Review of the Escarpment Cancer Research Institute Dr. Simon Sutcliffe May 2015

INTRODUCTION

The Escarpment Cancer Research Institute (ECRI) was established in 2011 as a joint McMaster University/Hamilton Health Sciences Research Institute. ECRI represented the culmination of many years of discussion and planning and the collective commitment of its founding partners: the Department of Oncology in the McMaster University Faculty of Health Sciences (FHS); Hamilton Health Sciences (HHS) and the Juravinski Cancer Centre (JCC). ECRI will undergo a five year review in 2016. Based upon performance and demonstration of value, it will be eligible for further renewal.

The current review was undertaken at the request of the inaugural and founding Scientific Director, Dr. Mark Levine, to gain an external perspective regarding the performance and positioning of ECRI relative to its anticipated review and potential for renewal. The thoughts and recommendations are based on face-to-face meetings with ECRI members, associate members and research staff (June 4-5), background material made available prior to the review, and a number of conversations after the review with Dr. Levine, Deputy-Scientific Director Dr. Melissa Brouwers, and Director Ms. Anne Snider.

This external, single-person review has been undertaken in the context of a retrospective assessment of performance from 2011-2015, and as a prospective assessment of the strengths and challenges of ECRI's performance to date in a manner that would align with reconsideration and re-positioning of ECRI's strategy for the impending full review in 2016.

THE RETROSPECTIVE REVIEW (2011-2015)

Establishment of ECRI

A number of factors contributed to the plan to establish ECRI:

- The establishment of the Department of Oncology, in the McMaster FHS in 2006.
- · An HHS strategic research plan in 2006 aligning priority clinical and research programs at the Henderson site.
- Emergence in 2008 of significant cancer research opportunities through the establishment of the Ontario Institute for Cancer Research (OICR) and a desire for McMaster to coalesce a research agenda across multiple departments, disciplines and faculties in order to be competitive.

Together these factors enabled the recruitment of scientists/methodologists to the Department of Oncology (Pond, Brouwers, Seow, Muti); enhanced collaboration with other key cancer research groups at McMaster (Immunotherapy – Bramson; Probe Development – Valliant; Stem Cell – Bhatia, Hassell); and led to the recruitment of additional scientists supported by OICR (Juergens, Bane). Research space was made available by HHS to support ECRI. With these enablers, the associated recruitment and building on the strength of pre-existing research groups (OCOG, PEBC, Surgical QI, JCC CTD and OAPN), ECRI was launched with potentially broad ranging multidisciplinary interests and capabilities, all aligned to the idea of making an impact on the burden of cancer in the population.

The Challenges associated with Establishing ECRI

Notwithstanding the importance of the founding enablers for ECRI, the environment was characterized during the initial ECRI years with several potentially destabilizing challenges including the integration of the cancer centre with the hospital; the loss of core CCO operating funds for research; pressure on clinicians to provide more clinical service; the strain on clinical trials units in Canadian cancer centres to maintain sustainability; and an increasingly competitive research funding environment.

It is important to note that despite these challenges in the internal and external environment, ECRI researchers have remained both committed to their research and have continued to be highly productive, using the common measures of publications and research funding.

The Vision, Mission, Core Values and Founding Themes of ECRI

- · *Vision*: ECRI will be the national leader of innovative and sustainable solutions that will put research into action for the benefit of people affected by cancer.
- Mission: ECRI is dedicated to improving the lives of people affected by cancer. The ECRI research strategy includes clinical advancements, system innovations and knowledge translation.
- Core values: Evidence based; multi-disciplinary; burning passion to succeed; committed to community and international in reach.
- Founding themes: Translational Research, Clinical Trials and Quality Care & Knowledge Translation.

While the vision, mission, core values and founding themes of ECRI are important and reasonable, they are somewhat standard. At this stage in its development and as it looks to the future, there is an opportunity for the ECRI group to seek a more innovative path, to sharpen its vision and mission by being more specific in terms of action, and to build on its multidisciplinary strength in an integrated way by abandoning the silo structure of the separate themes.

Operating Resources for ECRI

ECRI scientists rely on external funding (peer-review agencies and industry) to conduct research. This is to be expected and would be an expectation in any serious research group. There are explicit guidelines in place defining role expectations for Full and Associate members of ECRI.

Full Membership

- Full membership in ECRI requires an active scholarly research program in an area relevant to the cancer research goals of the Institute.
- ECRI scientists are expected to hold peer-reviewed funding.
- · Salary support for ECRI scientists is the responsibility of their primary academic department and may consist of University base funding, endowed Chairs, Canada

- Research Chairs, other external career awards, or other hospital or external sources of funding.
- Every effort will be made to co-locate all Full members of ECRI within ECRI designated research space.
- · All Full ECRI members will participate in an annual review with the Scientific Director of ECRI.
- ECRI members are expected to reference their membership in ECRI in grants, presentations and publications.
- ECRI members are expected to participate in the development and core activities of ECRI including attending research in progress seminars, participating in scientific events, supporting trainees, and attending ECRI meetings and annual retreats.

Associate Membership

- Associate membership in ECRI is appropriate for faculty members collaborating with Full members or projects of relevance to the mission of the Institute or new members with less than 2 years of peer-reviewed funding in a relevant area.
- · Associate ECRI members are encouraged to reference their membership in ECRI in grants, presentations and publications.
- · Associate ECRI members are expected to participate in research in progress seminars, and participate in scientific events.
- For larger and more established groups, such as OCOG or PEBC, scientists have been able to create management and infrastructure roles to support overall day to day management and development. For ECRI members who hold appointments in the Department of Oncology, management, finance, and HR support is available within the Department. The host institutions also provide services such as account management, contract management, and external reporting on grants.

However, from an operating point of view, ECRI as an entity lacks operating funds and therefore has been unable to put in place a robust infrastructure to support its activities. Core operating funds to support day to day administration; IT and website management; a broader communication effort; coordination of collaborative ECRI research projects; coordination of ECRI events; and recruitment of trainees are examples of core ECRI activities that would benefit from infrastructure support.

As noted above, there is some reliance on existing support within specific research groups and ECRI uses the infrastructure provided by the Department of Oncology. In addition, ECRI has seconded senior managers from various research groups to help with selective functions, e.g. development of an IT needs assessment; development of a website; support for an annual research day, and support for development of the ECRI research plan and related projects. While productive in some areas, and useful for engaging research staff in the development of ECRI, this model is challenging to sustain and has led to delays in moving good ideas forward in a timely manner, results in diffusion of responsibility or duplication of effort, and hinders ECRI from realizing its full potential. Core operating funds would surely help facilitate ECRI moving from its current state of development and success to a more visible, coordinated and ultimately impactful state.

The Performance of ECRI

The ECRI Faculty:

There were 16 founding scientists in ECRI in 2011 and shortly thereafter a 17th scientist joined (Table 1). The choice of the scientists was based on a number of factors including: time available for research, track record, and training. However, this was somewhat arbitrary and decided on by the Scientific Director. Actual definitions and role expectations for membership were more formally developed after ECRI was established.

One of the unique features of ECRI is that it is embedded within a tertiary academic regional cancer centre. The importance of linking the research program with the JCC clinical cancer program was recognized. For example, in 2013, the clinical program identified palliative care and survivorship as strategic priorities. ECRI is working to build bridges with the clinical program in these areas. In order to further build this bridge between the clinical and research programs a number of associate members were appointed (Table 1). The idea was that these individuals (all clinicians) would bring their clinical experiences to ECRI and partner with ECRI researchers in developing a research agenda. This would be one way of ensuring that ECRI would focus on issues that are relevant to patients and clinicians in the cancer centre and the surrounding community.

The one exception to this approach re associate members was the appointment of a non-clinician, Jonathan Bramson, PhD, in order to enable collaboration between ECRI clinician scientists and immunology researchers, clearly an area of strength in ECRI and at McMaster and an important and promising area of cancer research.

Table 1: ECRI Members

Scientist	Discipline	Theme	Award
Andrew Arnold	Medical Oncology	Clinical trials	
Anita Bane	Molecular pathology	Translational	OICR Scientist
Jonathan Bramson†	Immunology		John Bienenstock Chair
			in Molecular Medicine,
			Canada Research Chair
			in Translational Cancer
			Immunology
Melissa Brouwers	Psychology	Quality Care & KT	
Denise Bryant-Lukosius	Nursing	Quality Care & KT	
Ian Dayes†	Radiation Oncology	Clinical trials	
Bindi Dhesy†	Medical Oncology	Clinical trials	
Laurie Elit	Gynecology Oncology	Quality Care and	
		KT	
Peter Ellis†	Medical Oncology	Clinical trials	
Karen Gulenchyn†	Nuclear Medicine	Clinical trials	
Hal Hirte	Medical Oncology	Translational	
Sebastien Hotte	Medical Oncology	Translational	
Rosalyn Juergens	Medical Oncology	Translational	OICR Scientist
Jim Julian	Biostatistician	Clinical trials	
Peter Kavsak	Clinical Chemistry		

Table 1: ECRI Members

Scientist	Discipline	Theme	Award
Mark Levine	Medical Oncology	Clinical trials	Buffett Taylor Chair in
			Breast Cancer
Som Mukherjee†	Medical Oncology	Clinical trials	
Paola Muti	Epidemiology	Translational	Arcelor Mittal Dofasco
			Chair in Experimental
			Therapeutics
Gregory Pond	Biostatistician	Clinical trials	OICR Scientist
Hsien Seow	Health Policy	Quality Care and	CIHR Investigator, Tier
		KT	II Canada Research
			Chair
Marko Simunovic	General Surgery	Quality Care and	
		KT	
Jonathan Sussman	Radiation Oncology	Quality Care and	Provincial Radiation
		KT	Clinician Scientist
Anand Swaminath†	Radiation Oncology	Clinical trials	
Timothy J. Whelan	Radiation Oncology	Clinical trials	Canada Research Chair
			in Breast Cancer
Jim Wright†	Radiation Oncology	Clinical trials	
† Associate Member			

Performance Parameters for ECRI:

ECRI was launched with three research themes: translational research, clinical trials and quality healthcare & knowledge translation (KT). These themes were established based on existing strengths and research groups. The clinical trials program is vibrant. The Ontario Clinical Oncology Group (OCOG) continues to design and execute a spectrum of trials, from first in-human to large Phase III trials. In some cases the principal investigators are ECRI members or associate members. There has been an effort to link with basic scientists on the McMaster campus and conduct first in-human proof of principal trials (M. Bhatia - stem cells in patients with AML; J. Valliant and K. Gulenchyn - imaging; and J. Bramson - cell based therapies).

The Quality Healthcare and KT team is productive and vibrant. Key programs of research include investigations in supportive cancer care and transitions between active treatment and survivorship, palliative care and models of end of life care, and implementation science with particular focus on the role of evidence and its use by clinicians, policymakers and system leaders. Other areas of inquiry include quality improvement, cancer surgery and roles of advanced practice nurses. In terms of collaborative work, Sussman, Seow, Pond and Brouwers have been particularly successful in pursuing new research initiatives amongst themselves and with other partners (e.g. Ontario Ministry of Health, Cancer Care Ontario, and OICR).

The translational research program is the least developed of the ECRI programs, but has grown substantially from 2011. It has focused on prevention, biomarkers, imaging and immunology/cell based therapies.

Details of ECRI publications are presented in Table 2 and awards/grants in Table 3.

Table 2: Summary of Publications and Funding ECRI Membership 2011-2015

		-			PEBC
First name	Last name	ECRI Role	Publications	1st Author	Guidelines
Andrew	Arnold	Member	4		2
Anita	Bane	Member	10	3	
Jonathan	Bramson	Associate Member	29		
Melissa	Brouwers	Member	38	11	3
Denise	Bryant-Lukosius	Member	9		1
Ian	Dayes	Associate Member	7	2	1
Bindi	Dhesy	Associate Member	13	2	
Laurie	Elit	Member	58	19	4
Peter	Ellis	Associate Member	29	10	2
Karen	Gulenchyn	Associate_Member	12	1	1
Hal	Hirte	Member	29	1	
Sebastien	Hotte	Member	34	1	1
Rosalyn	Juergens	Member	7	2	
Jim	Julian	Member	24		
Pete	Kavsak	Member	54	27	
Mark	Levine	Member	45	4	
Som	Mukherjee	Associate Member	22	3	
Paola	Muti	Member	50	5	
Gregory	Pond	Member	84	11	
Hsien	Seow	Member	30	8	
Marko	Simunovic	Member	25	8	1
Jonathan	Sussman	Member	18	3	2
Anand	Swaminath	Associate Member	11	2	1
Tim	Whelan	Member	23	3	
Jim	Wright	Associate Member	16		
Total ECRI Publications 2011-2015		667	129	19	

Table 3: Summary of Funding ECRI Membership 2011-2015

				Co-
Member	Principal Investigator			Investigator
	Peer		Industry	
	Reviewed	Other	Grants	
Andrew Arnold	\$0.00	\$1,000,000.00	\$0.00	\$0.00
Anita Bane	\$2,304,645.00	\$186,240.00	\$0.00	\$350,000.00
Jonathan Bramson	\$4,855,000.00	\$1,605,000.00	\$398,000.00	\$8,380,460.00
Melissa Brouwers	\$6,637,159.00	\$12,542,826.00	\$0.00	\$49,142,776.00
Denise Bryant-Lukosius	\$385,500.00	\$494,000.00	\$0.00	\$620,887.50
Ian Dayes	\$215,504.00	\$0.00	\$0.00	\$84,000.00
Bindi Dhesy	\$0.00	\$31,064.36	\$0.00	\$213,330.20
Laurie Elit	\$1,285,524.51	\$124,884.00	\$68,000.00	\$1,411,686.00
Peter Ellis	\$0.00	\$58,705.54	\$0.00	\$30,000.00
Karen Gulenchyn	\$30,000.00	\$0.00	\$757,506.00	\$1,632,950.00
Hal Hirte	\$0.00	\$0.00	\$440,774.17	\$0.00
Sebastien Hotte	\$999,131.00	\$0.00	\$353,130.00	\$1,272,499.88
Rosalyn Juergens	\$1,450,000.00	\$100,000.00	\$500,000.00	\$2,337,852.00
Jim Julian	\$0.00	\$0.00	\$0.00	\$5,294,685.00
Peter Kavsak	\$394,135.00	\$336,517.00	\$158,486.00	\$3,820,854.20
Mark Levine	\$1,999,309.00	\$1,296,586.00	\$0.00	\$3,712,271.00
Som Mukherjee	\$100,000.00	\$0.00	\$0.00	\$0.00
Paola Muti	\$1,526,000.00	\$0.00	\$180,000.00	\$300,000.00
Gregory Pond	\$257,624.00	\$0.00	\$0.00	\$1,185,695.00
Hsien Seow	\$1,059,529.00	\$1,414,066.00	\$0.00	\$1,211,565.60
Marko Simunovic	\$2,019,562.00	\$24,285.00	\$0.00	\$3,734,006.00
Jonathan Sussman	\$1,120,000.00	\$225,195.00	\$100,000.00	\$3,717,762.20
Anand Swaminath	\$1,290,186.00	\$0.00	\$0.00	\$568,514.00
Timothy J. Whelan	\$2,744,699.00	\$120,813.00	\$0.00	\$6,057,458.00
James Wright	\$0.00	\$13,975.00	\$0.00	\$188,250.00
Total Funding	\$30,673,507.51	\$19,574,156.90	\$2,955,896.17	\$95,267,502.58

The Evolving Characteristics of ECRI

[&]quot;Things may appear the same, but something pretty substantial happened to shore-up the sameness".

[&]quot;Success is the ability to sustain a stable productive faculty without their awareness of the everpresent and increasing reality of failure due to the constraints and challenges of the prevailing healthcare and operating environment".

These statements during the review highlight the changes occurring during the period from 2007 associated with the global financial downturn, healthcare funding constraints, institutional reorganizations and mergers, "downsizing" of faculty and personnel, "retrenchment" of the clinical and scientific research enterprise, erosion of "protected time" for research by clinical staff and increasing competition for diminishing donor funds and peer-research grants. Thus, to remain as a competitive research institution in 2015 with an established program and performance, in and of itself, is a substantial achievement and "against the odds" of the last five years.

These circumstances pertaining to the political, healthcare, fiscal and social environment have shaped the evolution of ECRI:

- · Culture of ECRI: An allegiance and loyalty to a vision for research and its relationship to practice enhancement, and to personal and collaborative scientific research career development. The culture is accountable to science, research and knowledge application for improved health and illness control.
- · Leadership of ECRI:
 - Establishment of a secure, supportive environment with minimization of bureaucracy and administrative encumbrance.
 - Creation of an environment in which the vision can be achieved through enabling
 inclusivity and collaboration, focused research excellence, openness to opportunity
 within an overall strategy and mitigation of hurdles, barriers and challenges.
 - Non-authoritarian leadership, inspiring "followership by setting a compelling vision, culture and direction".
- Driving imperatives: Conducting relevant, health solutions-oriented research for population application; pursuit of new or augmented capabilities, capacity and resources (e.g. CIHR-Foundation, SPOR); and fostering, enabling and equipping "highperforming" teams addressing health research priorities.

PROSPECTIVE REVIEW 2015 ONWARDS ANALYSIS AND RECOMMENDATIONS

ECRI was established in 2011 and now has almost four years of practical experience in leadership, management and operations. It is anticipated that its formal five-year review will be commissioned in 2016. Thus, the findings and recommendations of the present review (May 2015) serve two purposes: 1) an assessment of performance to date with an opportunity to embellish strengths and to mitigate challenges or deficiencies, and 2) create an opportunity to consider strategic and business planning for ECRI's second five-year term (2016-2021), including principles for succession, new directions and consolidation of its strengths. To this end, a number of ideas are put forward for consideration in strengthening ECRI's focus and impact.

The Vision, Mission, Core Values and Key Directions

Vision:

The current vision: ECRI will be the national leader of innovative and sustainable solutions that will put research into action for the benefit of people affected by cancer.

Considerations in revising the vision statement: The vision is built upon "innovative and sustainable solutions" to transform health systems and services for those affected by cancer through research knowledge applied into clinical practice.

Strengthen the latter ideas in the statement.

Mission:

The current mission: Dedicated to improving the lives of people affected by cancer, the ECRI research strategy includes clinical advancements, system innovations and knowledge translation.

Considerations in revising the mission statement: The current mission statement is not really different or more explanatory than the vision. A key element of the mission includes "improving the lives of those affected by cancer through application of research knowledge". This implies:

- · more effective, evidence-based practice through clinical trials,
- · more effective and efficient health system interventions to enhance quality of care and the patient experience with cancer,
- development and integration of new approaches for the identification, characterization and selection of interventions to optimize with individual ("personalized") and population-based health outcomes.

Strengthen these action-oriented themes in the statement and create greater distinction between the Vision and the Mission.

Core Values:

The original core values (evidence-based, multidisciplinary, burning passion to succeed, committed to community and international in reach) stated in the 2011 ECRI charter should not change.

Key Directions:

ECRI's research started with three themes and is evolving. The research in clinical trials is a strength, particularly the focus on trials that generate knowledge which contributes to evidence-based medicine and which informs evidence-based care. The health services research in the theme of quality healthcare is also a strength with the unique aim of optimizing individual and societal health and healthcare. Moreover, the health services research directed to knowledge application can drive individual and population-based healthcare and cancer control. While the productivity of the translational research theme is adequate, it is significantly challenged by competing translational research groups elsewhere in Ontario (e.g. Toronto) and elsewhere in Canada (e.g. British Columbia).

In conceptualizing its future, ECRI should examine how it can best leverage its scholarly assets to optimize its impact and productivity.

The Conceptual Model for ECRI

ECRI is at a state of its maturity to reflect upon the questions:

- · What makes it strategically different from other cancer research institutes?
- · In what does ECRI excel?
- · What makes ECRI unique or special?

Considerations when answering these questions include:

- · underlying political and organizational relationships
- · strategic and clinical research model
- · scientist participation model
- · business model
- · LINH as a "living laboratory" for ECRI

Each of these issues will be addressed in turn.

The Underlying Political and Organizational Relationships:

To be successful ECRI needs to ensure that certain enabling conditions are optimized. To this end, an analysis identifying key existing and potential collaborators (e.g. McMaster University, Hamilton Health Sciences, Cancer Care Ontario, Faculty of Health Sciences), what ECRI requires from these relationships (e.g. resources, brand, space), and what ECRI offers to these relationships (e.g. innovative research, effective solutions) should be undertaken. In doing so, ECRI can structure and organize its aims and activities to seek and optimize those collaborations which result in mutually satisfying benefits. Moreover, it will help define expectations in the

relationships with other key leaders required to support the success of ECRI (e.g. administration of JCC, HHS and the University).

A unique aspect of ECRI is the multidisciplinary make-up of its scientists and associate members who come from the McMaster Departments of Oncology, Surgery, Obstetrics & Gynecology, Clinical Epidemiology & Biostatistics, Pathology & Molecular Medicine and the School of Nursing. Many of the members have their academic home in the Department of Oncology, a relatively new department at McMaster (established in 2006). The additional relationships beyond Oncology afford unique opportunities to the ECRI scientists with respect to research innovation and access to expertise. For example, relationships have been established between ECRI clinicians and basic scientists on McMaster campus including imaging (Valiant), stem cells (Bhatia, Hassell) and immunology (Bramson). These occurred for a number of reasons including capitalizing on funding opportunities, mentoring of young scientists and the enthusiasm for translational research. Going forward however, a decision needs to be made regarding which existing relationships should be pursued and additional relationships that ought to be explored, in terms of net benefit for ECRI in terms of its vision and mission.

The ground work for ECRI was being laid at the same time as the new Department was conceived. Having the same individual as the Chair of Oncology and the Scientific Director of ECRI has been opportune in terms of having one voice to advocate for cancer research and facilitating access to space and funding. At times, however, it has led to confusion with regards to a common understanding of the different research mandates of ECRI and the Department. A common and continued communication strategy is warranted and future succession planning should explore the best leadership governance to optimize the success of ECRI.

The Strategic Clinical Research Model:

Context:

Healthcare is rapidly changing and will continue to do so for the foreseeable future. The burden placed on the Canadian healthcare system by cancer is substantial and increasing. There are a number of reasons for this: the aging population, improvements in treatment and the impact of lifestyle including diet on non-communicable diseases such as cancer, diabetes and vascular disease. Healthcare systems in Canada, the United States and Europe are struggling to cope with the financial burden of healthcare. Major drivers for rising costs include anticancer drugs and new technology, e.g. imaging and genomic testing. There are many challenges to the healthcare system in Ontario. Hospital budgets are stressed. Funding by the MOHLTC is flat-lined, which means each year cuts are necessary to keep up with increased costs as a result of union contracts, drugs and technology. Stringent benchmarks for hospital length-of-stay result in sick patients being discharged home. Community services are stretched to the limit to support patients' out-of-hospital, chronic care and palliative care facilities are limited. As a result, cancer patients and their families have many unmet needs.

Meanwhile improvements in genomic technology have given rise to the era of "personalized medicine" (now called "precision medicine") in recent years. It is believed that knowledge of the molecular biology of a tumour and the host (the patient) will enable individualizing

treatments to patients. There has been much excitement related to the potential for precision medicine. There is no doubt that there are examples of the recent success of precision medicine in specific cancers, e.g. trastuzumab in Her2 positive breast cancer, imatinib in CML and GIST, and immune check point inhibitors in melanoma. However, these therapies are very expensive and as of yet the promise of precision medicine has not been realized for many of the common cancers.

Given this environment, the challenge for ECRI is to identify areas where it can have the biggest impact. This involves reflecting on its strengths, potential collaborations and the unmet needs of the patients it serves. There is also the practicality that the domain of drug discovery research falls mainly in the purview of pharma and ECRI per se has only limited basic science research capability.

ECRI Research - the Proposition:

Consider ECRI to be an "open space" in which to address the priority questions – in essence, a "cloud" where the constraints of contextual, circumstantial and relationship issues are without boundaries, where any solution can be pursued and determined within the bounds of sound, disciplined, methodologically rigorous science and medicine. In this proposition, ECRI is not constrained from the outset by the traditional parameters defining the status of research institutions (philanthropy; institutional mandate; employment and funding relationships; interinstitutional relationships; space; access to technology; recruitment by discipline of research, etc.) and the competing considerations of health system, institutional and academic politics. Thus, ECRI provides the environment and intellectual capital to perform clinical applied research rather than the facility, the employer, the technology and the budget within which to host research. These considerations are necessary, but are secondary to the primary purpose of undertaking important and relevant health research.

In this model, the starting proposition is to define the focus of the Institute's research. Figure 1 illustrates that the realization of research translation over time engages domains of activity that are driven by different governance, funding and incentives, and populated by a different mix of health professionals, policymakers, patients and publics.

- Domain 1: Discovery science and clinical validation; typically undertaken by biomedical research institutes in tertiary academic environments, usually with robust foundations and access to philanthropy.
- Domain 2: Technology and business development involving intellectual property registration, licensing and commercialization, regulatory practice and policy and marketing.
- Domain 3: The application, uptake and adoption of valid clinical science into population health and illness control, including measures to determine contextual, ethical and socioeconomic aspects of health service interventions.

It is proposed that ECRI's research strength is in Domain 3. This does not preclude engaging in Domains 1 and 2, but rather such engagement needs to be strategic for success in Domain 3.

Using this as a conceptual basis, the next step is to identify and prioritize health research appropriate for ECRI with respect to expertise, interest and commitment to lead.

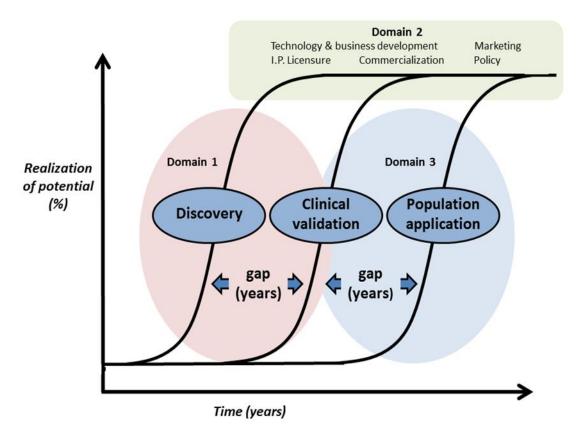


Figure 1: Research Domains of Activity

To this end, questions/themes/problems will need to be prioritized for ECRI research. This will involve the need to:

- · identify the relevant populations for study
- · define the relevant and available data sources and methodological innovations
- · identify the necessary infrastructure to enable the project
- · prepare and submit the application for research funding support

Underpinning these steps is the need to identify the appropriate investigators who may currently exist within the Hamilton academic environment or currently exist in other institutional settings and can be willingly co-opted into the research team, or need to be recruited to bring expertise that is both necessary in the longer term and is required to be a "continuous presence" in the Hamilton/ECRI environment.

In summary, ECRI exists to address and improve cancer control through a predominant focus on knowledge development, transfer and application to health system challenges. To do so effectively can be enhanced by creating the conditions in which health challenges can be addressed without contextual and/or circumstantial boundaries, i.e. "the cloud concept".

Solutions or conclusions may then be contextualized to prevailing circumstances and culture as a means to their realization in current healthcare.

Scientist Participation Model:

It should be noted that there is little operational funding directly attributable to the personnel of ECRI. The support for scientists comes from many sources including career awards from external agencies (e.g. OICR, federal government), endowed chairs, the Dean, McMaster Department of Oncology, HHS and physician practice plans. Research staff are supported through operating grants. Despite this rather heterogeneous funding model, ECRI has been very productive. However, it is important for the following issues to be addressed:

- · What are the incentives for performance by ECRI members?
- · Over which funded appointments does ECRI have direct or discretionary authority to inform the portfolio of activities undertaken by the scientist?
- · What are the criteria for an ECRI appointment at full member, associate member? With a new problem-based approach described above, how can conventional appointments and categories of appointments be used optimally?

The ECRI Business Model:

The ECRI business model is currently built upon the items described below in Table 4.

Table 4. ECKI Business Model		
ECRI	No direct operational funding	
ECRI-McMaster University	Assignment of endowed Chairs and CRCs	
	Dean's Fund	
	Department of Oncology in-kind & administrative support	
	Home Departments for ECRI members	
ECRI-HHS	Access to HHS-appointed clinical staff	
	\$150,000 annual support for statistician in OCOG	
	Debt of \$600K redirected from CCO to HHS operations	
ECRI-JCC	Access to clinical staff	
ECRI-JCC Foundation	Some access to research funds. Funds are neither guaranteed	
	nor targeted to ECRI activities.	
ECRI-Pharma Industry	Study support: \$3 million	
ECRI Grants	Peer-review: \$30.7 million/4 yrs	
	Other: \$19.6 million/4 yrs	
	Co-Investigator grants: \$90 million/4 yrs	

Table 4: ECRI Business Model

An analysis of the current business model and future options is warranted. Essentially, there are two strategies for sustainability and growth: 1) to expand the funding (pharma, grants, other non-peer review awards, philanthropy), and 2) focus the available resources in areas of science, on people or platforms with the greatest strategic potential to achieve the vision and mission. The following issues should be considered:

- · How can core operational funds be secured and leveraged?
- · What are the implications for ECRI if core funding is not secured?
- · What is the possibility and probability that the situation could change?

- What are the areas of greatest strategic potential?
- · Who are the people with the greatest strategic potential?
- · Are they existing and to be retained?
- Existing but need to be "re-positioned" or to be recruited?
- · Are there opportunities for commercialization?

The LHIN as a Living Laboratory for ECRI:

One of the unique features of ECRI is that it is embedded within a tertiary academic regional cancer centre. The importance of working closely with the JCC clinical cancer program has been recognized. The clinical programs are ideal for identifying the key questions and issues for patients that ECRI research could address. For example, the clinical program has identified palliative care and survivorship as important issues and ECRI is working to build bridges with the clinical program in these areas. Based on these considerations the "LHIN as a lab" was identified as a thematic opportunity for ECRI researchers to rally around. Furthermore, the HHS just announced their strategic priorities which include research on their community.

For the LHIN to be a key enabler of a living laboratory for ECRI research, the LHIN relationship would need to facilitate population access; organizational and professional relationships; data availability (link to population health data sets, including services utilization by geography and cost); definition of LHIN-relevant research questions and research and access to the "levers and controls" for population health performance. There are advantages to the LHIN as a living laboratory:

- · Circumscribed population with accessible link to health data sets
- · Engagement of health and illness continuums across:
 - Health, illness, treatment, cure, palliation and end-of-life
 - Infancy, childhood, adolescents, young adult and senior life
 - Primary, community, specialty/tertiary, hospice
 - Discovery, validation, application of health innovations

How can this opportunity be better optimized and integrated both strategically and operationally into the ECRI fold?

SUMMARY: FROM CONCEPT TO ACTION

ECRI has demonstrated the potential and performance associated with collaborative relationships between key partners across the academic, tertiary and population domains of the health system. This performance has been based upon capitalizing on strengths and opportunities (assets), but the potential has also been constrained by the challenges inherent within and also external to, ECRI (liabilities). As with any organization, an opportunity to reflect and refine on its strategy and practices enables growth and success. In this review, there have been several questions and issues that the ECRI team is encouraged to work through to provide a foundation for the next stage in its development.

The strengths and opportunities:

The ECRI culture:

- the primacy of knowledge application to outcomes (the focus on Domain 3 Figure 1)
- · inclusivity and collaboration, based upon intellectual contribution, not affiliation or funding source
- · mutual accountability and responsibility
- · interdisciplinary teams across the continuum of healthcare and health services
- · maximizing and optimizing the resources available to perform high quality research
- virtual problem-based "Institute" providing an "open space/cloud" concept for collaborative research

The research concept:

- the creation and sustainability of an "open space/cloud" for the conduct of research, unconstrained by traditional and conventional definitions of "Research Institute", i.e. organization, institution, employer, funder, etc.
- a permissive, secure, unencumbered and enabling environment for the pursuit of research and its application to health service improvement
- · performance is the realization of health improvements through ECRI research

The research context:

- · clarity of focus based on translating knowledge into health application and optimization
- · coherence based upon unifying strengths
- · excellence according to the conditions and circumstances for sustainable support

The research content:

- redefining ECRI's research strategy so that it is not about investment in the domains of research, but rather about the investment in the capabilities and capacity to perform relevant health research (science, technology, platforms, personnel, etc.) that can translate into improved health outcomes
- · researchers bring different skills to tackle problems that are important for patients
- envisioning and pursuing the future through a platform of core capabilities
- determining what the change in medicine and healthcare will be, and creating the opportunity through ECRI
- · recognizing individual strengths and establishing how they can create "collective capacity" for health research
- · strategic focus on recruitment, development, retention and succession to ensure security of the ECRI research culture, performance and capability

The weaknesses and threats:

- · minimal operating budget and the challenges for securing significant operating funding increases in the prevailing academic, health services and philanthropic climate
- · limited ability to facilitate operational support for individual and collective research capacity, e.g. research administrative support, grants preparation and management support, core infrastructure support

- · perceived "ambiguity" of overlapping institutional missions, goals and personnel
- · real and perceived competitive priorities of partner entities, e.g. McMaster University, Hamilton Health Services, JCC, Department of Oncology and JCC Foundation
- · differing cultures, contexts and content of health research priorities between partner affiliates of ECRI
- · variable strengths and supports for health research endeavors across Ontario and the proximate strengths of OCI/PMH and the Toronto academic and fiscal environment
- · moving from concept to action and facilitating buy-in, agreement, and leadership among the ECRI scientists.

Final Comments

ECRI has demonstrated substantial commitment and performance to the advancement of applied health/cancer research since inception in 2011. This is particularly prescient in the context of research outputs (extensive grants, publications and traditional measures of industry performance) relative to inputs (limited and little secure institutional endowment and/or operational funding). Furthermore, performance and productivity has been established through very challenging and ongoing adverse circumstances for research in Canada.

ECRI has established a particular collection of "assets", possibly arising as a result of this challenging environment that position it in a potentially advantageous way. Its' culture, concept, context and focus promote the concept of an "open-space" for health research ("cloud health research"). An example of this could be, "How can we rationally assess the potential value of health interventions amongst a plethora of competing possibilities in a way that would be transparent, socially and politically responsible, and evidence-based and aligned to the design of appropriate ("hypothesis-proving") studies?" Such a concept aligns to the creation of a virtual space for research – the assemblage of health researchers who are interested (both within and external to the Hamilton environment); assemblage of the database and technology platforms; creation of the virtual working forums and communications; and the design and execution of a mutually agreed health research program.

This concept can clearly be challenged from the perspective of prevailing health research resources, particularly operating and infrastructure support. Whilst relevant, these challenges demand mitigation, not obstruction to the "open space" concept for collaborative research. In reality, the required resources are not substantial – they are the resources necessary to facilitate the business and operations of collaborative teams of researchers assembled to address collectively defined health challenges. The characterization of this resource, and its scalability to accommodate the support of multiple research teams, would be a first step towards the establishment of a revised business plan for ECRI and the development of the funding strategy.

In summary, ECRI has demonstrated performance and capability according to traditional measures of institutional performance. However, its true capacity to perform is yet to be fully realized, based upon its unique opportunity to "rethink" the role and performance of a health research institute in the prevailing present and future health economy.