J. Thiel, R. Pierson, A. Malik (Obstetrics/Gynecology).*

**REB-06-14: Cost-effectiveness of the Essure tubal sterilization procedure in an ambulatory setting.** *Investigators: Drs. J. Thiel, G. Carson (Obstetrics/Gynecology).*

**REB-06-15: A multicenter, double-blind, randomized study to establish the clinical benefit and safety of Vytorin (Ezetimibe/Simvastatin tablet) vs simvastatin monotherapy in high-risk subjects presenting with acute coronary syndrome (IMPROVED Reduction of Outcomes: Vytorin Efficacy International Trial - IMPROVE IT).** *Investigators: Drs. R. Zimmermann, R. Mikhail (Cardiosciences).*

**REB-06-16: Merkel cell carcinoma of the skin.** *Investigator: Dr. P. Tai (Cancer Services).*

**REB-06-17: Cost effectiveness of outpatient total laparoscopic hysterectomy.** *Investigator: Dr. J. Thiel (Obstetrics/Gynecology).*

**REB-06-18: Core stability and cognitive intervention: A pilot project for children with developmental coordination disorder.** *Investigators: K. Kane, L. McFetridge, J. Sluser (Physical Therapy).*

**REB-06-19: Qualitative evaluation of a Continuity of Care Checklist.** *Investigators: Dr. H. Hadjistavropoulos, S. Garratt, K. Spice (Psychology).*

**REB-06-20: Aqueous humour penetration of the fourth generation fluoroquinolone antibiotics in eyes undergoing cataract surgery - a follow-up study to determine if increasing the concentration of the antibiotics in the wick improves its penetration.** *Investigator: Dr. L. Ong-Tone (Ophthalmology).*

**REB-06-21: Prevention of cerebrovascular and cardiovascular Events of ischemic origin with teRutroban in patients with a history of ischemic stroke or transient ischaemic attack. The PERFORM Study. An international, randomized, double-blind, two parallel group study comparing terutroban 30 mg o.d. versus aspirin 100 mg o.d. administered orally for a 3-year mean duration (event driven trial).** *Investigator: Dr. F. Veloso (Neurology).*

**REB-06-22: Comparison of the effects noted in the apoB/apoA-1 ratio using rosuvastatin and atorvastatin in patients with acute coronary syndrome.** *Investigators: Drs. R. Zimmermann, G. Garbe (Cardiology).*

**REB-06-23: Carotid endarterectomy: Are two surgeons better than one?** *Investigators: Drs. D. Kopriva, N. Thakur; D. McCarville (Cardiothoracic Surgery).*

**REB-06-24: Validity of the nutrition screening tool implemented at the DAC.** *Investigators: R. Nasser, M. Koshinsky, G. Garcia, B. Simpkins (Nutrition).*



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