Hamilton Health Sciences
Research Strategic Plan
2006 - 2011
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Obstetrics and Gynecology Research Program
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Strategic Plan

Institute for Gene Therapeutics
Intestinal Diseases Research Institute
McMaster Child Health Research Institute
Centre for Knowledge Transfer
Centre for Advanced Clinical Imaging
Infectious Disease Research Program
Obstetrics and Gynecology Research Program
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Strategic Priorities

Organization Structure
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  McMaster Child Health Research Institute
  Centre for Knowledge Transfer
  Obstetrics and Gynecology Research Program
Research Strategic Plan

Research activity at Hamilton Health Sciences is conducted in partnership with McMaster University to foster a culture of inquiry and provide support for development. The purpose of this plan is to develop research priorities for investments toward first, attracting and retaining excellent people who perform research in areas we lead or wish to further strengthen and second, developing and maintaining space, equipment, and other resources necessary to support the enhancement of research. This planned approach will be used to measure our success and progress using standard criteria, such as, publication record, grants, reference citations, and career investigator awards.

Mission

To advance excellence in health care through research and education to benefit the people and communities we serve. To share our knowledge by collaborating beyond borders and promoting the adoption of best practices within Canada and internationally.

Research Vision

Hamilton Health Sciences will be a world leader in advancing and creating new knowledge that informs patient care by bringing evidence into practice through translation and application.

Research Priorities

1) Consistent with, and is likely to enhance, the main clinical programs of Hamilton Health Sciences;
2) Multidisciplinary and collaborative (i.e. involves more than one department or program or healthcare discipline and institution); and
3) Builds on existing strengths.

Research Planning Principles

Research developments will:

1) Occur in collaboration with the Faculty of Health Sciences and other Faculties at McMaster University (refer to appendices A and B) and give consideration to related activities within the city of Hamilton;
2) Support and promote research programs which are of direct relevance to the clinical mission and strategic plan of Hamilton Health Sciences;
3) Allow flexibility in decision-making to react to opportunities (new funding initiatives, availability of excellent scientists);
4) Be pro-active in seeking out important new research areas that have the potential to enhance existing research and clinical programs; and
5) Strengthen research areas of high priority by recruitment or by linking them to strong research programs.

Most of our efforts will be directed towards consolidating and expanding existing research programs that comply with the principles described above.
Note: There are two necessary requirements for a flourishing research program. First, a critical mass of investigators and second an outstanding leader who has a commitment to research. Therefore, if a decision is made to develop research in an underdeveloped area that is a clinical priority, a concerted effort will be required to either recruit accomplished investigators or to train existing staff who have the potential and desire to become accomplished researchers. Alternatively, if the above isn’t possible, then consideration will be given to link an undeveloped area to a strong research program.

Research Paradigm

The framework for research activity adopted at Hamilton Health Sciences focuses on a view of the research process that is dependent on interaction between fundamental, translational, clinical, knowledge transfer and health services research platforms (Fig 1). While in reality, there are many overlaps and intersections, adopting this model helps clarify where individual research projects best fit within the research themes that are identified as areas of focus. In addition, this paradigm assists with describing the key strategic benefits derived from researchers interacting to pose better or more relevant questions within a research theme.

Figure 1

Research Development

Since Hamilton Health Sciences has multiple clinical sites, it is the expectation for research activities to continually interface with one another across sites, to enhance existing programs and/or create research networks through collaborations. Secondly, we are proposing to create a new Clinical Research Centre, a virtual research network across all Hamilton Health Sciences research sites established to accelerate the knowledge transfer process. This Centre will act as a resource, with strong alignments with McMaster University’s academic departments to ensure proven best practices for optimum health care delivery are communicated through education and adopted in practice.
Research Themes

Key research themes have been identified by hospital site. While the theme based research activities may occur across multiple sites the listing below captures HHS’ predominant research focus by site for strategic planning. The research areas that are well-established or strong developmental research units are shown in bold.

**Hamilton General Hospital Site**

- **Population Health Research Institute – Established**
  - Clinical trials in cardiovascular diseases and diabetes
  - Obesity and cardiovascular diseases
  - Prevention of atherosclerosis – a life course approach
  - Societal determinants of chronic diseases in developing countries
  - Psychosocial issues and health
  - Neurosciences – stroke and neurosurgery
  - Rehabilitation medicine and Orthopedic (trauma)

**Juravinski/Henderson General Hospital Site**

- **Henderson Research Institute (Circulation) - Established**
  - Thrombosis
  - Vascular biology including atherosclerosis
  - Clinical trials and clinical trials methodologies
  - Cancer and cancer/thrombosis interfaces (linked with Juravinski Cancer Centre)
  - Bone metabolism

- **Cancer Research Institute, Juravinski Cancer Centre - Developmental**
  - Clinical Trials in cancer
  - Bone Metastasis (mitochondria, photodynamic therapy & angiogenesis)
  - Health Services research
  - Advanced Therapeutic research (including Stem Cell Therapeutics)
  - Translational research in cancer
  - Musculoskeletal & Rehabilitation medicine
  - Orthopedic surgery

**McMaster University Medical Centre Site**

- **Institute for Gene Therapeutics – Established**
- **Intestinal Diseases Research Institute – Developmental**
  - Gastroenterology
  - Intestinal Inflammation
  - Infection

- **McMaster Child Health Research Institute – Developmental**
  - Pediatrics at McMaster Children’s Hospital & Offord Centre
  - CanChild
  - Neonatology
  - Metabolism
  - Pediatric Oncology
Infectious Disease
Centre for Knowledge Transfer
Centre for Advanced Clinical Imaging – Nuclear Medicine (animal imaging, PET)
Hematology (Hemostasis and Transfusion medicine)
Obstetrics and Gynecology

Research Strategic Planning Priorities

To summarize the key strategic activities are: building resources to provide additional physical space and related infrastructure to support demonstrated and continuing research growth; sourcing and providing operating funds and direct research support; and the provision or availability of base funding for research administration support to new or existing research groups. These areas of strategic priority for HHS research are identified by site below.

**Hamilton General Hospital Site:**

- Develop a new 165,000 square foot facility to accommodate expansion and relocation of the Population Health Research Institute and the Henderson Research Institute to an integrated Cardiac, Vascular and Stroke Research Institute.
- Expansion requiring large space available, additional recruitment and operational support with strong investments in:
  - Basic research in thrombosis, atherosclerosis and vascular biology
  - Animal facility to support basic research program in thrombosis, atherosclerosis and vascular biology
  - Population-based clinical studies
  - Population-based genetic studies and analyses
  - Bioengineering activities in blood-contacting devices
  - Research space (dry and wet laboratory) for new pain program
  - Biobank, Proteomics and Genetics
- Secure operating support for the relocations into the new facility allowing expansion in the following research focus areas:
  - Clinical research in thromboembolism
  - Expand population-based studies to include genomics and proteomics
  - Expand clinical research in stroke
  - Clinical research in obesity
  - Clinical research in metabolic diseases (diabetes, hyperlipidemia)
  - Clinical research in surgery

**Juravinski/Henderson General Hospital Site:**

- Develop an additional 25,500 gross square feet onto existing facility to accommodate expansion and relocation of existing research programs.
- Further develop and expand the Cancer Research Institute’s oncology research program in order to:
  - Support new and expanding research activity in the new space at the Juravinski Cancer Centre
  - Further expand oncology research when the new research facility at the General is in place and relocations have occurred.
  - Develop cell suite for stem cell therapies
Juravinski/Henderson General Hospital Site Continued:

- Expand the Orthopedic research program
  Support new and/or expand research activity in the Hamilton Arthroplasty Group
- Expand Vascular Biology and Atherosclerosis research programs in preparation for relocation to the Hamilton General Hospital

McMaster University Medical Centre Site:

- Expansion requiring space allocation, future recruitment and operational support for proposed centres of excellence and/or research institutes/programs:
  
  **New McMaster Child Health Research Institute to accommodate expansion and relocation of existing programs.**
  Support new and/or expand interfaculty, transdisciplinary research activities and training in basic, clinical and population research (a consortium of research units and academic departments within the faculties of Health Sciences and Social Sciences at McMaster University).

  **Programmatic expansion of Institute for Gene Therapeutics.**
  Support new and/or expand basic, clinical, and translational research activities in cancer, chronic inflammatory diseases and infectious diseases etc.

  **New Intestinal Diseases Research Institute**
  Upgrade and expand basic research labs
  Establish Clinical Research Centre to support translational research and interfaculty/transdisciplinary research and training
  Recruitment of investigator/scientists and expansion of clinical facilities

  **Expansion of Infectious Diseases Research Program**
  Programmatic and space expansion for emerging infectious diseases (West Nile, Influenza etc.) including population-based genetics research
  Support new and/or expand research activity to conduct large scale international clinical trials and development of national infectious diseases database
  Recruitment of investigator/scientists

  **Expansion of Molecular Radioimaging & Therapy Program (animal imaging & PET)**
  Recruitment of investigator/scientists
  New good manufacturing process facilities and pharmacology labs
  Update/redesign current nuclear medicine facilities to include capacity for phase I drug testing and multidiscipline assessment suite

  **Expansion of Obstetrics & Gynecology Research Program**
  Recruitment of investigator/scientists and project development to support new and/or expand research activities (Fetal Origins of Adult Diseases, Reproductive Endocrinology and Fertility, Gene Environment interactions)
**Hamilton Health Sciences (across all sites):**

- **New Centre for Optimum Healthcare Delivery** (Knowledge Translation Research Lab & Services). Hospital-based core will serve as a knowledge translation and application hub for citywide clinical research (Cardiovascular, Respiratory, Pediatrics, Oncology, Mental Health, Infectious Diseases and Digestive Diseases etc.) that links to external regional & global communities.

- Ongoing staffing and recruitment support for site-specific research plans. The hospital currently supports a number of initiatives for early-career research support through the New Investigator Fund and Hamilton Health Sciences Foundation Research Career Awards. The Hospital will also provide additional support for mid-career scientists.

- Establish funding to support equipment needs in high priority research areas across all sites. The Executive Council on Research, with advice from its Research Advisory Council, will make equipment determinations with respect to resources available and fund raising potential to support high priority research groups/areas of focus. An objective will be to establish an annual competition for funds and provide assistance and support for external application for equipment funds.
GUIDELINES FOR RELATIONSHIPS WITH RESEARCH INSTITUTES AND CENTRES

Scope:
These guidelines are applicable to those research institutes and centres created as a collaboration of the hospital and the university. While these guidelines do not preclude an affiliated hospital from establishing collaborative research groups under their sole jurisdiction, university regulations require formal review and approval where McMaster's name is part of the entity or where extra demand is made on university resources, faculty or students.

Definition:
A research institute or centre is defined as a major research group located at an affiliated teaching hospital that receives direct support from the hospital and the university.

Mandate:
Each research institute or centre shall have a clear, well-defined mandate including a statement of purpose or mission.

Financial and Infrastructure Support:
There shall be a written agreement between the hospital and the university with respect to the financial and infrastructure support (office space and research facilities) outlining the respective contributions of each institution prior to the establishment of a research institute or centre.

Name:
The hospital and the university shall participate in selection of the official title of the entity. Consistent with past practices, there shall be ascending hierarchy of terms from "research group" to "centre" to "institute" based on size, resources and reputation. Each institution’s name will be reflected in the official title of the institute or centre. There shall be appropriate identification of the hospital and university on all print and electronic materials using the institute or centre's name. Provisions can be made for naming of the research institute or centre after a major donor or benefactor. In this case, the hospital and university shall be described as co-sponsors of the research institute or centre in a descriptive footnote.

Legal Status:
Research institutes and centres of excellence shall be considered joint ventures of the hospital and the university. They shall not be separate legal entities and must operate within the existing legal structures, by-laws and rules and regulations of the sponsoring institutions. Research institutes and centres can propose the terms of contracts on behalf of the institutions but may only enter into contractual agreements as part of the hospital and the university which shall have the right to ensure that such contracts are in compliance will all applicable policies and not as an independent entity. Research institutes and centres shall not have the authority to engage debt or accumulate capital independently of the institutions.
Governance:
The senior policy-making structure for a research institute or centre shall be the "Institute/Centre Governing Body" with equal representation from the hospital and the university. The body shall typically be composed of the following positions:

- Director of the Research Institute
- Hospital President/CEO or delegate
- Hospital Vice-President, Research
- Faculty of Health Sciences Dean/Vice-President or delegate
- Faculty of Health Sciences Associate Dean, Research

Other individuals may be added to the governing body as appropriate to the circumstances. It may be appropriate to include the relevant Faculty Dean (or delegate) from Science, Engineering, Social Science or the Humanities depending upon the institute/centre’s mandate and/or other external parties.

The Governing Body’s duties and responsibilities shall include:

- Election of a Chair from among the Body members
- Defining the role description for the Director
- Recruitment and recommendation for appointment of the Director
- Approval of the strategic direction, annual business plan and operating budget
- Periodically reviewing the written progress report on research prepared by the Scientific Advisory Committee
- Periodically reviewing the educational contributions of the institute/centre

Dispute Resolution:
Disagreements or disputes shall, in the first instance, be resolved at the level of the governing body. Matters that cannot be resolved by the governing body shall be referred to the hospital/university liaison committee for resolution. Any subsequent conflict resolution shall follow the process outlined in the hospital university affiliation agreement.

Periodic Reviews:
A major review of the institute/centre shall be conducted periodically, normally once every five years in conjunction with the appointment of a director. The review shall examine the operation of the institute/centre with regard to its original mandate and its accomplishment. Where appropriate, the review may make recommendations on the appointment or reappointment of the director. A formal external review shall occur at ten-year intervals and/or prior to an external recruitment process. This review shall be consistent with the requirements of the sponsoring institutions.

Scientific Advisory Committee:
When desired by the director, a scientific advisory committee may be created as a sub-committee of the institute/centre governing body with membership composed of internal scientists and external experts appointed by the governing body. Normally, the director of the research institute/centre will serve as Chair of the Scientific Advisory Committee, although the governing body may choose to appoint an external expert as chair. Its mandate is to recommend the strategic direction of the institute/centre, advise on scientific quality of research, and to produce a periodic written research report for review by the institute/centre governing body.

Directorship:
The appointment of the director shall be a joint action of McMaster University and the Hospital. The appointment shall be made based on the recommendation of a search committee created in accordance with University Senate guidelines and any applicable
hospital guidelines with representation from the Institute, the Hospital and the University including:

- Hospital President/CEO or delegate
- Hospital Vice-President, Research
- Hospital Department Chief (as appropriate)
- Faculty of Health Sciences Dean and Vice-President or delegate
- Faculty of Health Sciences Associate Dean, Research
- University Department Chair (as appropriate)
- Representative(s) from physicians and scientists within the Institute
- Representative from the staff within the Institute

The director shall have joint accountability to McMaster University through the Dean/Vice-President or as delegated to the appropriate university department chair and to the hospital through the President/CEO or delegate. The director shall be responsible for establishing the goals and objectives for the institute/centre, its annual business plan and operating budget for approval by the governing body. The director shall also be responsible for annual scientific and financial reports to the university and the hospital, as well as any major donors.

**Term of Appointment:**
The director shall be appointed for a five-year term, renewable at the discretion of the institute/centre governing body based on the results of a review process with input from the scientific advisory committee. This review process shall focus on the success of the director in maintaining a high standard of research excellence for the Institute as determined by criteria measuring the support and development of productive, internationally recognized programs in leading-edge areas of research. This review process shall be carried out in conjunction with a periodic review of the institute/centre, as set out above.

**Position Description:**
The director shall have a formal position description drafted and agreed to by the institute/centre governing body. The rate of compensation and sources of funding for the position shall be determined by the Dean/Vice-President or as delegated to the appropriate University Department Chair and the Hospital President/CEO or delegate.

**Appointments to the Institute:**
The physicians and scientists in a research institute or centre shall hold faculty appointments in relevant university Department(s) or Schools and shall be accountable to their Departmental Chair/Associate Dean for their academic responsibilities.

Recruitment, appointment and hiring shall occur as a collaboration and respect normal approval processes of the hospital and the university. There shall be full disclosure of funding lines, both current and anticipated future support. Where individuals are recruited on external career awards (including CRC chairs), but anticipated to ultimately become the fiscal responsibility of the university department, there shall be an explicit agreement in advance with respect to funding of working notice and/or eligibility for university salary support upon expiry of the external award.

The director’s role shall include identifying potential candidates to join the research institute/centre drawing upon current physicians and scientists and through external recruitment. The director shall work collaboratively with the hospital chief and university chair during the search process. The final authority for faculty appointments shall remain with the university. The final authority for medical staff appointments shall remain with the hospital. Appointments to the research institute/centre shall be made by mutual
agreement of the hospital and university on the advice of the director. Any offers of appointment shall be made only after approval by both sponsoring institutions. For physician scientists, this approval shall also include compliance with the hospital’s physician resource plan, impact analysis and credentialing processes.

**Research Training:**
Research training is an important function of research institutes and centres. Physicians and scientists at the institute/center may be involved in the supervision of graduate students, research fellows and post-doctoral fellows subject to the established university guidelines.

**Educational Contributions:**
Educational contributions will be part of the responsibilities of the physicians and scientists in their role as faculty members. University department chairs shall remain responsible for monitoring the amount and quality of education provided by the members of the institute/centre. The Associate Dean (FHS), Graduate Studies as the delegate of the Dean, Graduate Studies shall retain the ultimate authority over graduate training.

**Research Overhead:**
A uniform research overhead policy has been developed through collaboration between the University, Hamilton Health Sciences, and St. Joseph’s Health Care. This policy shall be universally and consistently applied to all scientists working in affiliated research institutes and centres.

**Intellectual Property:**
Intellectual Property shall be governed by the Joint Intellectual Property Policy between the university and hospital.

**Research Contracts/Grants:**
Grant applications and contract proposals shall be reviewed and approved by the hospital and university prior to submission. Basic science, applied research contracts and clinical trial agreements shall be signed by the authorized agents of the hospital and the university.

**Human Resource and Financial Management Policies:**
Research institutes and centres shall abide by the relevant human resources and financial management policies of the hospital and the university in their daily operations.

**Sunset Clause:**
Research institutes and centres may be dissolved by mutual agreement of both parties. Either party may withdraw from participation in the research institute or centre with at least 12 months’ written notice and only with mutual agreement about severance and termination costs and the ongoing nature of the activities of the research group.

If the parties are unable to reach such mutual agreement on these issues, then matters in dispute between the parties shall be resolved pursuant to the dispute resolution process set out herein.
Appendix B

GENERIC TERMS OF REFERENCE FOR THE DIRECTOR OF A JOINT HOSPITAL/UNIVERSITY RESEARCH INSTITUTE/CENTRE

Reporting Relationship:
The director of an institute/centre that has been established jointly with approval from the hospital Board of Directors and the university Senate will be accountable to the hospital corporation through the President & Chief Executive Officer or delegate and to McMaster University through the Dean/Vice-President, FHS or as delegated to Departmental Chair as appropriate.

Responsibilities:
The responsibilities of the director include the overall leadership and vision of the institute/centre. The broad responsibility of the director is to nurture and strengthen the science of the institute/centre, and to interpret and implement policy advice of the Scientific Advisory Committee and the policy decisions of the institute/centre Governing Body. In carrying out this broad responsibility, the director will:

Research:
- Develop and articulate a vision and research mandate for the institute/centre
- Provide leadership to achieve standards of excellence in the institute/centre
- Communicate research and research training activities of the institute/centre to hospital and university departments
- Foster a collegial and interactive atmosphere that will support and enhance the research goals
- Act as an articulate spokesperson for the institute/centre locally, nationally and internationally and maintain a high visibility with granting councils and policy makers, in collaboration with the hospital and university
- Provide career guidance, mentoring and assistance in grant applications to members of the institute/centre
- Participate actively in the commercial development activities of the institute/centre, in compliance with hospital and university policies
- Interact with the clinical staff of the hospital to develop clinical research programs and foster the involvement of clinician-scientists in research

Human Resources:
- Recruit new health professionals and scientists, in collaboration with the hospital department chief and university department chair, and foster their development
- Work with McMaster University, affiliated teaching hospitals, and external stakeholders in the pursuit of research excellence

Education:
- Facilitate training opportunities for faculty and students in the areas of clinical and basic research
Management:
- Responsible for the management of the institute/centre (personnel, finance, purchasing, facilities, information systems) working within the relevant hospital and university structures
- Conduct an annual review of research activities with the institute/centre and provide an annual report on research to the governing body
- Develop annual research and operating budgets for the institute/centre and annual reports on the use of funds and resources provided by hospital and university to support the infrastructure
- Ensure the ethical conduct of research and the stewardship of funds for the institute/centre consistent with the mission of the institutions

Fundraising:
- Participate actively with the hospital and university foundations on the development and implementation of fundraising strategies needed to secure the necessary funding base for the Institute

Term of Appointment:
The director will be appointed for a five-year term, by the President/CEO of the hospital and the Dean/Vice President FHS, renewable for a further five-year term based on an independent external review, input from the Scientific Advisory Committee and subject to the availability of resources. This review process should focus on the success of the director in maintaining a high standard of research excellence for the Institute as determined by criteria measuring the support and development of productive, internationally recognized programs in leading-edge areas of research.
Appendix C

RESEARCH STRATEGIC PLAN WORKING COMMITTEES

HHS Research Strategic Plan and Development Plan:

B. MacLeod, VP Research & Corporate Development, Hamilton Health Sciences
S. Collins, FHS Associate Dean, McMaster University
J. Gauldie, Acting FHS Associate Dean, McMaster University

Research Advisory Council
A. Chan
S. Collins
S. Dore
M. Farrell
J. Gauldie
H. Gerstein
D. Henne
J. Hirsh
H. Holland
M. Levine
B. MacLeod
G. Singh
A. Snider
J. Weitz
J. Wright
S. Yusuf

General Site Research Development Plan:

C. Daniels
J. Gauldie
S. Gregoroff
P. Leonard
B. MacLeod
P. O’Byrne
J. Weitz
S. Yusuf

Juravinski/Henderson Site Research Development Plan:

B. Evans
J. Gauldie
M. Levine
B. MacLeod
G. Singh
A. Snider
J. Weitz

McMaster University Medical Centre (MUMC) Site Research Development Plan:

S. Collins
J. Capone
S. Dore
J. Gauldie
K. Gulenchyn
B. Haynes
M. Loeb
B. MacLeod
P. Steer
Hamilton Health Sciences Research Development Plan

Research Development Across All Sites

Research Themes

HHS Research Leadership
Centre for Optimal Healthcare Delivery
Research Support Services
  • Office of Integrated Research Services
  • HHS/McMaster Research Ethics Board
  • Intellectual Property Office
Executive Summary

Hamilton Health Sciences has created research site developmental plans for each acute care hospital location to ensure the unique needs of each site are addressed in association with its research themes. In addition to by-site development plans, HHS has included this overarching research developmental plan that encompasses the research support activities servicing all sites.

The research development across all sites includes establishing a unified leadership framework and decision-making body for all sites; creating a Centre for Optimum Healthcare Delivery that will integrate research and patient care activities; and ensuring research support services are effectively located accessible to service researchers needs.

In addition to creating a strong research leadership structure, HHS will ensure this new decision-making body endeavours to make resource allocation decisions consistent with the strategic priorities of each site developmental plan. Furthermore, this leadership will follow the Research Strategic Plan – Research Priorities and Research Planning Principles in making its resource allocation decisions.

Environmental Analysis

HHS Research Leadership

The strong research environment across HHS requires an integrated leadership structure that will ensure the activities of all sites are known to decision leaders. The hospital needs to reorganize its research decision-making structure to ensure Institute scientific leaders come together to discuss the activities occurring across sites. Furthermore, this leadership structure requires direct links to HHS’ senior leadership and McMaster University’s Faculty of Health Sciences. Other Faculty’s need to be involved as warranted for key research decisions that are multi-disciplinary. This leadership structure should be charged with making resource allocation decisions that will put into effect the HHS Strategic Plan and the site specific development plans.

Centre for Optimum Healthcare Delivery

As part of the HHS Strategic Plan, it is recognized that a new Centre for Optimum Healthcare Delivery, a virtual research network across all research sites needs to be established to accelerate the knowledge transfer process. This Centre would link research activities currently spread over multiple sites with the patient services and clinical organization. By linking key groups in related theme based disciplines, the Centre will be able to more quickly communicate new research evidence and support the timely adoption of new evidence-based medicine and best practices into the clinical setting. This Centre would represent HHS’ development resource center for knowledge transfer. Translation of evidenced-based medicine would be the Centre’s greatest challenge, and should draw upon models learned from other international institutes.
**Research Support Services**

Hamilton Health Sciences supports the research activities of its Institutes, Centres and Groups in affiliation with McMaster University. The support services of HHS include:

- Office of Integrated Research Services
  - Research Financial Services
  - Administration of the Research Ethics Board
  - Research Contract Review
  - Infrastructure Development and Capital Projects Management
  - Research Human Resources Support
  - Research Liaison
- HHS/McMaster University Faculty of Health Sciences Research Ethics Board (joint Board of HHS and McMaster)
- Intellectual Property Office (linked to McMaster University’s Office of Contracts and Intellectual Property)

These support services are temporarily located across from McMaster University Medical Centre, off hospital grounds. The long-term location of the research support services will be examined and should be located close to or central to the research activities it supports. Preference will be to house these support services at or in close proximity to a hospital site where it could be close to research activities and readily accessible to researchers. However, with HHS’ research occurring across all sites it is recognized that there could be no one acute care hospital location that would outweigh another site in preference. Another consideration for the Hospital is current space priorities for the acute care setting, which focus foremost on patient care needs. The long-term location of research support services will be examined further to ensure it is ideally situated to research activities.

**Strategic Plan**

**HHS Research Leadership Organization**

To ensure the HHS strategic plan along with the site developmental research plans are effectively acted upon, HHS will reorganize its research leadership into an overall decision-making body. This decision making body will be lead by a Chief Scientific Officer accountable to the VP of Research and Corporate Development. The research institute scientific directors and the research administrative director will be members of the Executive Committee on Research (ECOR). To ensure the Committee’s decisions are made consistent with the needs of both HHS and its affiliated McMaster University, both the VP of Research and Corporate Development and the Associate Dean for the Faculty of Health Science will be Committee members. Other University Faculty’s may be invited to ECORs membership or special meetings of the Committee as needed. This Committee will make resource allocation decisions consistent with the strategic plan priorities.

The Research Advisory Council (RAC), which represents a larger membership of research leaders, will remain in place as a sub-committee accountable to ECOR. The RAC will provide advice to ECOR in areas of priorities, potential recruits, resource allocation, funding opportunities, and other research related matters.
Centre for Optimum Healthcare Delivery

Hamilton Health Sciences plans to create a new Centre that will act as a centralized resource, with strong alignments with McMaster University’s academic departments. This Centre will ensure best practices find their way into everyday clinical practice at HHS and across Hamilton. The Centre for Optimum Healthcare Delivery (COHD) will be an integrating influence that ensures knowledge is transformed into practice for better clinical outcomes.

The Centre will create and enhance communication channels between researchers, clinicians, and administrators. It would empower decision making with the best expertise and the most up-to-date knowledge. Finally, it will ensure that tools are in place to promote knowledge transfer and improvement of healthcare delivery.

Along with this organizational activity, HHS will need to secure expanded space for scientists specialized in the field of knowledge translation expertise.

Vision for the Centre: To provide an integrated environment where knowledge flows between basic research, clinical research, and clinical care, leading to better education, clinically aligned basic research, and better clinical outcomes in disease management.

Profile of the Centre for Optimum Healthcare Delivery: The Centre for Optimum Healthcare Delivery is the missing link between research and healthcare provision. Research performed by members of the research institute will aim at understanding the mechanisms behind theme-based diseases (for example, oncology, cardiovascular, neurology), and evaluating drugs and procedures. The flow of discovery to medical practice is far from automatic. There are significant impediments in clinical care delivery that stem from issues in logistics and managerial procedures. This is where the Centre for Optimum Healthcare Delivery will focus. The Centre will evaluate practice and procedures within the HHS’s clinical services and will propose valid alternatives. Its role will involve such projects as the implementation of evidence-based medicine, the evaluation of data management, the evaluation of waiting list management, etc.
The Centre will leverage expertise currently available in Hamilton such as at the Population Health Research Institute and the department of Clinical Epidemiology and Biostatistics that host several research programs that address efficiency issues. In some cases, the Centre may seek an association with the Institute for Clinical Evaluative Science, an Ontario based Institute with the mission to enhance the effectiveness of healthcare through research. This organization collaborates extensively with other organizations across Ontario and Canada.

The Centre will work in close association with CARE. The CARE program is focused on assisting clinical programs in ensuring that the right provider delivers right care in the right place at the right time.

**Research Support Services**

To ensure research support services are effectively accessible to the research activities it supports, an examination of each support will occur relative to the activity that is generated by site. This analysis will be used to identify the long-term placement of support services. Ideally it will be beneficial to keep the research support services physically integrated. The benefits of its current co-location have been high and separation of support services will be examined against the merits of moving any one portion of support into a hospital site environment.

**Strategic Priorities**

**Organizational structure:**

1. Create a governance structure that integrates research decision-making across the sites and is closely linked to the priorities of HHS and McMaster University.
2. Establish the Centre for Optimum Healthcare Delivery for key research themes, such as oncology, cardiovascular, and neurology.
3. Consolidate health services research and clinical trials activities into a single organizational structure.

**Development Tasks:**

1. Develop a space plan for the Centre for Optimum Healthcare Delivery and Research Support Services.
2. Initiate an internal and external review for an appropriate leader for the COHD.
3. Summarize available funding resources for ECOR priority decision making in association with all strategic developmental plans and coordinate fundraising strategies for resource gaps.

**Priorities for Investment:**

The Executive Committee on Research will determine the priorities for investment in context of all site development plans. Investment decisions will be based on the objective of achieving all strategic priorities over the next five years. Funding decisions will be based on the Research Strategic Plan – *Research Priorities* and *Research Planning Principles*. 
Hamilton Health Sciences Research Development Plan

General Site Research Development Plan

Research Themes

Population Health Research Institute
- Cardiac
- Stroke
- Obesity
- Diabetes
- Cardiology
- Rehabilitation
Executive Summary

Beyond excellence in healthcare provision and clinical practice, HHS accounts for several research activities that span the research and development value chain, including:

- Basic research
- Preclinical drug development
- Clinical research, clinical drug trials, and population health studies
- Medical devices, bioengineering, and convergent technology expertise
- Behavioural research and life style modifications
- Rehabilitation research

One key research domain, arguably most prominent and reputable in HHS, is that of cardiovascular research within thematic areas such as:

- Hypertension
- Atherosclerosis, Thrombosis, and other Vascular Diseases
- Hyperlipidemia and Dyslipidemia
- Stroke and Rehabilitation
- Obesity, Diabetes, and the Metabolic Disease
- Blood Disorders

Unlike most research domains at HHS, and given its breadth and diversity, the cardiovascular domain has not yet fully benefited from the value associated with a single site focus. Although the Hamilton General Hospital accounts for a considerable share of the system’s research activity and tackles research issues within numerous themes; additional activities and foci, primarily emerging ones, are localized in disparate sites, at a distance from their complementary platforms.

For example, the Henderson General site host’s thrombosis and other vascular diseases research, whereas the Hamilton General site host’s stroke, rehabilitation and blood disorders research themes. Similarly, cardiovascular-focused population health research is spearheaded from the Hamilton General site. The interconnected nature of these themes and activities, and the potential synergy among them, warrants further clustering and proximity.

Capitalizing on its clinical and research strengths in the aforementioned domain, HHS needs to address the unmet needs in cardiovascular diseases management. The following section will present an overview of the environments that pertain to this endeavour. The strategy put forward in this plan aims at aligning HHS assets and strengths to best address the local as well as the global unmet needs.

A new physical infrastructure, the Cardiac, Vascular and Stroke Research Institute (CVSRI) will allow for the co-localization of two research groups of international stature, namely the Experimental Thrombosis and Atherosclerosis group, currently located at the Henderson General Hospital site, and the Population Health Research Institute (PHRI), which resides at the Hamilton General Hospital.

Beyond creating synergy between these groups, the Institute will bring complementary multi-disciplinary research teams to undertake innovative research projects. The new Institute will also provide opportunities and resources for smaller research teams to raise their profile and expand the scope of their research. Furthermore, clinicians with limited exposure to research will find incentives and support to undertake research projects.
The Institute has an estimated space need of 165,000 square feet, comprising wet and dry laboratories, office space, animal facilities, and communal rooms including auditorium, conference rooms, etc. It is estimated that this overall infrastructure project, including equipment, will add-up to approximately $84 million.

**Environmental Analysis**

Cardiovascular diseases (CVD) are the most economically burdensome of all diseases in Canada, killing close to 80,000 Canadians a year. Despite an improvement in hospitalization and mortality rates, much improvement is still needed at several levels, including a better understanding of the disease pathology, development of more effective drugs, improved surgical procedures; and better preventative practices.

As the referral centre for cardiovascular intervention for Central South Ontario, HHS, in affiliation with McMaster University, provides training for residents and graduate students. Furthermore, HHS has high-profile international scientists that carry out highly cited cardiovascular research.

Hamilton Health Sciences is a key organization in cardiovascular research and clinical care. However, its research activities are spread over several sites and despite the high-impact research performed by its scientists, the adoption of evidence-based medicine and best practices in the clinical setting is limited thus hindering optimized care for patients within the hospitals. HHS has tremendous assets for multi-disciplinary research and translational research, but it needs new and effective infrastructures to leverage these and create synergy. The envisioned infrastructure is the new **Cardiac, Vascular and Stroke Research Institute** (involving new physical infrastructures) and integration with the **Centre for Optimum Healthcare Delivery** a central HHS development resource for knowledge transfer.

Several heart centres and institutes around the country have been inaugurated with the objective of improving the quality of research and clinical care by strategically regrouping stakeholders in the field. These initiatives have generally been successful, (e.g. the **Montreal Heart Institute**) at an international scale. However, the translation of evidence-based medicine remains a challenge in most if not all of the examined models. HHS can learn from these models for cardiovascular research and healthcare, and adopt best practices.

At HHS, several other ongoing research themes bear high synergy potential with the cardiovascular research activities, namely, the expertise in angiogenesis, which currently focuses on cancer. This expertise could be leveraged in the field of CVD, since stimulation of angiogenesis after myocardial infarction represents a very promising approach to improve trauma recovery and rehabilitation. The cardiovascular scientists in Hamilton are well situated within a multi-disciplinary environment that is highly suited for performing integrated research.

Under the supervision of Dr. Salim Yusuf, the Population Health Research Institute (PHRI) carries out activities in population-based health studies, large international clinical trials, clinical studies, and studies in outcome research. As a testament to the high quality of researchers at PHRI, Dr. Salim Yusuf is among the top five Canadian scientists selected for the **Thomson-ISI Highly-Cited** list. Moreover, under Dr. Jeff Weitz’s direction, leading edge basic research in thrombosis and atherosclerosis is being conducted. Research themes explored by this team have a strong focus on potential clinical applications and involve clinical studies.
Researchers at McMaster University are currently performing more than 14% (30 of 206) of all Canadian Institute for Health Research (CIHR)-funded randomized controlled trials, accounting for $25.9 million annually. In the field of heart disease alone, investigators at McMaster are conducting 27% of the randomized clinical trials funded by the CIHR, which accounts for $9.6 million of total funding placing McMaster University first in terms of CIHR funding for clinical trials in heart diseases. In terms of funding, McMaster University is ahead of other research institutions, such as the Montreal Heart Institute, Ottawa Heart Institute, and Toronto’s University Health Network, each of which holds 13.3% of total CIHR funding in this research area. The PHRI’s HOPE (Health Outcomes and Prevention Evaluation) publication in the *New England Journal of Medicine* has been recognized as being the most cited clinical medicine publication in the Index Medicus collection, during the months of November and December of 2001.

McMaster University receives 21% of all CIHR funds dedicated to Thrombosis, which amounts to $5 million, while 4% of CIHR funds are targeted toward atherosclerosis research at McMaster, representing $1 million. Moreover, McMaster is the third most funded recipient of funds from the Heart & Stroke Foundation, receiving $2.4 million or 5% of total funds. For 2003, the Henderson Research Centre (HRC) contributed to 20% (68 of 337) of all peer-reviewed publications derived from Canada on the subjects of atherosclerosis and thrombosis. Undoubtedly, McMaster University is a Canadian leader in cardiovascular research and is by far the leading player in population studies as well as thrombosis.

The remainder of this section describes the current research that will be leveraged by the new research institute as well as research opportunities that need to be seized for the institute to establish itself as the international leader it aspires to be.

**Population Health Research Institute**

The Population Health Research Institute (PHRI) conducts research in numerous areas including: acute coronary syndromes; arrhythmias; interventional cardiology; heart failure; prevention of atherosclerosis; prevention in diabetes; prevention in perioperative ischemic events; and epidemiology. The institute conducts several large-scale international clinical trials. The HOPE trial (Heart Outcomes Prevention and Evaluation) is certainly the most well known of the group’s outstanding publications. The HOPE trial demonstrated that Ramipril, an ACE inhibitor, reduces cardiovascular incidents. This finding has impacted clinical practice on an international scope. Many other high profile trials have been conducted by the PHRI, and many are ongoing including POISE, a trial evaluating a beta-blocker for the prevention of post-operative cardiovascular incidents involving 10,000 patients, and PURE, a prospective study evaluating the effect of urbanization on heart diseases involving up to 100,000 patients in 66 countries around the world.

The PHRI has now built one of the largest biobanks, with about half a million samples linked to their respective clinical records. This unique asset puts the PHRI in a favourable position to venture into high potential endeavours including, human genetics, genomics, and proteomics.

**The Experimental Thrombosis and Atherosclerosis Group**

Basic research in thrombosis performed at the HRC involves studying the role of key factors involved in the coagulation cascade (thrombin inhibitors, Anti-thrombin/heparin complex, heparin co-factor II, Dp71, protein C, GRP78/BiP, TAFI, and more). As part of HRC’s studies on the mechanism for thrombosis, special attention is placed on plasminogen activation and fibrinolysis. The Experimental Thrombosis and Atherosclerosis group has developed and now
benefits from several mouse models for the study of cardiovascular diseases. These models represent extraordinary tools for advancing our understanding of Thrombosis and atherosclerosis as well as for testing innovative therapeutics.

In the area of atherosclerosis, basic research performed at the HRC involves studying the role of homocysteine in lipid metabolism, cholesterol transport, stress response, and inflammation. Scientists at McMaster are also studying fatty acid transport and their role in atherosclerosis, the HDL receptor, SR131, and more.

While thrombosis and atherosclerosis have historically been addressed as two different subjects, the interrelation between those two conditions is unravelling and is changing preconceived paradigms. The HRC has recently been awarded a new research chair for Atherothrombosis to address cardiovascular diseases in light of the new paradigm. This recognition puts the HRC at the forefront as a leading research team in the field.

**Obesity Research and Management**

Obesity is a growing global epidemic, which is having an increased impact on the health and welfare of Canadians. Dr. Arya Sharma is leading the management of obesity at Hamilton Health Sciences through a newly established Canadian Obesity Network. Funded through the federal National Centres of Excellence (NCE) program, this Network supported by over 25 Canadian universities aims to become the primary network of Canadian obesity researchers, health professionals and other stakeholders aimed at preventing and treating the health consequences of excess body weight.

**Dysglycemia and Cardiovascular Diseases**

Diabetes is a significant risk factor for cardiovascular events; PHRI researchers conduct several large population-based, cross-sectional, epidemiologic, and clinical trials focusing on the identification of risk factors, characterization of diabetes impact on cardiovascular disease, environmental impact and urban-rural differences on the prevalence of dysglycemia and clinical testing of preventive medicines and therapies to reduce mortality. This research receives both peer-reviewed and private industry funding; peer-reviewed support includes the National Institutes of Health, the Canadian Institutes of Health Research, and the Heart and Stroke Foundation.

**Basic Research in Medical Devices**

Scientists at HHS and engineers at McMaster University are studying the interactions between blood-contacting medical devices and the biological environment. This multi-disciplinary team is also developing biomaterials that may have a better interaction profile with biological tissues.

The importance of this research is highlighted by the fact that there is currently no existing material that does not cause coagulation, complement activation, inflammation, or does not undergo material degradation. Translational opportunities stemming from this research are exceptional.

On the investigative side, one major finding in this research area was that the lipoprotein ApoAI was found to be one of the major proteins adsorbed by common biomaterials. This finding helps to better understand the type of interaction these materials have with biological tissues, helping to further guide the effort in the development of new biomaterials. In this regard, coating agents for medical devices are being evaluated (e.g.
ATH-complex, elastatin) along with non-fowling surfaces (hydrophilic surface that exclude macromolecule) by this group of researchers.

Studies conducted by the biomaterial team at McMaster focus mostly on cardiovascular subjects. This team has a long track record in this field. This work is funded by both public and private funds. The NSERC and CIHR are counted among the public funding agencies supporting the blood-contacting device team, and collaborations with private firms bring additional research support. The team is composed of four faculty members, research assistants, and students. Altogether, this team is comprised of about 20 scientists.

**Research in Surgery**

Several research protocols are being undertaken at the HHSC in surgery, notably, the evaluation of off-pump surgery, and investigation of drug therapy to prevent or minimize post-surgery complications. Among the surgeons that perform research at HHS, the research group CADENCE performs protocols related to drug prevention of inflammation from the pulmonary/heart machine, ACE therapy following surgery, evaluation of off-pump surgery, and engages in some research on new equipment evaluation.

There is currently no basic research expertise within the surgical discipline at the HHSC. However, once animal facilities are built at the general site as part of CVSRI, some clinical surgeons may seize the opportunity to initiate such research. A close relationship between medical device research and surgical research would create excellent synergy.

**Rehabilitation Research**

Both the Cardiac & Vascular program and the Neuroscience & Trauma program undertake rehabilitation activities. Furthermore, rehabilitation research is being conducted at HHS, much of which involves the cardiovascular and stroke field. This research activity will be relocated on-site within the CVSRI to benefit from the shared assets, expertise, and patient services. Rehabilitation is a critical component of the clinical care continuum and rehabilitation requires tight integration with other research activities.

**Cardiac Vascular Nursing Science Unit**

Dr. Heather Arthur, from the School of Nursing at McMaster, currently holds the only nursing research Chair in Canada that is related to cardiovascular research. The Heart and Stroke Foundation of Ontario (HSFO) Chair in Cardiovascular Research was endowed by the following partners: the HSFO, McMaster University, Hamilton Health Sciences Foundation, the Population Health Research Institute and the Henderson Research Institute. In partnership with Dr. Arthur, HHS is creating a Cardiovascular Nursing Science Unit to engage nurses in scientific enquiry across the research spectrum from utilization to generation of evidence.

**Population Genetics**

Despite the strong role of environmental risk factors, it is known that genetic factors are also important in the progression of heart disease. The role of genes in the development and progression of heart disease is generally complex as it often results from multi-gene and gene-environment interactions. For instance, a polymorphism in the lipoprotein lipase gene will increase by 10-fold the risk for CVD in male smokers. A further example relates to cholesterol lowering agents called statins. These medications are ineffective in some
patients and cause serious side effects in others. An understanding of the causal link between genetic predisposition and therapeutic outcome would be extremely useful for optimizing prescription of these drugs.

The PHRI has acquired a strong expertise in large international population studies and has developed know-how in building and managing large studies involving several thousands of patients. Its expertise, patient access, and data management tools put the PHRI in a unique strategic position to conduct research in human genetics.

Engaging in human genetics is not only a strategic opportunity aligned with the PHRI assets; it is an imperative to stay abreast in the post-genome era. The FDA now recommends the collection of genetics and genomics data and requires it's filing when available. Moreover, most, if not all, major pharmaceuticals are investing in pharmacogenetics and pharmacogenomics. Therefore, being able to address pharmacogenetics and pharmacogenomics data will become fundamental for the PHRI if it aspires to remain a leader in cardiovascular clinical trials in the future and keeps attracting contracts from the private sector.

**Stroke Program**

The clinical stroke program at HHS is one of the best-integrated stroke programs in the country, enjoying a unique model where neuroscience and rehabilitation converge to provide integrated services along the continuum of acute and rehabilitation care. This program shares some commonalities with those in the cardiovascular area. However, there is currently very little research in strokes conducted at HHS. Recruitment of a clinician to perform clinical research in strokes has recently filled this gap, and will leverage broader clinical expertise and patient access. There is potential synergy between the activities of the cardiovascular research groups and research that is relevant to strokes given that strokes can result from thrombosis and atherosclerosis.

The stroke vision incorporates assembling an integrated peripheral vascular and stroke clinic that would enable broader expertise to review patient cases and link to related researchers; this concept would enable faster and potentially better diagnosis and reduce or eliminate multiple referral needs, which add wait time to both diagnosis and treatments. The goal is to position this multi-disciplinary initiative to include patient care, research and education making Hamilton a powerhouse of excellence. The timing for this initiative is ideal given the current opportunities for fundamental and translational research. Ideally, we need to capitalize on the strengths we have, which would include stroke, thrombosis, vascular surgery, vascular medicine, interventional radiology and lipid therapy, etc. Having the CVSRI building and its multi-disciplinary team will enhance the ability to build an integrated peripheral vascular and stroke clinic representing a reconciliation of existing widespread clinical services.

**Proteomics and Genomics**

In the post-human genome era, medical research paradigms are gradually changing. In light of this, one opportunity for the newly proposed research institute is to provide its researchers with access to proteomics and genomics technologies as they mature. It is not foreseen at this moment that the newly proposed research institute would be a leader in developing these technologies, but it should become a skilled user of these platforms to bring cardiovascular research to the next comprehensive and investigational level.
McMaster University is highly involved in the area of proteomics and has a state-of-the-art proteomics laboratory directed by Dr. McQueen. The expertise and facilities in proteomics could be used to leverage the invaluable assets that represent the patient protein bank that is held by the PHRI.

**Strategic Plan**

**Cardiac, Vascular and Stroke Research Institute**

The strategic plan at the Hamilton General site will focus on the development of the CVSRI building, including associated fundraising strategies. Additionally, the membership of CVSRI will work toward close integration with the Centre for Optimum Healthcare Delivery (COHD) established across all sites. The CVSRI will provide the appropriate research infrastructure for promoting inter-related fields of research to interact and create new synergies.

HHS is one of five academic health science centres in Ontario responsible for clinical care in the Central South region of the province, health professional education along with innovation and research. There is a need for regrouping cardiovascular activities to optimize resource usage and access to expertise. This strategic plan proposes to bring together key research activities under the CVSRI and through the COHD initiative across all sites link CVSRI research activities and outcomes directly with clinical services.

Solutions to the growing burden of cardiovascular diseases reside in research that spans areas relating to prevention, drug development, surgical intervention, rehabilitation, and healthcare delivery.

To best serve its population, HHS needs to integrate its cardiovascular activities and further invest in research and research translation. HHS has outstanding scientists to pilot the transformation that is needed to improve cardiovascular research and clinical practice. The new CVSRI will empower its researchers and clinicians to do more high profile and innovative research.

Aligned with the vision of integrating research and clinical practice; effective management tools need to be developed to promote interactivity. HHS clinicians need better access to research expertise and opportunities, to integrate prevention efforts, to streamline the translation of research findings into clinical practice, and to optimize resource usage.

HHS needs to create:
  i) Synergies among multidisciplinary research teams,
  ii) An environment that invites clinicians to engage into research, and
  iii) An effective channel to translate research advances into clinical practice. This plan proposes to build a new Cardiac, Vascular, and Stroke Research Institute and to integrate its membership with the new Centre for Optimum Healthcare Delivery across all sites.
The proposed Cardiac, Vascular and Stroke Research Institute with its integration to the Centre will aspire to:

1) Provide an integrated organization for clinicians and researchers involved in cardiac, vascular and stroke research and clinical care to coordinate their efforts in order that they perform high quality research in cardiovascular diseases and provide leading edge clinical care.

2) To create synergies among multidisciplinary research activities that will explore new opportunities and address current activities with novel approaches.

3) To promote the visibility; i.e. local awareness and international recognition of the high-profile research performed in cardiovascular diseases by the scientists in Hamilton. This will facilitate recruitment of the best clinicians and scientists to further develop the high-impact science undertaken in the region.

4) Create a culture of integration between basic research, clinical research, and healthcare provision. This empowered culture will steer the research toward clinically relevant projects, and promote the implementation of evidence-based medicine.

5) To train residents and graduate students in a dynamic and integrated environment that will provide them with a holistic understanding of cardiovascular diseases, and equip them with the most up-to-date practices.

Objectives: At the operational level, the CVSRI and its constituents will achieve their objectives by undertaking initiatives in four operational areas:

1) **Building a strong multidisciplinary research environment:** To achieve this, CVSRI will bring together the basic research group of Experimental Thrombosis and Atherosclerosis lead by Dr. Weitz and the Population Health Research Institute lead by Dr. Yusuf within a new research infrastructure. This research institute will host researchers from the McMaster engineering faculty that are active in blood contacting devices. These scientists will work at the interface of biological and clinical expertise. This close interaction between engineers, biologists, and clinicians will provide the appropriate environment for prompt knowledge transfer and efficient multidisciplinary problem solving in a high-potential area of cardiovascular research.

The CVSRI will provide physical facilities and operational support for research areas such as human genetics. Given the availability of the large blood bank of patient samples linked with clinical records and the expertise in large population studies at the PHRI, a group focused on human genetic studies located in the proposed institute will have access to this valuable resource. Successful recruitment of a human genetics group would result in spin off activity that is not currently available in Hamilton. The CVSRI will explore opportunities in genomics and proteomics that can leverage the large patient pool and clinical data bank.

The proposed CVSRI will also provide space for other groups involved in clinical research, such as cardiac surgery clinical research (ex. CADENCE), stroke research, and other new research initiatives. For example, it will provide physical space for rehabilitation research involving cardiovascular patients. The institute will create strong links with research groups involved in related disciplines that impact on the cardiovascular field, namely lipid metabolism, obesity and diabetes. Localizing research in surgery and in medical devices in the same building will create a favourable environment for these two activities to interact and create excellent synergy.

2) **Uniting the ‘cardiovascular’ franchise:** To achieve this, the proposed CVSRI will work with the Centre for Optimum Healthcare Delivery to bring together all affiliated stakeholders involved in the cardiovascular field and will coordinate and align strategic
decisions toward the common goal of improving healthcare delivery through evidence-based medicine. The Centre will evaluate clinical practice and improve process based on evidence-based solutions. This Centre will aim at becoming a national model for improving efficiency in clinical practice.

3) Providing the best educational environment for training medical residents and graduate students: It is anticipated that the new Institute will achieve this by providing an outstanding opportunity for residents and graduate students to learn from the best scientists and clinicians. This environment will enable residents and students in attaining experience with the most advanced technologies, the most up-to-date knowledge, and best practices.

4) Adding resources to maximize commercial opportunities: To achieve this, CVSRI will create a position for a business development officer that will be responsible for pro-actively managing commercial assets, such as mouse models and the blood bank. In addition, this business development officer will seek research contracts for scientists of the institute, and search for collaboration opportunities with the private sector. This new position would work with the research support services of HHS and McMaster, in particular, the Office of Contracts and Intellectual Property, McMaster University and the Office of Integrated Research Services, HHS for contract development.

Roles and Responsibilities of the Cardiac, Vascular and Stroke Research Institute: An Institute Director that is accountable to the VP of Research & Corporate Development of HHS will govern the proposed CVSRI. The different research groups will remain under the supervision of their current directors, to be renamed "Scientific Directors".

The relationship with McMaster University will follow the terms HHS already has in place with the University under the affiliation agreement.

The Director of the CVSRI will have the responsibility of allocating the common resources, while being mindful of the needs of all members. The director will especially ascertain that smaller groups and independent researchers readily get access to space and technical resources that is otherwise prohibitive.

Strategic Priorities

Organizational structure:

1. Consolidate cardiac, vascular and stroke research into one integrated institute and organization structure and appoint a leader of the CVSRI.
2. Develop the infrastructure for CVSRI with a strong cardiovascular themed link to the Centre for Optimum Healthcare Delivery creating an environment that invites clinicians to engage into research.

Development Tasks:

1. Continue the CVSRI fundraising strategy to build and sustain the 165,000 square foot infrastructure plans.
2. Develop human genetics research capabilities, including the collection of genetics and genomics data, and pharmacogenetics and pharmacogenomics data.
3. Further develop the Stroke research program and assemble an integrated peripheral vascular and stroke clinic.
4. Further develop the Clinical Trials Research and Proteomics Laboratory, one of the largest repositories of biobank materials in Canada, in close collaboration with the researchers to be located at the new CVSRI.

**Priorities for Investment:**

Hamilton Health Sciences greatest research priority is the development of the 165,000 square foot Cardiac, Vascular and Stroke Research Institute. Significant fundraising strategies are underway to ensure this capital project gets underway. With one-third of the required $84 million in funding, HHS will begin the construction of this building in 2007. This building will enable several of the General site development plans to be achieved, including the consolidation of activities focusing on cardiac, vascular and stroke.
Hamilton Health Sciences Research Development Plan

Juravinski/Henderson Site Research Development Plan

Research Themes

Cancer
Circulation
  • Thrombosis
  • Atherosclerosis
  • Vascular Biology
Musculoskeletal & Rehabilitation
Executive Summary

The consolidation of cancer, orthopedics and rehabilitation services at the Henderson General Hospital creates a unique set of opportunities for research. Using well-accepted measures of research excellence such as grants and publications, the site already hosts significant world class research strength in cancer across a continuum from fundamental to health services research, in vascular biology and thrombosis at the fundamental level and in clinical thromboembolism, again across the research continuum. There is extensive clinical trials activity in these areas and a clinical trials methodology group providing support and leadership.

Projected growth in joint arthroplasty and surgical oncology on the site creates an opportunity to enhance surgical research. Investigators and clinicians have already initiated collaborations and the hospital and university have both invested in recruitment of surgeons with protected time for research in order to advance in this area.

Research ideas in rehabilitation, particularly as they relate to the clinical populations served by the site, are being formulated through collaborative workshops. Interest in this area spans several university departments including kinesiology, rehabilitation sciences, medicine, surgery and nursing. A planning framework is being established to advance thinking in this area.

There is strong interest in developing synergies in research that will reflect and support the clinical focus for the site, thus setting the stage for the development of a comprehensive research culture that will help fulfill the mandate of the site as a teaching hospital while acting as a magnet for investigators and learners, as well as for investment. Not only is there a strong track record of research funding, particularly in cancer, vascular biology and clinical thromboembolism, but also there are significant external funding opportunities that investigators will be well positioned to compete for in the next three years.

As we look to the future, there are key areas where investment will be critical to maximizing the ability of the site to capitalize on its strengths and compete on emerging frontiers of knowledge important to the care of patients.

In cancer, investment in translational research infrastructure will position researchers in several established research programs to take advantage of the emerging trend towards molecular targeted therapies and the rapid translation of new drugs into clinical care. This infrastructure includes recruitment in clinical pharmacology, bio-informatics, nuclear medicine and molecular pathology, as well as investment in supporting bio-bank facilities to collect, store and study tumor blocks, blood, tissue and bone.

The second area for immediate investment in cancer research is in health services research and knowledge transfer. This includes investment in information systems to support database analysis as well as the increasingly sophisticated information management requirements of clinical trials, including the capture of resource utilization data. It also includes recruitment of additional statisticians and epidemiologists with the analytical skills to support both clinical trials, outcomes research, and health services research. Recruitment of social scientists is required in order to improve our understanding of implementing clinical guidelines in order to achieve best practice. Relocation of the Program in Evidence-Based Care to the Henderson campus should be a priority.
In the next three years the Vascular Biology and Clinical Thromboembolism research programs will require investment in order to continue on their trajectory towards developing a world class program in cancer and thrombosis and building critical mass in atherosclerosis research. In order to continue to develop research strength at the interface of cancer and thrombosis, recruitment of a clinician scientist is an area of high priority. The potential relocation of part or all of the Vascular Biology Program to the Hamilton General site needs to be given careful attention in order to ensure that this research program is coordinated between the two campuses and this important and established research program is not weakened. A challenge will be the transition period as a Cancer Research Institute is established at the Henderson site, while the Vascular Biology Fundamental Research Program, and the rest of the existing Henderson Research Centre, remains at the Henderson until the Hamilton General site is ready.

Strategic planning for the Henderson campus needs to be well integrated with strategic planning at the other teaching hospital sites, within HHS and at SJHC, as well as with McMaster University. The research strengths and programs at the Henderson need to interdigitate with the research strengths and programs on the other sites in order to coordinate investment and recruitment efforts.

The organization of research on the Henderson site is complex and it is recommended that this complexity be addressed early on in the strategic planning exercise in order to enhance communication, provide mentoring and development where needed, build critical mass in key areas, and make strategic choices regarding investment.

The pending redevelopment of the Henderson campus is a perfect time to be enhancing and developing the research agenda, and research should be an integral part of planning the capital infrastructure.

This is an exciting and opportune time for research at the Henderson and the investigators on the site should move quickly to actively plan and implement change for the future.

**Environmental Analysis**

Over the past two years, Hamilton Health Sciences (HHS) has developed a strategic plan that aligns its core clinical programs with each of its three acute care sites, thus allowing the hospital to maximize the use of its resources while meeting the health needs of the community. Some of this program consolidation was driven by the Ministry-led hospital restructuring initiative that rolled out across the province over a decade ago. Some program consolidation has occurred more recently as part of an ongoing strategy to maintain critical mass and fiscal viability at all sites. While the imperative to implement this approach may have been driven by external policy directives and fiscal imperatives, it does provide an opportunity for each site to develop a unique identity in the community, a unique culture, and a unique focus for research.

A strategic plan for research can take advantage of and help shape the emerging identity resulting from the consolidation of clinical services and by doing so, help foster a research culture that contributes to excellence in patient care.

HHS is committed to supporting research as part of its mandate as a teaching hospital and will do so in collaboration with the Faculty of Health Sciences, McMaster University. As evidence of this collaboration, the recruitment of physicians and clinician scientists is
managed jointly by both organizations. Recruitment of researchers (clinical and non clinical) should be aligned with both the clinical and research priorities of the Henderson site. Building bridges between the hospital and the university across a multidisciplinary continuum of research will help advance understanding of the mechanisms of disease as well as the treatment and delivery of care. Shared strategic planning and collaborative recruitment across this continuum are both essential elements in building an effective research environment in the teaching hospital setting.

Notwithstanding the importance of building a site-based research culture, it is important that a strategic plan for research not artificially constrain research to a single site-based model. The research community is driven by the search for knowledge within an international context. While clinical application of research to improve patient care should be considered the responsibility of each clinical program, the research programs at each site must not lose sight of their need to compete in this larger international context.

**Juravinski/Henderson General Hospital**

The HHS core clinical programs at the Henderson site are cancer, joint arthroplasty, and rehabilitation. The Henderson is a busy general hospital that supports these programs through diagnostic imaging, care of the critically ill patient (ICU), and medical, surgical and emergency services. In addition, the Henderson is the site of an integrated regional academic clinical thrombosis program.

The Henderson campus currently hosts 3 organizational entities: the Henderson General Hospital, the Juravinski Cancer Centre, and the Henderson Research Centre. While integrated on some levels, all three of these entities have developed research programs along different trajectories, over different periods of time, with different leadership, and with varying degrees of success depending on opportunity, support, and individual research strengths and plans. An integrated research plan for the Henderson needs to take this history and context into account in order to make maximum use of current strengths and to be strategic about future development. It is also important for the Henderson plan to take into account research plans for the other two HHS acute care sites as there will be mid to long term relocation of research programs between sites, as well as short and long term inter-site synergies that need to be capitalized on.

Models of integrated clinical research programs do exist at the Henderson and should continue to be an important part of the hospital’s research plan at all sites. An extremely strong and well-established example of this is the clinical thrombosis program. With basic research based at the Henderson site, and clinical nodes at all sites of HHS and SJH, the program is designed to offer “state-of-the-art bench-to-bedside” care to patients with thrombotic conditions city-wide.

The current arthroplasty clinical research activities at the Henderson site, while not yet well developed, exemplify the applied and outcome oriented clinical research that has key meaning to the hospital. The arthroplasty program has recently begun to collaborate with cancer centre researchers in understanding bone degeneration, intervention and rehabilitation as well as with Henderson Research Centre investigators in looking at biomechanisms of bone formation in relation to implants. Opportunities to link research to clinical practice and to link well established research programs with emerging research programs in order to provide mentoring and to build critical mass should be central to the strategic plan for research on the Henderson site.
Juravinski Cancer Centre (JCC)

Until 2004 the JCC was one of 9 regional cancer centres in the province operated by Cancer Care Ontario (CCO). As such, its research program was supported by CCO and developed either in alignment with CCO priorities i.e. the development of a strong clinical trials program as a key indicator of the quality of cancer care; or in alignment with the research priorities that the leadership of the Centre developed in collaboration with the host academic departments in the Faculty of Health Sciences i.e. clinical trials, and the tumour metastasis research program.

In addition to a very strong clinical trials program and a strong basic research program in targeted areas, the JCC is also home to a supportive care research unit. This unit is the result of a Ministry initiative to develop research units in partnership with the end users of research in order to improve care for specific populations through targeted research and rapid uptake of research results. The unit is also considered one of several research units strategically developed and fostered by the Department of Clinical Epidemiology and Biostatistics (CE&B) to improve the quality of research across all clinical teaching sites in the city.

A relatively new research program in experimental therapeutics is under development at the cancer centre. Significant human and infrastructure investment will be required for this to become a strong program of clinical investigation.

Development of the cancer research program at the JCC and the Henderson must be considered in concert with the Centre for Gene Therapeutics at the McMaster site which develops approaches to delivering genes as therapeutic agents in human and animal disease. Current Phase ll clinical trials in cancer carried out at the Henderson site are the first application of cell-based gene therapy in humans in Canada and are being developed within a multi-pronged approach involving a combination of therapeutic strategies. The recent investment of $10 million by Michael DeGroote in cancer research has been used to recruit Dr. M. Bhatia and to develop a stem cell research program in cancer within the University’s newly created Cancer and Stem Cell Biology Institute. Building an integrated research plan for cancer between the two sites that takes advantage of this investment and builds a continuum of research from bench research through to clinical and health services research should be considered a priority. Success in this integration will depend on recruitment of clinician/scientists who can translate the fundamentals of stem cell research into clinical practice.

Henderson Research Centre (HRC)

The HRC was developed as a partnership between the Hamilton Civic Hospitals and McMaster University and embraces three programs of research: a research program in Vascular Biology which conducts fundamental research on the interplay between thrombosis, atherosclerosis, cancer, and inflammation; the Clinical Trials Methodology Group (another CE&B fostered unit) which conducts clinical trials and develops trials methodology to support the other programs at the HRC; and the Clinical Thromboembolism Research Program which performs research that informs optimal diagnosis and care of patients with thrombotic problems in the hospital and in the community and provides care of patients with thrombotic disorders or at risk of such events. This latter program is regional in nature and includes all HHS sites and St. Joseph’s Healthcare.

There is a formal governance structure for the HRC. In developing a research plan for the Henderson, the existence and potential role for this bench-to-bedside organizational
construct should be considered. In addition, the potential impact of the relocation of a component of Vascular Biology to the Hamilton General site of HHS also needs to be considered. The Henderson Research Centre is a jewel on the crown for HHS and McMaster University. It has a world-class reputation and a recent external review recognized its excellence.

**Setting the Stage for an Enhanced Research Platform for the Site**

These entities and issues create a complex but exciting opportunity for the Henderson campus to position itself around a research platform that will impact on patients served by the site, link to other research sites in the city and beyond, contribute to new knowledge in important knowledge frontiers, and create a magnet for learners and investigators excited by a thriving research culture. The history of research on the Henderson campus is complex but represents through this complexity the resilience and strength of the research enterprise. By bringing this history and strength together, research has the potential to be a significant and leading element of life on the Henderson campus.

In addition to taking into account the emerging configuration of clinical programs on the Henderson campus as well as the history of the site’s current research groups, it is essential that a strategic plan for research strive to achieve the highest possible standards for research. These standards are well articulated in the HHS research strategic planning document (Appendix A) and include the importance of recruitment and development of excellence, grants and publications of international standard, research leadership, and support for investigators through career awards. The HHS strategic research plan also acknowledges that the development of research at each site needs to take into account research strengths across the city and be well integrated with research strategic planning at McMaster University. These guiding principles of excellence and coordination will help facilitate not only research excellence on the Henderson campus but the development of collaborative and integrated research programs across the city.

This is particularly true in the case of cancer research where linkages between the Henderson and McMaster sites will be key in developing an integrated continuum from fundamental to clinical and health services research. Opportunities should also be sought to build collaborative research models in orthopedics and rehabilitation in order to test strategies across different acute and chronic populations.

Planning a research program at the Henderson must take into account the evolving role and structure of the Henderson Research Centre (HRC). Plans to relocate some of the activities of the HRC to the Hamilton General will require a reexamination of the research focus for the HRC, and short and long term planning of all groups in order to ensure coordinated and strategic transitioning.
Strategic Plan

Strategic Planning Principles

A strategic plan for research needs to include the following principles:

- In order to take advantage of the strengths and complexities of the Henderson campus described previously, a strategic plan of research needs to be dynamic so that multi-year strategies can plan for growth of existing strong programs, development of emerging priority programs and site transitioning as research groups relocate to other sites.
- The plan should be opportunistic in order to take advantage of new funding opportunities and emerging areas of research.
- The plan should link explicitly to research programs on other sites in the city.
- The plan needs to express an integrated research agenda for the core clinical programs of cancer, orthopedics and rehabilitation that focuses particularly on knowledge transfer to improve patient care and patient outcomes. An active knowledge transfer program will be key in building a research culture on the campus that will inform best practices and create not only an excellent experience for patients but also attract investigators and learners to the site.
- This research culture needs to be facilitated by the development of interdisciplinary clinical teaching units on the campus that provide excellent clinical learning opportunities for a range of undergraduate, graduate and postgraduate students in the Faculty of Health Sciences and exposes them to research.
- The interaction of research and education in the clinical environment provides an important mechanism for recruitment, which should be an integral part of the strategic plan for research.
- Historical research strength as well as emerging programs and collaborations must be considered within established standards of excellence in research, which include publications, grants, impact on practice, critical mass and mentorship.
- It is essential for a strategic research plan to take into account the varying strengths and developmental needs of research programs. This will require choices being made in terms of resources, recruitment, structure and strategic priorities.

The strategic plan for research on the Henderson campus will focus on cancer; orthopedics as it relates to metastatic disease and joint replacement; rehabilitation in oncology; and thrombosis, atherosclerosis and vascular biology. In each case, programs will be described as established (track record of international recognition, peer reviewed grants and publications), under development (programs designated as a priority but with limited resource or infrastructure), and emerging (programs of importance to the site but at this stage limited in development.) The following outlines these research programs, identifies the research focus for each research unit, identifies the challenges that need to be addressed to allow for further development, and lays out research priorities for the next five years.

Cancer

The Henderson campus is clearly positioned to develop as a strong centre for clinical cancer research with linkage to fundamental research at the McMaster University site, as well as to
provide opportunities to develop collaborative clinical research with orthopedics and rehabilitation programs. The recent establishment of the Department of Oncology in the Faculty of Health Sciences, strong external funding opportunities, and existing research strength on both the McMaster and Henderson campuses are all important elements that will make cancer research a strong focus of the Henderson strategic research plan.

Cancer includes:
- Tumour Metastasis Research Unit (established)
- Noninvasive Optical Diagnostics and Therapeutics (established)
- Experimental Therapeutics Program (under development)
- Clinical Trials: Clinical Trials Methodology Group (established)
- JCC Clinical Trials Department (established)

Health Services Research:
- The Supportive Cancer Care Research Unit (established)
- System Wide Quality Improvement in Surgical Oncology (under development)
- Program in Evidenced Based Care (established)

**Tumour Metastasis Research Unit**

The major focus of the tumor metastasis research unit, led by Dr. Gurmit Singh, is to integrate knowledge from diverse areas and disciplines in an attempt to better understand the mechanisms associated with tumor invasion and metastasis. The primary focus of the unit has been on bone metastasis associated with breast, prostate and lung cancer. The role of thrombosis, oxidative stress and proteases are being actively investigated in the unit with substantial peer-reviewed funding from the National Cancer Institute (NCI), CBCRA, and the Canadian Institutes for Health Research (CIHR).

Research Focus:
- Identification of new molecular targets and novel therapies for preventing bone metastasis,
- Prevention of bone breakdown in cancer patients,
- Understanding osteoporosis and bone metastasis,
- Development of novel methods to enhance bone formation in the vicinity of orthopedic hardware,
- Understanding the influence of joint implant biomaterials on bone metabolism.

Challenges:
- To recruit additional investigators and develop a critical mass of researchers.
- To recruit an expert in bone pathology
- To develop an integrated translational research arm in order to take new knowledge from the laboratory to the clinic.
- To develop relationships with Pharmaceutical companies and take advantage of drugs in the pipeline for the prevention and treatment of metastasis.
- To secure long-term infrastructure support to provide stability to this research group.

Priorities:
- Recruit an academic bone pathologist,
- Recruit investigators with expertise in molecular imaging and nanotechnology.
- Plan stable funding for infrastructure for the group especially as CCO funding ends in 2008.
**Noninvasive Optical Diagnostics and Therapeutics**

This research group, led by Dr. Mike Patterson, is exploring the use of optical technology for the diagnosis, staging and treatment of cancer. They work closely with the basic science bone metastases research group on molecular bioluminescence and fluorescence imaging in small animals. The group is led by Dr. Michael Patterson, Head of Medical Physics, and comprises approximately ten faculty members in Medical Physics, Pathology and Molecular Imaging, Biology and Radiation Oncology. It has extensive national and international collaboration; Dr. Patterson is a member of the Canadian Institute for Photonic Innovations, a federal Network of Excellence (NCE). Current research funding is provided by the National Institutes of Health (NIH-US), the National Cancer Institute of Canada (NCIC), the Canadian Institutes for Health Research (CIHR), the Ontario Cancer Research Network (OCRN) and the NCE Program. This group has also worked with various industrial partners with an emphasis on device and technology development. An international reputation has been established in biophysical modeling of light propagation in tissue, non-invasive optical spectroscopy and photodynamic therapy dosimetry. Collaboration with nuclear medicine in using radio imaging will be an important area for future development.

Research Focus:
- Photodynamic therapy (PDT) dosimetry and devices,
- Quantitative optical molecular imaging,
- Clinical applications of optical spectroscopy.

Challenges:
- Limited research time for clinical staff, limited lab space.

Priorities:
- The priority of this group is to expand translational PDT activities, and develop combined x-ray and optical imaging system for small animal applications.

**Experimental Therapeutics Program**

The JCC has a well-developed and growing Investigational New Drug (IND) Program led by Dr. Hal Hirte. About 25% of patients entered on clinical trials participate in Phase I or II studies. The activity has focused in three main areas of therapeutic intervention: i) invasion and metastasis, ii) cell signaling, and iii) tumour immunology. The program carries out these studies through the NCIC-Clinical Trials Group, the Princess Margaret Phase II consortium (which is funded through the NIH and allows access to novel agents licensed to the NCI-US as well as access to funding for translational research studies done in the context of these studies), and through industry-sponsored collaborations. Collaborating centres in the consortium include Princess Margaret Hospital, Juravinski Cancer Centre, London Regional Cancer Program, Ottawa Hospital Cancer Program, Toronto-Sunnybrook Regional Cancer Centre, Kingston Regional Cancer Centre, the BC Cancer Agency – Vancouver, the Cross Cancer Centre, Edmonton, the McGill Oncology Program, Montreal, the Nova Scotia Cancer Centre, and the Fox Chase Cancer Centre, Philadelphia.

Research Focus:
- Promoting the rapid translation of research from the laboratory to the patient through investigational therapies,
- Optimizing the efficiency of transferring novel targeted molecular therapeutic agents from the laboratory to the patient in order to improve quality-of-life and long-term survival outcomes for cancer patients, while minimizing toxicity.
Challenges:

- This program of research would benefit from dedicated pathologists with an interest in translational research, as well as radiologists and nuclear medicine physicians with expertise and interest in functional imaging modalities, such as DCE-CT, DCE-MRI, radiopharmacologic approaches, enhanced clinical trial infrastructure: (RN, CRA, lab technologists for correlative blood/serum/plasma sample handling), enhanced diagnostic infrastructure: equipment to enable work conducted in pathology and radiology/nuclear medicine, clinical pharmacology infrastructure: dedicated space for administration of experimental agents and monitoring of these patients, and staff to conduct the required pharmacokinetic research.

Priorities:

- In order for this area to develop in the future, significant investment is required in clinical pharmacology, molecular pathology, nuclear medicine and bio-bank facilities.

Clinical Trials

Clinical trials are an area of particular strength at the Henderson site. While housed in separate structures, there is considerable collaboration and interaction between the JCC Clinical Trials Department and the Clinical Trials Methodology Group in the Henderson Research Centre. Collaboration between JCC and CTMG positions the site to compete for a significant portion of the $70 million available in the new Ontario Cancer Research Institute (OCRI).

Collaboration between JCC, CTMG and CE&B will facilitate additional methodological research related to cancer trials, including economic analysis.

Clinical Trials Methodology Group (CTMG)

The Clinical Trials Methodology Group (CTMG), led by Dr. Mark Levine, is one of the largest academic-based clinical trials development organizations in Canada. It works with networks of clinician investigators locally, in Canada and abroad and is comprised of more than 40 individuals including methodologists, statisticians and clinician researchers who focus their work in the areas of cancer, and venous thrombosis (blood clots). It is affiliated with McMaster University’s Department of Clinical Epidemiology & Biostatistics and is located in the Henderson Research Centre.

This unit provides methodologic resources to design, conduct and analyze clinical trials, creates an environment that is attractive to young researchers and provides mentorship to young researchers at the JCC and other cancer centres in Ontario.

The CTMG has engaged in trials sponsored by peer-reviewed agencies including the Canadian Institutes of Health Research (CIHR), the Heart and Stroke Foundation of Ontario (HSFO), the National Cancer Institute of Canada and pharmaceutical companies. Many trials have led to the registration of new drugs with government regulatory agencies such as Health Canada and the United States’ Food and Drug Administration.

In 1982, Dr. Levine helped to create the Ontario Clinical Oncology Group (OCOG), which falls under the CTMG umbrella. This group was established by the Ontario Cancer Treatment & Research Foundation (subsequently Cancer Care Ontario) as a way to develop, coordinate and promote cancer clinical trials throughout Ontario’s regional cancer centres and the Princess Margaret Hospital in Toronto. Since then, more than 7,000 cancer patients
have been entered into OCOG trials for cancers of the breast, brain, head and neck, ovary, prostate, lung, brain metastases, and pre-malignant conditions for the lung and cervix.

The OCOG is currently leading a technology assessment of PET (Positron Emission Tomography) imaging in oncology sponsored by the Ontario Ministry of Health and Long-Term Care (MOHLTC). Through this research initiative, five multi-centre clinical trials are being conducted in Ontario in breast cancer, head and neck cancer, early stage lung cancer, locally-advanced lung cancer and colon cancer that has spread to the liver. The results of these trials will provide important information on the clinical utility of PET, which will be used by the MOHLTC to support public funding decisions.

Extensive internationally recognized research on the effect of the immune system on cancer has been conducted in laboratories at McMaster. This has led to the development of adenovectors that potentially can be used as tumour vaccines. Currently Drs. Dhesy and Foley both from the JCC are conducting a Phase I clinical trial of a tumour vaccine for women with breast cancer whose tumours overexpress the Her2 Neu oncogene. Dendritic cells which have been transduced with an adenovirus that expresses rat Her2 Neu is the vaccine. This study has received funding from the Ontario Cancer Research Network (OCRN) and the CBCRA.

Currently the majority of patients with early stage breast or prostate cancer are treated with radiation therapy as either primary or adjuvant treatment. The majority of such patients are unlikely to develop recurrence of the cancer. However in a significant number of patients the cancer will be resistant to radiation therapy and a smaller number will develop significant toxicity secondary to treatment. Recently genetic studies of patients’ tumours have identified important molecular predictors for cancer recurrence and responses to chemo and endocrine therapies, e.g. in breast cancer, reverse transcriptase polymerase chain reaction assays of 21 selected genes responsible for cell proliferation and invasion, and HER 2 Neu over expression for responses to chemotherapy and herceptin. Such approaches are currently also being investigated in prostate cancer.

Research Focus:
- Therapeutic trials (radiation, chemotherapy, novel antithrombotic agents)
- Assessment of diagnostic tests or technologies (PET imaging).

Challenges:

The development of new medical technologies and treatment regimens is increasing rapidly, providing CTMG with many opportunities to rigorously evaluate these innovations through the design and execution of clinical trials.

CTMG needs to upgrade its data management system. The research environment (industry, granting agencies, and regulatory agencies) requires the following capabilities in managing clinical trials: electronic data collection; fast tracking of data; instant access to data processing results; enforced standards in data presentation; and extended geographical boundaries of trials. There is an immediate need for CTMG to acquire a data management system with these capabilities.

CTMG needs to establish a tissue bank particularly for its cancer studies. This will enable CTMG to conduct ancillary translational studies retrospectively with carefully documented clinical histories and tissue and blood specimens stored under stringent conditions for both genomic and proteomic analysis. This initiative will require recruitment of investigators with
expertise in bio-informatics as well as academic pathologists with expertise in molecular pathology.

Other challenges for CTMG are to maintain a cadre of clinical epidemiologists and statisticians who can serve as core members of the unit, and to continue to obtain funding in a competitive environment.

Priorities:
- The immediate priority for the unit will be to upgrade its information management infrastructure and establish a tumor bio bank. An ongoing priority is to maintain the unit as a training ground for young clinical investigators.

**JCC Clinical Trials Department**

The clinical trials program at the JCC, led by Dr. Jim Wright, has an extensive portfolio of clinical research studies. Cooperative group sponsors include the National Cancer Institute of Canada Clinical Trials Group (NCIC-CTG), the Radiation Treatment Oncology Group (RTOG), the Ontario Clinical Oncology Group (OCOG), and the Princess Margaret Phase II Consortium (PHL). Many industry-sponsored trials are also conducted. Several investigators at the JCC work in collaboration with OCOG at the Henderson Research Centre, led by Dr. Mark Levine. The clinical trials department has over 100 actively accruing trials in operation at the cancer centre at any given time. As an indicator of quality cancer care, the department’s goal is to enroll 10% of all treated patients in clinical trials. The clinical trials department employs over 40 FTEs, including clinical trials nurses, clinical research associates and regulatory personnel to support the management of trials.

Trials in the cancer centre are first approved by the Disease Site Teams prior to approval by an internal Protocol Review Committee and the McMaster/HHS Research Ethics Board. Results of trials are presented to all staff in the cancer program on a regular basis and reflect the strong research culture within the cancer centre.

Funding from the Ontario Cancer Research Network (OCRN) ($1 million) has allowed the JCC clinical trials department to significantly increase its infrastructure thus enabling greater access by patients to the most up to date treatments. As part of the continued development of OCRN, a provincial oncology research ethics board (OCREB) will be adopted as the Board of record for all oncology clinical trials at HHS.

Research Focus:
- As provided by the local investigators through the various disease site teams.

Challenges:
- To develop a clinical research plan, establishing and detailing areas of priority for local investigators, including the development of experimental therapeutics.
- To address current resource constraints such as technology support (outdated PET technology, no CT/PET, immature IMRT program), diagnostic radiology (timely baseline investigations and volume of scans), systemic therapy, and pharmacy.
- To create new infrastructure to support growth in experimental therapeutics and new drug development (clinical pharmacology, molecular pathology).
- To develop links with other research groups, i.e. laboratory medicine, basic science (translational research), radiology and with industry to grow the volume and sophistication of trials activity.
- To manage a growing number of patients in the follow-up phase of trials,
To develop regional support for clinical trials by expanding presence at Brantford General Hospital and Joseph Brant Memorial Hospital.

To integrate financial reporting within the HHS system in order to support the timely collection of per patient funding and the implementation of the OCRN Clinical Trials Management System.

To balance the need for financial neutrality with the desire to conduct important clinical research.

Priorities:

- Creation of a clinical research committee within the academic Department of Oncology to discuss strategic research priorities,
- Creation of a Clinical Trials Advisory Board to prioritize research and fiscal issues within the department,
- To recruit a business manager or enhanced support from research support services (finance) to ensure the currency of the fiscal situation
  - Start up budgets and negotiation
  - Clinical Trials Management System
  - Invoicing industry for completed milestones
  - Invoicing HHS for co-op group RECIST reporting
- Development of mechanisms to coordinate and consolidate OCOG and JCC clinical trials.

**Health Services Research**

The cancer program includes investigators focused on health services research in a number of key domains including decision-making, quality of life, quality improvement, practice guidelines, and coordination of care. While active collaboration exists across this research agenda, current investigators are affiliated through both formal and informal structures.

**The Supportive Cancer Care Research Unit (SCCRU)**

The Supportive Cancer Care Research Unit, led by Dr. Tim Whelan, has been conducting seminal research into health services and cancer since 1991. The Unit was established as a health systems-linked research unit and is supported by the Ministry of Health and Long Term Care and Cancer Care Ontario, with in kind contributions from McMaster University, and the Juravinski Cancer Centre. The Supportive Cancer Care Research (SCCR) unit is led by Unit Director Dr. Tim Whelan, who holds a Canada Research Chair and Associate Director Dr. Jonathan Sussman, Clinician Scientist. The unit consists of a multidisciplinary group of investigators including oncologists, family physicians, health services researchers, biostatisticians, a medical sociologist and a health economist. Researchers affiliated with the Supportive Cancer Care Research Unit include Kevin Brazil, Director, St. Joseph’s Health Research Network; Peter Ellis, Medical Oncologist with an interest in shared decision making; Cathy Charles, a medical sociologist who focuses on conceptual models of shared decision-making; and Amiram Gafni, a health economist whose research interests lie in the area of economic evaluation of health care programmes. Unit staff includes a clinical research manager; six experienced research coordinators and two research assistants, as well as administrative staff. Over the last 14 years, the SCCR unit has been engaged in a large number of groundbreaking research projects; many of these have been supported by national and international research agencies. Unit research has been presented at numerous international conferences and published extensively in widely read cancer journals. Some of the key studies developed by the Supportive Cancer Care Research Unit have had major impacts on treatment of patients with cancer, improving efficiencies in the cancer system and increasing coordination of cancer services and patient quality of life.
Research Focus:

As with all experienced research units, priorities and foci of research shift over time. Originally, as per the goal of health systems-linked research units within Ontario, the Supportive Cancer Care Research unit responded to needs identified by partners, in particular the Juravinski Cancer Centre. More recently, the unit has responded to direct contract requests from the Ministry of Health and Long Term Care. The unit has adopted a conceptual model for health services research called the Needs Service Path. Along the path from a recognized need (patient or health system perspective) to an ideal service, there are certain steps or questions: e.g., is the need recognized, are services sought, are services available, are services effective, and are services efficient? Using such a model, the SCCR unit research focuses on identifying need, developing interventions, and evaluating the effectiveness of these interventions or health services within the cancer system. The research conducted by the Supportive Cancer Care Research Unit has extensively explored needs and gaps in various cancer service areas. Focus then shifts to a rigorous study of the impact of various models on the overall system of care and the cancer patient. The unit's research initiatives have evolved over time from initial exploratory or 'discovery' research to impact and evaluation analysis. The goals of the latter are to provide decision-makers in the health care system with concrete recommendations for system improvements in the area of coordination of services, patient support, and cost effectiveness. The perspective taken is always that of working to improve the lives of those patients living with cancer and their families, through sound evidence based research focusing on care delivery, coordination, practice guideline development and clinical treatment.

The Supportive Cancer Care Research Unit has organized its research inquiry around three major themes:

- Supportive cancer care / coordination of care
- Information exchange / shared decision making
- Uptake and evaluation of new cancer treatment technologies

Challenges:

The Supportive Cancer Care Research Unit will continue to focus on health services research dealing with supportive and palliative care, models of care delivery and new cancer treatment technologies. In order to continue these research initiatives the research unit will require the following resources:

- Information technology and additional expertise for access and analysis of available health system administrative databases to identify current trends that could inform interventions as well as monitor changes that occur as a result of system changes and interventions.

- Strengthening the current research group to include established researchers and content experts from specialty and primary clinical care as well as health services, medical sociology and health policy to create a comprehensive team of research excellence in both quantitative and qualitative sciences.

- Research initiatives at the Supportive Cancer Care Research Unit would benefit from having access to provincial databases that would allow for systems level analysis of patterns of care. An enhanced administrative relationship at the policy level would also contribute to the success of this systems level research.
Priorities:

The SCCRU will focus on the development and evaluation of optimal models for the delivery and coordination of supportive and palliative cancer care with a focus on health systems, the role of primary care practitioners, and knowledge transfer to support decision making at both the practitioner and policy level. In addition this research program will continue to research shared patient/clinician decision making and to develop and evaluate decision aids accessible for use in multiple settings. The SCCRU will also continue to research communication in the clinical encounter in order to gain an understanding of the important skills and behaviors that facilitate patient involvement in decision-making, with an ultimate goal of developing a training program for physicians and cancer patients to facilitate better communication and involvement in treatment decision-making.

System Wide Quality Improvements in Surgical Oncology

Cancer surgical health services research, with lead investigators Drs. Marko Simunovic and Laurie Elit, has focused on understanding access to care issues and the effectiveness of care. Utilizing large administrative databases in Ontario, Dr. Simunovic and colleagues have evaluated the relation between the volume of pancreatic and rectal cancer surgery and peri-operative mortality. In the case of the former cancer, a three-fold difference in outcomes provides a strong rationale for the concentration of pancreatic cancer surgery in a few high volume centres. Current work focuses on the impact of procedure volume and hospital teaching status on patient outcomes for high-risk (esophagus, liver and lung) and low-risk (breast and colon) cancer surgeries in Ontario. Studies have been conducted on the waiting times for cancer surgery in the facilities associated with cancer centres across the province. These studies have provided insights into the development of reliable methods to measure cancer surgery waiting times using administrative data. Dr. Simunovic has received CIHR funding to undertake a quality initiative related to rectal cancer surgery in which a strategy is being tested to determine if surgical outcomes can be improved. Specifically, the strategy involves training surgeons in a new rectal cancer surgical technique in order to reduce the rate of permanent colostomy and reduce local recurrence. Future work will focus on knowledge translation and improving the quality of surgical care.

Dr. Elit has conducted research to improve the quality of care for gynecologic malignancies, particularly ovarian cancer. She has received funding from NCIC to examine the surgical practice in Ontario for ovarian cancer and to determine the factors that determine best practice. She has conducted qualitative research on how women with ovarian cancer feel about the care they have received. She has led a multicentre international trial funded by CIHR that examines the best way to manage CIN1, a premalignant condition of the cervix.

Research Focus:

- To measure quality gaps in surgical cancer care in our LHIN through surveys, chart reviews, administrative database research, and qualitative research.
- To design, deliver and evaluate coordinated quality interventions that engage consumers and health care providers.
- To integrate successful quality improvement methods into the delivery of surgical cancer care at the regional level.

Challenges:

A program that targets surgical cancer care would serve as an excellent model for system quality improvement for numerous reasons including: the growing burden of cancer as our population ages; certain aspects of service delivery are already managed at a systems level.
(i.e. complex surgical, radiation and chemotherapy treatments) while others are not (i.e. prevention, screening, diagnosis and most surgical treatments); and current strengths in various aspects of relevant cancer research. Examples of such research strengths include the Supportive Cancer Care Research Unit, the Health Information Research Unit, the Program in Evidence Based Care, and the Clinical Trials Methodology Group. Most importantly there is interest and experience with research in quality improvement amongst surgeons through activities such as the Quality Initiative in Rectal Cancer Trial (Simunovic), the Centre for Minimal Access Surgery at St. Joseph’s Healthcare Hamilton (Anvari), and health services research in gynecologic malignancies (Elit). Lessons learned from a coordinated region-level quality improvement project could be applied, with appropriate modifications, to other aspects of cancer care or other chronic diseases.

Priorities:

- This area would benefit from closer integration with other health services researchers, particularly in the area of guideline development, dissemination and uptake.

**Program in Evidence Based Care (PEBC)**

The PEBC, directed by Dr. Melissa Brouwers, is a provincial initiative funded by Cancer Care Ontario and academically linked to CE&B. While not currently located on the Henderson campus, the opportunity to relocate the Program in Evidence Based Care from the downtown campus to the Henderson site is a strategic priority. The co-location of the PEBC with the clinical cancer program, cancer clinical trials, and other health services research in cancer, would foster collaboration and create opportunities to significantly strengthen clinical and health services research in cancer.

The evidence-based advice documents developed by the PEBC are the result of an expert knowledge synthesis process that is recognized to be amongst the very best in the world. The up-to-date guideline recommendations on specific aspects of cancer care are guides to best practice and to policy decisions on the most appropriate cancer care interventions. The Program in Evidence-based Care, led by Dr. M. Brouwers in the Department of CE&B is internationally recognized for its guidelines and its innovative methodology and program of research around the science, evaluation and application of evidence-based resources.

Many of the oncologists at the Juravinski Cancer Centre actively participate in the PEBC guideline development process through its 14 disease site and program groups. Dr. Bill Evans and Dr. Himu Lukka chair the provincial Lung and Genitourinary Disease Site Groups, respectively. The Lung DSG has produced 22 clinical practice guidelines and the GU DSG has produced 11 guidelines under their leadership. These guidelines have been published in a wide variety of international journals and posted on Cancer Care Ontario’s website.

Dr. Mark Levine from the Juravinski Cancer Centre chaired Health Canada’s Steering Committee for the Care and Treatment of Breast Cancer. This committee develops evidence-based guidelines for the treatment of breast cancer. Seventeen CPGs have been developed both in a technical form for physicians as well as a lay version. These guidelines are published in the Canadian Medical Association Journal and are also available on the CMAJ and Health Canada websites. The secretariat for the coordination of the development of these guidelines is located in Clinical Trials Methods Group (CTMG) in the Henderson Research Centre.
One of the great challenges in oncology is that guidelines are very complex, reflecting not only different disease sites but also different stages and extent of disease, which often require very different management approaches and the expertise of many different specialists. As a result, targeted and integrated evidence-based recommendations are required to optimize the uptake and application of evidence to improve quality cancer care within a multidisciplinary framework. Further, there is growing recognition while the health care provider team is important to the success of a quality care agenda, so too are other key stakeholders including clinical managers, administrators, policy-makers and the patients themselves. Therefore, there is an impetus to engage these individuals through the development of additional evidence-based products that can aid in their decisions. Clearly these complex interactions create an environment where evidence-based advice in oncology poses numerous challenges for implementation. Improved knowledge brokering and evidence implementation strategies are required to better bridge the academic – service divide.

The need for and interest in practice guidelines and evidence-based advice to support the needs of many decision makers in health care is international in scope. There is both opportunity and interest in building national capacity in order to avoid duplication and develop improved methods of adaptation.

Research Focus:

- To evaluate the implementation of CPGs as well as study the effects of CPGs on the processes of care and their ability to improve patient outcomes.
- Evaluate the target audiences for CPGs and determine whether the CPGs reach these audiences and whether they are able to be adopted and influence care.
- Developing an understanding of the barriers to reaching the target audiences and adoption by these audiences will help develop strategies to support guideline adoption.
- Understanding if the adoption of CPGs will impact on survival and quality of life.

Challenges:

The methods used by the Program in Evidence-based Care and the Steering Committee to create their guidelines are credible, well established and of high quality. There is an opportunity now to realign these efforts to focus on implementation and evaluation. This agenda is in keeping with the Canadian Strategy for Cancer Control.

This expanded CPG group will require upgrades in information technology to be able to access both provincial and national administrative databases as well as recruitment of programmers and statisticians specializing in analyses of administrative databases.

This program would benefit from closer links with McMaster University social scientists and would benefit from the recruitment of sociologists, psychologists, and anthropologists.

Priorities:

This research program would benefit from co-location with the clinical cancer program and other health services researchers on the Henderson campus. The program would benefit from shared recruitment in the social sciences in order to better understand how to overcome the challenges in the uptake of evidence in both clinical and administrative decision making. In addition the program would benefit from shared access to upgraded information system capability.
**Orthopedics**

**Hamilton Arthroplasty Group (HAG) (emerging)**

The Hamilton Arthroplasty Group, led by Dr. Justin DeBeer is a multidisciplinary clinical outcomes research group dedicated to improving joint replacement outcomes, specifically patient quality of life, through continuous quality improvement in clinical service, research and education.

As the Henderson campus takes on greater volumes of joint reconstruction, the clinical program will need to consider how best to structure itself to address the important clinical questions that can be asked. Building a critical mass of researchers as well as the appropriate clinical infrastructure to support the research enterprise will be important factors in taking advantage of this particular clinical focus for the campus.

Research Focus:
- Improving patient outcomes for patients undergoing arthroplasty.

Challenges:
- To further develop patient database and develop clinical trials in the management of joint replacement.
- The development of the joint replacement arthroplasty program at the Henderson campus provides an opportunity for a research focus that explores biomedical, surgical, and mechanical interventions to support active and independent quality of life for patients undergoing joint replacement.

Priorities:
- To collaborate with other research groups on the site in order to assist in developing a program of research.

**Orthopedics in Bone Metastases (under development)**

In addition to tracking outcomes, a collaboration between Dr. Steve Shaughnessy at the Henderson Research Centre and Drs. Michelle Ghert and Gurmit Singh in the bone metastases research program at the JCC is beginning to formulate common research questions. These include the investigation of the effects of joint implant biomaterials on bone metabolism, understanding bone formation in the vicinity of orthopedic hardware, preventing bone breakdown in patients with cancer deposits in the bone, and understanding molecular targets and novel therapies for bone metastasis.

Research Focus:
- See Cancer – Tumour Metastasis Research unit for research focus related to metastatic disease.

**Rehabilitation in Cancer (emerging)**

Challenges:

As a significant portion of the population ages, and as the population generally experiences not only longer life expectancy but also increased survivorship from chronic diseases such as cancer, the need for orthopedic intervention and rehabilitation support will continue to increase.
The co-location of the orthopedic and rehabilitation programs with the cancer program on the Henderson campus provides a unique opportunity for research as well as for integration of these clinical programs, particularly in the management of metastatic bone disease.

As cancer therapies become more specific and effective, and cancer itself is redefined as a chronic disease, the quality of life of for those surviving cancer provides an opportunity for research. It is well recognized that cancer and the therapies used to treat it, commonly lead to disability and impaired quality of life manifesting as fatigue and weakness. And yet little is known of the specific changes that occur in nerves, muscles or bone as a result of the cancer disease state or the treatments used to combat it.

Coping with the disabling effects of chronic disease in an aging population is likely to become a more significant area of focus in health care over the coming decades as the baby boomers enter their senior years.

This emerging research focus for the Henderson would benefit from an analysis of external funding opportunities, opportunities for external collaboration, and required recruitment. Opportunities to partner with the Children’s Hospital, where fundamental and clinical research on muscle and nerve function is strong, will be explored to make maximum use of research and clinical infrastructure and expertise.

While research collaboration at the Henderson might focus on cancer and orthopedic collaboration around bone metastases, there is also great potential to bring together multidisciplinary clinical and research expertise at McMaster and the Henderson to address broader challenges related to musculoskeletal oncology. Such a program could embrace a broad spectrum of researchers, educators and clinical professionals with an interest in improving the quality of life of cancer patients through greater understanding of the mechanisms of muscle, nerve, and bone dysfunction resultant from the cancer state and its treatment.

In January 2006 an invited workshop was held to explore the opportunities and interests amongst multiple disciplines, departments and Faculties. Over 40 individual investigators, clinicians and administrators expressed enthusiastic interest. This workshop led to the formation of a small working group charged with developing a framework for moving this initiative forward. In addition, several pilot projects will be funded by the JCC to generate data that will advance the research agenda in this area and ultimately lead to research into physical, nutritional and pharmacologic interventions.

Priorities:

To identify a research leader who will develop a research program in musculoskeletal oncology that advances understanding of the mechanisms of muscle, nerve and bone dysfunction resultant from cancer and its treatment and that considers the immediate and long-term rehabilitation needs of cancer patients impacted by both cancer and its treatment.

**Henderson Research Centre**

Dr. Jeff Weitz, an internationally recognized hematologist specializing in thrombosis research, is Director of the Henderson Research Centre. The Henderson Research Centre currently occupies 45,000 square feet. This includes laboratory space, an animal facility, offices, and storage. In 2003/04, the program received $8.5 million in funding. This includes $4.1 million in peer-reviewed funding and $4.4 million from industry. In 2004/05, the total funding increased to over $11 million.
The Research Centre has three programs that span a research continuum from basic to clinical: vascular biology, thromboembolism, and clinical trials methodology (described previously). There are synergies between these research programs, which are all closely aligned with cancer and represent a ripe opportunity for collaboration. Plans to consolidate cardiovascular research at the General site need to be meshed with plans for the Henderson Research Centre and the Henderson campus in order to ensure that synergy and stability across research programs are maintained throughout any planned change process. This coordination is essential to preserve and grow the world-class reputation of the Research Centre.

**Clinical Thromboembolism (established)**

Clinical investigators at the JCC and Henderson Hospital have been interested for many years in the thrombotic problems that occur in cancer patients. Trials have been conducted which have examined how to prevent thrombosis in women with breast cancer receiving chemotherapy and how best to treat acute thrombosis in cancer patients. There is still much research to be done. Examples of unanswered questions include: how to identify those patients with cancer at highest risk for thrombosis so that they can receive prophylaxis, the optimal method to prevent and treat catheter thrombosis and how to reduce the rate of recurrent thromboembolism in cancer patients with acute thrombosis. In addition, there is emerging evidence that low molecular weight heparins (LMWHs) can affect tumor growth and metastasis through a number of mechanisms. This data however, is preliminary and requires confirmation through large trials. There is a major opportunity for clinical investigators at the JCC and Henderson to tackle this research agenda.

In addition to investigating evidence-based treatment of thrombotic disorders in cancer patients, this unit also looks at thrombotic risk and treatment of patients undergoing major and traumatic orthopedic surgery. Current clinical thrombosis investigators at the Henderson site include Drs. C. Kearon, A. Lee, L. Linkins, M. O’Donnell, M. Levine and J. Weitz.

Research Focus:

- **The Clinical Thrombosis Program at the Henderson Hospital site is part of a larger program that has a node at each of the four campuses at HHS and at St. Joseph’s Hospital. Each of these sites provides a clinical service that offers inpatient and outpatient consultation for patients with suspected or documented thrombotic conditions.**

- **Individuals working at the Henderson site are involved in citywide, national and international clinical trials. Studies focusing on thrombosis prevention in orthopedic patients or diagnosis and treatment of thrombosis in cancer patients involve the Henderson site more than other sites in the city. Outcome studies, such as those dealing with the risk of recurrent thrombosis or long-term complications of thrombosis, are conducted citywide or as part of national or international trials.**

- **Research includes non-invasive methods for diagnosis of DVT and pulmonary embolism, optimal anti-coagulation treatment in cancer patients, the role of anti-coagulants as anti cancer agents, optimal anti-coagulant treatment in patients with thrombosis, counseling of patients at risk for thrombosis. Research in cancer/thrombosis interface, Identification of risk factors for stroke as well as prevention and treatment of stroke.**
• Building on the cancer focus at the Henderson site, further research activity in the cancer/thrombosis interface is planned. In addition, moving into the vascular arena, there is a push for increased research into arterial thrombosis. For both venous and arterial thrombosis, research is expanding into gene and environmental links to pathogenesis.

Challenges:

Opportunities for growth are in the area of health outcomes research and application of new diagnostic modalities. Success in health outcomes research requires recruitment of an individual with strengths in this area. This has been accomplished through the recruitment of Dr. Fred Spencer to the MUMC site. A cardiologist who specializes in vascular medicine, Dr. Spencer was recruited from the University of Massachusetts. A full Professor, Dr. Spencer has a long track record of research in health outcomes in patients with venous and arterial thrombosis.

Research in new diagnostic modalities requires better access to new imaging technology (e.g., 64-slice CT and MR) and a research-oriented person in diagnostic imaging who has expertise with these techniques.

To accommodate the current researchers, coordinated office and research space is needed to house Drs. Kearon, Lee, Linkins, and O'Donnell. Having these individuals in one place will enhance interactions and promote new synergies. Space for research nurses and fellows also will be necessary. Because of the reliance on diagnostic imaging, the Thrombosis Unit should be located in close proximity to the imaging facilities.

Recruitment will focus on an individual with an interest in thrombosis and cancer who can link effectively with the fundamental research group at the HRC.

Priorities:

The overall priority is to create a culture of research wherein staff and learners apply an evidence-based approach to all aspects of thrombosis management. Current research priorities focus on (a) non-invasive methods for diagnosis of thrombosis, particularly in complex situations, such as the postoperative state or in the setting of cancer, (b) optimal anticoagulation treatment for patients with cancer, (c) potential role of anticoagulants as anti-cancer agents, (d) optimal duration and intensity of anticoagulation therapy for patients with thrombosis, and (e) investigation of new anticoagulants for prevention of thrombosis in patients undergoing major orthopedic surgery or for treatment of acute thrombosis. An underlying theme is support of learners at all levels. In addition, the group has served as a model of mentoring where more established investigators have willingly provided time and resources to ensure the success of more junior colleagues. The success of these ventures is evident by the large number of faculty and trainees who have career support from external granting agencies or from local sources.

Vascular Biology (established)

The fundamental research group at the Henderson Research Centre is world-renowned for their work in thrombosis and is gaining national and international recognition for their work in atherosclerosis and cancer. Building on the unique strengths at the Henderson Hospital site, the vision for this research group is to expand its international reputation by developing a world-class research group on the interplay between cancer and thrombosis. Investigators in this program are supported with both career awards (Heart and Stroke
Foundation (Chan, Weitz, Austin, Werstuck, Liaw), PREA (Liaw), Tier 1 Canada Research Chair (Weitz), HSFO/J.F. Mustard Chair in Cardiovascular Research (Weitz) as well as grants-in-aid from CIHR, HSFC and ORDCF and a Team Grant from CIHR (Weitz).

Current vascular biology investigators at the Henderson include Drs A. Chan, J. Weitz, E. Young, R. Austin, G. Werstuck, P. Liaw, P. Klement, and S. Shaughnessy.

Dr. Rak has been recruited to an Endowed Chair position at McGill University and will be leaving the HRC this summer. Although he will continue to collaborate with scientists at the HRC, his departure leaves a gap in our research capabilities at the cancer/thrombosis interface. Consequently, recruitment to fill this gap is of high priority.

Research Focus:

- The current focus is on the interplay between thrombosis, atherosclerosis, inflammation, and cancer.

- In thrombosis, Dr. Chan’s research interests include developmental aspects of the coagulation and fibrinolytic systems, identification of novel methods to inhibit clotting triggered by blood-contacting medical devices, and studies of clotting on the surface of vascular and epithelial cells.

- Dr. Weitz’s research focuses on structure-function relationships of clotting enzymes and their inhibitors, identification of the factors involved in thrombosis at sites of vascular injury (e.g., ruptured atherosclerotic plaques), examination of the role of clot-associated clotting enzymes in thrombus expansion, and studies into the mechanism of action of novel blood thinning drugs (anticoagulants) and clot-digesting agents (fibrinolytic drugs).

- Dr. Young’s research focuses on heparin and heparin derivatives. In addition to studies into the metabolism of these commonly used anticoagulants, Dr. Young is studying their anti-inflammatory properties. He has evidence that the anti-inflammatory properties of these drugs can be dissociated from their anticoagulant effect. These data raise the possibility that modified heparin derivatives may represent a novel class of anti-inflammatory drugs.

- Focusing on atherogenesis, Dr. Austin uses hyperhomocysteinemia as a model for modulation of the atherosclerosis process. An independent risk factor for atherosclerosis, Dr. Austin has shown that hyperhomocysteinemia enhances the development of atherosclerosis. Furthermore, he has shown that the effects of hyperhomocysteinemia reflect its capacity to impair the function of the endoplasmic reticulum, the cellular organelle involved in protein packaging. Perturbation of this organelle causes cell death, fat accumulation, inflammation and thrombosis, hallmarks of the atherosclerotic process.

- Also focusing on atherogenesis, Dr. Werstuck is studying the mechanisms by which diabetes enhances this process. Diabetes is a well recognized risk factor for atherosclerosis and Dr. Werstuck has shown that, like hyperhomocysteinemia, the increased glucose concentrations found in diabetes also affect the protein packaging plant of cells thereby triggering cell death, fat accumulation, inflammation and thrombosis. Dr. Werstuck is exploring the effect of novel agents that block these pathways on diabetes-induced atherosclerosis.
Dr. Liaw is investigating why cancer patients receiving chemotherapy are particularly prone to clotting problems. She has shown that exposure of the cells lining the blood vessels to chemotherapeutic drugs cause these cells to lose their ability to prevent clotting on their surface. Dr. Liaw also is exploring the mechanisms responsible for the anti-inflammatory properties of activated protein C. Activated protein C is a naturally occurring anticoagulant that also has anti-inflammatory properties. This protein is reduced in patients with severe infections and supplemental activated protein C has been shown to improve survival in these patients by blocking both coagulation and inflammation.

Dr. P. Klement has developed models of cardiovascular disease and cancer that are invaluable to all members of the research group. Dr. Klement has pioneered the evaluation of new cardiovascular devices that include grafts and catheters. These studies are leading to the development of blood-contacting medical devices that are resistant to clotting.

Dr. S. Shaughnessy is investigating why heparin, a blood thinner, causes osteoporosis. This work has identified new molecular targets involved in osteoporosis. These targets not only play a role in drug-induced osteoporosis, but also are involved in bone breakdown in patients with metastatic cancer. Capitalizing on this information, Dr. Shaughnessy is developing new methods to block osteoporosis.

Challenges:

The major focus over the next 3 to 5 years is to develop a world-class program in cancer and thrombosis, and build critical mass in atherosclerosis research.

The program plans to recruit at least 2 scientists with expertise in cancer, thrombosis or their interface. These individuals will require at least 2000 square feet of equipped laboratory space. There is also a plan to recruit at least 1 scientist whose work focuses on atherosclerosis or vascular biology. This individual will require 800 to 1000 square feet of equipped laboratory space.

Longer-term plans will see the atherosclerosis program moving to the Cardiovascular and Stroke Research Institute at the Hamilton General site. The cancer/thrombosis group will remain at the Henderson Hospital site where it will become the premier research program in the field and will link with clinical researchers, including Drs. A. Lee, M. Levine, H. Hirte, S. Hotte and others. With these changes, it will be important to ensure that a critical mass is maintained at both the Henderson General and Hamilton General sites and that there is suitable leadership at these sites to foster growth and develop new programs.

As basic scientists at the Henderson Research Centre are conducting research on the role of the endothelial cell in the pathogenesis of thrombosis, the mechanisms by which chemotherapy–induces thrombosis and on tumor angiogenesis and a focus of the basic scientists at the JCC is metastasis, there is clearly an opportunity for collaboration between the two groups. At the JCC, there is a unique opportunity to collect tumor blocks, blood samples, and even fresh tumour from cancer patients who are at risk for thrombosis or who develop thrombosis. Hence, the clinical and basic investigators at the JCC and Henderson can lead the way in translational research examining why certain patients with particular cancers are resistant to conventional anticoagulants, the role tissue factor plays in thrombosis and tumour growth/metastasis, the mechanism underlying the anticancer affect of LMWHs, and the pathogenesis of thrombosis with new targeted anticancer agents, e.g. anti VEGF and thalidomide.
The fundamental research group at the Henderson Research Centre has a long track record of success in peer-reviewed and industry funding that will continue and expand. A Team Grant application to CIHR has recently been approved and will boost infrastructure funding and strengthen collaborations in Hamilton, across Canada and internationally. New recruits will apply for infrastructure support from the New Opportunities Fund and all will be expected to obtain external grant support for projects and for salary.

Laboratory space for new recruits will need to be equipped with (a) refrigerators, (b) -20°C freezers, (c) fume hoods, (d) safety cabinets, and (e) -70°C ultra-low temperature freezers.

Priorities:

To perform fundamental research on the interplay between thrombosis, atherosclerosis, inflammation and cancer that translates into advances in the prevention, diagnosis and treatment of these disorders.

**Strategic Priorities**

When considering strategic priorities it is important to remember that a research plan for the JCC/Henderson site needs to build on and be consistent with planning within the Henderson Research Centre for transition of aspects of the Vascular Biology Program to the new research centre planned for the Hamilton General.

As this transition and evolution occurs, the research focus of the JCC/Henderson site will shift to cancer and it is therefore important for the research plan to embody the concept of a Cancer Research Institute for the JCC/Henderson site.

As described elsewhere in this document, this transformation of research focus for the site represents a complex but important planning challenge. Therefore paying attention to organizational and communication structures early on and throughout the process will be extremely important.

The initial strategic planning priorities for the Henderson can be considered in three domains: organizational structure, developmental tasks, and priorities for investment. A three-year plan is suggested because of the work that needs to be accomplished within the short term to restructure and consolidate the management of research on the site and to make key investment decisions. This initial planning period should be considered as a building block that will help provide a foundation for moving the site from its current state of excellence and opportunity towards an extremely dynamic future. This future will include molecular research; the development and translation of targeted molecular therapies; health services research; knowledge transfer; and research that focus on the interface between cancer and thrombosis, cancer and orthopedics, and cancer and rehabilitation.

**Organizational structure:**

1. Appoint a leader for research development for the site.
2. Develop integrated planning and communication processes to support the development and transition of research programs across sites.
3. Develop a governance structure for the cancer institute.
4. Consolidate cancer clinical trials activities and health services research into a single organizational structure.
5. Consolidate research programs in areas of collaboration such as orthopedics and metastatic disease.

**Development Tasks:**

1. Develop a transition plan for the site in order to prepare for the move of vascular biology to the Hamilton General.
2. Confirm and develop a transition plan to move the Cancer Care Ontario Program in Evidence Based Care to the Henderson site. This move is likely 3 to 4 years off so the transition plan is critical.
3. Develop a plan to bring cancer clinical trials and health services research into a single structure.
4. Prepare a capital plan and fundraising strategy to build additional research space at the Henderson.
5. Continue to participate in the development of an integrated cancer research plan for McMaster University, and the multiple sites of HHS and SJHC.
6. Develop a framework for a musculoskeletal oncology research program.
7. Develop a knowledge transfer program at the Henderson site.
8. Continue to develop the CFI RHF application for this site.
9. Prepare to position cancer research to take advantage of opportunities provided by the creation of the Ontario Institute of Cancer Research.

**Priorities for Investment:**

An internal process was implemented in 2005/06 to collect data that would inform a strategic plan for research. This data includes current personnel and physical research resources as well as estimates of personnel and space needs over the next 5 years. This detailed information is preliminary to the actual research plan and therefore is not included in this document. This data will continue to be revised and enhanced as the plan begins to take shape and will be used to support investment decisions around recruitment processes as well as fundraising and capital planning.

It is important to quickly begin to implement plans for strategic investment in areas identified in this document. Given the initial strategic priorities, it is therefore recommended that planning begin immediately to support the following investments over the next five years:

**Personnel**

1. A clinician scientist for the cancer/thrombosis interface,
2. An internationally recognized leader in experimental therapeutics,
3. An academic molecular pathologist,
4. A clinical pharmacologist.
5. Social scientists including health policy researcher, bioinformatics expertise, and biostatisticians.

**Facilities**

1. Capital planning to house and support expanded and consolidated research programs including information systems infrastructure to support clinical research. It is estimated that approximately 25,500 sq ft of new dry lab space will be required to accommodate growth. Initial cost estimates put this development at approximately $10 million.
2. Develop funding applications and strategies to support the development of a tissue bank for enhanced molecular targeted clinical trials.
Hamilton Health Sciences Research Development Plan

McMaster University Medical Centre (MUMC) Site Research Development Plan

Research Themes

Institute for Gene Therapeutics
Intestinal Diseases Research Institute
McMaster Child Health Research Institute
Centre for Knowledge Transfer
Centre for Advanced Clinical Imaging
Infectious Diseases Research Program
Obstetrics and Gynecology Research Program
McMaster Transfusion Medicine Program
Executive Summary

Hamilton Health Sciences’ McMaster University Medical Centre (MUMC) is a large hospital facility shared largely with McMaster University’s Faculty of Health Sciences. The MUMC site is home to several well-established and developing research Institutes, Centres and Programs.

The predominant research themes at the MUMC site include:

- Gene Therapeutics
- Intestinal Diseases
- Pediatrics
- Knowledge Transfer, Clinical Epidemiology and Bio-statistics
- Molecular Radio Imaging and Therapy
- Obstetrics and Gynecology
- Hematology

These research themes are captured under strong research Institutes, Centres and Programs that have made significant contributions to our healthcare landscape in Hamilton, Canada and beyond borders. These areas are described an environmental analysis below.

The MUMC site strategic plan calls for a series of focused efforts to further enhance each research theme area. These plans include the development of additional leadership and governance structures in four specific areas: Intestinal Diseases Research Institute, McMaster Child Health Research Institute, Centre for Advanced Clinical Imaging and the Obstetrics and Gynecology Program.

Additional developmental plans HHS will undertake to further enhance the excellence in research at the MUMC site include: a funding and resource review in collaboration with McMaster University and the HHS Foundation for key strategic growth areas like the McMaster Child Health Research Institute; Additional development of the knowledge translation area including coordination with the Centre for Optimum Healthcare Delivery; Increased network initiatives linking related research activities across Canada; and enhanced coordination of research activities across Hamilton Health Sciences’ multi-sites.

Environmental Analysis

Institute for Gene Therapeutics (IGT)

The Institute investigates, creates and implements approaches utilizing the delivery of genes as therapeutic agents in the treatment of human and animal disease. This entails basic investigations to target gene product involvement, creation of vector systems for appropriate delivery of therapeutic genes and rapid translation of promising medicines to the clinical setting. The Institute is focused on developing novel cures for cancer, inflammatory diseases and infectious diseases using state-of-the-art gene transfer technology coupled with the most recent information derived from the application of genomics. Working as a team, scientists and clinicians will ensure a world-class institute boasting cutting-edge research facilities and provide the most up-to-date medical solutions for the people of Southern Ontario and Canada.

The Institute for Gene Therapeutics is built on the foundation of basic and clinical research activities that have been ongoing at McMaster for the past twenty years. Indeed, McMaster
has a history of world leading activities in pulmonary and gastrointestinal (GI) research, virology, immunology and cytokine biology. The Institute successfully brings together expertise in those areas with state-of-the-art gene transfer technology as demonstrated by our list of publications, patents, consultations and invitations to international conferences.

The Institute is investigating methods to introduce genes directly into cancer cells to modify their growth properties and stimulate rejection of the tumour mass by the immune system. This work depends strongly on advanced gene transfer technologies developed at IGT, as well as a thorough understanding of the molecular workings of the cancer cell. Jonathan Bramson and Yonghong Wan are developing gene-based and cell-based cancer vaccines to re-educate the immune system allowing it to attack the cancer and eliminate metastatic growth. Brian Lichty and Karen Mossman are working on oncolytic viruses as cancer therapeutics. The Institute’s lead clinical researcher, Ronan Foley, is responsible for bringing these new therapies to patients.

Asthma, allergic rhinitis, chronic obstructive pulmonary disease (COPD) and fibrosis are inflammatory diseases that cause extraordinary morbidity and mortality. Manel Jordana and Martin Stämpfli have used transient gene transfer technology to unravel the immune mechanisms associated with allergy and allergic airways inflammation to develop gene transfer-based therapeutic approaches to regulate the allergic immune responses. Dr. Stämpfli has also begun to approach COPD in a similar manner. Jack Gauldie has used similar approaches to understand the pathobiology and underlying molecular mechanisms of lung fibrosis and is working on new drug approaches to modify gene expression and fibrogenesis.

Kenneth Rosenthal, Charu Kaushic, Ali Ashkar and Jack Gauldie have an extensive infectious disease and gene-based vaccines program investigating the development of vaccines to induce potent mucosal immune protection against sexually transmitted infectious like Herpes Simplex Virus Type I and II and Human Immunodeficiency Virus (HIV). Zhou Xing has created a research program to identify key cell types and cytokines in host responses to both acute and chronic bacterial diseases, and to develop molecular vaccines against bacterial infections of the lung, the most notable being tuberculosis. There is a strong interaction between the prophylactic and therapeutic infectious disease vaccine development programs and the therapeutic cancer vaccine development program in association with the Networks of Centres of Excellence – Canadian Network for Vaccines and Immunotherapeutics (CANVAC).

**Intestinal Diseases Research Institute (IDRI)**

The goals of the Intestinal Diseases Research Institute (IDRI) are to understand the causes of chronic gastrointestinal diseases that are prominent in our society, and to develop new strategies for their treatment and prevention.

This Institute represents a natural progression for the strong multidisciplinary digestive diseases research group that was founded in 1983 following a national competition for establishment funds. This group was later integrated into the Faculty of Health Sciences as a formal Research Program – The Intestinal Diseases Research Program (IDRP) in 1995. The IDRP retained its diversity and critical mass, and ranks among the top 10 GI research groups for over 20 years. The long-term stability and competitive edge of this, now suitably entitled, Institute has been enhanced following the receipt of a private donation of $3.5 million for the establishment of a Research Chair and the Farncombe Gnotobiotic Unit, as well the establishment of 2 other endowed Research Chairs (The Astrazeneca-Richard Hunt Chair and the Glaxo-Smith-Kline Chair). The IDRI has 18 full time faculty members who
supervise 18 graduate students and 10 post-doctoral fellows. The group has maintained its interdisciplinary bench-to-bedside spectrum of research. The IDRI’s strength lies in its focus on translational research, and in the development and exploitation of models of common human GI diseases. Activities range from the molecular basis of GI disease to population-based studies. The research is inherently translational in nature and involves a mixture of clinician and non-clinician scientists.

The scientific focus of IDRI has recently shifted towards the interface between the gut and its vast population of commensal bacteria (flora). The award of the 2005 Nobel Prize for Medicine to Warren and Marshall for the discovery of *Helicobacter pylori* as the cause of peptic ulcers has prompted strong consideration of a pathogenic role of other “resident” bacteria in functional, inflammatory and neoplastic diseases of the GI tract.

Until recently, the complexity of two supersystems (the intestinal mucosa and the luminal content of a diverse and dense microflora) has proved extremely difficult to investigate systematically. There are two technical advances that have opened up this area. First, the McMaster gnotobiotic animal facility is specially designed to allow rederivation of murine strains germ-free by embryo transfer, which is a faster and more reliable method than the traditional means of Caesarian section used by most of the other units in the world. This means that it is feasible to carry out strain combination experiments where the function of specified host gene products can be studied in their interaction with defined populations of intestinal bacteria. Secondly, it is now possible with new ultrafast nucleotide sequencing systems to carry out detailed analyses of the composition, and some aspects of the functioning, of the intestinal microflora without the difficulty that many of the component species cannot be easily cultured ex vivo.

The clinical research component of the IDRI spans applied research, clinical trials and population-based research evaluating *H. pylori* associated disease, gastroesophageal reflux, NSAID induced injury to the gastrointestinal tract and inflammatory bowel disease. The recent recruitment of Dr. Paul Moayyedi as the first recipient of the Richard Hunt Astra-Zeneca Chair of Gastroenterology has further strengthened the clinical research component. He has conducted a large population randomized controlled trial evaluating the clinical benefits and health economics of community *H. pylori* screening and treatment involving over 8,000 participants. The IDRI also has a strong knowledge translation component and has produced several influential Cochrane systematic reviews on the management of dyspepsia, treatment of functional dyspepsia and the treatment of inflammatory bowel disease.

**McMaster Child Health Research Institute (MCHRI)**

The development of our children and youth determine our future. Nearly one million Canadian children have health conditions leading to physical, social, emotional, developmental, and/or intellectual problems. Over 500,000 Canadian children and youth have health needs that compromise their physical, social and/or emotional health, developmental capacities, and optimal participation in everyday life within our communities.

There is growing evidence that many acute and chronic diseases, disabilities and injuries that constitute major public health problems for children in both developed and developing countries result from life course exposures and not simply from discrete events in children’s and families’ lives. Until recently, most research on the early life origins of disease and disability focused on intrauterine growth and development, but the importance of postnatal growth and developmental trajectories in the development of disease risk across the life span have become recognized increasingly as important foci for study. The relative influence
of early (as compared with later life factors) is yet to be fully determined and is likely to
differ by disease and disability outcome and by time and place.

There are no major child health research institutes in Canada that focus on studying child
health and development issues from the life course perspective, i.e. from conception into
adulthood and old age. We believe that McMaster University is uniquely positioned to
become an international leader in understanding and measuring determinants of health and
well being in children and their families, and in identifying effects of these determinants
across the life span. Successful exploration of these issues will make it possible to develop
effective interventions to improve the health and well-being of children and their families,
and their health across all stages of life.

McMaster University and McMaster Children’s Hospital have world-class researchers and
educators in many of the areas that are required to create this Institute. Excellence resides
in faculties such as Health Sciences (e.g., clinical epidemiology, paediatrics, medicine,
rehabilitation science, psychiatry), Science (e.g., psychology, mathematics, biological
sciences), Social Science (e.g., sociology, economics, geography) and Humanities (e.g.,
languages, music and art).

McMaster has internationally renowned research groups who have consistently obtained
millions of dollars to study critical clinical, biological, genetic, behavioural, social and
economic issues related to children and youth, and the transitions into adulthood and
beyond. McMaster is one of the lead institutions in the development of a multi-million dollar
20 year longitudinal study as part of the Canadian Institutes of Health Research (CIHR)
Canadian Life-Long Health Initiative (CLHI). This CIHR initiative includes the development
of the Canadian National Birth Cohort study, Canadian Longitudinal Study on Aging and an
Intergenerational Study on understanding health from a life course perspective.

Centre for Knowledge Transfer

The Centre for Knowledge Transfer led by R. Brian Haynes includes several well established
research programs supported by external research funding of at least $1 million annually
each. These programs include: Clinical Advances through Research and Information
Translation (CLARITY), Diabetes Hamilton, Health Information Research Unit, Program in
Policy Development, and Patient Decision Aids.

The Centre’s mission is to conduct and coordinate an aggressive program of Knowledge
Translation Research, incorporating hospital priorities and supporting its research groups in
their KT research and responsibilities. With its vision of leveraging KT research talent at
McMaster University and HHS to become the premier KT research group in Canada and the
world.

Centre for Advanced Clinical Imaging

The Centre of Advanced Clinical Imaging led by Karen Gulenchyn includes molecular
radioimaging and therapy research. The Centre’s programs include:

- The development of innovative radiolabelled molecules for the investigation of
  biological and pathological processes led by Raman Chirakal (HHS) in collaboration
  with Gary Schrobilgen (McMaster) and John Valliant (McMaster).
- Biological & Pharmacological characterization of radiolabelled molecules led by Rene
  Labiris (McMaster).
- Imaging of radiolabelled molecules led by Troy Farncombe (HHS)
Investigation of body composition & occupational nuclear medicine with research leads Colin Webber (HHS) and David Chettle (McMaster).
Development of and management of clinical trials utilizing these techniques with leads Karen Gulenchyn and Christopher Marriott.

The Centre’s mission is to conduct a programme of Molecular Radioimaging and Therapy Research, incorporating hospital priorities and supporting its research groups in their biological research. It’s vision is to be Canada’s leading clinical and research centre for molecular radioimaging and therapy.

**Infectious Diseases Research Program**

The Infectious Diseases research program is strongly built on three components, a clinical epidemiology group headed by Mark Loeb, which has attained approximately $24 million in external research funding support spread over 2006 to 2011; An immunovirology group led by Jonathan Bramson supported by $3 million in external research grants over the next five years (to 2011); and a mathematical modeling group led by David Earn.

The Infectious Diseases program is located in the Michael DeGroote Centre for Learning connect to McMaster University Medical Centre. The purpose of the Program is to improve the understanding of pathogenesis, epidemiology, and to develop improved control strategies of infectious diseases. Furthermore, its vision is to be internationally recognized as a leading centre for infectious diseases research.

**Obstetrics and Gynecology Research Program**

The Department of Obstetrics & Gynecology has several well-established projects that address key emerging environmental and health issues for Canadians that encompass several of the Canadian Institutes of Health Research (CIHR) priority themes. Specifically, the CIHR Biomedical research theme is addressed by projects designed to investigate key mechanisms in the pathogenesis of endometriosis (CIHR, Foster and Holloway), altered tissue remodeling enzyme expression (NSERC, Foster), biomarkers of breast cancer (American Chemistry Council, Foster and Holloway), and the effect of developmental exposure to water disinfection by products on postnatal diabetes and obesity (Canadian Chlorine Coordinating Council, Holloway). The CIHR Clinical research theme is addressed by ongoing projects that are investigating the benefits of anti-angiogenic drugs in endometriosis (CIHR, Casper and Foster) and the association between developmental exposure to environmental toxicants and childhood thyroid and immune function (American Chemistry Council, Foster, Holloway, Crankshaw, and Wainman). The relationship between socioeconomic status and exposure to environmental toxicants (New York Community Trust Fund, Foster) address the CIHR’s Socioeconomic research theme.

In addition, the Department and Program of Obstetrics & Gynecology lead and participate in multi-centered trials that are focused on direct clinical application. These include Post Caesarean Nutrition Study (lead centre – Dore, Brennan), INTAPP (Winsor), and Twin trial (Mueller). Local clinical trials include bladder scanner post gyn surgery (Dore, Cotton, Fedorkow).

The mission of program is enhancing reproductive health through excellence in research. With a vision of establishing a dynamic program in reproductive medicine founded on excellence in research, clinical practice, and training that will lead to improved treatment Options for Canadians.
The Departmental and Program research objectives are to:
1. Develop multidisciplinary research teams in the pursuit of groundbreaking research in reproductive biology and obstetrics & gynecology;
2. Enhance the translation of bench research into novel and innovative treatment strategies; and
3. Increase the number of highly qualified personnel trained in reproductive biology.

**McMaster Transfusion Medicine Program**

The McMaster Transfusion Research Program is dedicated to the advancement of innovative evidence-based diagnostic, clinical, and therapeutic practices in Transfusion Medicine. The Program's ultimate goal is to provide scientific evidence that will inform transfusion practice and enhance the safety of blood recipients.

The Program is actively involved in four broad research areas:
- Conducting multi-centre clinical research in Transfusion Medicine. Randomized controlled trials, qualitative studies, economic evaluations, and cohort/case control studies are being conducted in the areas of blood utilization/conservation, transfusion practices, quality management, donor-related issues, and education;
- Initiating and supporting transfusion research across Canada through establishment of Research Networks;
- Promoting education by disseminating research results and conducting research methodology training;
- Providing evidence-based scientific information for policy development.

A major interest within the Program is the establishment of a national Donor Research Network to bring together individuals from across Canada, individuals focused on identifying the most effective ways to recruit and retain blood donors. The number of blood donors has dropped over the past ten years and at times there has been a shortage of blood and blood products. To ensure the demand for this vital resource can be met, it is important that a stable pool of active blood donors be developed and maintained. A collaborative Canadian program of blood donor research is the first step in the process of gathering national evidence on the most effective ways to increase the number of donors, enhance the donor experience, improve donor return, and hopefully ensure that an adequate blood supply is always available. In addition, a reference manager database of donor related publications has been compiled for the convenience of individuals searching for scholarly articles and reports.

The Program also leads the Quality Essentials for Safe Transfusion (QUEST) project, a project actively involved with teaching and community hospitals. The following initiatives have been implemented or are underway for use in hospital laboratories:
- A policy and procedures manual
- An error management program
- A document control and training program
- A tracking system for IVIG
- New guidelines for a maximum surgical blood donor schedule
- A patient notification program
Strategic Plan

Institute for Gene Therapeutics (IGT)

**Disease Targets and Research Areas:** IGT will focus on developing novel intervention approaches targeted to cancer, chronic inflammatory diseases and infectious diseases. The Institute’s ongoing phase II clinical trials in cancer are the first application of cell-based gene therapy in humans in Canada, and it is uniquely positioned to develop further applications in this and, possibly, other clinical areas in the next few years.

**Cancer:** Dr. Foley’s group, in collaboration with clinicians at the Juravinski Cancer Centre, has completed a phase II trial in skin cancer using a cell-based cancer vaccine designed at the Institute, and initiated a second cell-based cancer vaccine trial in breast cancer in collaboration with Dr. Mark Levine and Dr. Bindi Dhesy-Thind. Together, a multi-pronged approach to the treatment of cancer will be developed, which will likely involve a combination of therapeutic strategies.

**Respiratory Diseases and Allergy:** IGT will continue to investigate respiratory diseases and allergy in relation to high morbidity and mortality. The Institute will collaborate closely with researchers in the Firestone Pulmonary Research Institute to advance research knowledge and healthcare in this area.

**Infectious Diseases and Gene-Based Vaccines:** IGT will further its research in close collaboration with the Digestive Diseases Research Unit in mucosal immunity.

Intestinal Diseases Research Institute (IDRI)

**Host-microbial interactions:** Following the discovery of the *Helicobacter pylori*, McMaster will play a lead role in this field following the recent establishment of a gnotobiotic facility, which enables the study of host-microbial interactions under controlled conditions. This facility is unique in Canada and few exist in academia worldwide. Dr. Andrew Macpherson who was recently recruited from the Institute of Experimental Immunology in Zurich directs the facility.

**Gastrointestinal Disease:** The IDRI has received funding from The Ontario Research & Development Challenge Fund (now part of ORF) valued at $18.2M, with ORDFC providing $4.1M and the private sector $6.1M. This grant enables the study of “The Gut and The Environment: A Centre for the Study of Chronic Gastrointestinal Disease.” The research support will be aimed at identifying and commercializing the therapeutic application of host-microbial interactions (probiotics). Funding has also been received from Genome Canada to study the interactions of the intestinal microflora in the genesis of autoimmunity in the non-obese diabetic mouse model of Type 1 diabetes ($6.5M).

**Clinical Trials:** McMaster’s IDRI will be the coordinating site of a national GI trials a series of individual and cluster randomized trials throughout Canada. This involves over 100 gastroenterologists in approximately 20 hospitals throughout Canada. The Canadian Association of Gastroenterology is currently obtaining funding for the establishment of this initiative to create the McMaster GI Clinical Trials Unit. Projects that will first utilize this Unit are colonoscopy screening to prevent colorectal cancer, the evaluation of aggressive acid suppression and/or aspirin to prevent esophageal adenocarcinoma in patients with Barrett’s esophagus (AspECT study) and the value of endoscopy surveillance in detecting early
esophageal cancer (BOSS study). The AspECT study collaboration between the UK and Canada and is already funded by $20 million from Cancer Research UK and AstraZeneca. BOSS is funded by $2 million from Health Technology Assessment UK.

**Upper GI and Pancreatic Diseases:** Dr Moayyedi has been approached to lead the Upper GI and Pancreatic Diseases Cochrane Group and move it from its current location at the University of Leeds UK to McMaster University. There will be bridge funding from the UK Department of Health of approximately $500,000 and the National Canadian Cochrane Centre in Ottawa will obtain additional funding through CIHR. This will build on McMaster's strengths in evidence based medicine and knowledge translation.

**Bacterial Dysentery:** The outbreak of bacterial dysentery in Walkerton from the contamination of the municipal water supply has initiated a study on the impact of an acute gastrointestinal infection in relation to chronic gastrointestinal disease. Over 4000 residents have registered to participate in the Walkerton Health Study - a 7-year prospective study of health outcomes. The Institute will evaluate the impact this has on post-infectious irritable bowel syndrome ($414,000 funded by the Ontario Ministry of Health) and the incidence of inflammatory bowel disease ($360,000 funded by the Crohn’s and Colitis Foundation of Canada).

**Knowledge Translation:** IDRI will establish an Intestinal Diseases theme based franchise under the Unit of Optimum Healthcare Delivery. By forming a multidisciplinary franchise of researchers, patient services and clinical staff, IDRI will initiate and coordinate broad based research and facilitate efficient translation of basic research findings to benefit patients.

The Intestinal Diseases Research Institute will serve as a model of multidisciplinary translational research in which both clinical and basic research activities will flourish. As such, it will provide a unique and stimulating environment for training of young investigators. The Institute will generate new insights into the causes of common GI diseases as well as new strategies for these conditions, and will harness its well-established linkages with the private sector to facilitate the commercialization of these discoveries.

**McMaster Child Health Research Institute (MCHRI)**

**Life-Course Approach:** Studying child health and development issues from the life course perspective is an initiative being developed as a consortium of several Faculties and Departments across the University and Hamilton Health Sciences led by McMaster's Children’s Hospital and the academic department of Pediatrics. As a consortium, the Institute will coordinate, initiate, and support interfaculty, interdisciplinary research and training in child health and family well being from the life course perspective.

This consortium and life-course approach is important the dynamic and multi-faceted process of child and youth development can only be examined appropriately through interdisciplinary research that captures the changing lives of individuals and populations within an emerging social context and incorporates multiple levels of inquiry, from the molecular and cellular levels to the individual, the family, and society. Furthermore, in order to advance our understanding of the causal pathways leading to adverse events or favourable outcomes and to meet the needs of the children/youth and their families and generations of today and tomorrow, there is an urgent need to develop expertise relating to developmental trajectories and the long-term effects of child disease and disability on the life course of children and their families.
By building on the existing research capacity, and integrating expertise across the lifespan, the Institute will foster national and international leadership in child health and its influence on the life course not possible in other academic centers in Canada. This will provide a secure platform for faculty retention and a platform for the recruitment of leading national and international investigators.

The mission of the Institute is to foster collaborative research and educational efforts dedicated to understanding the forces and experiences that shape human development and health as children and youth move throughout the life-course. Employing a life-course perspective, focusing on long-term outcomes of early experiences, we aim to address the needs of those children and youth (developmental, mental, physical and psychosocial) that compromise their physical, social, and/or emotional health and developmental capacities and potential, and to understand the impact of these forces on families raising these children. Through this work, we can promote an understanding of existing and emerging challenges to the effective functioning of individuals and families across the life-span, and identify potential treatment solutions and preventive strategies.

The strategic plan objectives of MCHRI are to:

- Conduct child health research focused on understanding and optimizing physical, social and/or emotional health, and developmental capacity of children at risk by virtue of chronic health problems, developmental impairments, or social adversity.
- Develop knowledge regarding the long-term effects of childhood disease and disability on the life course of children and families.
- Leverage diverse initiatives to foster collaborative research across campus through links with Collaborations on Health and partnerships on specific research projects.
- Train highly qualified personnel through i) graduate program in child health, ii) graduate courses in longitudinal research methodologies, and iii) post doctoral training positions.

The Institute will provide the opportunity for the development of innovative program themes, including:

- Building on modern frameworks of health from the World Health Organization, shifting the developmental pathways of children with special needs toward improved function, and societal participation.
- Exploring variations in children's development or current functioning resulting from interactions of conditions that are intrinsic to the child, and environmental factors which may present opportunities or barriers to full development.
- Opportunities to promote health development through nutrition/exercise at the clinical and population levels.
- Basic / biomedical, applied / clinical, and population research on topics employing a life-course perspective, focusing on long-term outcomes of early experiences (e.g. the effects of biology, genes, behaviour, environment, health and economic factors).
- Knowledge transfer/translation – the Institute will play a crucial role in the translation of knowledge to inform and improve practice and policy. This will ensure the promotion of optimal development of children and youth and their families; the prevention of adult-onset disease where possible; and the treatment of key health impairments of childhood to prevent ill health and impaired development in children and families across the life course.

These programmatic themes will ensure that activities within the Institute benefit from the full engagement of existing expertise at McMaster Children’s Hospital, the University and the core “enabler” support themes identified within the University’s Collaborations for Health Initiative (knowledge translation strategies, information / learning technologies, networking mechanisms, and cross-cutting perspectives and methodologies).
Centre for Knowledge Transfer

Intervention Research: The Centre will focus on the development and testing of interventions that increase the uptake of highly efficacious care, targeting two or more of the following players: patients, practitioners, managers, policy makers. Furthermore, the Centre will work with the Unit for Optimum Healthcare Delivery to enhance its franchise approach with models of knowledge transfer that will contribute to timely adoption of new research findings into patient care.

The Centre is in current need of additional space, inhibiting its ability to recruit additional personnel. The Group will work with McMaster and HHS toward addressing additional space needs as well as the desire to co-locate its members to enhance collaboration efforts among its programs.

Centre for Advanced Clinical Imaging

Advanced Imaging: The Centre will utilize advances in imaging to promote individualized medicine, characterising not a “case” representative of a syndrome, but a person with particular tissue and organ structure and function and subsequently designing interventions to address the specific need and exploit the strengths of that individual person.

The Centre will also review its current organizational structure and consider the creation of new programs in molecular radioimaging and therapies. Along with the program growth plans additional space to accommodate the recruitment of new staff will be required as well as sustained funding for base research operations.

Infectious Diseases Research Program

Emerging Infectious Diseases: Building a program of research on emerging infectious diseases, such as West Nile virus, and expanding to viral infections that have a substantial impact on health, such as influenza. This will include expanding to do large-scale international clinical trials and to use these trials as a platform to answer basic questions, through use of biological markers, genetic epidemiology, data for modeling, etc. Research priorities include using mathematical modeling to understand past patterns of epidemics and to develop improved control strategies for influenza and many other diseases, e.g. childhood diseases such as measles, pertussis, chicken pox, malaria, and polio.

Data Archiving: A particular priority of the Program is the development of an international infectious disease data archive, which will go significantly back in time enabling testing of new theories and models on historical patterns.

Obstetrics and Gynecology Research Program

Clinical Research under Research Themes: Ongoing clinical research is a major thrust of resident, nursing and staff studies. Additionally, three research themes have been identified to guide research direction of the Program over the next several years and focus strategies for staff recruitment and project development, these are:

1. Fetal origins of adult disease (FOAD);
2. Reproductive endocrinology and fertility (REF); and
Development of an Advisory Board: To be successful the Program requires an effective management team that remains abreast of all emerging issues relevant to its program of study. The Program Research Director and members of an Advisory board will assess program priorities, direction, and evaluation on a regular basis. Therefore, several internationally recognized experts in reproductive biology and women’s health have been identified as potential members of our advisory panel.

Partnerships: Several ongoing productive collaborations with scientists at the local, national and international levels have been established. Our goal is to continue to enhance existing collaborative projects and explore new relationships that will augment efforts to develop novel animal models of human reproductive disease and facilitate mechanistic studies at the molecular level.

McMaster Transfusion Medicine Program

Donor Research Network: An ongoing initiative of the Program is the creation of a Donor Research Network that will bring together individuals interested in blood donor research from across Canada. The objective of this venture is to develop research projects focused on providing answers to important donor-related issues.

Idiopathic Thrombocytopenic Purpura Network: The Program is working with a group of physicians across Canada to establish a network of individuals interested in addressing optimal therapy for adults with Idiopathic Thrombocytopenic Purpura (ITP).

Quality Essentials for Safe Transfusion (QUEST): The QUEST project is an important component of the Program’s research. Additional external funding will be required to continue the QUEST project. The Program will respond to request for applications to secure funding to further its work on QUEST (currently on hold pending additional funding).

Strategic Priorities

Organizational structure:

1. Develop the governance structure and identify a governing body chair for the Intestinal Diseases Research Institute that is integrated with the leadership of McMaster University and HHS.
2. Formalize the governing body of McMaster Child Health Research Institute and appoint a Director.
3. Establish a formal organization structure for the Centre for Advanced Clinical Imaging, including a governance structure linked with McMaster University and HHS.
4. Develop and appoint members to an Advisory Board for the Obstetrics and Gynecology Research Program.

Development Tasks:

1. Define the role of the IDRI Director and identify future resource requirements.
2. Formalize the HHS Foundation commitment on fundraising for MCHRI.
3. Develop the Knowledge Translation Group’s interventional research to increase knowledge uptake and collaborate with the Centre for Optimum Healthcare Delivery.
4. Further develop the Infectious Diseases Research Program on influenza and possibly on herpes zoster and respond to requests for applications (with specific focus on a CIHR Team Grant, RFAs from NIAID and CDC).
5. Create a Donor Research Network for blood donor research activities across Canada for the McMaster Transfusion Medicine Program.
6. Create a Idiopathic Thrombocytopenic Purpura (IDP) Network aimed at addressing optimal therapy for adults with IDP from physicians/researchers across Canada.
7. Secure additional funding for the McMaster Transfusion Medicine Program QUEST project to continue.
8. Further develop the McMaster Transfusion Medicine in coordination and collaboration with the clinical transfusion activities across Hamilton Health Sciences.

Priorities for Investment:

**Intestinal Diseases Research Institute**

Hamilton Health Sciences has committed the following physical resources in support of the Institute and its affiliated physicians and scientists:
- Offices provided for clinicians and their administrative needs in the 4W8 area (1,490 sq ft) and the 2F clinic area (1,610 sq ft).
- A Central Endoscopy Suite (approximately 10,000 sq ft) in MUMC with access to 25 recovery beds and potential for expansion to incorporate endoscopic ultrasound, laser therapy and interactive teaching facilities.
- An Increase of outpatient clinic capacity through new GI ambulatory care clinics in MUMC 2F.
- New endoscopy equipment (approximate cost of $2M)
- Investigation and lab space: 4W1 GI investigation unit (1,337 sq ft) and GI 4W6 Clinical Physiology Lab (547 sq ft).
- Development of a Medical Day Care Unit including space for a Home PN/Nutritional Support.
- Increased access to inpatient beds at the MUMC site.
- Implementation of a coordinated central booking process for clinic visits and diagnostic GI investigations.

**McMaster Child Health Research Institute**

In partnership with Hamilton Health Sciences Foundation a long-term fundraising initiative is underway for both infrastructure and support. Furthermore, MCHRI is in negotiation with a major donor to support the position of the MCHRI Director and an endowed Chair. The Institute will use these resources and assist in seeking additional external philanthropic support to build its personnel and work with McMaster and HHS to identify and develop suitable space to physically consolidate the Institute members.

**Centre for Knowledge Transfer**

The Centre’s current need for space is a strategic priority that would enable the recruitment of additional scientists, a bioengineer and a computer scientist all identified needs. The Centre will work with McMaster and HHS to identify and project the space needs and together will build a plan to support the additional infrastructure needed to sustain and develop the Centre, which will require external fundraising initiatives.

**Obstetrics and Gynecology Research Program**

The Program’s focus for recruitment will be to build its membership around its three strategic research themes. Additional external fundraising will be required as well as strong partnerships with McMaster and HHS to ensure suitable research space for the Program’s continued development can be accommodated.