



2003 ANNUAL REPORT

of the

REGINA QU'APPELLE HEALTH REGION

RESEARCH ETHICS BOARD

Issued December 2004

by

Dr. Elan Paluck
Chair, RQHR Research Ethics Board



Research Ethics Board

2003 Annual Report

Regina Qu'Appelle Health Region
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I. Purpose of the RQHR 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.

II. Background

The RQHR REB was established in 1998. Its main functions are 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 that is being 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.

The RQHR REB is responsible for the review of biomedical and behavioural research projects:

- *Biomedical research* involves protocols with medically invasive procedures, physical interventions, surgical procedures including the collection of blood or other specimens, and the use of permanent 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

Research Ethics Board

decision regarding approval of *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 or patient surveys for example, are reviewed through an expedited process using the Chair and/or a sub-committee of REB members.

The REB makes a decision on each research proposal it reviews, resulting in one of four possible outcomes:

- **Approval:** A *Certificate of Approval* is issued for a term of one year.
- **Provisional Approval:** The study is approved pending some requested modifications or clarifications. The REB Chair grants final approval when the concerns addressed to the researchers in the *Notice of Provisional Approval* have been satisfactorily addressed.
- **Deferral or Resubmit:** Based on the documentation provided by the researcher, the REB is unable to make a decision. The decision is deferred until the next meeting at such time as the researchers submit supplementary information or documentation as specified by the REB.
- **Not Approved:** The REB does not authorize the conduct of the research in the RQHR.

Investigators are required to submit an annual status report to the REB and may maintain the REB Certificate of Approval for up to five years without seeking re-approval from the Board.

III. Membership

The REB includes a minimum of five 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 2003 REB are listed in Table 1.

Table 1 2003 RQHR Research Ethics Board Membership List (as of Dec 31/03)

Dr. Elan Paluck , Research Scientist Research & Performance Support Regina Qu'Appelle Health Region <i>Chair, RQHR REB</i>	Ms. Jordana Ball , Director South Regional Leadership Centre Canadian Diabetes Association <i>Community member</i>
Dr. Krishna Kumar , Head Section of Neurosurgery Regina Qu'Appelle Health Region <i>Physician</i>	Mr. Francis Loos , Clinical Development Educator, Day Surgery Regina Qu'Appelle Health Region <i>Nurse</i>
Dr. David Elliot , Assistant Professor Department of Philosophy and Classics University of Regina <i>Ethicist</i>	Mr. Timothy MacLeod , Senior Counsel Saskatchewan Government Insurance <i>Lawyer</i>
Ms. Marilee Allerdings , Utilization Analyst Research and Performance Support Regina Qu'Appelle Health Region <i>Researcher</i>	Dr. William Semchuk , Manager Clinical Pharmacy Services Regina Qu'Appelle Health Region <i>Pharmacist</i>
Dr. Patrick Duffy Department of Internal Medicine Regina Qu'Appelle Health Region <i>Physician</i>	Rev. Dan Cooper , Chaplain Palliative Care Services Regina Qu'Appelle Health Region <i>Clergy</i>

RQHR Research Ethics Board Members who Retired in 2003

Dr. Derrick K. Larsen , Executive Director Research and Performance Support Regina Qu'Appelle Health Region <i>Chair, RQHR REB</i>	Mr. Mark Sagan , Research Associate Research and Performance Support Regina Qu'Appelle Health Region <i>Researcher</i>
Dr. Dennis Alfano , Professor Department of Psychology University of Regina <i>Researcher, Professional Psychologist</i>	

IV. Statistics¹

a. Requests for Ethical Review

The RQHR REB processed 464 requests for ethical review in 2003 (see Figure 1). These requests included the review of new applications, renewal of ongoing projects, amendments to the protocol of ongoing projects, and adverse event (AE) reports.

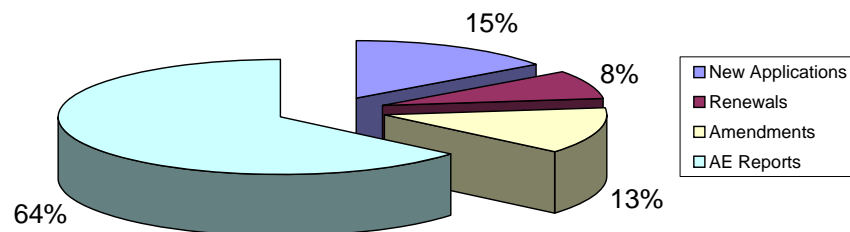


Figure 1: Requests for Ethical Review in 2003 (N = 464)

b. Description of New Project Applications

The REB reviewed 78 new project applications in 2003 (Figure 2). Relative to 2002, there were increases in the overall number of applications reviewed, as well as a shift in the type of applications reviewed, with substantially more biomedical applications being reviewed. A list of the new project applications reviewed by the REB in 2003 is included in the appendix.

¹ All statistics presented in this report reflect the 2003 calendar year of January 01 2003 to December 31 2003. Subsequent Annual Reports will provide statistics that reflect the RQHR's fiscal reporting period.

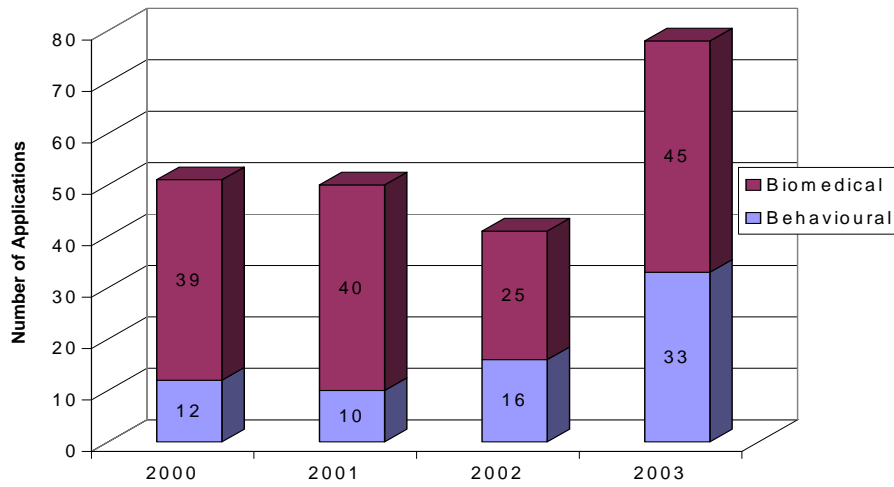


Figure 2: New Project Applications

The process for reviewing applications varies according to the level of risk that a research subject could experience as a result of the particular type of research procedure used. Minimal risk studies are reviewed by the REB Chair and/or a sub-committee of its members. Moderate- to high-risk studies are reviewed at a full Board meeting. Figure 3 displays the proportion of reviews requiring full Board and expedited reviews.

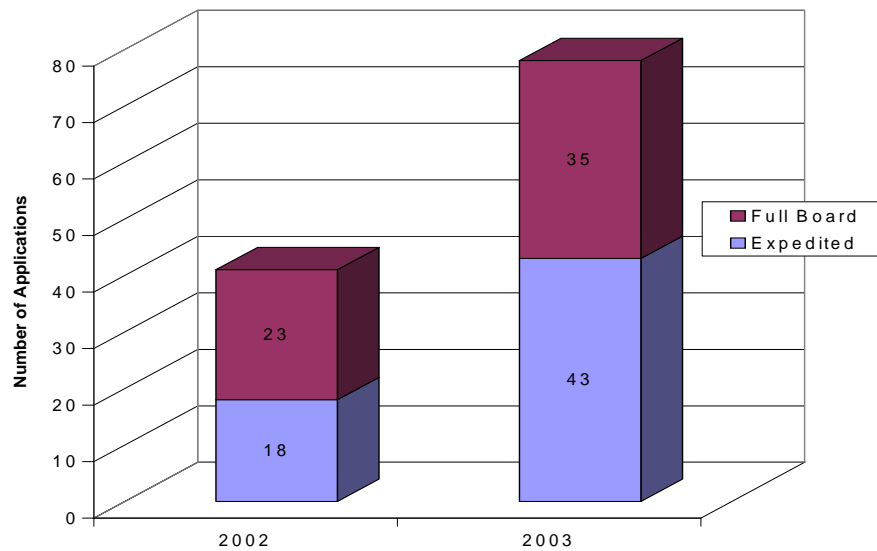


Figure 3: Review of New Project Applications

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c. Protocol Amendments

Once a study has been granted ethical approval, any changes to the protocol must be reviewed and approved by the REB. Minor protocol changes are approved in an expedited manner by the REB Chair, while substantive changes that may potentially pose greater risks for research subjects are reviewed by the full Board. All of the 57 protocol amendments submitted in 2003 were classified as minor protocol amendments (Figure 4).

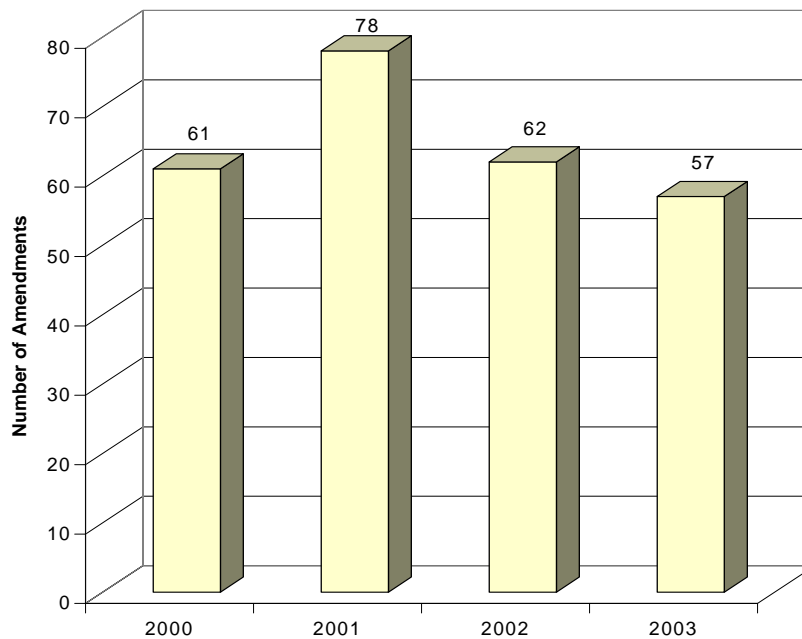


Figure 4: Number of Protocol Amendments Reviewed

d. Adverse Event (AE) 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. During the course of a study, all AEs and SAEs must be reported to the appropriate regulatory authorities and the local REB (even if

they occurred at a research site outside the RQHR). In 2003, 302 AEs were processed and reviewed by the REB (Figure 5). Of these 302, nine SAEs occurred within the RQHR and none were deemed to be causally linked to the study drug or therapy.

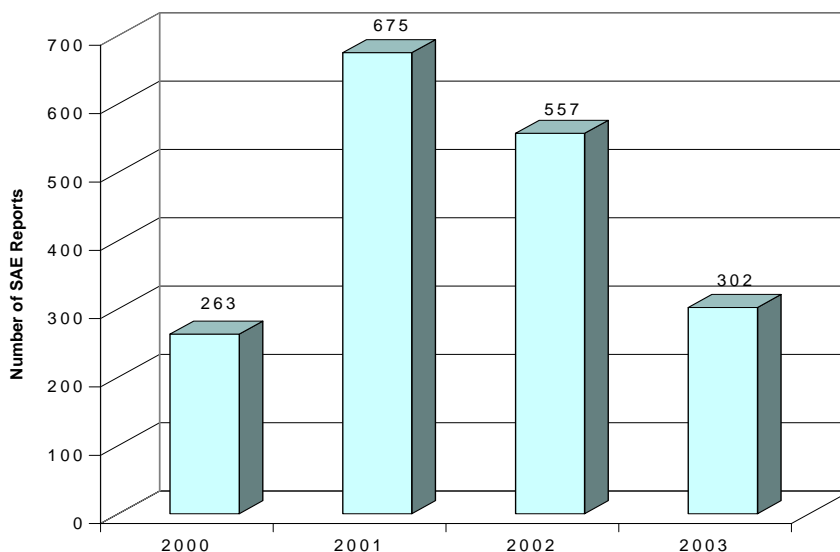


Figure 5: Number of SAE Reports Reviewed

e. Disposition of Projects Reviewed

Approval was granted to 19 (25%) of the projects reviewed in 2003. The majority of studies (66%), however, were granted *Provisional approval*, requiring minor modifications to the protocol or consent form before receiving final approval. Seven (9%) of the applicants were required to resubmit the entire protocol and provide additional information for a second full review of their project by the Board.

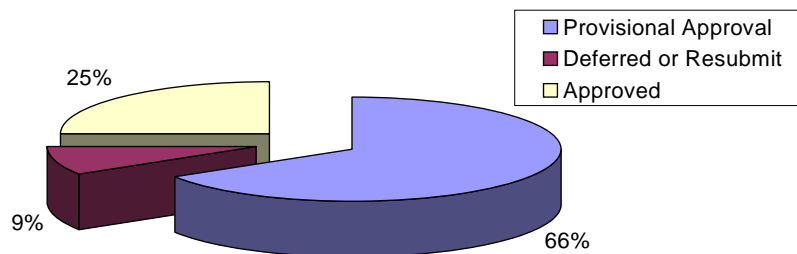


Figure 6: Disposition of 2003 REB Review (n =73)

f. Timelines for Studies Reviewed at Full Board Meetings

In 2003, 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 7.0 (Figure 7). 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. The median timeline for receiving a NER in 2003 exceeds the 2002 timeline of 4.0 business days. This difference likely reflects the change in the volume of applications reviewed by the REB.

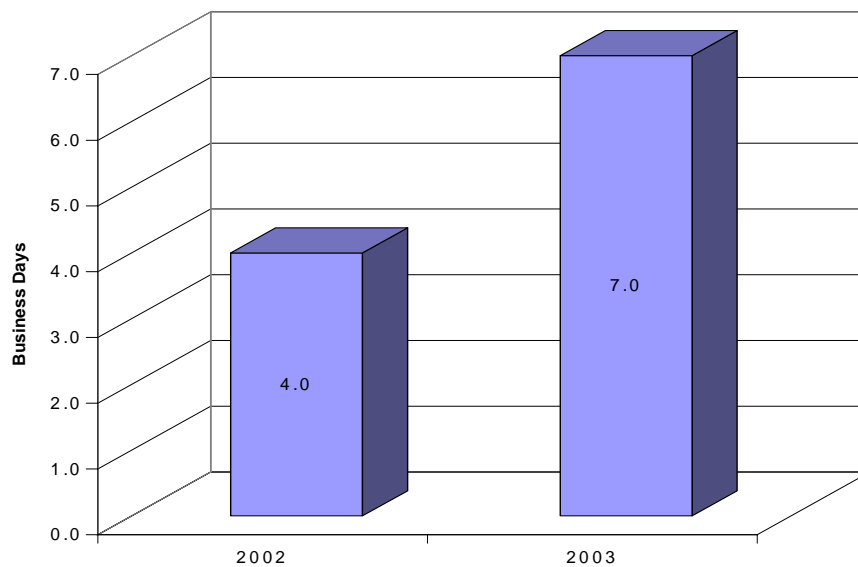


Figure 7: Median number of Business Days from Full Board Review to Notice of Ethical Review

g. 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 10.0 in 2003 (Figure 8), which is down from the 2002 value of 11.5 business days. While the number of days from which a study was received to the date it was reviewed dropped substantially since 2002 (7.5 versus 3.0 days), the number of days required to issue the NER increased (4.0 versus 7.0 days).

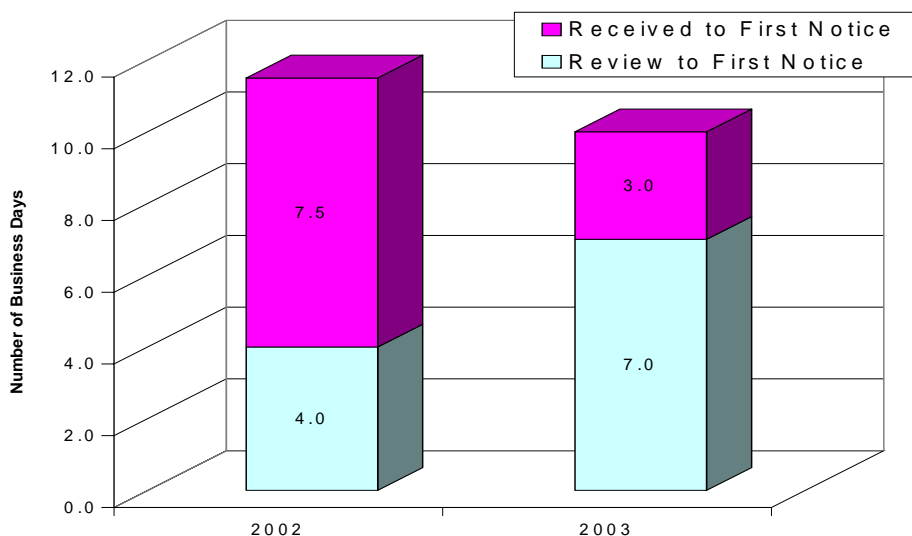


Figure 8: Median Number of Business Days Required for an Expedited Review

h. Proportion of Projects Receiving a Notice of Ethical Review within Five Business Days

Receiving timely information from the REB regarding the status of an application under review is of paramount importance to researchers. While there does not exist a universally agreed upon time frame that is considered reasonable, other Canadian REBs have adopted standards ranging from five to seven business or calendar days.

Figure 9 below reveals that 40% of the applications reviewed by the RQHR REB in 2003 received a *Notice of Ethical Review* within five working days. This number is down from 2002, where almost 57% of applicants received notification within that same time period.

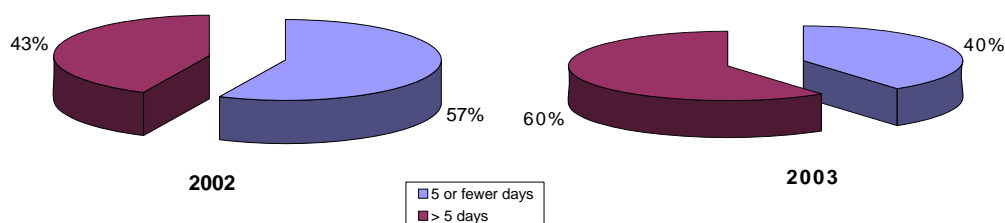


Figure 9: Proportion of Investigators Issued a Notice of Ethical Review within Five Business Days

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V. Additional Activities

Education

Two training sessions were provided in 2003 to introduce pharmacy and family medicine residents to the RQHR's research policies, requirements for completing RQHR application forms, and preparing consent forms.

Guidance

Through RQHR Research and Performance Support (RPS), researchers may receive assistance in preparing submissions for ethical review. Preliminary reviews of research applications by the RPS staff greatly reduce the number of revisions that the REB requires subsequent to the official review of the project.

VI. Financial Summary for 2003

Revenue	1998	1999	2000	2001	2002	2003	2004/05
Fees Collected ¹	10,500	3,500	4,250	3,700	10,500	3,000	9,000

Direct Expenses	1998 ²	1999 ²	2000 ²	2001 ²	2002	2003	2004/05
Committee expenses	--	--	--	--	1,591	2,029	
Education	--	--	--	--	00	96	00

¹ The review fee is only collected for industry-sponsored applications (\$500 for RQHR studies and \$1,000 for office-based studies)

² Figures not available

VII. Challenges for 2004 and Beyond

The year 2003 brought many changes for the RQHR REB in terms of the volume of research applications and in the type of applications requiring review. Coupled with the rapidly evolving standards in research ethics, the RQHR REB is presented with a set of challenges for 2004 and beyond.

New Application Forms and Guidance Notes

Current REB application forms and accompanying guidance notes require a revision. The revision must reflect current RQHR policies and facilitate the efficient review of a protocol, without being cumbersome to the applicant. A revised form is being drafted and is scheduled to replace the current application forms in 2005.

Separation of Research Ethics Review from Research Impact Review

New procedures separating the 'RQHR Impact Review' from the review of applications for ethical acceptability are required. An updated policy and procedure manual outlining these and other changes is required.

Resources

Financial resources are required to build infrastructure and provide educational opportunities such as workshops for RQHR investigators and REB members. This type of outreach serves to develop a research ethics culture within the RQHR and is considered to be a *best practice* among REBs.

APPENDIX: Summary of 2003 Research Projects

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-01 Patient-physician relationships of aboriginal and non-aboriginal peoples with diabetes	Ms. Allisson Quine Dr. H. Hadjistavropoulos	University of Regina Department of Psychology	Behavioural	1/13/03 by Full Board	1/28/03	In progress
REB-03-02 Anticoagulant therapy practices in cataract surgery	Dr. Lindsay Ong-Tone Dr. E. Paluck	Regina Qu'Appelle Health Region	Behavioural	1/13/03 by Full Board	3/5/03	In progress
REB-03-03 A 24-Week, Multi-Center, Randomized, Double-Blind, Placebo-Controlled Evaluation of the Efficacy, Safety and Tolerability of Donepezil Hydrochloride (E2020) in Patients with Dementia Associated With Cerebrovascular Disease	Dr. F. Veloso Drs. Asmundson, Larsen	Office-based	Biomedical	1/13/03 by Full Board	3/21/03	In progress
REB-03-04 A phase II, double-blind, randomized, dose-ranging, placebo-controlled, multicenter, safety and efficacy evaluation of three doses of NS 2330 in patients with mild to moderate dementia of the Alzheimer's type	Dr. F. Veloso	Office-based	Biomedical	1/13/03 by Full Board	2/14/03	In progress
REB-03-05 The Pharmacist as a Primary Care Team Member: A comparison of usual care versus pharmacists in primary care practices on the acceptance and appropriateness of pharmacists'	Dr. William Semchuk S. Neubauer, Y. Shevchuk	Regina Qu'Appelle Health Region Clinical Pharmacy Services	Behavioural	1/10/03 by Expedited	1/17/03	In progress
REB-03-06 Efficacy and safety of Drotrecogin Alfa (activated) in adult patients with early stage severe sepsis	Dr. D. Jones Drs. Baird, Chan, Dobson, Betcher	Regina Qu'Appelle Health Region (SDRI) Surgical Intensive Care Unit	Biomedical	1/21/03 by Expedited	2/24/03	In progress
REB-03-07 The fear-avoidance model applied to cardiac rehabilitation	Dr. Kim Dorsch Dr. G. Asmundson	University of Regina Faculty of Kinesiology and Health Studies	Behavioural	2/10/03 by Full Board		Resubmit

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-08 Control of Hypertension in Pregnancy Study: The pilot trial	Dr. G.D. Carson	Regina Qu'Appelle Health Region Department of Obs/Gyne	Biomedical			by Full Board Awaiting application
REB-03-09 Palliative Care Services Client Quality of Life Survey	Rev. Dan Cooper V. Clark, J. Bowman, B. Deets, M. Sagan, D. Wiszniak	Regina Qu'Appelle Health Region Palliative Care Services	Behavioural	2/10/03	2/19/03	by Full Board In progress
REB-03-10 High-fibre Study in the Long Term Care Setting	Ms. Erin McNaughton K. Klein, J. Shea, R. Nasser	Regina Qu'Appelle Health Region Nutrition and Food Services	Biomedical	2/10/03	2/11/03	by Expedited In progress
REB-03-11 Chart Audit of Utilization of Risk Assessment and Prophylaxis of Venous Thromboembolism in Acutely ill Medical Patients in Canada - RGH	Dr. William Semchuk	Regina Qu'Appelle Health Region Clinical Pharmacy Services	Biomedical	2/17/03	3/3/03	by Expedited Closed 3/19/04
REB-03-12 Chart Audit of Utilization of Risk Assessment and Prophylaxis of Venous Thromboembolism in Acutely Ill Medical Patients in Canada - Pasqua Hospital	Ms. Susan Poulin	Regina Qu'Appelle Health Region Pharmacy Services	Biomedical	2/17/03	2/21/03	by Expedited In progress
REB-03-13 Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance	Dr. R. Zimmermann	Regina Qu'Appelle Health Region (SDRI) Cardiac Care Unit	Biomedical	2/17/03	3/6/03	by Expedited In progress
REB-03-14 A Causal Model of Depression for Rehabilitation Clients with Chronic Low Back Pain	Ms. Gloria Lee Steve Jacobson, FRP	University of Wisconsin-Madison RQHR Functional Rehabilitation Program	Behavioural	3/10/03		by Full Board Provisional Approval
REB-03-15 Enhancing Practice and Programs in the Family Medicine Unit (Regina)	Ms. Gail Greenberg Bathgate, Bradel, Butler-Jones, Ganshorn, Gruszczynski, Huntley, Jones, Kuzmicz, Lawrence, Mahood, Shabotoski, White, Zagozeski	U of S and Regina Qu'Appelle Health Region Family Medicine Unit	Behavioural	3/10/03	3/27/03	by Full Board In progress

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-16 Direct Statin Comparison of LDL-C Values: An Evaluation of Rosuvastatin Therapy: An open-label, randomized, multicentre, phase IIIb/IV, parallel group study to compare the efficacy and safety of rosuvastatin, atorvastatin and simvastatin in patients with type IIa and IIIb hypercholesterolaemia	Dr. S.S. Mann	Regina Qu'Appelle Health Region MEDEC	Biomedical	3/10/03	5/23/03	In progress
REB-03-17 A prospective, randomized, controlled study to evaluate the effectiveness and cost-effectiveness of spinal cord stimulation using the Synergy System in reducing pain in patients with failed back surgery syndrome compared to conventional medical management	Dr. K. Kumar	Regina Qu'Appelle Health Region Neurosurgery	Biomedical	3/10/03	3/24/03	In progress
REB-03-18 End-of-life health care delivery: Completing the circle in aboriginal and conventional medicines	Dr. Mary Hampton A. Baydala, D. Wiszniak, R. Boekelder	University of Regina, Luther College RQHR Palliative Care; Aboriginal Health	Behavioural	3/10/03	5/13/03	In progress
REB-03-19 Incorporating Aboriginal ways of knowing, healing, and culture into health professions' education programs and health service delivery in Saskatchewan	Mr. Rick Kotowich Dr. Marlene Smadu	Regina Qu'Appelle Health Region Working Together Towards Excellence Project	Behavioural	2/26/03		Closed 11/20/03
REB-03-20 An open label non-comparative protocol for the emergency use of Voriconazole (UK 109,496) in patients with life-threatening invasive mycoses who are failing on currently available antifungal agents	Dr. K. Sivaratnam	Regina Qu'Appelle Health District Infectious Diseases Clinic	Biomedical	3/4/03	3/4/03	In progress
REB-03-21 Client perceptions of past weight loss attempts	Ms Natalie Ferrara Joel Sanden, Janelle Striha	Regina Qu'Appelle Health Region Nutrition & Food Services	Behavioural	3/6/03	3/12/03	In progress
REB-03-22 A phase 3, randomized, double-blind, comparative trial of Micafungin versus placebo as preemptive prophylactic antifungal therapy in patients in the Intensive Care Unit	Dr. D. Jones	Regina Qu'Appelle Health Region (SDRI) Intensive Care Unit	Biomedical	3/14/03	3/28/03	In progress
REB-03-23 A randomized trial of educational interventions in implementing Clinical Practice Guidelines for nutrition support in the critically ill	Ms. Stephanie Cook	Regina Qu'Appelle Health Region Clinical Nutritional Services	Behavioural	3/14/03	3/19/03	In progress

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-24 Direct Statin Comparison of LDL-C Values: An Evaluation of Rosuvastatin Therapy	Dr. R. Zimmermann	Regina Qu'Appelle Health Region (SDRI) Cardiac Care Unit	Biomedical	3/21/03	3/21/03	by Expedited In progress
REB-03-25 A quantitative analysis: Chronic substance abuse and frequent utilization of Regina Emergency Department services	Ms. Cynthia Hawes	University of Regina, Faculty of Graduate Studies RQHR Emergency Department	Behavioural	3/25/03	4/16/03	by Expedited In progress
REB-03-26 Dietary intervention for hyperlipidemia: How does it affect folate, vitamin B6 and B12?	Ms. Roseann Nasser S. Cook	Regina Qu'Appelle Health Region Clinical Nutrition Services	Biomedical	3/26/03	3/27/03	by Expedited In progress
REB-03-27 Revealing the voices of experience: Insights of Registered Nurses	Ms. Liz Domm G. Donnelly, M. Leurer	SIAST RQHR Nurses	Behavioural	3/21/03	11/20/03	by Expedited In progress
REB-03-28 Validation of two postpartum screening scales in a sample of Saskatchewan's First Nations and Metis women	Ms. Pamela J. Beattie	University of Regina, Luther College RQHR Gyne/Obs	Behavioural	4/14/03	5/1/03	by Full Board In progress
REB-03-29 Implementation and evaluation of a Pain Assessment Program for seniors (Case Coordination)	Dr. T. Hadjistavropoulos H. Hadjistavropoulos, K. Craig, R. Martin	University of Regina Department of Psychology	Behavioural	4/14/03	4/30/03	by Full Board In progress
REB-03-30 A multicenter, randomized, double-blind, parallel group, placebo-controlled, clinical evaluation of Rosiglitazone in combination with Glimeperide compared to Glimeperide plus placebo for 24 weeks in subjects with Type 2 Diabetes Mellitus who are inadequately controlled on non-TZD oral monotherapy	Dr. S.S. Mann	Regina Qu'Appelle Health Region MEDEC	Biomedical	4/14/03	Resubmit	by Full Board Closed 5/23/03
REB-03-31 Analysis of discrepancies between implanted and recommended types of pacemakers in the Regina Health District	Dr. I. Mota Dr. O. Schussler	Regina Qu'Appelle Health Region, and U of S Family Medicine Unit	Biomedical	4/1/03	4/1/03	by Expedited In progress

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REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-32 A long-term, open-label, flexible study of the efficacy and safety of Sumanriole in patients with idiopathic restless legs syndrome	Dr. G. Sridhar	Regina Qu'Appelle Health Region (SDRI) Sleep Disorders Program	Biomedical	4/7/03	4/29/03	by Expedited In progress
REB-03-33 Universal versus selective screening for gestational diabetes mellitus in the Regina Qu'Appelle Health Region: A retrospective chart review	Dr. Domenica Tambasco Drs. G.D. Carson, K. Lawrence	Regina Qu'Appelle Health Region and U of S Family Medicine Unit	Biomedical	4/16/03	4/22/03	by Expedited In progress
REB-03-34 Implementation and evaluation of a Pain Assessment Program for seniors (Community Assessment)	Dr. T. Hadjistavropoulos H. Hadjistavropoulos, K. Craig, R. Martin	University of Regina, Dept of Psychology RQHR Community Services	Behavioural	5/12/03	6/12/03	by Full Board In progress
REB-03-35 Patient knowledge of self-care activities in CHF	Dr. William Semchuk D. Kuntz	Regina Qu'Appelle Health Region Clinical Pharmacy Services	Behavioural	5/12/03	6/18/03	by Full Board In progress
REB-03-36 Ethnocultural affiliation, gender and cardiovascular disease management	Dr. Kathryn M. King	University of Calgary, Faculty of Nursing RQHR Aboriginal patients, Cardiac Rehab Program	Behavioural	5/12/03	7/15/03	by Full Board In progress
REB-03-37 Evaluation of symptom relief provided by esomeprazole 40 mg once daily in subjects with non-heartburn dominant endoscopy negative dyspepsia: A placebo-controlled randomized trial	Dr. Susanne Arndt Dr. Dickson, McHattie, Gorman, Carter	Office-based	Biomedical	3/28/03		by Expedited Not required
REB-03-38 A double-blind, placebo-controlled, parallel, multicenter study on Extended VTE prophylaxis in acutely ill patients with prolonged immobilization	Dr. P. Duffy	Regina Qu'Appelle Health Region (SDRI) Internal medicine	Biomedical	4/17/03	5/23/03	by Expedited In progress
REB-03-39 Characteristics of Pregnant Substance Abusers and the Pregnancy Outcome in a Prairie City Hospital	Dr. Shanthy Thamilvaanan Drs. S. Senthilmohan, S. Mahood, G. Carson	Regina Qu'Appelle Health Region and U of S Family Medicine Unit	Behavioural	5/13/03	5/23/03	by Expedited In progress

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-40 Addressing the value of primary angioplasty after combination therapy or eptifibatide monotherapy in acute myocardial infarction	Dr. R. Zimmermann	Regina Qu'Appelle Health Region (SDRI) Cardiac Care Unit	Biomedical	5/14/03	7/15/03	by Expedited Closed 11/19/03
REB-03-41 Women's Recovery from Sternotomy	Ms. Coby Scheidt	Regina Qu'Appelle Health Region Cardiac Surveillance Unit	Behavioural	6/9/03		by Full Board Provisional
REB-03-42 A Phase II, Randomized, Double-Blind, Placebo-controlled, Dose-response Study of the Efficacy and Safety of Sumanrole in Patients with Idiopathic Restless Legs Syndrome	Dr. G. Sridhar	Regina Qu'Appelle Health Region (SDRI) Sleep Disorders Program	Biomedical	5/29/03	6/12/03	by Expedited In progress
REB-03-43 Active Safety Surveillance Plan to Prospectively Monitor the Incidence of Pure Red Cell Aplasia (PRCA) Among Patients Receiving Epoetin Alfa Therapy or Other Erythropoietins	Dr. Siva Karunakaran Dr. M. Abdulhadi	Regina Qu'Appelle Health Region Renal Unit	biomedical	6/9/03	8/25/03	by Full Board In progress
REB-03-44 A Phase 3, Randomized, Double-blind, Placebo-controlled, Multicenter Trial to Evaluate the Safety and Efficacy of BMS-298585 in Combination with Metformin Therapy in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Metformin Therapy Alone	Dr. S.S. Mann	Regina Qu'Appelle Health Region MEDEC	Biomedical	6/9/03		by Full Board Revise/Resubmit Closed 11/5/03
REB-03-45 Enoxaparin and Thrombolysis Reperusion for Acute Myocardial Infarction Treatment - Thrombolysis in Myocardial infarction - Study 25. A randomized, double-blind, double-dummy, parallel group, multinational, clinical study to evaluate the efficacy and safety of Enoxaparin versus Unfractionated Heparin in patients with acute ST-segment elevation myocardial infarction receiving fibrinolytic therapy	Dr. R. H. Zimmermann Dr. J. Javier	Regina Qu'Appelle Health Region Cardiac Care Unit	Biomedical	5/29/03	5/30/03	by Expedited In progress
REB-03-46 Evaluation patients' experiences with Bupropion SR (Zyban) for smoking cessation in ambulatory family medicine practice	Dr. Lili Naghdi	Regina Qu'Appelle Health Region and U of S Family Medicine Unit	Behavioural	6/4/03	7/25/03	by Expedited In progress

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REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-47 An International Randomized Double-Blind Study evaluating the Efficacy and Safety of Fondaparinux versus Enoxaparin in the Acute Treatment of Unstable Angina/non-ST-segment Elevation MI Acute Coronary Syndromes	Dr. R. Zimmermann Dr. Garbe	Regina Qu'Appelle Health Region (SDRI) Cardiac Care Unit	Biomedical	6/9/03	7/15/03	by Expedited In progress
REB-03-48 Characteristics of Saskatchewan women having repeat therapeutic abortions	Dr. G. Laxdal Dr. M. Lees, Dr. T. O'Carroll	Regina Qu'Appelle Health Region and U of S Family Medicine Unit	Behavioural	9/8/03	11/19/03	by Full Board In Progress
REB-03-49 Evaluation of the RQHR Lipid Clinic	Ms. Roseann Nasser S. Cook, B. Semchuk	Regina Qu'Appelle Health Region Clinical Nutrition Services	Behavioural	6/16/03	6/26/03	by Expedited In progress
REB-03-50 Correlation between HPV genotype, integration status and expression of HPV genes with the malignant transformation in cervical exfoliate cell samples.	Mr. Nick Antonishyn	University of Regina RQHR, Gyne/Obs	Biomedical	7/15/03	8/26/03	by Expedited In progress
REB-03-51 An open-label extension evaluating the safety of Eplerenone in patients with heart failure	Dr. R. Zimmermann	Regina Qu'Appelle Health Region (SDRI) Cardiac Care Unit	Biomedical	7/16/03	8/26/03	by Expedited In progress
REB-03-52 Aggressive reduction of inflammation stops events. Reduction of vascular inflammation and coronary atherosclerosis, with AGI 1067, a V-protectant, reduces cardiovascular events in patients with coronary artery disease	Dr. V. Gebhardt	Regina Qu'Appelle Health Region (SDRI) Cardiology	Biomedical	7/24/03	10/3/03	by Expedited In progress
REB-03-53 Perioperative Ischemic Evaluation Study	Dr. P. Duffy	Regina Qu'Appelle Health District Internal Medicine	Biomedical	9/8/03	11/19/03	by Full Board In progress
REB-03-54 Problem Stealing Behaviour in 8 to 11 Year Old Boys: Examining the Role of Social Cognition	Ms. Della Hunter	U of Regina, Social Work RQHR, Child and Youth Services	Behavioural	9/8/03	10/15/03	by Full Board In progress

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-55	Dr. Raul Garcia	Regina Qu'Appelle Health Region Ophthalmology	Biomedical	9/8/03	10/15/03	In progress
Triamcinolone acetonide as an adjunctive treatment to Verteporfin therapy in neovascular age-related macular degeneration: A randomized, placebo-controlled clinical trial			by Full Board			
REB-03-56	Dr. Raul Garcia	Regina Qu'Appelle Health Region Ophthalmology	Biomedical	9/8/03	10/15/03	Closed
A phase IIIB randomized, double-masked, active controlled, dose-ranging, multicenter comparative trial, in parallel groups, to compare the safety and efficacy of intravitreal injections of EYE001 (Pegaptanib sodium, Macugen TM) given every 6 weeks for 102 weeks, to PDT with Visudyne(R), in patients with exudative age-related macular degeneration (AMD)			by Full Board			12/5/03
REB-03-57	Dr. Donna Holton	Regina Qu'Appelle Health Region Infectious Disease Clinic	Biomedical	8/27/03	9/5/03	In progress
Long term impacts of severe West Nile virus infection: A cohort study			by Expedited			
REB-03-58	Dr. F. Veloso Dr.s. G. Asmundson, D. Larsen	Office-based	Biomedical	10/14/03	11/6/03	In progress
Phase II multicentre, randomized, double-blind, placebo-controlled study of the effect of daily treatment with MPC-7869 on measures of cognitive and global function in subjects with mild to moderate dementia of the Alzheimer's type with optional, follow-on, double-blind, MPC-7869 treatment after Month 12			by Full Board			
REB-03-59	Dr. F. Veloso	Office-based	Biomedical	10/14/03	11/6/03	In progress
Prevention regimen for effectively avoiding second strokes: A double-blind, active and placebo controlled study of Aggrenox(R) vs. clopidogrel with and without Micardis(R)			by Full Board			
REB-03-60	Ms. Joanne K. Shymkiw	University of Regina, Dept of Psychology RQHR, Functional Rehabilitation Program	Behavioural	9/11/03	9/25/03	In progress
Readiness to self-manage chronic pain: Individual and relational factors			by Expedited			
REB-03-61	Dr. G.D. Carson	Regina Qu'Appelle Health Region Department of Obs/Gyne	Behavioural	9/18/03	9/22/03	In progress
Practice Enhancement Program - Assessors Evaluation			by Expedited			
REB-03-62	Dr. F. Veloso	Office-based	Biomedical	11/10/03		Provisional
A randomized, double-blind, parallel-group study examining the efficacy and safety of Memantine on behavioural symptoms in patients with moderate to severe dementia of the Alzheimer's type			by Full Board			

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REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project	Date Reviewed	Initial Date Approved	Status at Dec 31, 2003
REB-03-63 A 24 week, multicentre, randomized, double-blind, placebo-controlled study of the efficacy, tolerability and safety of Donepezil (ARICEPT(R) in Parkinson's Disease patients with dementia	Dr. F. Veloso	Office-based	Biomedical	11/10/03	by Full Board	12/18/03 In progress
REB-03-64 A 52-week, multicentre, open label extension study of the safety, tolerability and efficacy of Donepezil (ARICEPT(R)) in Parkinson's Disease patients with Dementia	Dr. F. Veloso	Office-based	Biomedical	11/10/03	by Full Board	12/18/03 In progress
REB-03-65 An open-label, multicenter, one-year extension of the evaluation of the safety of Donepezil Hydrochloride (E2020, ARICEPT(R)) in patients with dementia associated with cerebrovascular disease	Dr. F. Veloso	Office-based	Biomedical	11/10/03	by Full Board	Provisional
REB-03-66 Evaluating a mentoring program for new Registered Nurse graduates, RQHR	Dr. Marlene Smadu Dr. Derrick Larsen	University of Saskatchewan, College of Nursing RQHR RNs	Behavioural	11/7/03	by Expedited	11/10/03 In progress
REB-03-67 The assessment of family needs following acquired brain injury: A rural/urban perspective in Saskatchewan	Ms. Heather Murray Dr. Bonnie Jeffery	University of Regina, Faculty of Social Work RQHR, Sask South ABI Outreach Program	Behavioural	11/5/03	by Expedited	11/18/03 In progress
REB-03-68 An exploration of interactions that occur between nurses and adolescent mothers	Ms. Roberta Evans Dr. Margaret McKinnon	University of Regina, Faculty of Education RQHR, Public Health	Behavioural	11/5/03	by Expedited	11/26/03 In progress
REB-03-69 Psychometric testing of a new measure of "lay" caregiving for adults receiving dialysis	Dr. Martha E. (Beth) Horsburgh G. Laing, L. Harwood, H. Beanlands, S. Fox, S. Beckermann, C. Thrasher	University of Saskatchewan, College of Nursing RQHR, Renal Program	Behavioural	11/5/03	by Expedited	11/14/03 In progress
REB-03-70 Southern Saskatchewan/Urban Aboriginal Health Coalition: Exploring culturally respectful care in Aboriginal communities for innovation and improvement in health professions education and health service delivery	Dr. Marlene Smadu R. Kotowich, C. Bourassa	University of Saskatchewan, College of Nursing RQHR, Aboriginal Health	Behavioural	12/8/03	by Full Board	Provisional

REB Number and Title	Primary Co-Investigators	Organization/Department	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical by Full Board Pending Review
REB-03-71 Introduction of the Group B Streptococcal Rapid Assay to Regina Qu'Appelle Health Region	Dr. G.D. Carson Dr. E. Thomas, M. Kanchana	Regina Qu'Appelle Health Region Department of Obs/Gyne	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical by Full Board Pending Review
REB-03-72 Impact of a Collaborative Care Model in a Medication-Optimisation Clinic: A Randomized, Standard-care controlled, Prospective Study	Dr. Tejal Patel Dr. W. Semchuk	Regina Qu'Appelle Health Region Clinical Pharmacy	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical 12/8/03 by Full Board Revise/Resubmit
REB-03-73 An active safety surveillance plan to conduct serologic testing for anti-erythropoietin antibodies and prospectively monitoring the incidence of pure red cell aplasia (PRCA) among patients receiving Epoetin Alfa or another erythropoietin	Dr. Siva Karunakaran	Regina Qu'Appelle Health Region (SDRI) Nephrology	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical 11/16/03 by Expedited 11/25/03 In progress
REB-03-74 A phase IIIb-IV, randomized, open-label trial evaluating the efficacy and safety of tenecteplase together with unfractionated heparin prior to early PCI as compared to standard primary PCI in patients with acute myocardial infarction	Dr. R. Zimmermann Dr. Garbe; Dr. P. Duffy	Regina Qu'Appelle Health Region (SDRI) Cardiac Care, Internal Medicine	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical 11/25/03 by Expedited 12/2/03 In progress
REB-03-75 Prophylactic Heparin during Xigis(R) (Drotrecogin Alfa (activate)) treatment of high-risk severe sepsis	Dr. D. Jones Drs. J. Baird, J. Dobson, J. Chan, J. Betcher, E. Gibbings	Regina Qu'Appelle Health Region (SDRI) Intensive Care Unit	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical 12/5/03 by Expedited 12/5/03 In progress
REB-03-76 ADVIA Centaur HIV 1/0/2 Evaluation Protocol	Dr. Greg Horsman	Sask Health Laboratory Medicine	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Biomedical 12/18/03 by Expedited 12/18/03 In progress
REB-03-77 Regina Family Study	Ms. Lynn Loutzenhiser	University of Regina, Dept of Psychology RQHR, Public Health Nursing	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Behavioural by Expedited Awaiting review
REB-03-78 A community-based approach to understanding the health promoting and disease preventing needs in a rural Saskatchewan community	Dr. Elan Paluck M. Allerdings, H. Dorgan, T. Wilkins, K. Kealy	Regina Qu'Appelle Health Region Research & Performance Support	Type of Project Date Reviewed Initial Date Approved Status at Dec 31, 2003	Behavioural 12/23/03 by Expedited Provisional