



WILLIAM
OSLER
HEALTH
CENTRE

ETOBICOKE GENERAL HOSPITAL
PEEL MEMORIAL HOSPITAL
BRAMPTON CIVIC HOSPITAL

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Here for you... caring for you

RESEARCH PROGRAM ANNUAL REPORT 2005/6

Mission Statement

"To identify and promote Clinical Research as a significant commitment, strength and approach at William Osler Health Centre in our quest to provide leading-edge, evidence-based patient care".

1. Introduction and Background

This is the first annual report of the WOHC Research Program and is based on data from Jan 1st 2005 to March 31st 2006. The 2006/7 report will reflect a true fiscal year from April 1st 2006 to March 31st 2007. A history of research participation at both Etobicoke General Hospital and Peel Memorial Hospital exists from the early 1980's. In the spring of 2003, it was decided to begin the infrastructure development to sustain a cost-neutral participation in research clinical trials. Corporately, both an ethicist and a coordinator of the clinical research program were hired.

2. Program Functions

- **Infrastructure Development**

Policies on "Research at WOHC" and "Cost Neutrality" of Studies have been written and approved by the Research Ethics Board (REB) and the Corporate Ethics Committee and are now on the way to the Senior Team and the Medical Advisory Committee.

Forms were developed and approved by the Research Ethics Board on Applications for Study Review, Amendment Review Requests, Applications for Annual Renewal, Request for Invoice from Finance Department, and Overhead Percentage Distribution.

With the help of Planning and Decision support, Microsoft Access has been used to create a **Data-Base Management** Tool to begin a data base file for the studies and associated information and contacts, to enable appropriate reporting and tracking thus saving laborious task repetition.

A cost-neutral **agreement** for transparency of REB review costs, overhead and monetary distribution through the WOHC finance department has been achieved with the Oncology Group of Physicians.

The Coordinator of Clinical Research now **manages** two personnel working in the Oncology Research Program – the Oncology Study Nurse was transferred from the Oncology Program and a new position of Oncology Research Assistant has been created through a five year grant from the Ontario Cancer Research Network.

- **Consulting**

24 consultations have been carried out regarding research and the Research Ethics Board processes between both sites of Osler with physicians and study coordinators.

- **Communications**

Internal

- A Research Folder on Q drive was initiated in 2005 to provide hospital staff with access to the Research Ethics Board policies and forms.
- A Research Page on the Oslernet went live in March 2006, containing information on Research at Osler, Research Policy, The Research Ethics Board and associated processes and forms, a study review flowchart, a copy of the Annual Report, related links and a Frequently Asked Questions feature.

External

The next step will be a Research Link on the Osler website to service queries from external physicians and research organizations.

- **Funding**

The operating budget has been largely supported by the Medical Program but in the last year revenue from overhead of sponsored studies is beginning to fund the program. Much of this overhead is based on per patient study enrollment and is received upon patients reaching pre-determined milestones in the study and can be distributed over several years of the study. Additionally, a grant for \$214,200.00 over 5 years was obtained from the Ontario Cancer Research Network to assist in increasing the number of oncology patients accrued to clinical trails and the employment of the necessary staff to service these open studies, thus growing the Oncology Research Program.

- **Contract Review and Negotiation**

All sponsored Clinical Trials have a 3 way (Sponsor, Principal Investigator and Institution) contract that is reviewed by the Office of Clinical Research with input from the hospital attorney. Both REB approval and contract approval are required to happen before a sponsored study is opened and patients are enrolled.

Turnaround time from receipt of contract by Office of Clinical Research and return of contract with areas identified for negotiation or approval to execute for final printing for signing has been reduced and is presently approximately 2 to 4 weeks depending on complexity of contract and negotiations.

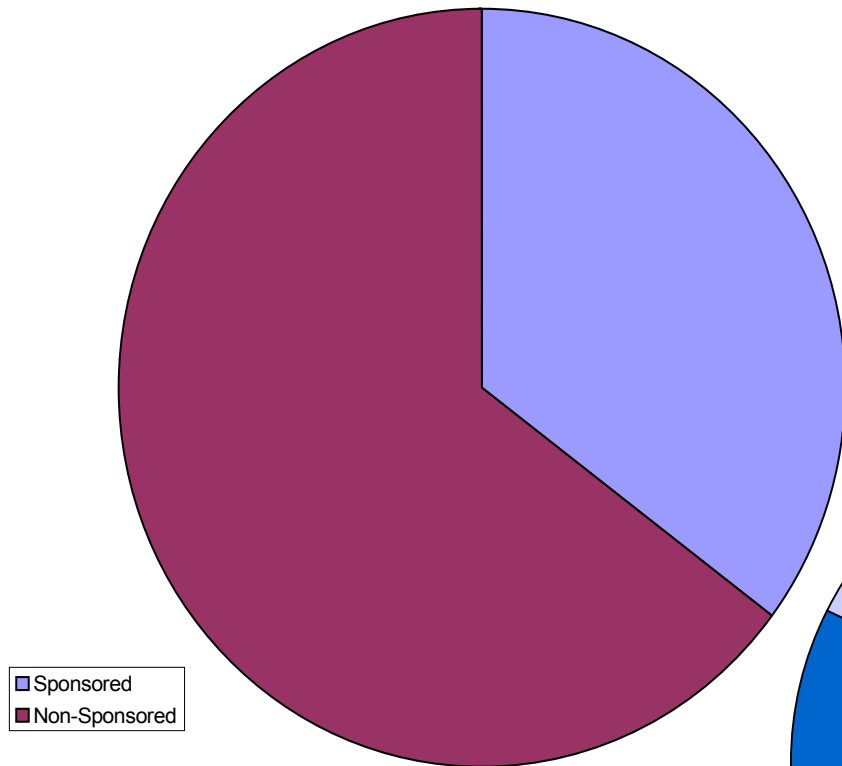
- **Clinical Trails opened in 2005/6**

A total of 34 clinical trials have been opened with 22 non-sponsored trails and 12 sponsored trials through reviews by the full Research Ethics Board or Expedited Review. The sponsored studies involve Eli Lilly, Aventis, Roche (Genentech), Bristol-Meyers-Squibb, WEX, Astra Zeneca, Novartis, Sanofi Canada, Pfizer, Janssen/Ortho, Ortho Biotech, Bayer, Amgen and Schering-Plough Pharmaceutical Companies. The non-sponsored studies include physician and principal investigator initiated studies as well as studies from the University of Waterloo,

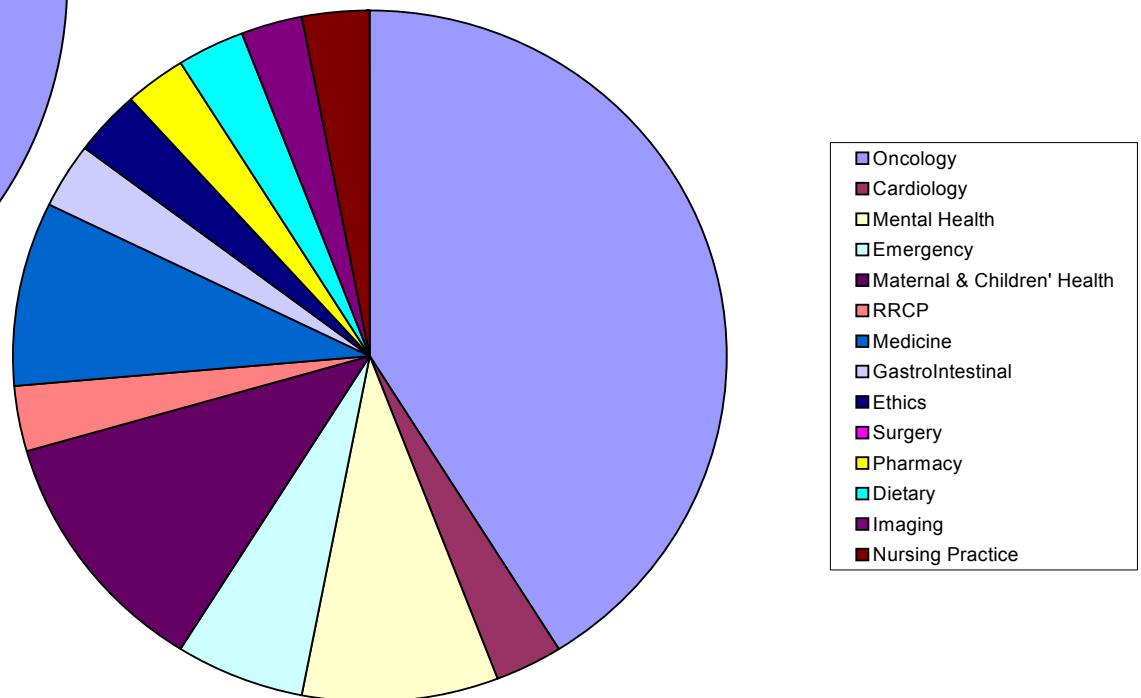
- Clinical Trails opened in 2005/6 continued...**

European Organization for Research and Treatment of Cancer (EORTC), the University of Western Ontario, the Institute for Clinical Evaluative Sciences (ICES), the National Cancer Institute of Canada (NCIC), Halton Health Care, the University of Alberta, MacMaster University, Queen’s Cancer Research Institute, Osler Pharmacy Program, the Hospital for Sick Children, and the Toronto Western Hospital of the University Health Network. Study and Suspected Adverse Event (SAE) Monitoring, as well as amendment reviews and annual renewals are ongoing once a trial is opened.

Sponsored and Non-Sponsored Studies



WOHC Program Involvement



- **Research Ethics Board (REB) Support**

The mandate of the REB is to ensure that all research involving human subjects carried out at William Osler Health Centre meets the highest scientific and ethical standards prior to activation; and to ensure safeguards are developed which provide the greatest protection to patients and members of the community who serve as research subjects. It is conducted in accordance with hospital policies and the "Tri Council Policy Statement: Ethical Conduct for Research Involving Humans" taking into consideration the ethical standards for the various professions represented, the standard reflected in the bioethics literature and the personal and community values as represented by the REB members. The REB is mandated to approve, reject, propose modifications to, or terminate any proposed or ongoing research.

The REB has representation from Chaplaincy, Nursing, Advanced Practice Nursing, Ethics, Medicine, Pharmacy, Health Information Management, Privacy Specialist and the Community.

The REB meets regularly on the 2nd Tuesday of each month for 2 hours. The Office of Clinical Research is responsible for supporting the REB through:

- Application receipt and review,
- Agenda and pre-reading package preparation and circulation,
- Meeting minutes and circulation,
- REB meeting follow-up and communications to applicants for study approvals, amendments, renewals,
- As part of the requirements to monitor research activity and individual open trials, suspected adverse events are reviewed and serious events are reported to the REB for further discussion and recommendation. This applies to trials opened this fiscal year as well as those previously opened and running for multiple years,
- Policy and Procedures development with REB input and approval. Policies have been written and REB approval received on; Expedited Reviews, Continuous Reviews, Cost Recovery and a draft policy on Genetic Research is under development.
- Capacity Building for REB Membership
 - Circulation for discussion of stimulating articles & video's involving ethics, science, research and pharmaceutical business practices,
 - Presentations and discussion with the Hospital Privacy Consultant on the new Personal Health Information Protection Act (PHIPA) and REB implications for the consent process of clinical trials,
 - Guest speakers from the Ontario Cancer Research Ethics Board (OCREB) introduced the concept of using the OCREB Research Ethics Board as "Board of Record" for selected qualifying inter-provincial studies,
 - Invitations to attend the University Health Network Issues in Clinical Research Speakers Series which is accredited by the Royal College of Physicians and Surgeons of Canada,
 - Canadian Association of Research Ethics Boards (CAREB) Membership and continuing education and conferences,
 - Encouragement for REB Members to take the 4 hour Tri-Council Policy Statement on-line Tutorial.

3. Future Challenges

- [Database entry for Office of Clinical Research](#)

Although the tool has been developed, time is limited for the actual data input and assistance is required.

- [Program Marketing](#)

Plans exist to partner with Dawne Dunn in Communications to increase the visibility of the Research Program within the Organization through articles in the Voice of Osler and other organizational communication tools.

A brochure is in the early design stages for physicians and principle investigators of other professions about how the Clinical Research Program works, how to access it, and how approvals are requested through the Research Ethics Board.

- [Equipment Upgrades](#)

As with all operational equipment, depreciation and upgrading is an issue for Personal Computers (those not on contracts with Information Systems), Software licensing, printers, photocopiers, fax machines etc. and are a cost to the Program as well as the purchase of new equipment for an expanding staff.

- [Physical Space](#)

Oncology Research Study Nurse and Assistant requested space for study monitors to use and a small office has been located in the basement of the PMH site but as oncology research and the whole corporate research program grows so will the space requirements. This office space requirement needs to be included in the planning for the Brampton Civic Hospital and the renovations to the existing Peel Memorial Hospital. File storage in the Clinical Research Office continues to be a challenge and more space is required for this office as well.

- [REB Membership and Recruitment](#)

The workload of being a REB member is heavy with at least 3 hours of preparatory study review as well as the 2-hour monthly meeting. It is important to keep the REB vital with interested and motivated members. A new pharmacy member and another Physician member were recently welcomed but we continue to seek a member from the hospital Board and from the community at large.

In conclusion, the past 3 years and especially the last one have seen significant progress in the development of the Research Program. This Program reaches all disciplines and practice areas of the organization as we strive to develop leading-edge technologies and empower WOHC staff and physicians so they may provide the best, evidence-based care for our patients. With the support of the senior team and all participants, continued research program growth will be rewarded by a greater satisfaction for Osler's staff, physicians and patients.

Respectfully Submitted,

Kathy Wortley
Coordinator, Clinical Research, March 22, 2006